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Vienna, Paris

Study Report

Audible Package Insert Leaflet and Product Information

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of the academic non-interventional Study Net (ANISNet) of the Department of Health Law and Science of the Sigmund Freud Private University Vienna

Audible Package Insert Leaflet (PIL) and Product Information

Scientific evaluation of application safety of an innovative system with blind and visually impaired people as well as opinion survey on consumer acceptance in Austria.

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Due to the cooperation with the Austrian Federation of the Blind and Partially Sighted (BSVÖ) all publications are additionally published as audiobook and are conducted as joint projects.
For better readability the male form is used throughout the publication, all terms however equally refer to both genders.

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Foreword

The Federal Ministry of Labour, Social Affairs and Consumer Protection traditionally is the contact centre for all issues concerning people with disabilities. Special attention is granted to the barrier-free accessibility of information for all people to ensure the participation of disadvantaged persons in our society. New media and technologies have contributed to improve the accessibility especially for visually impaired and blind people. From personal experience as frequent user I appreciate the assistance, which modern smart phones and their apps can provide. Still it took conversations with blind and visually impaired people for me to fully understand the scope of opportunities of modern smart phones for this target group.

In this context I also see the benefit of new technologies such as the "Speech Code" for the target group of people with disabilities: It is the simple use and easy availability that is provided with mobile phones. If it can be ensured that the code can be found and therefore be used by visually impaired and blind people without lengthy search, this technology certainly will establish itself quickly for the benefit of the target group. I envision the application of the new "Speech Code" especially for medicines - here I think of the use f. ex. on package inserts. I therefore hope that commerce and industry will take on this development and ensure that the spreading of this technology will actually take place in the desired magnitude.

Hence I congratulate the authors of this study to the interesting results of their work. I am sure that this technology will soon find widespread usage.

Federal Minister Rudolf Hundstorfer

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1. Introduction

„Speaking package insert“ for pharmaceutical products - especially for blind and severely visually impaired people

Before the end of lengthy discussions during the reviews of the pharmaceutical legal basis (2000 – 2004) a new requirement was included into the EU Directive for human pharmaceuticals at short notice: Regulations regarding the name in Braille on the labelling and the provision of instructions for use in a format suitable for blind and severely visually impaired people.

A very important regulation, which however was new for us in the area of Drug Law. Up to then we only knew the labelling with Braille from for example elevators. The implementation of this regulation therefore represented certain challenges both for the authorities and for the industry. On the part of the authority we wondered, how and which kind of documentation we should demand and how we could control and survey the information. Should we hire an expert knowledgeable in Braille?

It became obvious that in addition to the legislative text there is a need to develop further standardised requirements and practical directions. Hence the EU commission decided to have EU Guidelines prepared and appointed me as rapporteur.

In the course of my research I had contact with associations of blind people - nationally and internationally – and I learned a lot on how autonomously blind people master their lives. During a conversation with the president at that time of the Austrian association of the blind - himself being blind - he asked me to send him documents. I was almost embarrassed - how should I send him documents? Very simply - by e-mail - as there are special keyboards with Braille available, which enable blind and severely visually impaired people to read and write on their computers. I learned how important it is for blind people to label cleaning liquids and beverages with a Braille labelling device to avoid dangerous mix-ups. And how much they would appreciate the labelling of pharmaceutical products in Braille, because they want to be self-reliant on taking the right medicines. A blind father mentioned how important it was for him to be sure on giving his infant the right medicine.

I more and more understood, how important the labelling of medicines in Braille was and developed regulations that make a product identification possible and are accomplishable for the industry. These regulations are published on the DG Health website in the “EC-Guideline on the readability of the labelling and package leaflet of medicinal products for human use“ in chapter „Specific recommendation for blind and partially-sighted patients”.

Well, the identification of pharmaceutical products was one, but there was another requirement that needed to be put into practice: The MAH's provision of the information and direction for use - pacakge leaflet - in a format accessible also for blind and severely visually impaired people.

At that time we discussed various options, on the one hand printing the text in larger print (16 – 20 point font, good contrast, etc.), on the other hand the provision as audio file, digital text document via e-mail or information via a Hotline. None of these possibilities was ideal, hence the guideline did not require a certain format, but rather recommended various options. Ultimately it remained in the responsiblity of the MAH to provide a suitable format upon request.

I am pleased that now a new possibility becomes available - "the speaking package insert"! A great development, which not only makes the text of a package insert accessible to blind and severely visually impaired people, but also facilitates their participation in readability tests - and in due course their inclusion in the efforts to improve the readability of product information.

During the last years we got used to QR-Codes, especially on food products, but also on any kind of folders - for pharmaceutical products their use is still under discussion. Maybe the „Speech-Code“ is the next step, a step into the right direction - especially for blind and visually impaired people, as this study shows.

DI Dr. Christa Wirthumer-Hoche
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2. Legal background

2.1. Product safety through correct presentation and information

In Austria general products in respect to safety are regulated in the "Produktsicherheitsgesetz 2004 – PSG 2004" (BGBl. I Nr. 16/2005 in its latest version)[2]. If safety requirements for products are regulated in special federal legal administrative directives, as it is the case for medicines and medicinal products, this federal law will only apply for those aspects, risks and risk categories, which are not regulated in the relevant federal legal administrative directives according to the objective of this federal law, or which are not regulated in this law at all. For medicinal products please refer to the statements in the following chapters.

Therefore the PSG 2004 regulates **"Products of daily life":**

- Any mobile thing including energy, also in context of the provision of a service.
- The product must be supplied or made available under conditions of a business activity, whereas it is irrelevant, whether this is free of charge or at cost and whether it is new, used or re-engineered.

A product is considered as safe, if - under the condition of normal or forseeable usage - there is no or limited and justifiable danger, which is consistent with its usage and ensuring a high level of protection for the health and safety of consumers. The usage includes also the duration of use as well as initial operation, installation and maintenance where applicable.

For the evaluation of safety it is therefore of utmost importance:

- Who the consumers or consumer groups are, f.ex. children, elderly people or people with impairments, and whether they are subject to a higher risk under the condition of a reasonably forseeable usage of the product
- The characteristics of the product, in particular its composition, execution, packaging, the conditions for its assembly and its performance at maintainance, storage and transport
- The effect of the product on other products, if a combined or joint usage with other products is reasonably forseeable
- The appearance, presentation, labelling, directions for use and operation, instructions for the maintenance, storage and disposal as well as all other statements and information from the producer or importer

[2] The Austrian "Produktsicherheitsgesetz" is based on the product safety directive 2001/95/EG. For special kinds of products additional directives are applicable (f.ex.: Toys: 88/378/EEC).

Information obligation of the producer

Within the framework of their respective business activity producers and importers must provide the consumers with information such as safety warnings and instructions and directions for use that allow the users to recognise and protect themselves from any dangers that are related to the product and its use during normal and reasonably forseeable duration of usage and that are not immediately recognisable without relevant safety warnings[3].

However, even the most comprehensive information and safety warnings do not indemnify the producer or distributor from the obligation to fulfill the above mentioned safety requirements (according to § 4 Abs. 1 PSG 2004).

Product safety advisory committee

It is the task of the committee to provide councelling on the protection of consumers from dangerous products, on the prevention of household, leisure and sports accidents and on the market surveillance.

One of the tasks is the formulation of recommendations on issues of product safety and accident prevention, even for products that are not or only partially subject to the application of this law.

Voting members of the advisory committee are one representative each of:

1. The Chamber of Commerce Austria
2. The Federal Chamber of Workers
3. The President's Committee of the Chamber of Agriculture Austria
4. The Austrian Federation of Trade Unions
5. The General Accident Insurance Institution
6. The Institute "Sicher Leben" at the "Kuratorium für Schutz und Sicherheit"
7. The Austrian Committee for Infancy Accident Prevention
8. The Board of Senior People
9. The Association for Consumer Information
10. The Association of authorised and accredited Research Centres and Test Stations (Austrolab)
11. The Consumer Board at the Austrian Standardisation Institute
12. The Austrian Syndicate for Rehabilitation
13. The Federal Ministry for Economy and Labour
14. The Federal Ministry of Health
15. The Federal Ministry for Agriculture, Forestry, Environment and Water Management
16. The Federal Ministry for Transport, Innovation and Technology
17. The Federal Ministry for Social Affairs, Generations and Consumer Protection as well as
18. One joint representative of the federal provinces

[3] If necessary, unsafe products must be "re-called" from the market. Intetec in cooperation with Eurocommerce 2004 and other organisations has formulated a guideline on corrective measures and recalls, www.eurocommerce.be.

2.1.1. Aspects of product liability from legal directives and jurisdiction

The product liability in Austria is regulated in the "Produkthaftungsgesetz", PHG (BGBl I 1989/99 in its latest version)[4]. It comprises personal damage and material damage that were caused by product failures at the time of bringing it into circulation by the liable entity. In § 5 PHG the directive defines the failure of a product as a deficit in safety, when the product does not offer the level of safety that can be expected under the consideration of all conditions. Failures occur either as failures in the construction (or composition), production or presentation. In the latter case these failures are also referred to as failures of instruction.

Deficient product information in the context of presentation

Special attention is granted to the presentation, which includes besides oral statements, in particular the printed directions for use and instructions that have to facilitate the safe usage. As measure for the eligible safety expectations an objective standard is applied, i.e. an average, ideal type consumer. This is applicable only conditionally, if products are meant for specialists only and if this group of people has certain knowledge. In such a case the safety expectations may be lower. On the other hand the level of safety expectations can be increased by marketing messages or special warranty conditions. In the judicature especially the failure of instruction or failure of presentation has led to numerous decisions that mostly were in favour of the consumer, as a very high level of safety requirement was assumed[5]. Particular emphasis is laid on directions for use, as these are meant to inform the consumer of any dangers in relations to the product usage – including the kind and intensity of dangers - and to ultimately avoid them.[6] If a producer must anticipate that especially visually impaired or blind people will use a certain product or medicine, he is obliged to inform these people on the usage in an adequate manner.

Also crucial is the usage of the product itself that can normally be anticipated. Contrary to this, the deficiency in liability and warranty directives refers to the usage property of the delivered good.

Liability in the PHG

The PHG determines liability irrespective of the fault and can neither be excluded nor limited in advance. In principle the producer of end and part products or base materials, the pseudo producer, a company labelling third party products with its own lgo, name, brand, etc. as well as the importer, who brings the product to the European market resp. the EU for the first time, are liable for indemnities. Even a retailer can become liable, if the damaged person cannot determine the producer or importer. The retailer however can avoid the own liability, if he can provide the qualified data of the producer or his own supplier within a reasonable time period.

[4] Based on the directive "Produkthaftungsrichtlinie" 85/374/EG.
[5] 9 Ob 20/00g in ZVR 2001/36; 2 Ob 207/99a in ecolex 2000/9; 8 Ob 183/00w) ecolex 2001/167 Thaler; 10 Ob 399/97t in ecolex 1998,834; 1 Ob 53/98w in ecolex 1999/120 Wilhelm.
[6] See Welser/Rabl, "Produkthaftungsgesetz PHG[2"], §5, 16.

2.1.2. Product information for blind and visually impaired people

Due to the wide scope of "visual impairment" to full blindness it is not possible to reach a uniformed standard on how in general blind and visually impaired people must be informed. It rather is necessary to specify these requirements for each respective user group of products. While it might suffice for people with a low or medium degree of visual impairment to provide product information in appropriate type sizes and zoom options, for almost or totally blind people specific auxiliary means must be provided. The currently most important means is Braille as well as systems reading out information, if they are available for certain applications.

Braille

The system developed by the Frenchman Louis Braille in 1825, enables blind and highly visually impaired people to read and write texts. Basic symbol is the so-called Braille cell, consisting of 6 dots that represent certain letters, numbers or punctuation marks in certain arrays. As Braille should be readable by touching with the fingers, certain minimum sizes must be adhered to, in order to provide proper reading.

Also for labelling and identification of medicinal product packages Braille must be used (see 2.2.). The recommended standard for size of cells, dot distance, height and form is the „Marburg Medium“, a standardised center print.

Braille can also be used with so-called embossed printing machines or special computer applications. In terms of offering a form of support for an as large as possible group of people, Braille faces the problem, that people turning blind at a later stage in life often did not learn Braille and are almost or totally unable to learn it then due to various reasons (f.ex. periphere reduction of sensibilities in combination with Diabetes Mellitus as cause of turning blind from a Diabetic Retinopathy).

Electronic auxiliary means

Computers can be operated with the use of Screenreader Software, which allows blind people to get the screen content and operating controls read out. Prerequisites for comfortable navigation in the internet are barrier-free or at least fairly accessible websites. Printed texts can only be read out with the help of scanners and text recognition software. For accessible books and publications audio libraries are available, which provide and rent out such publications in a special DAISY (Digital Accessible Information System) format that is suitable for blind people.

The latest technical developments are electronic codes and tags that can be scanned with the smartphone camera and then are read out with a special software. Product information and instructions for use often are provided on or in packages in a folded, creased form, which significantly impede the scan processes or even make them impossible in the case of bent product forms. Access to information via bar codes and tags with modern smartphones additionally have the disadvantage, that they are connected to fixed databases, which are not navigable sufficiently and that cause costs to the consumer (Internet connection/ data base required).

2.2. Special legal requirements for package insert leaflets and labelling of pharmaceutical products

2.2.1. European directives for member states

Based on the European regulatory guidelines for the regulatory admission of medicinal products the Regulatory Guidelines[7] contain the formulation of directives for the production of SPC and PIL as well as the labelling of medicinal products in the European Community. The guideline "Summary of Product Characteristics, SmPC", which is provided in its second revision since 2009, can be considered as the base document. This core document of all national SPC regulates the exact field of application of the pharmaceutical product, which also is the regulation for the labelling and directions for use. Requirements for the labelling and the package insert leaflet, also called directions for use, are outlined in the "Guideline on the Packaging Information of Medicinal Products for Human Use authorised by the European Community, 2008".

Labelling and package insert leaflet of medicinal products

In addition to the general directives of the guideline on package labelling information, the member states of the EU have the possibility to require or to permit for their territory special potentially needed information on the package of medicinal products. For this kind of important information the term „Blue-Box" has been defined. Such additional information must be presented in local language without exception in the so-called "Blue Box", a special section on the package and/or package insert leaflet.

Blue-Box Requirements in Austria:

- reference whether the medicinal product is „on prescription and available only in pharmacies", „on prescription" or „available only in pharmacies"
- For radio-pharmaceuticals: "On prescription only. To be delivered only to holders of a permit for handling radioactive materials persuant the radiation protection laws"
- Vaccines and blood products: „Officially released charge", "Charge marketable" as well as on the inner package: "Product name, Ch.B., verw. bis." and a label with the notice; "Each application should be documented in the patient's clinical record or vaccination passport with the enclosed adhesive labels"
- Notice in the package insert leaflet: "The application of the pharmaceutical product might lead to positive results in doping control checks" or inform on important risks
- EAN Code is permitted but not required
- Symbols and pictogrammes: „Warning: This medicinal product can affect the ability to respond and the roadworthiness". As well as „The Green Dot" or any other recycling symbols and the radioactivity symbol

[7] Notice to Applicants Volume 2C – Medicinal Products for Human Use – Regulatory Guidelines of the Rules governing Medicinal Products in the European Community, http://ec.europa.eu/health/documents/eudralex/index_en.htm.

Blue-Box requirements differ within the EU, therefore the latest versions of requirements should be requested from the respective national authorities. While in Austria and Hungary prices and reimbursement may not be printed on the package, this is an important requirement in Belgium and Portugal, in other countries it is not required, yet not prohibited. Details are available in the guideline, these however are dating back to 2008 and therefore might have been adapted nationally in the meantime.[8]

Language requirements, perceivability and readability

The texts of the labelling have to be presented in the language(s) of the country, where the medicinal product will be put in circulation. If multiple languages are printed, the contents must be identical. The same is valid for the package insert leaflet. Samples for labelling, SPC and PIL have been formulated by the EMA (European Medicines Agency) in all European languages and are available on the official EMA website.[9]

A general requirement for the formulated texts is - apart from the correct linguistic translation - the "readability and perceivability" for users of the medicinal product, to avoid misapprehensions and errors. In this respect the leading document is the guidline by the European Commission, currently available in its first revision, the „Guideline on the Readability of the Labelling and Package Leaflet of Medicinal Products for Human Use, 2009".

Centrally authorised medicinal products that are not on prescription only are handled with a separate recommendation of the EMA, as in some countries they must accommodate safe usage without pharmacy advice.[10] Apart from the name of the medicinal product, its strengh and form of application, particularly the therapeutical indication, dosage, warnings and application information are important for the patient, who must be able to understand this information without any doubt.

Readability of the package insert leaflet/directions for use

Pursuant to the guideline on readability (see above) numerous considerations have led to detailed requirements for the directions for use. On the one hand such a document is directed at the patients, who in most cases are medicinal laymen, on the other hand the population of patients is very diverse in terms of age and educational background and in some cases might even be impaired by various diseases or handicaps. The guideline therefore should provide - next to national basic requirements - also a recommendation on the design of a package insert leaflet/direction for use. The recommendations in this sector refer to font type and font size, design, layout and kind of paper, print colours, syntax, linguistic style and the use of symbols and pictograms. For example easily readable font types should be chosen, with well distinguishable letters and a minimum font size of 9pt and a line spacing of minimum 3mm (f.ex. for Times New Roman). The absolute minimum however is a font size of 8pt with regular letter width.

[8] Notice to Applicants: „Guideline on the Packaging Information of Medicinal Products for Human Use authorised by the Community, 2008, Eudralex Volume 2, http://ec.europa.eu/health/documents/eudralex/index_en.htm.

[9] On the official EMA homepage refer to chapter: " Product information: Regulatory and procedural guidance", and there to the notice on QRD Templates, Mock-Ups and samples and other sections.

[10] QRD recommendations on pack design and labelling for centrally authorised non-prescription human medicinal products, EMA/275297/2010 from March 2011.

Readability of the labelling

Sector B of the guideline details the design of the labelling. In this respect the guideline differentiates the outer from the inner package, whereas for the inner package in most cases blisters or containers are used, which only offer very limited space for texts. As minimum font size on the labelling a 7pt font size with line spacing of 3mm is required.

Crucial information is the name of the medicinal product, its strength and where applicable the total content as well as the dosage form. To provide a best possible readability, layout and design must especially consider colour aspects and contrasts. In terms of danger of confusion measures for a better differentiation must be taken. The inscriptions on blisters and small containers have to be made in such a way, that single units can still be identified accordingly.

Specific recommendations for blind and visually impaired people

A) **Labelling** requirements and recommendations:

The European Directive 2004/27/EG provided significant changes to the Directive 2001/83/EG[11], which was interpreted by the guideline accordingly.

First and foremost emphasis is on a clear differentiation of each package of a medicinal product. For this reason the outer package must be labelled both in normal print and in Braille. The elevated dots of Braille may be embossed also on existing printed text, if such text remains legible.

If the medicinal product is available in only one strength, the indication of only the product name is sufficient, otherwise an indication on the strength is required as well. Producers of parmaceutical products however are permitted to provide additional information in Braille on an optional basis, for example if the medicinal product can be used for infants, children or adults, or also the date of expiry. For small packages the use of recognised abbreviations is permitted.

If the package is labelled in multiple languages, also the identification in Braille must be provided in these respective languages. Correct translations must be guaranteed also in Braille.

For medicinal products that are only applied by health care professionals, as f.ex. vaccines, Braille may be omitted. Also on inner packages the labelling in Braille may be omitted. For larger containers without inner package a label with Braille may be applied directly on the container. On an optional basis also here additional information in Braille may be provided.

A later labelling with Braille in the course of sales or distribution to patients is not recommended due to the high danger of confusion of various labels.

[11] Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 56(a): *"The name of the medicinal product, as referred to in Article 54, point (a) must also be expressed in Braille format on the packaging. The marketing authorization holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted."*
Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 54(a): *"The name of the medicinal product, followed by its strength and pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international nonproprietary name (INN) shall be included, or, if one does not exist, the common name."*

B) **Package insert leaflet/directions for use** for blind and visually impaired people:

According to the guideline, recommendation and request from patient organisations the holder of the permit to bring the product into circulation (marketing authorisation holder) is required since May 2005 to use a font size and font type (16 to 20 pt without serifs) as well as contrasts and line spacing that are suitable for visually impaired people and that the package insert leaflet is available in formats that are suitable/accessible for blind and visually impaired people. Recommended are audible formats such as CDs or audio tapes, but also a production of the entire package insert leaflet in Braille.

This requirement therefore is valid throughout Europe and has to be integrated into national laws by all member states. These recommendations are also binding for parallel-importers and distributers.

Consultation of patient target groups (User Tests)

The guideline on readability includes at this point also the requirements of the previously released guideline of the European Commission on the consultations with patients' target groups.[12] The procedures are detailed in a recommendation of the EMA and have been extended from patient organisations also to consumer associations.[13]

Such tests serve the evaluation of the directions for use by the target group itself and should assist in identifying deficiencies in the perceivability, design and formulations in the course of the application for the initial registration or at the occurance of significant amendments of the text or package design. In this procedure no conclusions on the test persons in regards to their education or power of comprehension are undertaken. The user tests are reviewed and evaluated by an official assessor. As a tool the EMA has published a checklist „QRD Guidance and Checklist for the Reviewer of User Testing Results“, whereas a nationally different emphasis of certain issues is possible.

Consulted organisations must fulfill certain criteria, which are listed in a separate document of the EMA.[14] They are asked to name experts for the testing and document them in an updated list. The assignment of organsiations then is made based on the indications and fields of application. The tests include all multilingual documents as well as product-specific summaries of the EMA, the so-called European Public Assessment Reports, or EPAR, which the EMA publishes on their website.

The testing includes reading, understanding and the answer to respective questions or in form of an interview. Test persons must be able to find specific sections in the respective document and to understand them in order to turn the information into correct answers to the posed questions. The crucial question is: Can the user find the information quickly and easily and once found, can he understand it and act accordingly?

Additionally the EFPIA (European Federation of Pharmaceutical Industries Associates) has formulated a suggestion on the execution and organisation of such tests, that is described briefly as follows.

[12] Guidance concerning consultations with target patient groups for the package leaflet, according to Article 59(3) and 61(1) of Directive 2001/83/EC as amended by directive 2004/27/EC; May 2006.
[13] Procedure for review of information on medicinal products by patients´and consumers´organisations; EMA/174255/2010; April 2010.
[14] Criteria to be fulfilled by patients’ and consumers’ organisations involved in European Medicines Agency (EMA) activities.

The test included, to which extent the text content, structure and layout of the package insert leaflet were designed to make patients understand the key information on field of application, directions prior to application, adverse reactions as well as on storage of the medicinal product. In the representational project a questionnaire with 18 questions was developed: The test was considered as passed successfully, if a minimum of 80 percent of the participants answered each question correctly.

Apart from the test method described in the documents, also other methods may be implemented, as long as they deliver reliable results. The goal of the tests is the formulation of information material that is patient- and consumer-oriented in regards to special requirements of the user group.

Test methods:

- **Australian Method - Sless and Wisemen** (structured verbal interview)
  Performance of individual interviews in at least 2 test turns.
  Tests are conducted until a satisfactory result has been reached with 20 participants. The test group should be representtive and include a variety of age groups.
  Test persons should not know the medicinal product and should not deal with written information on a professional basis.
- **Package Insert Test** (PAINT, written readability tests)
- **Psychological Analysis** of patient information (PAPI Personality and Preference Inventory)
  This is a personality test with a questionnaire that offers several multiple choice answers. The result is interpreted in graphs and the test person has the opportunity to react upon it.
- **Methods of Communication Sciences**
- **Multiple Choice** and others

Due to the unavailability of suitable methods currently blind and visually impaired people cannot actively participate in such tests.

Revision by the EMA

For centrally authorised medicinal products the EMA (European Medicines Agency) has developed an authorisation process for printed materials for packaging and labelling. The goal is to further improve the quality of inner and outer labelling as well as of the package insert leaflets prior to bringing it into circulation or for amendments of the permit.

The marketing authorisation holder is required to present models of the package (Mock-up) as well as sample texts for the package and package insert leaflet to the respective authorities. The exact procedure of mock-ups and sample texts is outlined in a document of the EMA[15]. In this process the high responsibility of the marketing authorisation holder is considered as well as the significant importance of printed materials for the safe use of medicinal products. The process is focused on the linguistical evaluation of the nationally translated materials in regards to their correctness and perceivability compared to the authorised product information (Summary of Product Characteristics, SmPC) and the available space on the package. Especially in cases of safety or product relevant incidents EMA can perform a revision at any time.

[15] EMEA/305821/2006 (The Revised Checking Process of Mock-Ups and Specimens of outer / immediate labelling and packaging leaflets of human medicinal products in the Centralised Procedure) dated 22.01.2007.

At submission of sample texts the marketing authorisation holder must confirm towards the EMA

- that he formulated the sample texts according to national requirements,
- and that these are written in the official national language(s)
- that national „Blue-Box“ requirements have been adhered to,
- that the responsible producer named on the outer package is identical with the producer named in the directions for use and
- that the required text on the outer package is also embossed in Braille.

If serious deficiencies are identified, these must be corrected prior to bringing the medicinal product into circulation, or can - in the worst case - lead to a re-call of the already distributed product from this market.

2.2.2. Implementation of European medicinal products directives in Austria

For Austria the European directives - especially regarding the directions for use - are standardised in the "**österreichisches Arzneimittelgesetz (AMG)".**

Pursuant § 16c. (1) AMG and the request of patient organisations, the marketing authorisation holder or the holder of a registration must assure that the package insert leaflet is available in formats that are suitable for blind and visually impaired people.
(2) further outlines that the package insert leaflet must consider the results of the cooperation with patient target groups. The Federal Ministry of Health additionally can decree more detailed directives on the readability, clarity and user-friendliness of the package insert leaflet.

The sequence of the data in the directions for use is regulated in § 16 AMG. All information must be formulated in accordance with the summary of product characteristics.

Pursuant § 2. (1) "**Gebrauchsinformationsverordnung 2008"** the directions for use must be provided in German language, generally perceivable, well-arranged and well visible and readable. The font size (size of capital letters) must be a minimum of 1,8 mm.
(2) To fulfill the requirements as outlined in section 1 the directions for use must consider the results of the cooperation with patient target groups. In this context of assuring the readability, clarity and user-friendliness of the directions for use, the principles published in Art. 59 Abs. 3 und Art. 61 Abs. 1 of the guideline 2001/83/EG, „Guideline on the readability of the label and the package leaflet of medicinal products for human use“ must be adhered to.

§ 3. (1) leg.cit.: The directions for use must be added to the package in the respective form as package insert leaflet.
(2) The package insert leaflet may contain further information as long as they are relevant in the context of safety of medicinal products. Such notice must be clearly seperated from the directions for use, must not contradict the information given in the directions for use and must not suggest an effectiveness of the medicinal product that does not result from the directions for use. Medicinal product advertisment is not permitted neither in the directions for use nor in the additional information on the package insert leaflet.

3. Social, medical and psychological background

3.1. Blind and visually impaired people

3.1.1. Medical classification and definitions

According to the International Classification of Functioning, Disability and Health (ICF) by the World Health Organisation (WHO) „Seeing“ is defined as the sensitive function that refers to the cognition of light, form, size, shape and colour of a visual stimulus. Determinative factors are visual acuity (Visus), visual field and quality of ability to see[16]. Blindness generelly refers to the strongest form of visual impairment with completely missing or very limited ability to see with one or both eyes. Blindness can be congenital or acquired and usually is irreversible.

The usual method to measure the degree of visual impairment is to quantify the factors "visual acuity" and "visual field". Limitations of the visual acuity are indicated as percentage or fraction of the "full visual acuity" (norm). A normal visus therefore equals 100 %. The visual field is defined as the area, in which visual stimuli can be noticed without having to move (eyes, head, body). It encompasses an area of 175° for people without viual impairment and decreases with age[17]. The criteria for blindness vary with the applied definition.

WHO Definition (Report 2004)

- Low Vision (Grade 1+2): Visus 0,05 to 0,03
- Blindness (Grade 3-5): Visus <0,05, VF<10 Degrees

Visus refers to the optimally corrected visus of the better eye.

Definition by the Austrian and German Association of Ophthalmologists

- Visual impairment: up to a maximum visus of 0,3 on the better eye
- Profound visual impairment: up to a maximum visus of 0,05 on the better eye
- Blindness: up to a maximum visus of 0,02 on the better eye
- Amaurosis: no cognition of light and optical stimuli
- A reduction of the visual field to less than 5 degrees also is defined as blindness

Definition of Blindness according to German Law[18]

- A person is visually impaired, if he/she - even with glasses or contact lenses - cannot see more than 30 % of what a person with normal visual functionality can see.
- A person is profoundly visually impaired, if he/she - even with glasses or contact lenses - cannot see more than 5 % of what a person with normal visual functionality can see.
- A person is blind, if he/she - even with glasses or contact lenses - cannot see with his/her better eye more than 2 % of what a person with normal visual functionality can see.

[16] ICF - International Classification of functionality, handicap and health. WHO 2001 (German translation 2005), P.. 60 f.
[17] Rau, U. (Hrsg.): "Barrierefrei – Bauen für die Zukunft. Bewegungsräume optimieren-intuitiver Gebrauch-kontrastreichgestalten". Bauwerk, Berlin 2008.
[18] Association of the blind and visually impaired people Schleswig-Holstein e.V.

- A limitation to less than 5 % can mean, that a person can identify an object only at a distance of 5m, which a person with normal visual capacities can identify already from a distance of 100m. A limitation to less than 5 % can however also mean, that a person can only see 5 % of the visual field (like through a tunnel).

Definition of Blindness in Austria according to the Viennese Attendance Allowance Act 2008 § 4a.(5)

People with a visual acuity below 0,02 (2 % of norm) are considered blind irrespective of the level of visual field reduction. Blindness additionally includes impairments with lesser limitations of the visus, but a higher degree of visual field reduction as follows:

- Visus ≤ 0,02 (1/60) – no visual field impairment
- Visus ≤ 0,03 (2/60) – quadrant anopia
- Visus ≤ 0,06 (4/60) – hemianopsia
- Visus ≤ 0,1 (6/60) – tubular visual field impairment

The values refer to the respective visual functionality of the better eye subject to best possible correction. Besides the quantitative value of visual capacity the assessment of the level of actual visual impairment considers additionally how the remaining visual capacities can qualitatively be used and to what extent other sensitive functions (f.ex. accoustic perception) are recruited. According to the various definitions generally not only those people are considered as blind, who have no cognition of visual stimuli („Amaurosis"), but also persons, whose visual cognition is limited to a degree that does not allow an orientation with the visual sense.

3.1.2. Morphology – Diseades affecting the ability to see

Visual impairments of varying degree to blindness can be caused by damages to various structures: Cornea, lense, vitreous, macula, retina, visual nerve, visual centre of the brain. Depending on the affected structure the limited or missing visual perception is rooted in varying functions of the perception process (Sensation of stimulus in the eye - stimulus transmission from the eye to the brain via receptors and visual nerve - stimulus processing in the brain). The visual impairment can appear as reduced visus, an increased sensitivity for contrasts and glares, various reductions of visual field and as combination of these symptoms. The visual impairment can be inherent, can become manifest genetically during life or can be acquired from diseases or injuries.

Subsequently some examples of common diseases of the visual system, which can lead to a significant visual impairment and blindness:

Cataract

A clouding of the normally clear eye lens leads to blurred vision and deteriorated contrast perception with increased sensitivity for glares.

Retinal Detachment

The detachment of the retina leads to malfunctions of many neurosensoric processes. Common symptoms are sudden dense shadows (black veil) or central visual loss. Typical signs are also flashes of light or increase of floaters, which are noticed by patients during the early stage. Causes often are diabetic retinopathy, myopia or genetic factors.

Retinitis Pigmentosa

Retinitis Pigmentosa is a genetic disease of the retina, characterised by the progressive loss of retina cells, which leads to night blindness (nyctalopia) and a reduced field of vision with tunnel vision. Other symptoms are a deterioration of the contrast and colour vision as well as the visus.

Macular degeneration

Macula is the medical expression for the retina centre, the area with the best vision acuity. A macular degeneration leads to a partial or total loss of the visus. First symptoms are often noticed as blurred spot while reading. With time this spot becomes larger, in an advanced stage faces, street signage, etc. can only be recognised dimly. The spatial orientation however remains intact and can be supported through training.

Glaucoma

This disease is caused by increased intra-ocular pressure and reduced blood supply. Glaucoma is noticeable by the increasing reduction of the vision field and by characteristic symptoms such as: headaches, vertigo, blurred vision and seeing halos around lights.

3.2. Social Situation

International

Worldwide there are approx. 39 million blind and 285 million profoundly visually impaired people. In 2004 the WHO published an article on blindness and visual impairment, which includes European data as well. A comparison of different countries however remains difficult, as the applied definitions of blindness and visual disorders vary significantly across countries (Definitions see 3.1.1.).

The report states that globally 1,5 to 2,2 times more women go blind than men. In terms of age groups the 49+ group represents 0,5% of the population, followed by the group 15-49 with 0,1% and the under 15 group with 0,03%.

Germany

According to the WHO 2004 Report there are 164.000 (0,2 %) blind and 1.066.000 (1,3 %) visually impaired people in Germany. Approx. 10.000 people go blind (Incidence 12,3/100.000) and approx. 160 children are born blind per year (2 of 10.000). While from 1990 till 2002 only a moderate increase

of blindness by 9 % was registered, the increase of visual impairments reached 80 % in the same period.

This increase is mainly due to the increased life expectancy. While optic atrophy is the most prevalent cause for visual impairment in the group <39 years, the 40-79 age group suffers mostly from diabetic retinopathy and the 80+ group from macular degeneration, followed by glaucoma. As 48 % of all blindnesses occur at the age of 80+, the age-related macular degeneration is the most frequent cause of all blindnesses in Germany. 68 % of all people going blind are women. Main reason seems to be their higher life expectancy making them overproportionally represented in this age group.[19]

Austria

The last survey of the Central Statistical Office registered 7.800 people in Austria as " practically blind"(i.e. orientation in an unknown environment without help is not possible due to their visual impairment) and 4.600 „totally blind" (i.e. They cannot differenciate light and darkness and they need other senses, especially hearing and tactile sense for orientation - even in a well known environment.) 43,4% of the Austrian nationals suffer from a visual impairment, which is permanent for 318.000 people - 3,9% of the population[20].

3.2.1. The Austrian Federation of the Blind and Partially Sighted

Even today blind and visually impaired people still have very limited access to books and other information published in printed media. The wast majority of books and newspapers in accessible formats such as Braille, large print or audio are not produced by the commercial publisher, but by non-commercial organisations. The Austrian Federation of the Blind and Partially Sighted runs such a facility producing and distributing accessible audio books[21] as well as a training & education centre.[22]

The Austrian Federation of the Blind and Partially Sighted (BSVÖ) is active in international cooperations and accessibility measures and particularly pursues the implementation of the regulation on improved access to books and print products - as presented by the World Blind Union (WBU) in 2009 - into the regulations of the World Intellectual Property Organisation (WIPO). This contract should solve the conflicts on international intellectual property rights for audio books and support their international distribution.

The political will of the European Unions (EU) citizens led to the acceptance by the European Parliament in February 2012: The resolution on the acessibility of books and print media for people with functional reading impairments passed - with significant majority. In 2008 Austria ratified the European Fundamental Rights Charter as well as statutory law for people with disabilities as agreed on by the United Nations (CRPD) and is now challenged to engage in the implementation. Especially the

[19] "Bertram, der Augenarzt", December 2005, p.267-268. See also www.augeninfo.de/separee/aa.
[20] ÖSZ 1998.
[21] The audio library of the BSVÖ produces audio books in cooperation with professional actors and speakers and comprises currently approx. 10.000 books, which can be played and navigated with a DAISY Player.
[22] SEBUS was founded under the sponsorship of the Austrian Federation of the Blind and Partially Sighted. The project is financed by the Federal Social Service Department from Austrian governmental funds for handicapped people..

articles 21 and 30 of the CRPD emphasise the right of access to information and cultural goods for people with disabilities by providing barrier-free formats.[23]

3.2.2. Psychosocial Aspects

Many blind and visually impaired people suffer from additional illnesses, which results in further impairment and a higher need for medical assistance and care. Especially those people, who do not live in a family or partner-relation, become frequently isolated. Psychological consulting and treatment therefore should focus on stimulating the existing capabilities of the affected patients to support them in leading - as much as possible - a self-reliant and active life in society.

Part of this self-reliance is also the access to information, which is an important prerequisite for equal participation in the social life in our society. The main objective therefore is the optimisation of the bio-psycho-social well-being by strengthening health-supporting resources, whereas these resources as social and personal means should contribute to master the life situation, such as a positive self-esteem.

Promotion of a self-reliant Life

The UN Convention on the Rights of Persons with Disabilities, which is valid law also in Austria, regulates among other things in article 19 the independent conduct of life and the social inclusion ("Unabhängige Lebensführung und Einbeziehung in die Gemeinschaft"), in article 20 the personal mobility ("Persönliche Mobilität") and in article 28 the appropriate life standard and social protection ("Angemessenen Lebensstandard und sozialen Schutz"). All these regulations are aimed at an as much as possible self-reliant life of people with disabilities.

While in the area of education and access to universities already many achievements like barrier-free education and teaching methodology have been accomplished, there are still many problems for this group of people in the area of daily life, leisure, social inclusion and mobility. Many of these problems are caused by the restrictions of self-reliant information access. Without help currently blind and profoundly visually impaired people cannot perform simple activities such as finding the route of a bus, the right metro perron or train schedules, identifying food products in the refrigerator, checking dates of expiry or gathering information on the effects of a pharmaceutical drug. To improve the quality of life of this group of people in a sustainable manner, innovative systems will be required. Such solutions need to be developed with strong involvement of the people concerned to ensure functionalities suitable for the practical application.

Compliance and Sef-Reliance of Patients

Especially for the self-reliance of patients as well as the aplomb of consumers it is important that the information available on package inserts or instructions for use of a purchased product are not only correct and comprehensive, but also "readable"/"audible" and understandable.

[23] See also the official website of the BSVÖ (www.blindenverband.at).

An AOK[24] survey on the occasion of patient opinion poll showed that 83,8% of the interviewed patients acquire information about pharmaceutical products, which they need to use, from their physician, 65,2% from their pharmacist and **65,3% from the package insert** (multiple answers were permitted).

The question, how important patients rate the package insert on a scale from 1 (very important) to 5 (not at all important), was answered by 71,9% of the interviewed people with 1 (= very important), 18% with 2, 6,7% with 3 and only 1,7% each with 4 and 5.

On a virtual scale of 1 (not at all important) to 5 (very important), the test group rated information on dosages and dosage forms, preventive measures and safety instructions, tolerances, interactions and adverse reactions and fields of application as very important. Information on the producer (3) as well as ingredients and composition (4) were rated less important by the consumers.

A survey, which was conducted in 2007 by the central association of the Austrian social insurance carriers[25] shows a similar result. **69% of the interviewed always read the package insert,** when taking a new drug, 35% of the interviewed stated that they consider it important to read the package insert to control the correctness of the prescription.
As a conclusion it can be said that this data shows a high interest among the population in such information, which currently is not available in the same extent and form to blind and visually impaired people. The telephone hotline, which was implemented in Austria in cooperation with pharmacists, can cover a substantial part of the urgent needs - which corresponds with above indicated consultation rate for pharmacists of 65,2% of the interviewed - but the demand of 65,3% of the interviewed people in Germany to read/hear the directions for use autonomously as well even 69 % of the interviewed people in Austria, who always want to read the package insert, remains unmet.

[24] Nink/Schröder, "zu Risiken und Nebenwirkungen: Lesen Sie die Packungsbeilage?" 2005.
[25] Press information of the central federation of the Austrian social insurance carriers dated 28.12.2007 on results of a representative survey of the GFK Austria with 4.000 Austrians from the age of 15 years onwards.

4. The survey test product „Speech Code“

4.1. Technical basic information and requirements for application

"Speech Code" is a 2-dimensional, coloured data matix code, which allows to encode binary data as so called colour "dots" and to apply the coded data with grid- and colour calibration information on a surface as fixed image in automatically optically readable form. The optically readable, coded data are scanned with optoelectronic sensors and decoded by use of the grid and colour calibration information, whereas the information of the fixed image is decoded into the original binary data and transferd into a mobile display with speech output.

The grid and colour calibration information provides the possiblity to make a much higher amount of different colours differentiable and in due course to increase the data density on a presentation surface. By applying the compressed data on a surface as fixed image in automatically optically readable form, initially a more or less inhomogenuous coloured area is provided, which does not make any information readable with the naked eye, except for additionally applied uncoded information such as logos or icons.

Commonly known technologies, such as for example the "QR Code", process the information captured via a mobile phone's camera to identify a link that then triggers the respective down-load of data. Contrary to such technologies "Speech Code" processes the fixed image information without any external data connection or data transfer into text data, which instantaneously appears on the display and in speech output.

The combined use of data redundancy via linear correction with "low-density parity-check (LDPC) code" by Gallager and non-dissipative data compression by Huffman ensures that decoding only takes place, if the LDPC data flow is complete and in due course also the CRC-test after decompression has been successful. Hence 100% data accuracy and security is guaranteed, due to the extremly complex structure "Speech Codes" are also highly fraud-resistant. The use of "seeds" as numeric basis for the data compression during the production of "Speech Codes" additionally allows for the use of PIN-codes to limit information access to defined user groups.

Due to lateral distribution of the applied grid and colour calibration information it is assured that "Speech Codes" can be decoded, even if the surface is partly or entirely shaded or exposed in certain colours.

To decode "Speech Codes" also from bent surfaces, an efficient, adapted, non-linear regression analysis by Kerchler is applied, allowing the decoding of data from surfaces with a minimum radius of 2cm.

To meet "Speech Code's" claim of barrier-free accessibility, the user is audio-guided through the scan process in such a way, that the optical cone of the smartphone camera is positioned optimally in relations to the "Speech Code" and the image then is recorded automatically without any further intervention by the user. This ensures that visually impaired people can scan "Speech Codes" self-reliantly and that the image recording is always happening at the very moment, when the algorithm captures the "Speech Code" in the optimal resolution, exposure, orientation and position.

"Speech Codes" serve well for barrier-free, secure data transfer, whereas the decoded information is made available as navigable text on the mobile display and in audible format via "text-to-speech" (TTS) technology. The encoded information is language-specific and can support more than 40 languages by Nuance™. The quality of the speech output can be improved by making use of the phoneme functionalities/transcriptions, which allow for a correct pronounciation even of loanwords and foreign language words.

Additionally there is the possibility to use control characters to reduce the data load of recurring text modules. Next to the regular "Speech Code Information" with flexible "dot" number, there is also a special code format with a fixed "dot" number intended for food product labelling, as food product safety information can be standardised language-independently by using control characters.

The process of generating and decoding "Speech Codes" happens in 3 steps:

1. Encoding of text with optional use of phonemes and generation of the "Speech Codes"
2. Print and application of the "Speech Codes"
3. Scan and decoding of the "Speech Codes" with immediate presentation of the information in readable and/or audible format

Prerequisites for the described processes are:

ad 1. Use of the "Speech Code Generator" either as application on a PC, as service on production servers or via the website "www.speechcode.eu".

ad 2. "Speech Codes" must be printed on surfaces that are non-reflecting and providing a certain colour stability, especially regarding UV-rays.

ad 3. Any smart phone equipped with a camera with a minimum resolution of 1 megapixel can be used to decode "Speech Codes". Furthermore the possibility for audio output via built-in loudspeakers and the information presentation on a display will be advantageous. The required scan application (App) "Speech Code" is available for the platforms Android and iOS with other platforms such as WinPhone to follow.

4.2. Fields of Applications

As the production of information in "Speech Code“ format is incorporated in regular printing processes and there is no need for technical infrastructure such as electricity, batteries, internet connectivity, etc., the technology "Speech Code" can be considered to be very cost-effective with low maintenance requirements. "Speech Codes" are much more "socially inclusive" than f.ex. DAISY formas as they can be presented on the very same piece of print as the regular text.

"Speech Codes" are 100 % accessible all the time and everywhere due to not requiring a connection to any other device, platform or communication means.

In contrast to technologies like "QR Codes" - delivering marketing information by tracking the user's online behaviour -, "Speech Code“ qualifies for all applications that legally require 100 % data accuracy, data privacy and barrier-free accessibility.

This is valid for any kind of product information, especially for the labelling of cosmetics, medicinal and food products. With one and the same "Speech Code" it is possible to provide the speech output of the contained product information in all available languages, if a standardised format of the information can be applied across languages and countries (f.ex. EU-wide standards).

Additional fields of application for providing barrier-free and self-reliant information access to blind and visually impaired people are:

- Documents, certificates, contracts and forms
- Invoices, bank statements and other financial information
- Medical reports
- Newspaper articles and job advertisments
- Safety instructions in public transport facilities and public buildings
- Orientation guides, signage and notices in public spaces and buildings, train stations, airports, museums, concert halls, hotels, restaurants and leisure facilities
- Recipies and prescriptions
- Menus in restaurants
- Products with identical packaging
- Vouchers and special offers
- Colour information for clothing

The multi-lingual availability of information allows the use of "Speech Code" also for the purpose of providing information access to citizens with language deficits. Government agencies and authorities can improve the social integration of immigrants by providing information in multiple languages in a space-saving, cost-effective way.

The same is valid for any public information campaign; By placing "Speech Codes" in multiple languages on posters and brochures, the integration and inclusion of citizens with language barriers can be improved - at moderate costs.

As the access to "Speech Code" information does not incur costs to the consumer, also financially handicapped people will have access.
"Speech Code's" multilingualism with currently more than 40 available languages and the omission of roaming-fees for visitors from abroad facilitate applications in the tourism sector:

Cities/countries with a high percentage of international guests can address their guests barrier-free and in their national language. Especially tourists from the large growth markets Brasil, Russia, India and China (BRIC) often have no or very limited knowledge of a foreign language and therefore have a high need for information in their own language.

An example of successful information accessibility is Gstaad in Switzerland, where all signage and information is available also in Japanese to facilitate a self-reliant visitor experience for their numerous Japanese visitors. Due to the small space requirements for "Speech Code" (2 pages A4 in approx. 5cmx5cm) signage in multiple languages becomes possible for international destinations.

Hence, the following touristic applications are possible:

- General information and safety instructions in airports, train stations and other public transport facilities
- Information on rates, schedules and routes at stops of trams & sight seeing buses
- Museums for signage and detailed information on each exhibit
- Event centres such as concert halls and opera for information and programs
- Sights such as churches, historic buildings, monuments or fountains for detailed information in multiple languages
- Leisure and theme parks for safety instructions and warning notices of attractions and facilities.
- Hotels and convention centers for emergency plans and instructions as well as for service information
- Restaurants for menues
- Detailed information on history and making of high quality souvenirs and clothes
- Sport facilities such as ski lifts, golf courses and fitness centres
- Destination marketing for theme walks, hiking, cycling and adventure trails

5. Academic background - Study SFU 007AT in Austria

The Sigmund Freud University Vienna, in cooperation with the ESQH (European Society for Quality in Healthcare) Vienna Office, is cooperating for quite some time with the Austrian Federation of the Blind an Partially Sighted (BSVÖ) with the purpose of supporting the interests of blind and visually impaired people in regards to accessible teaching, publication of audio books and development of new auxiliary tools. Thus the SFU Department of Health Law and Science has chosen to publish all their publications additionally in an audible format.

The preparatory academic evaluation of the study found a high demand for accessible information channels and tools among blind and visually impaired people. Especially in the field of product information there is a high demand for access to package insert texts and to autonomously navigate to the needed information. A respective tool would enable blind and visually impaired people to participate in „Readability-Tests“ for pharmaceutical products and to promote the accessibility needs of their target group.

Furthermore the prevailing legal norms stipulate for producers and distributers high standards for correct product presentation (generally, and especially for medicinal products) and product safety, i.e. end consumer product information. Should deficient or incomplete consumer information lead to personal harm, the producer or importer is fully liable for all related costs as well as for resulting alimentary payments and medical treatments for the victim.

For these reasons all involved parties have a valid interest in technologies that can support product safety issues.

The objective study therefore aimed at testing the innovative auxiliary tool, "Speech Code" as „Audible product information and direction for use“ with the involvement of the prime target group. Furthermore the scope included the evaluation of an adequate navigation within the text of such „Audible product information" to give blind and visually impaired people self-reliant access to the needed information and to allow their participation in „Readability Tests“. The evaluation of „Readability Tests“ could follow in a seperate project with the involvement of the associations.

Survey

The first part of the evaluation deals especially with blind and visually impaired people. The data was collected in direct tests from probands with different levels of impairment/blindness. Members of the Austrian Federation of the Blind an Partially Sighted as well as students and teachers of the BBI (Federal Institute of Education for blind and visually impaired children) were invited to participate in the test and a following interview.

To assess to what degree the results are specific for blind and visually impaired people, a survey was conducted with not affected people (mainly students). These interviews omitted the foregoing test of the tool due to no or only slight visual impairments of these probands.

In parallel with this study a detailed evaluation was started with patients and consumers, to evaluate the implementation of the "Speech Code" technology for people under medical treatment. Probands with varying degrees of visual impairment and from diverse fields of indication as well as rare diseases patients test the tool to evaluate its benefit for use in the regular therapy.

From an academic point of view a high demand for accessible information channels was identified in the research area, which will be further evaluated by subsequent projects on providing information to probands and patients for a variety of purposes such as patient passports, medical record documentations, adverse drug reaction reporting, etc.

Implementation

The data that became available in this study will be presented to authorities (competent authority for drug regulation, Product Safety Advisory Body), consumer organisations, the Austrian Chamber of Commerce, industry associations (Pharmig, etc.), and other groups to conjointly consider further fields of application and to thus provide broad information access via this new tool.

The academic consortium includes important players in the area of product information for blind and visually impaired people. Some of its members also contributed as authors to the present publication.

6.Study design, methodology and analysis

6.1. Questions

6.1.1. Distinguishing blindness from visual impairment with respect to the application

Is there a fundamental difference with respect to the **acceptance** of the system? Based on the questions as to whether people would use the system if it was available, and whether they would like to be able to use the system also for other purposes, the intention was to find out if a higher degree of visual impairment or blindness (since birth or any later loss of eyesight) correlates with a higher degree of acceptance of technological applications of this type.

Another fundamental question was to find out if the application is considered a positive development, with the potential to facilitate the daily life of persons affected by visual impairments of varying degrees, and how the two groups **evaluate the general usefulness** of the application, based on questions as to whether and how often people would have needed such a system already, and if they would use it if it was available.

Subsequently, this evaluation of usefulness had to be compared to the evaluation of the ease of operation (based on the question: What is your evaluation of the application overall?). For consumers to actually be ready to use the tool in practice, it must be easy to operate.

6.1.2. Comparison with a control group of persons without, or with only slight visual impairment, with respect to acceptance and evaluation of usefulness without test of operation

A comparison as to whether people with good eyesight assess the usefulness of the application in a similar way would suggest that the demand for a system of this type is much higher than originally assumed. In order to create a comparable situation, primarily students equally used to handling technological products of this type were interviewed as the control group for the blind and visually impaired persons accustomed to the use of assistive technology.

6.1.3. Impact of age on the evaluations obtained

The selection of the three age groups was essentially based on the assumption that these groups approach technological products in different ways. While the first two groups are very likely to be accustomed to mobile phones, this would only apply to the third group to a lesser extent. The idea was to show the extent to which acceptance and perceived usefulness in the groups with different visual impairment depend on age, and whether due to the usefulness of the application, persons that are not used to handling technological devices would basically be prepared to buy a mobile phone to use the service (based on corresponding questions as to whether the person has a mobile phone that would be suitable, or if not, whether they would buy one).

6.1.4. Preparation of a profile of potential system users

From the data obtained already, it should be possible to prepare an approximate profile of the groups that are most or least interested in the development, and to answer the question if the target groups may be assumed to dispose of adequate technological equipment already.

Said profile also includes a direct evaluation of the system components, namely handling of the scanning procedure, evaluation of audio instructions, as well as the quality and speed of speech, which are all going to be decisive criteria for acceptance within the scope of further development.

6.1.5. Finding the information required

The code submitted to the test subjects included complete instructions of use with anonymised designations of the pharmaceuticals. Based on the navigation steps, it was to be tested if people get to the information they are looking for. Evaluating the question "how easy was it for you to handle the software in order to get the required information" was the starting point for a targeted search within the text. It is the basis for the future possibility of participation in "readability tests" on the part of blind and visually impaired people. In another project stage, the test requirements of EMA will be specifically simulated and evaluated.

6.2. Standardised tests with blind and visually impaired persons

6.2.1. The study protocol

The present academic, non-interventional study of talking product inserts and product information was planned in the first stage with voluntary participants from the Austrian association of blind and visually impaired people (Blinden- und Sehbehindertenverband Österreich) under the management of Mag. Gerhard Höllerer (former president of BSVÖ) and DI Doris Ossberger (head of the division for barrier-free building construction, BSVÖ), and carried out in a second trial run in the training and education division under the management of Prof. Erich Schmid (Bundes-Blindenerziehungsinstitut; federal educational institute for the blind) with youths in training.

It was merely a product application study implemented outside of any health facilities, consisting in a mere test of an experimental setup including a brief interview; also based on the type of questions asked, it cannot be classified as interventional in any way. The application itself was presented on a commercially available mobile phone, so there was no risk for the test subjects.

6.2.2. The questionnaire

The questionnaire was prepared in cooperation with the consortium members and worked out by SFU. All data were collected by the responsible team members in anonymised form. With a view to the questions asked, only the respectively required information regarding the person and his/her case history was recorded.

Personal data:

- Sex (female / male)
- Age group (under 18 years, 18 - 50 years, over 50 years)
- Blindness (since birth or later loss of eyesight) or visual impairment
- If visual impairment is indicated: the test subjects were asked if they were still able to orientate themselves using their eyesight (yes/no)
  and they were asked to indicate if they were still able to perceive visual information
  Indication of the subjective assessment of perceptive faculty
  on a scale of 0-10

Questions concerning the use of the system and concerning the basic requirements:

- Question as to whether the person has a mobile phone,
  whether the mobile disposes of a camera function, and whether it is basically suitable for the application,
- If the test subject does not have a mobile phone, question as to whether he/she would buy one,
- Question as to whether the test subject would use the system if it was available (yes/no),
- Question as to how often the test subject would already have needed such a system (daily, weekly or less frequently)
- And question as to whether the test subjects could imagine that such a system might also be useful in other areas (food, cosmetics, patient passports, other applications).

Questions concerning the evaluation of the system:

- Application in general
- Handling of the scanning procedure
- Clarity of audio instructions
- Usefulness of audio signals
- Quality of voice output
- Speed of voice output
- Usability of navigation within the text

See also the illustration on the following page.

6.2.3. Execution of the test

Within the scope of collective appointments arranged by the Blinden- und Sehbehindertenverband Österreich (BSVÖ; Austrian Federation of the Blind and Partially Sighted) that were held in Vienna, Carinthia and Upper Austria to provide for regional spreading, blind and visually impaired volunteers were provided with an opportunity to try and test the system. The standardised test setting consisted of five mobile phones with camera function on which the programme had been installed, including one copy each of the code that was meant to be read, and oral instructions regarding operation of the mobile, with a presentation of the application before the group of test subjects (consisting of 5-10 persons).
Then a group of 5 test subjects were simultaneously asked to test the application. Those same persons were then asked for an interview, with the method of data collection applied consisting in an interview conducted by the ANISNet team members with the test subjects and recorded in the questionnaire.
The same test setup was also used at the Bundes-Blindenerziehungsinstitut (BBI) where youths of different age groups and educational levels tested the application.

3. Information about the System:

How do you evaluate the application overall 1 2 3 4 5 1= best value, 5= worst value

Comments:

How do you evaluate **the handling of the scanning procedure** 1 2 3 4 5 1= best value, 5= worst value

Comments:

Is the clarity of **audio instructions adequate** 1 2 3 4 5 1= best value, 5= worst value

Comments:

How useful are the **audio signals** 1 2 3 4 5 1= best value, 5= worst value

Comments:

How do you evaluate **The quality of the voice output** 1 2 3 4 5 1= best value, 5= worst value

Comments:

How do you evaluate **The speed of the voice output** ☐ **too quick** ☐ **just right** ☐ **too slow**

Did you find the handling of the software to **obtain the desired information easy** 1 2 3 4 5 1= best value, 5= worst value

Comments:

Signature by member of trial network

6.3. Opinion survey among consumers without visual impairment or with only slight visual impairment (control group)

In order to be able to compare the group of blind and visually impaired people with a control group of people that are not blind or affected by severe visual impairment, and to evaluate the benefit of the application, an opinion survey among 634 passers-by (mainly students) was carried out in public.
It consisted of two brief questions only, without testing the application:

Question 1: The speech code also enables persons without visual impairment to accurately read or hear text in very small print. Would you use a speech code on product inserts? (1=yes, 2=occasionally, 3=very rarely, 4= rather not, 5=never) In case the answer is 4 or 5: Why rather not/never? (A=too cumbersome, B=I don't have a mobile that can scan the code, C=I don't need that because I have good eyesight, D=I simply think that is unnecessary, E=other reasons)

Question 2: Do you think it's useful to attach small codes on foodstuffs that provide you with special information that is currently missing due to the various EU-wide regulations (e.g. information about ingredients, notes for allergic persons, diabetics, persons suffering from nephropathies, and other persons)? Please evaluate using school grades (1=very useful/5=not useful). In case the answer is 4 or 5: Why (rather) not useful? (A=too cumbersome, B=I don't have a mobile that can scan the code, C=I don't need that because I am not very interested to get more information, D=I simply think that is unnecessary, E=other reasons)

6.4 Statistical analysis and results

The following statistical analysis offers an overview of the data structure of the 105 responses by the blind and visually impaired respondents and of the distribution of variables, as well as a more thorough analysis where reasonable.
In a first step, we try to give maximum insight into the data providing information in the most compact form possible. The most important questions are explained in greater detail below. In chapter 6.4.4 we try to examine in particular which factors explain the overall evaluation of the system (talking product inserts and product information). Moreover, potential patterns of use as well as the user-friendliness are evaluated, especially by comparing the "blind persons" group with the group of "non-blind persons".
Chapter 6.4.5 includes detailed information about the opinion survey without product test among persons without visual impairment or without any severe visual impairment.

6.4.1. Summary table

Table 1 graphically summarises the features surveyed. The level of measurement (binary, multinomial, ordered, continuous) as well as the possible manifestations of the features are described. Moreover, mean values and the pertaining confidence intervals are estimated: arithmetic means for continuous variables and medians for ordered categorical variables. Confidence intervals for proportions are estimated using the normal distribution approximation [see e.g. Hartung et al., 2005], confidence intervals for medians using the bootstrap procedure [Efron and Tibshirani, 1993]. The last column of the tables graphically illustrates the distribution of the variables.

It is obvious that the number of item non-responses (refusal to respond to certain questions) is high for a few variables only. In particular, this concerns the question about the time recorded (55 missing values), the question about the operating system of the mobile phone (77, with 35% missing structurally), the question about 'other than patient passports', and the question about perceptive capacity.

Summary table of the features surveyed including description of the level of measurement (including the number of missing responses), the mean value and the pertaining confidence interval as well as a graphic illustration of the distribution of variables

Variable	Type (non-response)		Mean/Prop.
Time	continuous (55)		**48** (31.9, 64.1)
Mobile phone user	binary (0)	yes/no	**0.87** (0.78, 0.92)
Camera	binary (0)	yes/no	**0.65** (0.55, 0.74)
Operating system	multinomial (77)	15 levels	
Purchase	binary (0)	yes/no	**0.42** (0.32, 0.52)
Use	binary (0)	yes/no	**0.83** (0.74, 0.89)
Frequency	multinomial (0)	daily/weekly/rarely	
Food	binary (0)	yes/no	**0.89** (0.81, 0.94)
Cosmetics	binary (0)	yes/no	**0.33** (0.25, 0.43)
Patient passports	binary (0)	yes/no	**0.15** (0.09, 0.24)
Others	multinomial (41)		
Sex	binary (0)	male/female	
			0.57 (0.47, 0.67)
Age group	multinomial (0)	<18 / 18-50 / 50+	
Blindness	binary (0)	yes/no	**0.29** (0.2, 0.38)
Visual impairment	binary (0)	yes/no	**0.65** (0.55, 0.74)
Since birth	binary (0)	yes/no	**0.32** (0.24, 0.42)
Later loss of eyesight	binary (0)	yes/no	**0.26** (0.18, 0.35)

Variable	**Type (non-response)**		**Mean/Prop.**
Orientation			
Visual capacity	binary (0)	yes/no	**0.46** (0.36, 0.56)
Perceptive			
Capacity	ordered (38)	scale of 1-10	**3.7** (2.9, 4.6)
Evaluation	ordered (1)	scale of 1-5	2 (2.2)
Scanning procedure	ordered (1)	scale of 1-5	2 (2.2)
Audio instructions	ordered (1)	scale of 1-5	1 (1.1)
Audio signals	ordered (4)	scale of 1-5	1 (1.2)
Quality	ordered (1)	scale of 1-5	1 (1.1)
Speed	multinomial (1)	too quick/just right/too slow	just right

The time recorded is continuously scaled with approximately log-normal distribution. A more detailed analysis of the time in chapter 6.4.2 will show that especially blind persons need more time to follow the instructions.

The majority of respondents do possess a mobile phone, but only some 65% dispose of a camera function. The dominant operating system of mobile devices with camera function is Symbian, which is exclusively used on Nokia-branded devices.

Although only about half of the respondents consider buying a mobile phone that meets the system requirements, the majority of them want to make use of the talking product inserts and product information, especially to buy food. Chapter 6.4.3 will reveal that blind people, in particular, want to do that either daily or weekly.

Table 1 shows that the frequency both of the two sexes and of the age groups is approximately the same across all categories. Some 29% of persons interviewed are blind, while 65% have some form of visual impairment.

Visual perceptive capacity was assessed quite differently on a subjective level, with a majority of visually impaired persons indicating that their perceptive capacity is very good.

The overall evaluation on a scale of 1-5 is mostly very good, i.e. "grade" 1 or 2. All other questions as to user-friendliness are also assessed to be very good. The speed of the instructions was assessed to be just right by almost all respondents.

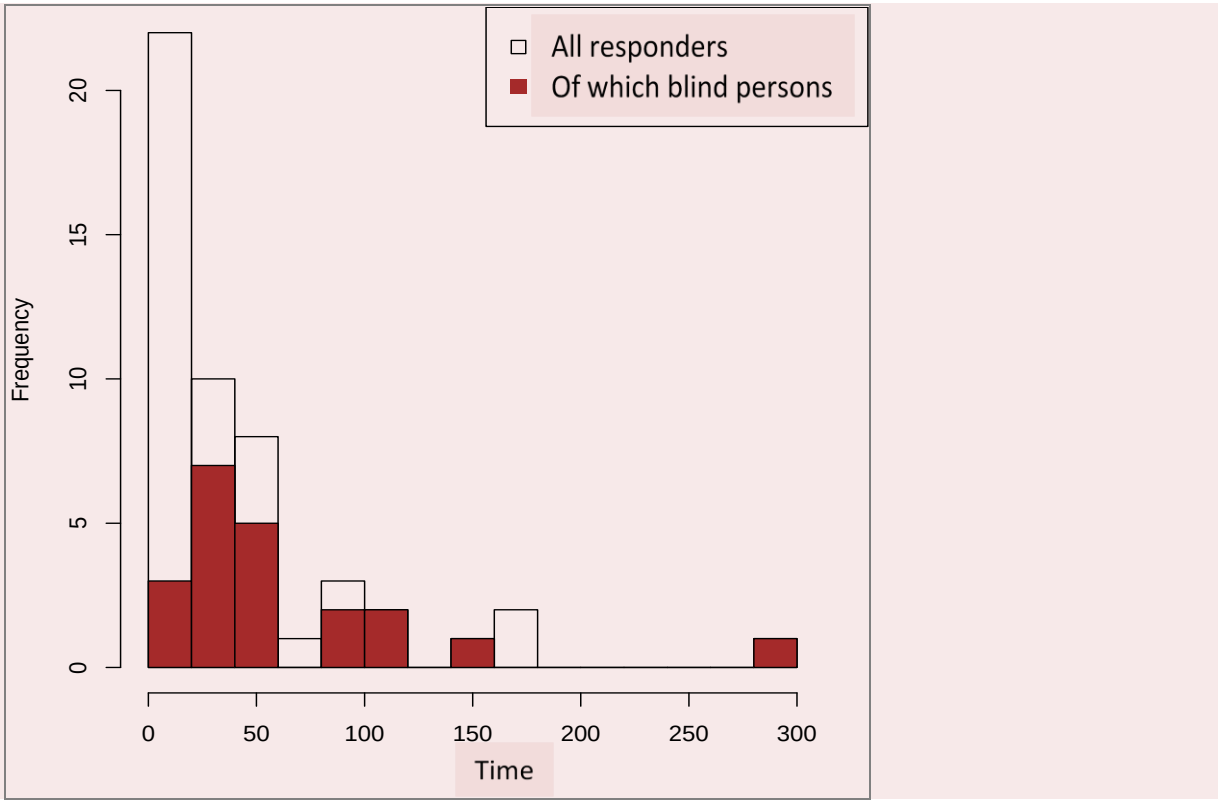
6.4.2 Time recorded

For 55 of 105 respondents, this information was not indicated due to interruptions of the interview. The arithmetic mean of the time recorded is 48.02. The actual mean lies between 31.92 and 64.12 with a probability of 95%.

The arithmetic mean of the time recorded for blind respondents is 67.33, while for not - or only slightly - visually impaired persons, it amounts to 34.03.

Hypothesis *H0 : Blind respondents need the same amount of time as respondents withou, or with only slight visual impairment* and the alternative hypothesis: *H1: blind respondents need more time*, must be rejected at a level of significance of 0.05 (p = 0,0261). That means, the time recorded for blind persons is longer than that for people without or with only slight visual impairment. The alternative hypothesis may be formulated unilaterally, since it cannot be assumed that blind persons will follow the instructions more quickly than non-blind persons. This is also clearly evident from figure 1. It is obvious that blind respondents needed more time. There are even two outliers in the group of persons without or with only slight visual impairment, and one significant aberration in the group of blind persons. The test result would become even more significant, if the data were adjusted for these three aberrations (p = 0.001).

Visualisation of the distribution of the time recorded using a histogram



The proportion of the group of blind respondents was highlighted in red.

6.4.3 General usefulness

While roughly half of the respondents (true proportion between [0.32, 0.52]) would even buy a device with the required functionality, the vast majority would also use the system - regardless of their buying behaviour (true proportion between [0.74, 0.89]).

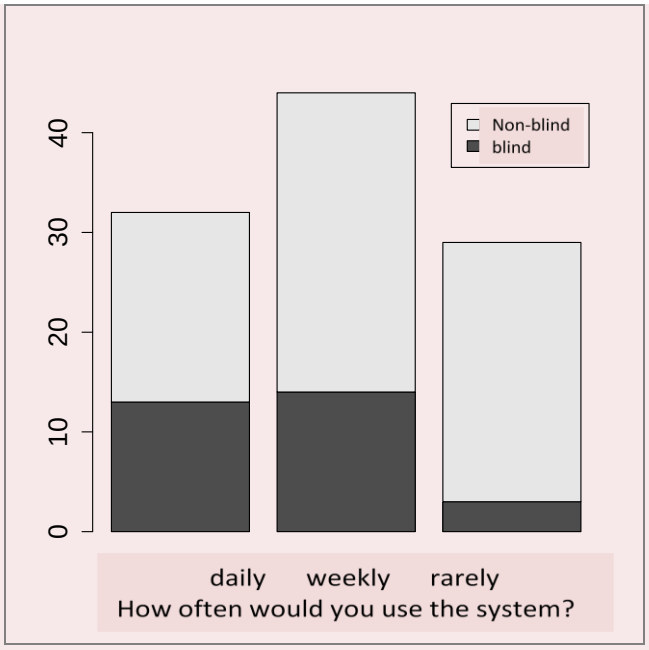
If restricted to the group of blind persons, a similar picture arises, see table 3. Here, the difference between blind and non-blind persons is particularly big. While non-blind persons would rather not buy a mobile device that can handle the talking product inserts and product information, a majority of blind persons would definitely be prepared to buy a suitable device. Furthermore, almost all blind persons would use the system (confidence interval between 0.81 and 1).

Buying behaviour and patterns of use

	Proportion	Confidence interval
buy (all)	**0.42**	(0.32, 0.52)
buy (non-blind persons)	**0.27**	(0.17, 0.38)
buy (blind persons)	**0.8**	(0.61, 0.92)

use (all)	**0.83**	(0.74, 0.89)
use (non-blind persons)	**0.77**	(0.66, 0.86)
use (blind persons)	**0.97**	(0.81, 1)

Distribution of responses of blind and non-blind respondents to the questionas to how often they would use the system



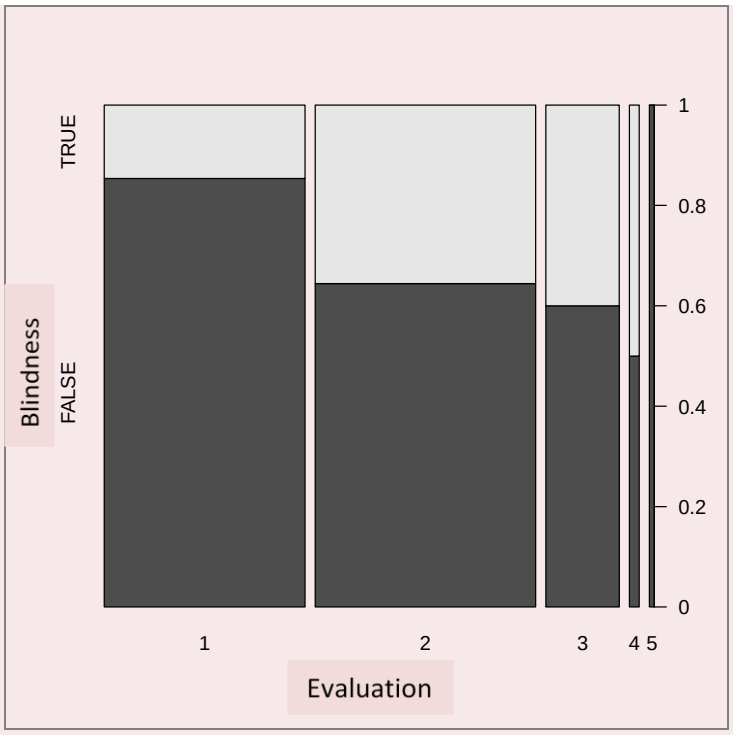
While blind persons would rather use the system daily or weekly, the group of non-blind persons would rather only use it weekly or rarely.

6.4.4 Evaluation of the system

Below you will find an overall evaluation of the system and of the influencing factors that were decisive for its evaluation.
One of 105 respondents did not answer this question. The mean (median) of the overall evaluation is 2. The actual mean lies between [2, 2] with a probability of 95%, i.e. with a 95% probability the actual value is 2.
The median of the overall evaluation for blind respondents is 2 (arithmetic mean = 2.07); for respondents without or with only slight visual impairment it is also 2 (arithmetic mean = 2).
Hypothesis *H0 : "Blind respondents evaluate the system in the same way as respondents without or with only slight visual impairment*, and the alternative H1: *blind respondents evaluate the system differently as compared to the other group"*, must be rejected at a level of significance of 0.05 ($p = 0.0214$), i.e. the overall evaluation for blind persons is less favourable than for persons without or with only slight visual impairment. For the test, a non-parametric Mann-Whitney Test was applied [see Hollander and Wolfe, 1999].

Visualisation of the distribution of overall evaluations

The following illustration clearly shows that blind respondents tend to evaluate the system less favourably than non-blind persons or persons with visual impairment. While a great number of respondents not affected by blindness evaluate the system with the top grade, the top grade is given by relatively few blind respondents only.



Nevertheless, the system is also evaluated favourably by blind persons on average, although it is received better by non-blind persons with visual impairment.
Ordinal regression to explain the overall evaluation: the levels of measurement of many variables in the study are ordinal, i.e. there is a ranking of response options.
For instance, the overall evaluation of the system is made on a scale of 1-5, with 1 being the best possible evaluation and 5 the worst possible evaluation.
If an ordinal variable is used as a dependent variable in a regression model, a special linear method of regression should be used. In doing so, the probabilities of the manifestations are modelled depending on the ranking [for details see e.g. Rufibach, 2011].

Searching for a model: as optimal a model as possible was searched for exploratively, i.e. a model that has a high explanatory degree and, on the other hand, is as simple as possible.
After the search the following model was found:
Evaluation: audio instr. + blindness + information, with the variable to be explained "evaluation", the overall evaluation of the system, and the variables (to be explained) of "audio instructions", "blindness" and "ease of obtaining information".

Generally it may be said that only the audio instructions, the ease of obtaining information and the severity of the impairment (blind or visually impaired with residual visual capacity) greatly influence the overall evaluation of the system, while age, sex, audio signals and time effort do not have any significant influence. Accordingly, the overall evaluation is also influenced by whether the persons are totally blind or not, i.e. totally blind respondents accord a less favourable overall evaluation.
Moreover, the audio instructions are highly significant, i.e. the evaluation of the audio instructions is closely related to the overall evaluation. The ease of obtaining information also has a highly significant influence on the overall evaluation.

Determination of the relevance of the factor of "blindness" on the overall evaluation of the system

```
formula: as.factor(Beurteilung) ~ Audioanw + Blindheit + Info
data:    x

 link  threshold nobs logLik AIC    niter max.grad cond.H
 logit flexible  101  -94.77 203.54 6(0)  3.69e-09 5.9e+02

Coefficients:
             Estimate Std. Error z value Pr(>|z|)
Audioanw       1.1410     0.3154   3.618 0.000297 ***
BlindheitTRUE  0.8677     0.4447   1.951 0.051004 .
Info           1.1414     0.3125   3.652 0.000260 ***
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Threshold coefficients:
    Estimate Std. Error z value
1|2   3.1118     0.6685   4.655
2|3   5.8696     0.8699   6.747
3|4   8.2024     1.1500   7.133
4|5   9.3119     1.4085   6.611
(4 observations deleted due to missingness)
```

Determination of the relevance of various influencing factors with respect to the overall evaluation of the system

```
formula:
as.factor(Beurteilung) ~ Audioanw + Blindheit + Info + as.factor(age) +
    Geschlecht + Zeit + Audiosignale + Lebensmittel + Blindheit +      schnell
data:    x

 link  threshold nobs logLik AIC   niter max.grad cond.H
 logit flexible  46   -28.03 80.05 6(0)  1.07e-07 5.4e+05

Coefficients:
                 Estimate Std. Error z value Pr(>|z|)
Audioanw         2.343625   0.721121   3.250  0.00115 **
BlindheitTRUE    1.916134   0.969605   1.976  0.04813 *
Info             1.038521   0.728957   1.425  0.15425
as.factor(age)2  2.453657   0.985155   2.491  0.01275 *
as.factor(age)3  2.367173   1.270300   1.863  0.06240 .
GeschlechtTRUE   1.523536   0.927860   1.642  0.10059
Zeit            -0.007516   0.009320  -0.806  0.41997
Audiosignale     0.166599   0.289208   0.576  0.56458
LebensmittelTRUE 0.039017   1.170608   0.033  0.97341
schnell         -0.666426   0.781425  -0.853  0.39375
---
Signif. codes:  0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1

Threshold coefficients:
    Estimate Std. Error z value
1|2    5.583      2.636   2.118
2|3    9.726      3.056   3.183
(59 observations deleted due to missingness)
```

If we use all (reasonable) variables to explain the overall evaluation, the following result is obtained: in the full model, a slight influence of age becomes visible. Persons between 18 and 50 years of age evaluate the system less favourably than young persons under 18 years of age. The greatest influence on evaluation originates from the audio instructions. However, no influence at all was found in the full model for the following variables: ease of obtaining information, sex, time, audio signals, food, and the assessment as to whether the information is displayed too quickly, at just the right speed or too slowly. The full model should be used with caution, however, since overfitting may easily occur. Yet tendencies can be observed here, too.

6.4.5. Ease of use

The following variables can be allocated to "ease of use": evaluation of audio instructions, evaluation of audio signals, evaluation of the scanning procedure, evaluation of speech quality, evaluation of the system regarding the time sequence of instructions (too slow, just right, too quick).

At first, it was examined for which variables a significant difference occurs (level of significance 0.05). While no significant differences were observed between blind persons and non-blind persons as regards the audio instructions and the audio signals, a significant difference was determined with respect to responses regarding the evaluation of the scanning procedure, the speed of the sequence of instructions and the quality of voice instructions.
While blind persons tended to evaluate the scanning procedure and the speed of the sequence of instructions less favourably, they tended to evaluate the quality of voice instructions more favourably on average. For the test, non-parametric Mann-Whitney Tests were applied again [see Hollander and Wolfe, 1999].

Mean values and confidence intervals of the variables relating to ease of use

	Median	Confidence interval	Arithmetic mean
Audio instructions (all)	1	(1, 1)	1.44
Audio instructions (non-blind)	1	(1, 1)	1.41
Audio instructions (blind)	1	(1, 2)	1.52
Audio signals (all)	1	(1, 2)	1.89
Audio signals (non-blind)	1	(1, 2)	1.85
Audio signals (blind)	2	(1, 2)	2
Scanning procedure (all)	2	(2, 2)	2
Scanning procedure (non-blind)	2	(2, 2)	1.84
Scanning procedure (blind)	2	(2, 2)	2.41
Quality (all)	1	(1, 1)	1.3
Quality (non-blind)	1	(1, 1)	1.39
Quality (blind)	1	(1, 1)	1.07

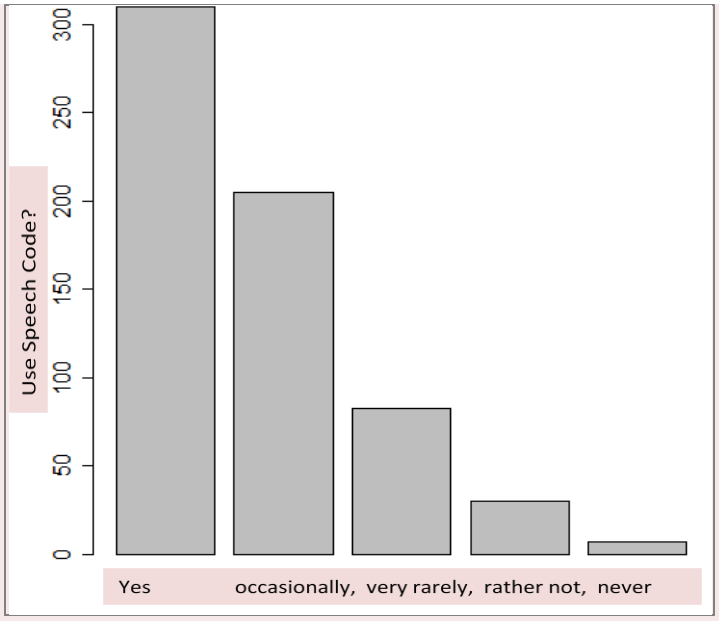
The table shows the medians and the pertaining confidence intervals as well as the arithmetic means. It is evident that all questions were answered in a clearly positive manner. (Very) slight differences with respect to the responses of blind and non-blind respondents were observed.
The results only deviate to the extent that here the confidence intervals of the median were examined, while above the mean values of ordinal variables were calculated in a test based on rank order statistics.

6.4.6. Acceptance within the control group of persons without or with only slight visual impairment

In addition to the survey among blind persons and persons with severe visual impairment, a control group of 635 persons (617 of them between 18 and 50 years of age, 18 persons without indication of age) was asked about the usefulness of a Speech Code on product inserts and about the usefulness of small codes on foodstuffs.

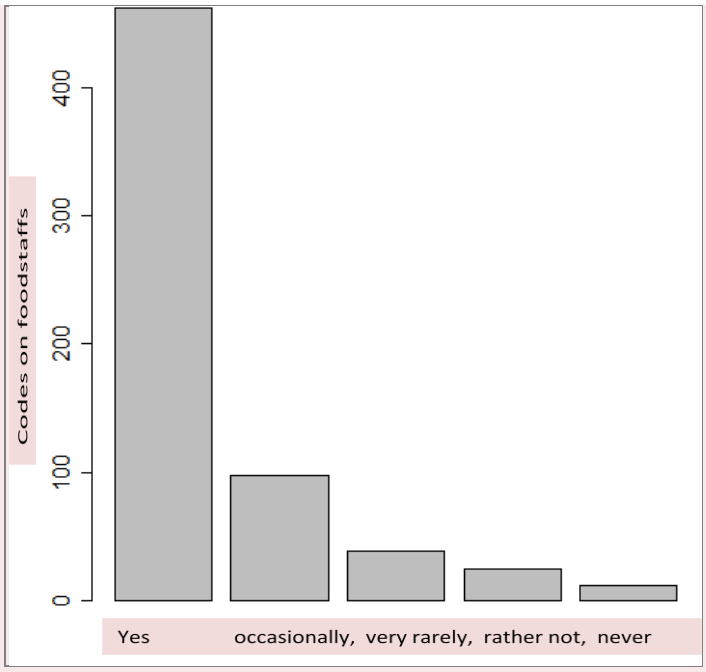
Question as to the use of a Speech Code:
Distribution of answers of persons without, or without severe, visual impairment to the question of whether they would use the Speech Code

The illustration shows the distribution of answers of persons without, or without severe, visual impairment to the question of whether they would use the Speech Code It turns out that a majority of the respondents would use the Speech Code, and only a very small proportion of interviewees would do without the Speech Code.



Distribution of answers bypersons without, or without severe, visual impairment to the question of the usefulness of small codes on foodstuffs

The following illustration shows the distribution of answers by persons without, or without severe, visual impairment to the question of the usefulness of small codes on foodstuffs. We may derive that the majority of interviewees considers the availability of small codes on foodstuffs useful (72.76%). As compared to that, 88.57% of blind or visually impaired persons had stated that they would use the system for buying foodstuffs.



6.4.7. Comparison of the control group with the blind and visually impaired persons

Comparison of blind and visually impaired persons with the control group of persons without, or without severe, visual impairment

Blind and visually impaired persons		
daily	weekly	monthly or less frequently
32 (30.48 %)	44 (41.90 %)	29 (27.61 %)

Persons without, or without severe, visual impairment				
yes	occasionally	very rarely	rather not	never
310 (48.81%)	205 (32.28%)	83 (13.07%)	30 (4.72%)	7 (1.10%)

The table shows a comparison of blind and visually impaired persons (group 1) with the control group of persons without, or without severe, visual impairment(group 2). While group 1 was asked how often they would use the system, a different question was asked in group 2 - "would you use a Speech Code on product inserts". Therefore, the results are not directly comparable, but a tendency is clearly visible. Both groups would use the system, or at least parts of the system (for group 2, the Speech Code for text in small print), frequently or at least occasionally.

As mentioned already and illustrated in the last table, a majority of persons without, or without severe, visual impairmentinterviewed considers the availability of small codes on foodstuffs useful (72.76%). As compared to that, 88.57% of blind or visually impaired persons had stated that they would use the system for buying foodstuffs.

7. Conclusio

7.1. Assessment Summary

The assessment was based on 105 data sets on blind and visually impaired people and 635 data sets on persons with no or only a slight visual impairment as control group. While the Speech Code system was tested in real terms by the blind and visually impaired probands as main target group, the control group was subject to an opinion survey interview only without practical system tests.

The result clearly shows that both groups would use the Speech Code tool: 30,48 % of the blind and visually impaired people would use it at least once a day, 41,90% weekly and 27,61% at least once per month or more seldomly. In the control group 48,81% stated to use the system regularely, 32,28% occasionally and 13,07% only rarely. Only in the group of people with no or only a slight visual impairment (control group) a total of 5,82% said they would rather not want to use such a tool.

Within the group of blind and visually impaired people it became apparent, that blind people would use the tool daily (and muliple times per day) or weekly, while severely visually impaired persons would use it weekly or more rarely. The interest and willingness of blind people was slightly higher than of those with a severe visual impairment, apparently due to the lack of alternatives. Still the willingness of people with no or only a slight visual impairment was generally high and it was only in this control group that very few people would not use the system at all. It therefore can be concluded that all groups would strongly benefit from the implementation of such a system/tool.

Facit:

All blind and visually impaired test persons as well as 94% of those with no or only a slight visual impairment (control group) would use the system.

Besides the application for pharmaceutical product package inserts and similar, the willingness for use is dominant for food product information with 88,57% in the group of blind and visually impaired people versus 72,76% in the control group of people with no or only a slight visual impairment.

Despite using the tool only in its early beta version for the tests, the evaluation was generally very positive, by fully blind probands slightly less than by people with a severe visual impairment from the same group. This might be due to the understandably high expectations of this group and the high quality standards of conventional technical auxiliary tools for this target group, which the tested beta version of Speech Code did not yet meet in full. Still in median all groups rated the quality and audio guidance with the best grade (1), all groups except the blind people for the audio signals with grade 1 (blind people in median with 2) and all groups (who tested the tool) the scan process with grade 2.

Generally the audio guidance, the ease of information access and the level of blindness/visually impairment had a significant influence on the evaluation of the system, while age and gender had no influence at all.

Facit:

Audio scan guidance and the ease of access to a particular information were highly contributing to the clearly positive assessment by all test groups.

Almost all profiles of the group of blind and visusally impaired people show the possession of a mobile phone (Median 0,87), of which in median 0.65 dispose of a camera as needed for the application. At the same time the willingness to purchase an adequate device with a camera can be rated very high in this target group due to the lack of alternatives for blind and visually impaired people to access printed information. From the group of not or only slightly visually impaired people (control group) this data was not gathered.

Mobile phones, which are used by blind and visually impaired people, are equipped with so called Text-to-Speech Software, which audio-guides (i.e. reads) the navigation and other functions of the device to allow its usage without optical cognition of the display. The tested technology Speech Code uses a text-to-speech software that does not interfere with the other software and settings of the device.

Facit:

All groups fulfilled the basic system conditions of Speech Code, as most of the even elder test persons in the group of blind and visually impaired people possess mobile devices, often even with cameras.
For this target group the mobile device represents a very important communiction tool as technical functions and auxiliary tools can be used mobile.

In the group of not or only slightly visually impaired people (control group) it can be taken as basic principle that this group possesses adequate mobile devices with camera and typically has an interest and demand for new technologies and applications ("apps").

7.2. Prospective applications and their evaluation

From the legal and academic standpoint the results of the conducted evaluations allow for numerous applications of the Speech Code system, which could support particularely self-reliance and reduce discrimination and social exclusion of blind and visually impaired people. Such applications however still require further academic evaluations.

7.2.1. Speech Code for the participation of blind and visually impaired people in „Readability-Testings“

Currently blind and visually impaired people as well as their associations are excluded from these important tests in the pharmaceutical trade, because so far no method or system was available allowing explicit text navigation and targeted finding of certain information for visually impaired people.

Due to increased capabilities of the other senses upon loss of the sense of vision, it can be concluded that texts will be heard very carefully. Thus their understandability and comprehensibility could be tested also by this group of people to enhance the overall quality of the test results.

Additionally this opportunity can offer new work engagement for interested blind and visually impaired people, as these tests represent services with costs, that must be ordered by all pharmaceutical companies.

The Department of Law and Science of the Sigmung Freud Private University Vienna therefore plans in cooperation with the Austrian Federation of the Blind an Partially Sighted (BSVÖ) and with international consortium partners under the academic supervision of the Federal Austrian Agency for Health and Food Safety (AGES Medizinmarktaufsicht LCM) and the Federal Ministry of Labour, Social Affairs and Consumer Protection to conduct a test validation with the goal to allow the national and international associations of blind and visually impaired people in cooperation with the SFU to offer such services in high quality and in an academic setting. Thus this project could contribute to the support of such organisations and associations.

7.2.2. Combination of Speech Code with an innovative system to automatically collect consumer reports on adverse drug reactions (especially for blind and visually impaired consumers)

The European Regulations and Directives regarding Pharmacovigilance stipulate, that now also patients/consumers should be entitled to use adequate systems for reporting any adverse drug reactions also autonomously (i.e. not just via doctors and pharmacists). In the future also package inserts shall inform patients of these reporting facilities in case of adverse reactions or risks.

For blind and visually impaired people this new opportunity is, similar to the package insert as such, almost impossible to access and use, as downloads, completing and mailing of printed forms are not barrier-free methods. Even documentation via internet is difficult for this group of people.

The Department of Law and Science of the Sigmung Freud Private University Vienna therefore plans in cooperation with the Austrian Federation of the Blind an Partially Sighted (BSVÖ) and with international consortium partners under the academic supervision of the Federal Austrian Agency for Health and Food Safety (AGES Medizinmarktaufsicht LCM) and the Federal Ministry of Labour, Social Affairs and Consumer Protection to conduct a test validation of a telephone reporting system in conjunction with Speech Code, providing an automated, law conforming system for adverse drug reaction reporting (also multilingual).

7.2.3. Speech Code in the food product industry

Due to the prevailing lack of detailed information on food products, especially for allergy sufferers, already the project concept included a sub-study in the food product trade.

The Department of Law and Science of the Sigmung Freud Private University Vienna therefore plans in addition to the original tests with the „Young People & Patient Alliance“ (YPPA) also the evaluation of a food-coding-system in cooperation with the initiatives of the alliance, particularly the nutrition diary for children and adolescents, and those clinic studies, which are complemented with nutrition concepts.

7.2.4. Speech Code for medical information and patient passports

Patients, who participate in long-term clinical studies (especially when suffering from rare diseases), are included in a special theraphy scheme, which is developed by the supervising medical clinic. In cases of consultation of a general practitioner or in emergency situations these patients seldomly have the detailed information (up to 30 pages) at hand, which they have received at the beginning or during the study. Additionally general doctors and emergency personnel are not familiar with important academic information on the specific study. A patient passport could remedy this potentially dangerous situation, by providing the needed, valid and updated information on the study in a compact Speech Code format. In the area of oncological diseases medics currently discuss the implementation of a "survival passport" for patients, who are considered cured after a cancer-therapy, but as a result of such therapy often face high risks of drug intolerances and adverse reactions.

The Department of Law and Science of the Sigmung Freud Private University Vienna The Department of Law and Science of the Sigmung Freud Private University Vienna therefore plans in cooperation with scientists, ethics commission and authorities to develop a standardised patient passport. With Speech Codes all important information can be provided in a very space-saving way with the option of pin-protection and coding for different addressees.

8. Overview ANISNet

The academic, independent study network **ANISNet** (Academic Non-Interventional Study Net) is focused on the research of safety-relevant scientific questions and the evaluation of innovative auxiliary solutions for consumers and patients. ANISNet acts as provider of non-interventional studies in the area of patient and consumer safety.

For each project an **independent and responsible academic consortium** is appointed, supported by the scientific advisory board. This procedure allows the early evaluation of the potential benefit for the relevant target group(s). The consortium represents the study provider, approves the project unanimously, meets several times during the project execution, clarifies any upcoming questions and problems in the review process (per mail) and monitors the execution of the study until its finalisation. Qualified staff members of the SFU provide the administration as well as optionally required monitoring of the studies.

All material of the study are compiled **neutrally and free of advertising, to legally compliant standards** and is completed with validated academic information. If applicable due to the research topic or data protection issues, the study is presented to an ethics committee and national authorities for review and registration.

9. Abbreviations, Literature and Legal Documents

9.1. List of abbreviations

BSVÖ = Blinden und Sehbehindertenverband Österreich (Austrian Federation of the Blind and Partially Sighted)
mm = Millimeter
pt = Point
SFU = Sigmund Freud Private University Vienna

9.2. Literature

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9.3. Legal Documents

9.3.1. Bundesgesetz zum Schutz vor gefährlichen Produkten (Product Safety Act 2004 – PSG 2004)

BGBl I Nr. 16/2005, Latest version per 16.8.201 2
(www.ris.bka.gv.at) only german version.

1. ABSCHNITT
Allgemeine Bestimmungen

Geltungsbereich und subsidiäre Anwendung
§ 1. Dieses Bundesgesetz regelt Sicherheitsanforderungen an Produkte, Verpflichtungen für In-Verkehr-Bringer/innen sowie behördliche Maßnahmen mit dem Ziel, insbesondere Leben und Gesundheit von Menschen vor Gefährdungen durch gefährliche Produkte zu schützen.

§ 2. (1) Dieses Bundesgesetz findet auf Produkte gemäß § 3 Z 1 Anwendung.
(2) Sind Sicherheitsanforderungen an Produkte gemäß § 3 Z 1 in besonderen bundesgesetzlichen Verwaltungsvorschriften festgelegt, gelangt dieses Bundesgesetz nur für jene Aspekte, Risken oder Risikokategorien zur Anwendung, die in den betreffenden bundesgesetzlichen Verwaltungsvorschriften nicht dem Ziel dieses Bundesgesetzes entsprechend geregelt sind. Zudem sind die Bestimmungen der §§ 7 bis 29 jedenfalls dann anzuwenden, wenn die besonderen bundesgesetzlichen Verwaltungsvorschriften keine entsprechenden Regelungen enthalten.
(3) Sofern die Festlegung von Sicherheitsanforderungen an Produkte in den Zuständigkeitsbereich der Länder fällt, gelangt dieses Bundesgesetz für die betreffenden Produkte nicht zur Anwendung.

Begriffsbestimmungen
§ 3. Im Sinne dieses Bundesgesetzes gelten folgende Begriffsbestimmungen:

1. „Produkt“ ist jede bewegliche Sache einschließlich Energie, auch wenn sie Teil einer anderen beweglichen Sache oder mit einer unbeweglichen Sache verbunden worden ist, die – auch im Rahmen der Erbringung einer Dienstleistung – für Verbraucher/innen bestimmt ist oder unter vernünftigerweise vorhersehbaren Bedingungen von diesen benutzt werden könnte, selbst wenn sie nicht für diese bestimmt ist. Das Produkt muss im Rahmen einer Geschäftstätigkeit geliefert oder zur Verfügung gestellt werden, wobei unerheblich ist, ob dies entgeltlich oder unentgeltlich erfolgt und ob es neu, gebraucht oder wiederaufgearbeitet ist. Keine Produkte im Sinne dieses Bundesgesetzes sind Antiquitäten und solche Produkte, die vor ihrer Verwendung instandgesetzt oder wiederaufbereitet werden müssen, sofern dies der/die In-Verkehr-Bringer/in der von ihm/ihr belieferten Person nachweislich mitteilt.

2. „Ernste Gefahr“ ist jede schwerwiegende Gefahr, die ein rasches Eingreifen der Behörden erfordert, auch wenn sie keine unmittelbare Auswirkung hat.

3. „Zuständige Behörden“ sind der/die gemäß § 32 zuständige Bundesminister/in sowie die Landeshauptleute.

4. „Hersteller/in“ ist

a) wer seinen Sitz in der Europäischen Gemeinschaft hat und ein Produkt im Rahmen einer Geschäftstätigkeit hervorbringt sowie jede andere Person, die als Hersteller/in auftritt, indem sie auf dem Produkt ihren Namen, ihr Markenzeichen oder ein anderes Unterscheidungszeichen anbringt

oder das Produkt wiederaufarbeitet;

b) wer den/die Hersteller/in vertritt, wenn dessen/deren Sitz nicht in der Gemeinschaft liegt, oder, falls kein/e Vertreter/in mit Sitz in der Gemeinschaft vorhanden ist, wer das Produkt in die Europäische Gemeinschaft einführt;

c) darüber hinaus jede Person in der Absatzkette, die im Rahmen ihrer Geschäftstätigkeit die Sicherheitseigenschaften eines Produktes beeinflusst.

5. „Importeur/in“ ist, wer seinen Sitz in Österreich hat und im Rahmen einer Geschäftstätigkeit

a) eine/n Hersteller/in in Österreich vertritt oder

b) ein Produkt nach Österreich einführt, um es im Inland in Verkehr zu bringen.

6. „Händler/in“ ist, wer in der Absatzkette im Rahmen einer Geschäftstätigkeit ein Produkt liefert oder zur Verfügung stellt und dessen Tätigkeit die Sicherheitseigenschaften des Produktes nicht beeinflusst.

7. „In-Verkehr-Bringer/innen“ sind Hersteller/innen, Importeure/Importeurinnen und Händler/innen.

8. „In-Verkehr-Bringen“ ist das Feilhalten, Verkaufen, Einführen, unentgeltliche Abgeben oder Verteilen eines Produktes sowie seine Anwendung oder Überlassung im Rahmen einer Dienstleistung.

9. „Rückruf“ ist jede Maßnahme, die auf Erwirkung der Rückgabe eines den Verbrauchern und Verbraucherinnen von dem/der In-Verkehr-Bringer/in bereits gelieferten oder zur Verfügung gestellten gefährlichen Produkts abzielt.

10. „Rücknahme“ ist jede Maßnahme, mit der verhindert werden soll, dass ein gefährliches Produkt vertrieben, ausgestellt oder den Verbrauchern und Verbraucherinnen angeboten wird.

Sicherheitsanforderungen und Risikobewertung

§ 4. (1) Ein Produkt ist sicher, wenn es bei normaler oder vernünftigerweise vorhersehbarer Verwendung keine oder nur geringe, mit seiner Verwendung zu vereinbarende und unter Wahrung eines hohen Schutzniveaus für die Gesundheit und Sicherheit von Personen vertretbare Gefahren birgt. Die Verwendung schließt auch die Gebrauchsdauer sowie gegebenenfalls Inbetriebnahme, Installation und Wartungsanforderungen ein. Bei der Beurteilung der Sicherheit ist vor allem Bedacht zu nehmen:

1. auf Verbraucher/innen (Verbrauchergruppen), wie zB Kinder, ältere Menschen oder Menschen mit Behinderungen, die durch das Produkt bei einer vernünftigerweise vorhersehbaren Verwendung einem erhöhten Risiko ausgesetzt sind;

2. auf die Eigenschaften des Produktes, insbesondere seine Zusammensetzung, seine Ausführung, seine Verpackung, die Bedingungen für seinen Zusammenbau und sein Verhalten bei der Wartung, Lagerung und beim Transport;

3. auf seine Einwirkung auf andere Produkte, wenn eine gemeinsame Verwendung mit anderen Produkten vernünftigerweise vorhersehbar ist;

4. auf seine Aufmachung, seine Präsentation, seine Etikettierung, gegebenenfalls seine Gebrauchs– und Bedienungsanleitung, Anweisungen für seine Wartung, Lagerung und Beseitigung sowie alle sonstigen Angaben oder Informationen seitens des Herstellers/der Herstellerin oder des Importeurs/der Importeurin.

(2) Als gefährlich ist ein Produkt dann anzusehen, wenn es nicht den Anforderungen des Abs. 1 entspricht. Die Möglichkeit, einen höheren Sicherheitsgrad zu erreichen, oder die Verfügbarkeit anderer Produkte, von denen eine geringere Gefährdung ausgeht, ist hingegen kein ausreichender Grund, um ein Produkt als gefährlich anzusehen.

Konformitätsbeurteilung

§ 5. (1) Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat die Fundstellen von Normen, die eine europäische Norm umsetzen, auf die die Europäische Kommission gemäß Art. 4 der Richtlinie über die allgemeine Produktsicherheit 2001/95/EG im Amtsblatt der Europäischen Gemeinschaften verwiesen hat, sowie die Streichung solcher Fundstellen im Bundesgesetzblatt II kundzumachen. Diesen Normen sind entsprechende Normen gleichzuhalten, die im Rahmen einzelstaatlicher Verfahren von Vertragsstaaten des Europäischen Wirtschaftsraumes bekanntgegeben wurden.
(2) Sofern es keine besondere bundesgesetzliche Verwaltungsvorschrift gemäß § 2 Abs. 2 oder § 11 gibt, ist von der Übereinstimmung eines Produktes mit den Sicherheitsanforderungen gemäß § 4 Abs. 1 dann auszugehen, wenn es den Normen gemäß Abs. 1 entspricht. Die Vermutung der Übereinstimmung gilt nur insoweit, als es um Risiken und Risikokategorien geht, die durch die betreffenden Normen geregelt werden.
(3) Gibt es weder eine besondere bundesgesetzliche Verwaltungsvorschrift gemäß § 2 Abs. 2 oder § 11 noch eine Norm entsprechend Abs. 1, wird die Übereinstimmung eines Produkts mit der Sicherheitsanforderung gemäß § 4 Abs. 1 unter Berücksichtigung insbesondere folgender Elemente – soweit vorhanden – beurteilt:

1. die nicht bindenden innerstaatlichen Normen zur Umsetzung einschlägiger europäischer Normen, die nicht von Abs. 1 abgedeckt sind;

2. sonstige innerstaatliche Normen;

3. die Empfehlungen der Europäischen Kommission zur Festlegung von Leitlinien für die Beurteilung der Produktsicherheit (Art. 3 der Richtlinie 2001/95/EG);

4. die im betreffenden Bereich geltenden Verhaltenskodizes für die Produktsicherheit;

5. der Stand des Wissens und der Stand der Technik (§ 2 Abs. 8 ArbeitnehmerInnenschutzgesetz);

6. die Sicherheit, die von den Verbrauchern und Verbraucherinnen vernünftigerweise erwartet werden kann;

7. die Empfehlungen des Produktsicherheitsbeirates gemäß § 21 Abs. 1 Z 4.

(4) Die Übereinstimmung eines Produktes mit den Kriterien für die Konformitätsbeurteilung gemäß Abs. 2 und 3 hindert nicht, Maßnahmen gemäß § 11 zu treffen, wenn sich trotz dieser Übereinstimmung herausstellt, dass das Produkt gefährlich ist.
(5) Wurde

- durch eine Behörde eines Vertragsstaates des Europäischen Wirtschaftsraumes oder

- durch in- oder ausländische akkreditierte Prüf-, Überwachungs- und Zertifizierungsstellen im Sinne des § 3 des Akkreditierungsgesetzes, BGBl. Nr. 468/1992 in der jeweils geltenden Fassung

festgestellt, dass ein Produkt Sicherheitsmängel aufweist, so kann allein auf Grund dieser Bewertung das betreffende Produkt als gefährlich im Sinne dieses Bundesgesetzes beurteilt werden. Dies gilt insbesondere dann, wenn ein Produkt Gegenstand einer Notifizierung im Rahmen des EU-Produktsicherheitsnotfallsverfahrens RAPEX ist.

2. ABSCHNITT

Pflichten für In-Verkehr-Bringer/innen

§ 6. (1) Hersteller/innen und Importeure/Importeurinnen dürfen nur sichere Produkte in den Verkehr bringen.

(2) Sofern dieses Bundesgesetz nur auf bestimmte Aspekte, Risken oder Risikokategorien von Produkten anzuwenden ist (§ 2 Abs. 2), dürfen sie aufgrund dieses Gesetzes nur in Verkehr gebracht werden, wenn sie bezüglich dieser Aspekte, Risken oder Risikokategorien den Sicherheitsanforderungen des § 4 Abs. 1 entsprechen.

§ 7. (1) Hersteller/innen und Importeure/Importeurinnen haben im Rahmen ihrer jeweiligen Geschäftstätigkeit den Verbrauchern und Verbraucherinnen Informationen (zB Warnhinweise, Gebrauchsanweisungen) zu erteilen, damit sie die Gefahren, die von einem Produkt und seiner Verwendung während der üblichen oder vernünftigerweise vorhersehbaren Gebrauchsdauer ausgehen und die ohne entsprechende Warnhinweise nicht unmittelbar erkennbar sind, beurteilen und sich dagegen schützen können. Diese Informationen und Warnhinweise entbinden nicht von der Verpflichtung, die Sicherheitsanforderungen gemäß § 4 Abs. 1 einzuhalten.
(2) Hersteller/innen und Importeure/Importeurinnen haben ferner im Rahmen ihrer jeweiligen Geschäftstätigkeit geeignete und dem entsprechenden Produkt angemessene Maßnahmen zu treffen, damit sie imstande sind, die etwaigen von diesen Produkten ausgehenden Gefahren zu erkennen und zu deren Vermeidung zweckmäßige Vorkehrungen treffen zu können, erforderlichenfalls einschließlich der Rücknahme vom Markt, der angemessenen und wirksamen Warnung der Verbraucher/innen und nötigenfalls des Rückrufs von den Verbrauchern und Verbraucherinnen.

Diese Maßnahmen können beispielsweise umfassen:

1. eine entsprechende Kennzeichnung, die die Identifizierung des Produktes und die Rückverfolgbarkeit zum/zur Hersteller/in ermöglicht;

2. die Kennzeichnung der Produktionscharge;

3. die Durchführung von Stichproben bei den in Verkehr gebrachten Produkten, die Prüfung von Beschwerden und gegebenenfalls die Führung eines Beschwerdebuchs sowie die Unterrichtung der Händler/innen über die Ergebnisse dieser Tätigkeiten.

(3) Händler/innen haben mit der gebotenen Umsicht zur Einhaltung der anwendbaren Sicherheitsanforderungen beizutragen, indem sie insbesondere keine Produkte liefern, von denen sie wissen oder auf Grund der ihnen bei zumutbarer Sorgfalt zugänglichen Informationen wissen müssten, dass sie diesen Anforderungen nicht genügen. Im Rahmen ihrer jeweiligen Geschäftstätigkeit haben sie außerdem an der Überwachung der Sicherheit der in Verkehr gebrachten Produkte mitzuwirken, insbesondere durch Weitergabe von Hinweisen auf eine von den Produkten ausgehende Gefährdung, durch Aufbewahren und Bereitstellen der zur Rückverfolgung von Produkten erforderlichen Dokumentation und durch Mitarbeit an Maßnahmen der Hersteller/innen und zuständigen Behörden zur Vermeidung der Gefahren. Sie haben im Rahmen ihrer Geschäftstätigkeit eine wirksame Zusammenarbeit mit anderen In-Verkehr-Bringern/In-Verkehr-Bringerinnen, Verbrauchern/ Verbraucherinnen und Behörden zu ermöglichen.
(4) Wenn In-Verkehr-Bringer/innen anhand der ihnen im Rahmen ihrer Geschäftstätigkeit vorliegenden Informationen wissen oder wissen müssen, dass ein Produkt, das sie in Verkehr gebracht haben, für die Verbraucher/innen eine Gefahr darstellt, die mit der allgemeinen Sicherheitsanforderung gemäß § 4 Abs. 1 unvereinbar ist, haben sie unverzüglich eine der zuständigen Behörden zu informieren. Dies gilt jedenfalls für Vorkehrungen – insbesondere Rückrufe -, die die In-Verkehr-Bringer/innen zur Abwendung von Gefahren für die Verbraucher/innen treffen.
(5) In-Verkehr-Bringer/innen haben im Rahmen ihrer Geschäftstätigkeit mit den zuständigen Behörden in Bezug auf Maßnahmen zur Abwendung von Gefahren zusammenzuarbeiten. Sie sind insbesondere verpflichtet, diesen Behörden

1. Auskünfte zu erteilen (zB über Vorlieferanten/Vorlieferantinnen und Vertriebswege);

2. Produktdokumentationen, Prüfzeugnisse und andere geeignete Unterlagen, die die Risikobewertung von Produkten ermöglichen, vorzulegen;

3. Produkte für Untersuchungen zur Verfügung zu stellen, insbesondere Produkte, die zu einer Schädigung von Personen geführt haben; Veränderungen an den betreffenden Produkten sind zu unterlassen;

4. Vorschläge zu unterbreiten, wie eine Gefahr abgewendet werden kann.

(6) Um den zuständigen Behörden eine rasche und effiziente Risikobewertung und Konformitätsbeurteilung zu ermöglichen sowie von In-Verkehr-Bringern/In-Verkehr-Bringerinnen getroffene Maßnahmen (Abs. 1 bis 3) beurteilen zu können, kann der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz durch Verordnung nähere Bestimmungen über die Informations- und Auskunftspflichten gemäß Abs. 4 und 5 festlegen.

3. ABSCHNITT

Überwachung, behördliche Maßnahmen, Information der Öffentlichkeit

Auskunfts- und Meldepflicht

§ 8. (1) Die Leiter/innen des ärztlichen Dienstes bzw. die aufsichtführenden Ärzte/Ärztinnen von Krankenanstalten haben den zuständigen Behörden auf deren Anfrage Auskünfte über dienstliche Wahrnehmungen über Produkte, von denen aufgrund eines Unfalles oder einer Erkrankung anzunehmen ist, dass sie nicht den Anforderungen der §§ 4 und 5 entsprechen, zu übermitteln. Sofern verfügbar haben diese Auskünfte Angaben

- zum Unfallhergang oder zur Erkrankung,

- zu den Folgen der Verletzung oder Erkrankung,

- zum Produkt sowie

- zu den In-Verkehr-Bringern/In-Verkehr-Bringerinnen einschließlich personenbezogener Daten, die eine Rückverfolgung des Produktes in der Vertriebskette ermöglichen,

(2) Sofern im Rahmen der Vollziehung dieses Bundesgesetzes zur Vermeidung von weiteren Unfällen oder Erkrankungen detaillierte Kenntnisse über den Unfallhergang und das beteiligte Produkt erforderlich sind, die nur der Person zur Verfügung stehen, die den produktbezogenen Unfall erlitten hat, haben die Leiter/innen des ärztlichen Dienstes bzw. die aufsichtführenden Ärzte/Ärztinnen von Krankenanstalten auf Anfrage der zuständigen Behörden die vom Unfall betroffene Person oder deren gesetzliche Vertreter/innen um schriftliche Zustimmung zur Übermittlung ihrer Namen und Adressdaten zu ersuchen und diese gegebenenfalls an die zuständige Behörde weiterzuleiten.

(3) Alle für den Bund tätigen Vollziehungsorgane sowie die Träger der gesetzlichen Unfallversicherung, soweit sich deren Einrichtungen mit der Prävention für Sicherheit und Gesundheitsschutz befassen, sind verpflichtet, dienstliche Wahrnehmungen über Produkte, von denen anzunehmen ist, dass sie nicht den Anforderungen der §§ 4 und 5 entsprechen, dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz und dem örtlich zuständigen Landeshauptmann zu melden. Die Meldung hat unverzüglich zu erfolgen und eine Angabe über den Verwendungszweck des Produktes, die Art der vom Produkt ausgehenden Gefährdung sowie alle verfügbaren Daten, die zur Identifizierung der In-Verkehr-Bringer/innen, des Produktes und zur Risikobewertung erforderlich sind, zu enthalten. Die Weitergabe personenbezogener Daten von Unfallopfern ist nur mit deren Zustimmung zulässig.

(4) Die Zollbehörden sind – unbeschadet der Bestimmungen der Verordnung (EWG) Nr. 339/93 des Rates vom 8. Februar 1993 über die Kontrolle der Übereinstimmung von aus Drittländern eingeführten

Erzeugnissen mit den geltenden Produktsicherheitsvorschriften, Abl. Nr. L 040 vom 17.2.1993 – verpflichtet, den zuständigen Behörden auf deren Anfrage Daten einschließlich personenbezogener Daten über den Import, Export und die Durchfuhr von Produkten zur Verfügung zu stellen.

§ 9. Zur Gewährleistung eines hohen Gesundheitsschutz- und Sicherheitsniveaus für die Verbraucher/innen sind die zuständigen Behörden zur automationsunterstützten Verarbeitung der für die Vollziehung dieses Bundesgesetzes benötigten Daten, insbesondere der gemäß § 8 gemeldeten Daten, ermächtigt. In-Verkehr-Bringer/innen haben jederzeit das Recht, eine Gegendarstellung zu den ermittelten Daten abzugeben. Eine Löschung der ermittelten Daten hat unter Bedachtnahme auf § 27 des Datenschutzgesetzes 2000, insbesondere wenn deren Unrichtigkeit erwiesen ist, zu erfolgen.

Ermächtigung zum internationalen Datenaustausch

§ 10. (1) Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat innerhalb der festgelegten Fristen den auf Grund internationaler Verträge vorgesehenen Stellen Informationen über gefährliche Produkte sowie Maßnahmen gemäß den §§ 11, 15 und 16 zu melden. Dies gilt insbesondere für das Produktsicherheitsnotfallsverfahren (RAPEX) gemäß Art. 12 sowie das Schutzklauselverfahren gemäß Art. 11 der Richtlinie 2001/95/EG.

(2) Die zuständigen Behörden sind ermächtigt, Daten, die bei der Vollziehung dieses Gesetzes erhoben werden, insbesondere Daten zu Produkten und zur Marktüberwachung, an ausländische und internationale Behörden zu übermitteln. Dies umfasst auch die Übermittlung von Daten zur Verwendung in ausländischen oder internationalen Datenbanken, sofern diese durch eine Behörde unterhalten werden oder unter Aufsicht einer Behörde stehen.

(3) Daten zu In-Verkehr-Bringern/In-Verkehr-Bringerinnen, die gemäß Abs. 1 und 2 übermittelt werden, können auch personenbezogen sein, sofern dies für die Identifizierung eines Produktes, seine Rückverfolgung in der Vertriebskette und die Risikobewertung erforderlich ist.

Behördliche Maßnahmen

§ 11. (1) Sofern den Sicherheitsanforderungen (§§ 4 und 5) durch die In-Verkehr-Bringer/innen nicht entsprochen worden ist sowie zur Gewährleistung eines hohen Gesundheitsschutz- und Sicherheitsniveaus für die Verbraucher/innen hat der/die gemäß § 32 zuständige Bundesminister/in unter Berücksichtigung des Vorsorgeprinzips behördliche Maßnahmen zu ergreifen, die sich an die In-Verkehr-Bringer/innen oder, falls zur Gefahrenabwehr erforderlich, an jede andere Person richten können. Diese Maßnahmen umfassen insbesondere:

1. die Verpflichtung zur Beigabe oder Verbesserung der Gebrauchsanweisung oder zur Anbringung von Kennzeichnungselementen auf der Verpackung oder auf dem Produkt;

2. die Verpflichtung, auf dem Produkt so vor Gefahren zu warnen und Verhaltenshinweise zu deren Vermeidung zu geben, wie es der Dringlichkeit der Gefahrenabwehr entspricht;

3. die Verpflichtung zur Veröffentlichung von Warnhinweisen oder anderen dringenden Informationen in der für die betroffenen Verkehrskreise geeigneten Weise und den dafür geeigneten Medien;

4. Gebote und Verbote betreffend Werbemaßnahmen für Produkte;

5. die Festlegung bestimmter Beschaffenheitsanforderungen (zB Sicherheitsvorkehrungen), insbesondere durch die gänzliche oder teilweise Verbindlicherklärung von nationalen oder internationalen Normen;

6. die Verpflichtung zum Nachweis der Erfüllung bestimmter Prüfanforderungen;

7. Verbote oder Beschränkungen des In-Verkehr-Bringens (zB hinsichtlich eines bestimmten Personenkreises oder der Vertriebsart);

8. Verbote oder Beschränkungen des Exports (zB hinsichtlich eines Bestimmungslandes);

9. die Verpflichtung zur unverzüglichen Rücknahme eines bereits in Verkehr gebrachten Produktes oder Produktpostens aus der Vertriebskette und nötigenfalls dessen Vernichtung unter geeigneten Bedingungen;

10. die Verpflichtung zur Durchführung eines unverzüglichen und effizienten Rückrufes eines bereits in Verkehr gebrachten Produktes oder Produktpostens von den Verbraucher/innen, gegebenenfalls die Veröffentlichung dieses Rückrufes in den für die betroffenen Verkehrskreise geeigneten Medien sowie nötigenfalls die Vernichtung des Produktes oder Produktpostens unter geeigneten Bedingungen.

(2) Maßnahmen gemäß Abs. 1 sind – mehrere Maßnahmen in Verbindung untereinander oder eine Maßnahme für sich allein – von dem/r gemäß § 32 zuständigen Bundesminister/in mit Verordnung oder – falls die Maßnahmen sich an individuell bestimmte Personen richten – mit Bescheid zu treffen. Dabei ist jeweils das gelindeste noch zum Ziel führende Mittel anzuwenden. Sofern angemessene Maßnahmen zur Gefahrenabwehr auf freiwilliger Basis herbeigeführt werden können, ist diesen der Vorzug zu geben.
(3) Der/die gemäß § 32 zuständige Bundesminister/in kann mit Verordnung näher bestimmen, welche Mindesterfordernisse bei der Durchführung von behördlich angeordneten oder freiwilligen Rückrufen zu erfüllen sind. Diese Erfordernisse können je nach Produktgruppen und Risken auch unterschiedlich festgelegt werden.
(4) Im Falle einer Entscheidung der Europäischen Kommission gemäß Artikel 13 der Richtlinie 2001/95/EG hat der/die gemäß § 32 zuständige Bundesminister/in - sofern in der Entscheidung keine andere Frist genannt ist - innerhalb von 20 Tagen nach ihrer Verlautbarung geeignete Maßnahmen gemäß Abs. 1 bis 3 zu erlassen, mit denen die Entscheidung umgesetzt wird; wird die Maßnahme mit einer Verordnung getroffen, kann die Befassung des Produktsicherheitsbeirates gemäß § 21 Abs. 5 entfallen.
(5) Der/die gemäß § 32 zuständige Bundesminister/in hat Bescheide gemäß Abs. 2 dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz unverzüglich zur Kenntnis zu bringen.

§ 12. Zur Vermeidung von Gefährdungen durch gefährliche Produkte kann der/die gemäß § 32 zuständige Bundesminister/in mit Verordnung bestimmen, dass Verbraucher/innen Maßnahmen gemäß § 11 unterstützen müssen, indem sie insbesondere Rückrufen Folge leisten.

Marktüberwachung
§ 13. (1) Für die Überwachung des In-Verkehr-Bringens von Produkten (Marktüberwachung) ist der Landeshauptmann zuständig, der sich zur Erfüllung dieser Aufgabe besonders geschulter Organe als Aufsichtsorgane (Produktsicherheits-Aufsichtsorgane) zu bedienen hat.
(2) Der Landeshauptmann hat die Aufsichtsorgane mit geeigneten technischen Hilfsmitteln so auszustatten, dass insbesondere die fotografische Dokumentation von Produkten, die manipulationssichere Kennzeichnung von Proben und beschlagnahmten Produkten sowie Recherchen im Internet (zB Zugang zum Firmenbuch) möglich sind.
(3) Bei der Marktüberwachung gemäß Abs. 1 hat sich der Landeshauptmann auch der Organe der Zollbehörden zu bedienen, soweit dies zur effizienten und kostensparenden Gestaltung der Marktüberwachung notwendig ist. Zu diesem Zweck kann der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz im Einvernehmen mit dem Bundesminister für Finanzen durch Verordnung nähere Bestimmungen über Umfang und Ausübung der den Organen der Zollbehörden zustehenden Befugnisse gemäß den §§ 14 bis 16 erlassen.
(4) Der Landeshauptmann hat die für Aufgaben gemäß den §§ 14 bis 16 bestellten Aufsichtsorgane dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz bekanntzugeben.
(5) Die vorgesetzte Dienstbehörde und der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz haben für die Aus- und Fortbildung der Aufsichtsorgane zu sorgen. Der

Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat dazu regelmäßig Fortbildungsveranstaltungen abzuhalten.
(6) Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat zumindest einmal jährlich eine Koordinationssitzung der zuständigen Behörden einzuberufen, die insbesondere dazu dient,

- Erfahrungen aus der Marktüberwachung auszutauschen;
- Konzepte für eine wirksame Marktüberwachung auszuarbeiten und zu koordinieren;
- sektorielle Überwachungsprogramme zu beschließen;
- wissenschaftliche und technische Kenntnisse über die Sicherheit von Produkten auszutauschen.

(7) Die zuständigen Behörden haben sich untereinander angemessen über ihre Marktüberwachungstätigkeiten zu informieren (zB durch Verwendung einer gemeinsamen Datenbank). Sofern einer zuständigen Behörde Mitteilungen gemäß § 7 Abs. 4 zugehen, die eine ernste Gefahr betreffen, hat sie diese unverzüglich an den Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz weiterzuleiten.

Befugnisse der Aufsichtsorgane, Proben
§ 14. (1) Die Aufsichtsorgane gemäß § 13 Abs. 1 und 3 und die von den zuständigen Behörden berufenen Sachverständigen sind befugt und ermächtigt, überall dort wo Produkte in den Verkehr gebracht werden, Nachschau zu halten und hierbei für die Risikobewertung erforderliche Proben zu ziehen. Nachschau und Probenziehung sind, wenn nicht Gefahr in Verzug ist, während der üblichen Geschäfts- und Betriebsstunden durchzuführen. Störungen und Behinderungen des Betriebes sowie jedes Aufsehen sind tunlichst zu vermeiden. Betriebsinhaber/innen oder seine/ihre Stellvertreter/innen sind von der Behörde spätestens beim Betreten des Betriebes oder der Lagerräume zu verständigen.
(2) Die entnommene Probe ist zweckentsprechend zu verpacken, amtlich zu verschließen und mit einem Dienstsiegel unverwechselbar zu kennzeichnen. Sind noch augenscheinlich gleiche Produkteinheiten vorhanden, so ist auf Verlangen des Betriebsinhabers oder der Betriebsinhaberin eine von diesen ebenso zu behandeln und zu Beweiszwecken im Betrieb zurückzulassen (Gegenprobe).
(3) Die entnommene Probe ist dem/der gemäß § 32 zuständigen Bundesminister/in oder einer von ihm/ihr genannten geeigneten Stelle (zB akkreditierte Prüf- oder Überwachungsstelle, Ziviltechniker/in, Technische Büros – Ingenieurbüros, allgemein beeidete und gerichtlich zertifizierte Sachverständige) zur Risikobewertung und Konformitätsbeurteilung zu übermitteln.
(4) Anlässlich der Probenziehung ist vom Aufsichtsorgan ein Begleitschreiben auszufertigen, in dem die wichtigsten Feststellungen und Wahrnehmungen des Organs enthalten sind. Dieses Begleitschreiben ist der Probe beizulegen, die an die Prüfstelle weitergeleitet wird. Eine Kopie des Begleitschreibens ist im Betrieb zurückzulassen oder innerhalb von drei Arbeitstagen nachzureichen.
(5) Auf Verlangen des/der Betriebsinhabers/Betriebsinhaberin ist die Probe nach Abschluss des Verfahrens zurückzugeben oder vom Bund eine Probenentschädigung in der Höhe des Einstandspreises zu leisten. Kann der Einstandspreis nicht festgestellt werden, ist als Entschädigung der halbe Endverkaufspreis festzusetzen.
(6) Rückgabe oder Entschädigung entfallen, wenn die Untersuchung des Produktes gemäß Abs. 3 ergibt, dass es nicht den Sicherheitsanforderungen dieses Bundesgesetzes entspricht. Diesfalls können dem/der Hersteller/in oder Importeur/in von dem/der gemäß § 32 zuständigen Bundesminister/in auch die für die Risikobewertung und Konformitätsbeurteilung gemäß Abs. 3 anfallenden Kosten mit Bescheid auferlegt werden. Für Gegenproben ist keine Entschädigung zu leisten.
(7) Betriebsinhaber/innen sowie ihre Stellvertreter/innen und Beauftragten sind verpflichtet, die Amtshandlungen gemäß Abs. 1 zu ermöglichen, insbesondere dem Aufsichtsorgan über Aufforderung alle Orte bekanntzugeben, an denen diesem Bundesgesetz unterliegende Produkte in Verkehr gebracht werden, den Zutritt zu diesen Orten zu gestatten, Einsicht in die Unterlagen (Datenträger) zu gewähren

und durch die Erteilung notwendiger Auskünfte über den/die Hersteller/in, den/die Lieferanten/Lieferantin und die Abnehmer/innen der Produkte, die Beschaffung und Vorlage notwendiger Unterlagen über die Beschaffenheit, Wirkungsweise und Eigenschaften der Produkte sowie durch Hilfestellung bei der Probenziehung die Amtshandlungen zu unterstützen.
(8) Die gemäß Abs. 7 erhaltenen Angaben dürfen nur zur Vollziehung dieses Bundesgesetzes verwendet werden. Betriebsinhaber/innen sowie ihre Stellvertreter/innen und Beauftragten dürfen aus den in § 49 AVG genannten Gründen die Aussage verweigern, wobei aber die Weigerungsgründe wegen Gefahr eines Vermögensnachteiles sowie eines Betriebs- oder Geschäftsgeheimnisses nicht gelten.

Vorläufige Maßnahmen zur Gefahrenabwehr
§ 15. (1) Die Aufsichtsorgane gemäß § 13 haben vorläufige Maßnahmen zur Gefahrenabwehr (zB Beschlagnahme, Verbot des In-Verkehr-Bringens, Anbringung von Warnhinweisen) zu setzen. Sie sind berechtigt, diese auch ohne vorausgegangenes Verfahren zu treffen, wenn

1. die von einem Produkt ausgehende Gefahr für das Leben oder die Gesundheit von Menschen entweder durch ein Gutachten einer in- oder ausländischen akkreditierten Prüfstelle oder eines/r befugten Ziviltechnikers/Ziviltechnikerin festgestellt wurde oder

2. der begründete Verdacht besteht, dass die Verwendung eines Produktes eine ernste Gefahr für das Leben oder die Gesundheit von Menschen darstellt oder

3. das In-Verkehr-Bringen eines Produktes offenkundig einer gemäß § 11 angeordneten Maßnahme widerspricht oder

4. das Produkt bereits Gegenstand einer Maßnahme in einem Vertragsstaat des EWR war und diese Maßnahme im Rahmen des RAPEX-Verfahrens aufgrund der Richtlinie 2001/95/EG über die allgemeine Produktsicherheit notifiziert wurde.

(2) Alle vorläufigen Maßnahmen im Sinne des Abs. 1 sind auf die Abwehr der drohenden Gefahr abzustellen, wobei ein hohes Schutzniveau für die Sicherheit der Verbraucher/innen zu beachten ist. Dabei ist jeweils das gelindeste noch zum Ziel führende Mittel anzuwenden.
(3) Die von einer vorläufigen Maßnahme erfassten Produkte sind tunlichst im Betrieb oder in den Lagerräumen zu belassen und so zu verschließen oder zu kennzeichnen, dass ihre Veränderung ohne Verletzung des Behältnisses oder der Kennzeichnung nicht möglich ist. Der/die über die Produkte bisher Verfügungsberechtigte ist vom Aufsichtsorgan schriftlich auf die strafrechtlichen Folgen ihrer Verbringung oder Veränderung sowie der Verletzung des Dienstsiegels aufmerksam zu machen.
(4) Von vorläufigen Maßnahmen gemäß Abs. 1 können auch Produkte erfasst werden, deren Überlassung von den Zollbehörden gemäß Artikel 2 der Verordnung (EWG) Nr. 339/93 des Rates vom 8. Februar 1993 über die Kontrolle der Übereinstimmung von aus Drittländern eingeführten Erzeugnissen mit den geltenden Produktsicherheitsvorschriften, Abl. Nr. L 040 vom 17.2.1993, ausgesetzt worden ist. Die betreffenden Produkte sind diesfalls in vorübergehender Verwahrung gemäß Artikel 50 der Verordnung (EWG) Nr. 2913/92 des Rates vom 12. Oktober 1992 zur Festlegung des Zollkodex der Gemeinschaften, Abl. Nr. L 302 vom 19.10.1992, zu belassen.
(5) Über die vorläufige Maßnahme hat das Aufsichtsorgan dem/der bis dahin Verfügungsberechtigten eine Bescheinigung auszustellen, in welcher der Ort der Lagerung sowie Art und Menge der betroffenen Produkte anzugeben sind.
(6) Die Bewahrung der von einer vorläufigen Maßnahme erfassten Produkte vor Schäden obliegt dem/der bisher Verfügungsberechtigten. Sind zur Bewahrung der Produkte vor Schäden nach der vorläufigen Maßnahme besondere Vorkehrungen erforderlich, so ist der Landeshauptmann vorher zu verständigen. Diese Vorkehrungen sind in Anwesenheit eines Aufsichtsorgans zu treffen, das über den

Vorgang ein Befundprotokoll aufzunehmen hat und dieses dem Landeshauptmann und dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz zur Kenntnis bringt.

§ 16. (1) Die Aufsichtsorgane haben eine vorläufige Maßnahme unverzüglich dem Landeshauptmann mitzuteilen. Dieser hat unverzüglich einen schriftlichen Bescheid zu erlassen und dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz sowie allenfalls dem/der gemäß § 32 zuständigen Bundesminister/in zur Kenntnis zu bringen.
(2) Der Landeshauptmann hat den Inhalt des Bescheides gemäß Abs. 1 in den für die betroffenen Verkehrskreise geeigneten Medien zu veröffentlichen, wenn diese Information zur Abwendung einer unmittelbar drohenden Gefahr für das Leben oder die Gesundheit bei einer größeren Anzahl von Menschen dringend erforderlich ist. Die Aufhebung einer derart veröffentlichten vorläufigen Maßnahme ist unter Angabe des Aufhebungsgrundes in denselben Medien ebenfalls zu veröffentlichen.
(3) Der Landeshauptmann kann, wenn dies im Interesse der Zweckmäßigkeit, Raschheit, Einfachheit und Kostenersparnis gelegen ist, durch Verordnung die Bezirksverwaltungsbehörde mit der Vollziehung der Abs. 1 und 2 an seiner Stelle betrauen.
(4) Die Kosten der Veröffentlichungen gemäß Abs. 2 sind von dem/der In-Verkehr-Bringer/in des Produktes zu ersetzen.
(5) Eine vorläufige Maßnahme gemäß § 15 Abs. 1 gilt als aufgehoben, wenn nicht binnen eines Monats der schriftliche Bescheid des Landeshauptmanns gemäß Abs. 1 erlassen wird. Die Maßnahme gilt jedoch dann nicht als aufgehoben, wenn der Bescheid gemäß § 19 des Zustellgesetzes, BGBl. Nr. 200/1982, wegen Unzustellbarkeit an die Behörde zurückgestellt worden ist.

(6) Bescheide gemäß Abs. 1 sind auf Antrag unverzüglich aufzuheben, wenn sichergestellt ist, dass das Produkt nicht mehr in Verkehr gebracht wird oder so verbessert wurde, dass es den Anforderungen des § 4 Abs. 1 entspricht.
(7) Bescheide gemäß Abs. 1 sind sofort vollstreckbar; wenn sie nicht kürzer befristet sind, treten sie mit Ablauf eines Jahres, vom Beginn der Vollstreckbarkeit an gerechnet, außer Wirksamkeit.
(8) Der/die gemäß § 32 zuständige Bundesminister/in ist berechtigt, in Vollziehung des § 11 die gemäß Abs. 1 erlassenen Bescheide nach jeder Richtung abzuändern; diese Bescheide gelten unbefristet, sofern im Bescheid kein kürzerer Zeitraum angegeben ist.

§ 17. Im Fall des § 15 Abs. 1 Z 2 sind auch die Organe der Behörden der allgemeinen staatlichen Verwaltung ermächtigt, die erforderlichen vorläufigen Maßnahmen zur Gefahrenabwehr auch ohne vorausgegangenes Verfahren und vor Erlassung eines Bescheides zu treffen; § 15 Abs. 2 bis 6 und § 16 sind sinngemäß anzuwenden.

Rechtsmittel
§ 18. (1) Gegen Bescheide gemäß § 16 Abs. 1 und 8 steht binnen zwei Wochen das Rechtsmittel der Berufung an den unabhängigen Verwaltungssenat zu, in dessen Sprengel die dem Bescheid zugrunde liegende vorläufige Maßnahme gesetzt wurde.
(2) Gegen Bescheide gemäß § 11 steht binnen zwei Wochen das Rechtsmittel der Berufung an den unabhängigen Verwaltungssenat zu, in dessen Sprengel der Geschäftssitz des Bescheidadressaten liegt.
(3) Die Entscheidungen der unabhängigen Verwaltungssenate sind unverzüglich auch dem/der gemäß § 32 zuständigen Bundesminister/in zuzustellen. Diese/r kann gegen die Entscheidungen sowohl zugunsten als auch zum Nachteil des/der betroffenen Bescheidadressaten/in Beschwerde wegen Rechtswidrigkeit an den Verwaltungsgerichtshof erheben.

Anlaufstellen und Information der Öffentlichkeit

§ 19. (1) Verbraucher/innen und andere Betroffene können Informationen über gefährliche Produkte einer vom Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz einzurichtenden Anlaufstelle mitteilen. Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat Verbraucher/innen und andere Betroffene über die Einrichtung dieser Anlaufstelle in geeigneter Weise zu informieren.

(2) Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat die Öffentlichkeit auf Grundlage der ihm zur Verfügung stehenden Informationen über Gefahren, die von Produkten ausgehen, angemessen (zB im Internet) zu informieren. Insbesondere ist der Öffentlichkeit der Zugang zu Informationen über Maßnahmen gemäß § 11 zu ermöglichen.

(3) Sofern der Landeshauptmann die Öffentlichkeit über Gefahren gemäß Abs. 2 informiert, hat er den Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz davon in Kenntnis zu setzen.

(4) Die auf Grund dieses Gesetzes gesammelten Informationen sind aber dann geheimzuhalten, wenn sie ihrem Wesen nach in hinreichend begründeten Fällen dem Geschäftsgeheimnis unterliegen, es sei denn, bestimmte Informationen über sicherheitsrelevante Eigenschaften von Produkten müssen unter Berücksichtigung der Gesamtumstände veröffentlicht werden, um den Schutz der Gesundheit und Sicherheit der Verbraucher/innen zu gewährleisten.

4. ABSCHNITT
Produktsicherheitsbeirat, Verbraucherrat

Produktsicherheitsbeirat

§ 20. (1) Beim Bundesministerium für soziale Sicherheit, Generationen und Konsumentenschutz ist ein Beirat (Produktsicherheitsbeirat) einzurichten. Die Tätigkeit im Beirat begründet keinen Anspruch auf Entgelt sowie auf Ersatz von Reise- und Aufenthaltskosten.

(2) Dem Beirat gehören als stimmberechtigte Mitglieder je ein/e Vertreter/in an:

1. der Wirtschaftskammer Österreich,
2. der Bundesarbeitskammer,
3. der Präsidentenkonferenz der Landwirtschaftskammern Österreichs,
4. des Österreichischen Gewerkschaftsbundes,
5. der Allgemeinen Unfallversicherungsanstalt,
6. des Instituts Sicher Leben im Kuratorium für Schutz und Sicherheit,
7. des Österreichischen Komitees für Unfallverhütung im Kindesalter,
8. des Seniorenrates,
9. des Vereins für Konsumenteninformation,
10. der Vereins zur Wahrung der Interessen von autorisierten und akkreditierten Versuchsanstalten und Prüfstellen (Austrolab),
11. des Verbraucherrates am Österreichischen Normungsinstitut,
12. der Österreichischen Arbeitsgemeinschaft für Rehabilitation,
13. des Bundesministeriums für Wirtschaft und Arbeit,
14. des Bundesministeriums für Gesundheit und Frauen,
15. des Bundesministeriums für Land- und Forstwirtschaft, Umwelt und Wasserwirtschaft,
16. des Bundesministeriums für Verkehr, Innovation und Technologie,

17. des Bundesministeriums für soziale Sicherheit, Generationen und Konsumentenschutz sowie
18. ein gemeinsamer Vertreter der Länder.

Die Beiratsmitglieder sowie jeweils ein Ersatzmitglied sind von den durch sie vertretenen Institutionen dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz bekanntzugeben.

(3) Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz kann zu den Sitzungen des Beirats darüber hinaus Sachverständige und Auskunftspersonen beiziehen; diese haben kein Stimmrecht; ihnen gebührt der Ersatz der Reise- und Aufenthaltskosten, falls ihr ordentlicher Wohnsitz oder Dienstort nicht mit dem Tagungsort übereinstimmt.
(4) Jedes Beiratsmitglied ist berechtigt, zu Sitzungen des Beirates Experten/Expertinnen im unbedingt nötigen Ausmaß beizuziehen. Diese haben kein Stimmrecht; ihre Mitwirkung im Beirat ist unentgeltlich und begründet keinen Anspruch auf Ersatz der Reise- und Aufenthaltskosten.
(5) Die Geschäftsführung des Beirates und seiner Fachausschüsse sowie der Vorsitz im Beirat obliegt dem Bundesministerium für soziale Sicherheit, Generationen und Konsumentenschutz. Der/die Vorsitzende hat kein Stimmrecht.

Aufgaben des Produktsicherheitsbeirates
§ 21. (1) Dem Beirat obliegt

1. die Beratung des Bundesministers für soziale Sicherheit, Generationen und Konsumentenschutz in grundsätzlichen Fragen des Schutzes von Verbrauchern und Verbraucherinnen vor gefährlichen Produkten, der Verhütung von Haus-, Freizeit- und Sportunfällen und der Marktüberwachung;

2. die Unterstützung des Bundesministers für soziale Sicherheit, Generationen und Konsumentenschutz bei der Risikobewertung und Konformitätsbeurteilung von Produkten;

3. der Austausch von Erfahrungen und Kenntnissen zur Erreichung der im § 1 umschriebenen Ziele;

4. die Erarbeitung von Empfehlungen zu Fragen der Produktsicherheit und Unfallverhütung.

(2) Der Produktsicherheitsbeirat kann auch über Produkte beraten, die gemäß § 2 nicht oder nur teilweise dem Anwendungsbereich dieses Bundesgesetzes unterliegen.

(3) Sofern dies für die Beratungen des Beirates erforderlich ist, hat der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz auf Verlangen des Beirates Auskünfte gemäß § 7 Abs. 5 einzuholen. Erforderlichenfalls sind In-Verkehr-Bringer/innen zur Auskunftserteilung den Beiratssitzungen beizuziehen. Diesfalls gebührt ihnen kein Ersatz der Reise- und Aufenthaltskosten.
(4) Empfehlungen gemäß Abs. 1 Z 4 sind vom Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz in geeigneter Weise, insbesondere durch Publikation im Internet, zu veröffentlichen.
(5) Der Beirat ist jedenfalls anzuhören, bevor eine Maßnahme gemäß § 11 in Form einer Verordnung erlassen wird. Der Verpflichtung zur Anhörung des Beirates kann auch durch schriftliche Befassung der Beiratsmitglieder entsprochen werden.

Arbeitsweise
§ 22. Die Sitzungen des Beirates sind nicht öffentlich. Die Beiratsmitglieder und die sonst bei den Sitzungen anwesenden Personen sind zur Amtsverschwiegenheit (Art. 20 Abs. 3 B–VG) verpflichtet; sie haben auf Verlangen des Vorsitzenden ihre Berechtigung zur Teilnahme an der Sitzung nachzuweisen.

Entscheidungsfindung und Geschäftsordnung

§ 23. (1) Der Beirat hat eine Geschäftsordnung zu beschließen, welche die Erfüllung der ihm übertragenen Aufgaben sicherstellt. Die Geschäftsordnung bedarf der Genehmigung durch den Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz.

(2) Der Beirat trifft seine Entscheidungen mit einfacher Mehrheit. Grundsätzlich wird getrachtet, eine einhellige Entscheidung zu finden. Die Beschlüsse des Beirates werden protokolliert, wobei Minderheitsmeinungen festzuhalten sind.

(3) Zur Vorberatung von Beiratsentscheidungen kann der Beirat auch Fachausschüsse einsetzen. Für diese gelten die §§ 20 bis 23 sinngemäß.

Verbraucherrat

§ 24. Der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz hat eine effiziente und unabhängige Vertretung von Verbraucherinteressen in nationalen und internationalen Normungsgremien zu gewährleisten, insbesondere durch Förderung einer geeigneten Institution wie etwa dem beim Österreichischen Normungsinstitut eingerichteten Verbraucherrat.

5. ABSCHNITT

Strafbestimmungen

§ 25. Ein/e In-Verkehr-Bringer/in, der/die gefährliche Produkte in Verkehr bringt, deren Gefährdungspotential zum Zeitpunkt des In-Verkehr-Bringens bekannt war oder bei angemessener Sorgfalt erkannt hätte werden müssen und die eine ernste Gefahr für Leben und Gesundheit von Verbraucher/innen darstellen, begeht eine Verwaltungsübertretung, die von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 25 000 Euro oder im Falle ihrer Uneinbringlichkeit mit einer Ersatzfreiheitsstrafe bis zu sechs Wochen zu bestrafen ist.

§ 26. Ein/e In-Verkehr-Bringer/in, der/die Maßnahmen, die gemäß § 11 oder § 16 zum Schutz vor gefährlichen Produkten durch Verordnung oder Bescheid auf Grund dieses Bundesgesetzes getroffen worden sind, zuwiderhandelt oder deren Durchführung vereitelt, begeht eine Verwaltungsübertretung, die von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 25 000 Euro oder im Falle ihrer Uneinbringlichkeit mit einer Ersatzfreiheitsstrafe bis zu sechs Wochen zu bestrafen ist.

§ 27. Ein/e In-Verkehr-Bringer/in, der/die

1. einer Verordnung auf Grund des § 7 Abs. 6,
2. Maßnahmen auf Grund der Bestimmungen des § 15,
3. den Bestimmungen des § 7 Abs. 4 und 5 oder
4. den Bestimmungen des § 14 Abs. 7

zuwiderhandelt, begeht eine Verwaltungsübertretung, die von der Bezirksverwaltungsbehörde mit einer Geldstrafe bis zu 3 000 Euro oder im Falle ihrer Uneinbringlichkeit mit einer Ersatzfreiheitsstrafe bis zu zwei Wochen zu bestrafen ist.

§ 28. Produkte dürfen nur dann für verfallen erklärt werden (§§ 17 und 18 des Verwaltungsstrafgesetzes 1991 – VStG), wenn den durch Bescheid oder Verordnung getroffenen Maßnahmen aufgrund dieses Bundesgesetzes nicht entsprochen wurde.

§ 29. Eine Verwaltungsübertretung liegt nicht vor, wenn eine in den §§ 25 bis 27 bezeichnete Tat den Tatbestand einer strafbaren Handlung erfüllt, die in die Zuständigkeit der Gerichte fällt.

6. ABSCHNITT

Schlussbestimmungen

Weitergeltung von Rechtsvorschriften

§ 30. (1) Folgende Verordnungen gelten weiter als Verordnungen aufgrund dieses Gesetzes:

Verordnung des Bundesministers für Bauten und Technik vom 30. Jänner 1985, mit der der Verkauf von mit gefährlichen Gasfedern ausgestatteten Bürodrehstühlen und ähnlichen Stühlen verboten wird, BGBl. Nr. 71/1985;

Verordnung des Bundesministers für Gesundheit, Sport und Konsumentenschutz über sonstige mit Lebensmitteln verwechselbare Produkte, BGBl. Nr. 418/1994;

Verordnung des Bundesministers für Gesundheit und Konsumentenschutz zur Kennzeichnung von Kinderlaufhilfen (KinderlaufhilfenV), BGBl. Nr. 51/1996;

Verordnung der Bundesministerin für Frauenangelegenheiten und Verbraucherschutz über das In-Verkehr-Bringen von schusswaffenähnlichen Produkten (Schusswaffenähnliche ProdukteV), BGBl. II Nr. 185/1997;

Verordnung der Bundesministerin für Frauenangelegenheiten und Verbraucherschutz über die Kennzeichnung von Öllampen (ÖllampenV), BGBl. II Nr. 13/1998;

Verordnung der Bundesministerin für Frauenangelegenheiten und Verbraucherschutz über das In-Verkehr-Bringen von Laserpointern (LaserpointerV), BGBl. II Nr. 321/1999;

(2) Folgende Verordnungen gelten als Verordnungen aufgrund dieses Gesetzes bezüglich jener Teile, die aufgrund des Produktsicherheitsgesetzes 1994, BGBl. Nr. 63/1995, erlassen wurden:

Verordnung des Bundesministers für Wissenschaft und Verkehr über Freisprecheinrichtungen für Kraftfahrzeuge (FreisprecheinrichtungsV), BGBl. II Nr. 152/1999;

Verordnung der Bundesministerin für Verkehr, Innovation und Technologie über Fahrräder, Fahrradanhänger und zugehörige Ausrüstungsgegenstände (Fahrradverordnung), BGBl. II Nr. 146/2001;

Verordnung der Bundesministerin für Frauenangelegenheiten und Verbraucherschutz über die Meldung von sehr giftigen, giftigen und ätzenden Zubereitungen und die Mitteilung von Vergiftungsfällen (Giftinformations-Verordnung 1999), BGBl. II Nr. 137/1999;

Außer-Kraft-Treten von Rechtsvorschriften

§ 31. Mit In-Kraft-Treten dieses Bundesgesetzes tritt das Bundesgesetz zum Schutz vor gefährlichen Produkten (Produktsicherheitsgesetz 1994 – PSG 1994), BGBl. Nr. 63/1995, zuletzt geändert durch das 1. Euro-Umstellungsgesetz, BGBl. I Nr. 98/2001, außer Kraft.

Vollziehung

§ 32. (1) Mit der Vollziehung dieses Bundesgesetzes ist – sofern nichts anderes bestimmt ist – der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz betraut.

(2) Sind Sicherheitseigenschaften von Produkten in anderen bundesgesetzlichen Verwaltungsvorschriften gemäß § 2 Abs. 2 oder durch unmittelbar anwendbares EU-Recht geregelt, so ist mit der Vollziehung der §§ 11, 12 und 16 Abs. 8 jeweils der/die Bundesminister/in betraut, in dessen/deren Wirkungsbereich die betreffende Verwaltungsvorschrift oder unmittelbar anwendbare Rechtsvorschrift der EU fällt. Für Maßnahmen gemäß den §§ 11 und 12, die mit Verordnung getroffen werden, ist das Einvernehmen mit dem Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz herzustellen.

(3) Mit der Vollziehung des § 13 Abs. 3 ist der Bundesminister für soziale Sicherheit, Generationen und Konsumentenschutz im Einvernehmen mit dem Bundesminister für Finanzen betraut.

§ 33. Mit diesem Bundesgesetz wird die Richtlinie des europäischen Parlamentes und des Rates vom 3. Dezember 2001 über die allgemeine Produktsicherheit 2001/95/EG, Abl. Nr. L 11 vom 15.1.2002, umgesetzt.

9.3.2. Directive 2001/95/EC of the European Parliament and of the Council of 3rd December 2001 on general product safety

Official Journal oft he European Communities
No. L 011 vom 15/01/2002 S. 0004 - 0017

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission(1),

Having regard to the opinion of the Economic and Social Committee(2),

Acting in accordance with the procedure referred to in Article 251 of the Treaty(3), in the light of the joint text approved by the Conciliation Committee on 2 August 2001,

Whereas:

(1) Under Article 16 of Council Directive 92/59/EEC of 29 June 1992 on general product safety(4), the Council was to decide, four years after the date set for the implementation of the said Directive, on the basis of a report of the Commission on the experience acquired, together with appropriate proposals, whether to adjust Directive 92/59/EEC. It is necessary to amend Directive 92/59/EEC in several respects, in order to complete, reinforce or clarify some of its provisions in the light of experience as well as new and relevant developments on consumer product safety, together with the changes made to the Treaty, especially in Articles 152 concerning public health and 153 concerning consumer protection, and in the light of the precautionary principle. Directive 92/59/EEC should therefore be recast in the interest of clarity. This recasting leaves the safety of services outside the scope of this Directive, since the Commission intends to identify the needs, possibilities and priorities for Community action on the safety of services and liability of service providers, with a view to presenting appropriate proposals.

(2) It is important to adopt measures with the aim of improving the functioning of the internal market, comprising an area without internal frontiers in which the free movement of goods, persons, services and capital is assured.

(3) In the absence of Community provisions, horizontal legislation of the Member States on product safety, imposing in particular a general obligation on economic operators to market only safe products, might differ in the level of protection afforded to consumers. Such disparities, and the absence of horizontal legislation in some Member States, would be liable to create barriers to trade and distortion of competition within the internal market.

(4) In order to ensure a high level of consumer protection, the Community must contribute to protecting the health and safety of consumers. Horizontal Community legislation introducing a general product safety requirement, and containing provisions on the general obligations of producers and distributors, on the enforcement of Community product safety requirements and on rapid exchange of information and action at Community level in certain cases, should contribute to that aim.

(5) It is very difficult to adopt Community legislation for every product which exists or which may be developed; there is a need for a broad-based, legislative framework of a horizontal nature to deal with such products, and also to cover lacunae, in particular pending revision of the existing specific legislation, and to complement provisions in existing or forthcoming specific legislation, in particular with a view to ensuring a high level of protection of safety and health of consumers, as required by Article 95 of the Treaty.

(6) It is therefore necessary to establish at Community level a general safety requirement for any product placed on the market, or otherwise supplied or made available to consumers, intended for consumers, or likely to be used by consumers under reasonably foreseeable conditions even if not intended for them. In all these cases the products under consideration can pose risks for the health and safety of consumers which must be prevented. Certain second-hand goods should nevertheless be excluded by their very nature.

(7) This Directive should apply to products irrespective of the selling techniques, including distance and electronic selling.

(8) The safety of products should be assessed taking into account all the relevant aspects, in particular the categories of consumers which can be particularly vulnerable to the risks posed by the products under consideration, in particular children and the elderly.

(9) This Directive does not cover services, but in order to secure the attainment of the protection objectives in question, its provisions should also apply to products that are supplied or made available to consumers in the context of service provision for use by them. The safety of the equipment used by service providers themselves to supply a service to consumers does not come within the scope of this Directive since it has to be dealt with in conjunction with the safety of the service provided. In particular, equipment on which consumers ride or travel which is operated by a service provider is excluded from the scope of this Directive.

(10) Products which are designed exclusively for professional use but have subsequently migrated to the consumer market should be subject to the requirements of this Directive because they can pose risks to consumer health and safety when used under reasonably foreseeable conditions.

(11) In the absence of more specific provisions, within the framework of Community legislation covering safety of the products concerned, all the provisions of this Directive should apply in order to ensure consumer health and safety.

(12) If specific Community legislation sets out safety requirements covering only certain risks or categories of risks, with regard to the products concerned the obligations of economic operators in respect of these risks are those determined by the provisions of the specific legislation, while the general safety requirement of this Directive should apply to the other risks.

(13) The provisions of this Directive relating to the other obligations of producers and distributors, the obligations and powers of the Member States, the exchanges of information and rapid intervention situations and dissemination of information and confidentiality apply in the case of products covered by specific rules of Community law, if those rules do not already contain such obligations.

(14) In order to facilitate the effective and consistent application of the general safety requirement of this Directive, it is important to establish European voluntary standards covering certain products and risks in such a way that a product which conforms to a national standard transposing a European standard is to be presumed to be in compliance with the said requirement.

(15) With regard to the aims of this Directive, European standards should be established by European standardisation bodies, under mandates set by the Commission assisted by appropriate Committees. In order to ensure that products in compliance with the standards fulfil the general safety requirement, the Commission assisted by a committee composed of representatives of the Member States, should fix

the requirements that the standards must meet. These requirements should be included in the mandates to the standardisation bodies.

(16) In the absence of specific regulations and when the European standards established under mandates set by the Commission are not available or recourse is not made to such standards, the safety of products should be assessed taking into account in particular national standards transposing any other relevant European or international standards, Commission recommendations or national standards, international standards, codes of good practice, the state of the art and the safety which consumers may reasonably expect. In this context, the Commission's recommendations may facilitate the consistent and effective application of this Directive pending the introduction of European standards or as regards the risks and/or products for which such standards are deemed not to be possible or appropriate.

(17) Appropriate independent certification recognised by the competent authorities may facilitate proof of compliance with the applicable product safety criteria.

(18) It is appropriate to supplement the duty to observe the general safety requirement by other obligations on economic operators because action by such operators is necessary to prevent risks to consumers under certain circumstances.

(19) The additional obligations on producers should include the duty to adopt measures commensurate with the characteristics of the products, enabling them to be informed of the risks that these products may present, to supply consumers with information enabling them to assess and prevent risks, to warn consumers of the risks posed by dangerous products already supplied to them, to withdraw those products from the market and, as a last resort, to recall them when necessary, which may involve, depending on the provisions applicable in the Member States, an appropriate form of compensation, for example exchange or reimbursement.

(20) Distributors should help in ensuring compliance with the applicable safety requirements. The obligations placed on distributors apply in proportion to their respective responsibilities. In particular, it may prove impossible, in the context of charitable activities, to provide the competent authorities with information and documentation on possible risks and origin of the product in the case of isolated used objects provided by private individuals.

(21) Both producers and distributors should cooperate with the competent authorities in action aimed at preventing risks and inform them when they conclude that certain products supplied are dangerous. The conditions regarding the provision of such information should be set in this Directive to facilitate its effective application, while avoiding an excessive burden for economic operators and the authorities.

(22) In order to ensure the effective enforcement of the obligations incumbent on producers and distributors, the Member States should establish or designate authorities which are responsible for monitoring product safety and have powers to take appropriate measures, including the power to impose effective, proportionate and dissuasive penalties, and ensure appropriate coordination between the various designated authorities.

(23) It is necessary in particular for the appropriate measures to include the power for Member States to order or organise, immediately and efficiently, the withdrawal of dangerous products already placed on the market and as a last resort to order, coordinate or organise the recall from consumers of dangerous products already supplied to them. Those powers should be applied when producers and distributors fail to prevent risks to consumers in accordance with their obligations. Where necessary, the appropriate powers and procedures should be available to the authorities to decide and apply any necessary measures rapidly.

(24) The safety of consumers depends to a great extent on the active enforcement of Community product safety requirements. The Member States should, therefore, establish systematic approaches to ensure the effectiveness of market surveillance and other enforcement activities and should ensure their openness to the public and interested parties.

(25) Collaboration between the enforcement authorities of the Member States is necessary in ensuring the attainment of the protection objectives of this Directive. It is, therefore, appropriate to promote the operation of a European network of the enforcement authorities of the Member States to facilitate, in a coordinated manner with other Community procedures, in particular the Community Rapid Information System (RAPEX), improved collaboration at operational level on market surveillance and other enforcement activities, in particular risk assessment, testing of products, exchange of expertise and scientific knowledge, execution of joint surveillance projects and tracing, withdrawing or recalling dangerous products.

(26) It is necessary, for the purpose of ensuring a consistent, high level of consumer health and safety protection and preserving the unity of the internal market, that the Commission be informed of any measure restricting the placing on the market of a product or requiring its withdrawal or recall from the market. Such measures should be taken in compliance with the provisions of the Treaty, and in particular Articles 28, 29 and 30 thereof.

(27) Effective supervision of product safety requires the setting-up at national and Community levels of a system of rapid exchange of information in situations of serious risk requiring rapid intervention in respect of the safety of a product. It is also appropriate in this Directive to set out detailed procedures for the operation of the system and to give the Commission, assisted by an advisory committee, power to adapt them.

(28) This Directive provides for the establishment of non-binding guidelines aimed at indicating simple and clear criteria and practical rules which may change, in particular for the purpose of allowing efficient notification of measures restricting the placing on the market of products in the cases referred to in this Directive, whilst taking into account the range of situations dealt with by Member States and economic operators. The guidelines should in particular include criteria for the application of the definition of serious risks in order to facilitate consistent implementation of the relevant provisions in case of such risks.

(29) It is primarily for Member States, in compliance with the Treaty and in particular with Articles 28, 29 and 30 thereof, to take appropriate measures with regard to dangerous products located within their territory.

(30) However, if the Member States differ as regards the approach to dealing with the risk posed by certain products, such differences could entail unacceptable disparities in consumer protection and constitute a barrier to intra-Community trade.

(31) It may be necessary to deal with serious product-safety problems requiring rapid intervention which affect or could affect, in the immediate future, all or a significant part of the Community and which, in view of the nature of the safety problem posed by the product, cannot be dealt with effectively in a manner commensurate with the degree of urgency, under the procedures laid down in the specific rules of Community law applicable to the products or category of products in question.

(32) It is therefore necessary to provide for an adequate mechanism allowing, as a last resort, for the adoption of measures applicable throughout the Community, in the form of a decision addressed to the Member States, to cope with situations created by products presenting a serious risk. Such a decision should entail a ban on the export of the product in question, unless in the case in point exceptional circumstances allow a partial ban or even no ban to be decided upon, particularly when a system of prior consent is established. In addition, the banning of exports should be examined with a view to preventing risks to the health and safety of consumers. Since such a decision is not directly applicable

to economic operators, Member States should take all necessary measures for its implementation. Measures adopted under such a procedure are interim measures, save when they apply to individually identified products or batches of products. In order to ensure the appropriate assessment of the need for, and the best preparation of such measures, they should be taken by the Commission, assisted by a committee, in the light of consultations with the Member States, and, if scientific questions are involved falling within the competence of a Community scientific committee, with the scientific committee competent for the risk concerned.

(33) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission(5).

(34) In order to facilitate effective and consistent application of this Directive, the various aspects of its application may need to be discussed within a committee.

(35) Public access to the information available to the authorities on product safety should be ensured. However, professional secrecy, as referred to in Article 287 of the Treaty, must be protected in a way which is compatible with the need to ensure the effectiveness of market surveillance activities and of protection measures.

(36) This Directive should not affect victims' rights within the meaning of Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products(6).

(37) It is necessary for Member States to provide for appropriate means of redress before the competent courts in respect of measures taken by the competent authorities which restrict the placing on the market of a product or require its withdrawal or recall.

(38) In addition, the adoption of measures concerning imported products, like those concerning the banning of exports, with a view to preventing risks to the safety and health of consumers must comply with the Community's international obligations.

(39) The Commission should periodically examine the manner in which this Directive is applied and the results obtained, in particular in relation to the functioning of market surveillance systems, the rapid exchange of information and measures adopted at Community level, together with other issues relevant for consumer product safety in the Community, and submit regular reports to the European Parliament and the Council on the subject.

(40) This Directive should not affect the obligations of Member States concerning the deadline for transposition and application of Directive 92/59/EEC,

HAVE ADOPTED THIS DIRECTIVE:

CHAPTER I

Objective - Scope - Definitions

Article 1

1. The purpose of this Directive is to ensure that products placed on the market are safe.

2. This Directive shall apply to all the products defined in Article 2(a). Each of its provisions shall apply in so far as there are no specific provisions with the same objective in rules of Community law governing the safety of the products concerned.

Where products are subject to specific safety requirements imposed by Community legislation, this Directive shall apply only to the aspects and risks or categories of risks not covered by those requirements. This means that:

(a) Articles 2(b) and (c), 3 and 4 shall not apply to those products insofar as concerns the risks or categories of risks covered by the specific legislation;

(b) Articles 5 to 18 shall apply except where there are specific provisions governing the aspects covered by the said Articles with the same objective.

Article 2

For the purposes of this Directive:

(a) "product" shall mean any product - including in the context of providing a service - which is intended for consumers or likely, under reasonably foreseeable conditions, to be used by consumers even if not intended for them, and is supplied or made available, whether for consideration or not, in the course of a commercial activity, and whether new, used or reconditioned.

This definition shall not apply to second-hand products supplied as antiques or as products to be repaired or reconditioned prior to being used, provided that the supplier clearly informs the person to whom he supplies the product to that effect;

(b) "safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons, taking into account the following points in particular:

(i) the characteristics of the product, including its composition, packaging, instructions for assembly and, where applicable, for installation and maintenance;

(ii) the effect on other products, where it is reasonably foreseeable that it will be used with other products;

(iii) the presentation of the product, the labelling, any warnings and instructions for its use and disposal and any other indication or information regarding the product;

(iv) the categories of consumers at risk when using the product, in particular children and the elderly.

The feasibility of obtaining higher levels of safety or the availability of other products presenting a lesser degree of risk shall not constitute grounds for considering a product to be "dangerous";

(c) "dangerous product" shall mean any product which does not meet the definition of "safe product" in (b);

(d) "serious risk" shall mean any serious risk, including those the effects of which are not immediate, requiring rapid intervention by the public authorities;

(e) "producer" shall mean:

(i) the manufacturer of the product, when he is established in the Community, and any other person presenting himself as the manufacturer by affixing to the product his name, trade mark or other distinctive mark, or the person who reconditions the product;

(ii) the manufacturer's representative, when the manufacturer is not established in the Community or, if there is no representative established in the Community, the importer of the product;

(iii) other professionals in the supply chain, insofar as their activities may affect the safety properties of a product;

(f) "distributor" shall mean any professional in the supply chain whose activity does not affect the safety properties of a product;

(g) "recall" shall mean any measure aimed at achieving the return of a dangerous product that has already been supplied or made available to consumers by the producer or distributor;

(h) "withdrawal" shall mean any measure aimed at preventing the distribution, display and offer of a product dangerous to the consumer.

CHAPTER II

General safety requirement, conformity assessment criteria and European standards

Article 3

1. Producers shall be obliged to place only safe products on the market.

2. A product shall be deemed safe, as far as the aspects covered by the relevant national legislation are concerned, when, in the absence of specific Community provisions governing the safety of the product in question, it conforms to the specific rules of national law of the Member State in whose territory the product is marketed, such rules being drawn up in conformity with the Treaty, and in particular Articles 28 and 30 thereof, and laying down the health and safety requirements which the product must satisfy in order to be marketed.

A product shall be presumed safe as far as the risks and risk categories covered by relevant national standards are concerned when it conforms to voluntary national standards transposing European standards, the references of which have been published by the Commission in the Official Journal of the European Communities in accordance with Article 4. The Member States shall publish the references of such national standards.

3. In circumstances other than those referred to in paragraph 2, the conformity of a product to the general safety requirement shall be assessed by taking into account the following elements in particular, where they exist:

(a) voluntary national standards transposing relevant European standards other than those referred to in paragraph 2;

(b) the standards drawn up in the Member State in which the product is marketed;

(c) Commission recommendations setting guidelines on product safety assessment;

(d) product safety codes of good practice in force in the sector concerned;

(e) the state of the art and technology;

(f) reasonable consumer expectations concerning safety.

4. Conformity of a product with the criteria designed to ensure the general safety requirement, in particular the provisions mentioned in paragraphs 2 or 3, shall not bar the competent authorities of the Member States from taking appropriate measures to impose restrictions on its being placed on the market or to require its withdrawal from the market or recall where there is evidence that, despite such conformity, it is dangerous.

Article 4

1. For the purposes of this Directive, the European standards referred to in the second subparagraph of Article 3(2) shall be drawn up as follows:

(a) the requirements intended to ensure that products which conform to these standards satisfy the general safety requirement shall be determined in accordance with the procedure laid down in Article 15(2);

(b) on the basis of those requirements, the Commission shall, in accordance with Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services(7) call on the European standardisation bodies to draw up standards which satisfy these requirements;

(c) on the basis of those mandates, the European standardisation bodies shall adopt the standards in accordance with the principles contained in the general guidelines for cooperation between the Commission and those bodies;

(d) the Commission shall report every three years to the European Parliament and the Council, within the framework of the report referred to in Article 19(2), on its programmes for setting the requirements and the mandates for standardisation provided for in subparagraphs (a) and (b) above. This report will, in particular, include an analysis of the decisions taken regarding requirements and mandates for standardisation referred to in subparagraphs (a) and (b) and regarding the standards referred to in subparagraph (c). It will also include information on the products for which the Commission intends to set the requirements and the mandates in question, the product risks to be considered and the results of any preparatory work launched in this area.

2. The Commission shall publish in the Official Journal of the European Communities the references of the European standards adopted in this way and drawn up in accordance with the requirements referred to in paragraph 1.

If a standard adopted by the European standardisation bodies before the entry into force of this Directive ensures compliance with the general safety requirement, the Commission shall decide to publish its references in the Official Journal of the European Communities.

If a standard does not ensure compliance with the general safety requirement, the Commission shall withdraw reference to the standard from publication in whole or in part.

In the cases referred to in the second and third subparagraphs, the Commission shall, on its own initiative or at the request of a Member State, decide in accordance with the procedure laid down in Article 15(2) whether the standard in question meets the general safety requirement. The Commission shall decide to publish or withdraw after consulting the Committee established by Article 5 of Directive 98/34/EC. The Commission shall notify the Member States of its decision.

CHAPTER III

Other obligations of producers and obligations of distributors

Article 5

1. Within the limits of their respective activities, producers shall provide consumers with the relevant information to enable them to assess the risks inherent in a product throughout the normal or reasonably foreseeable period of its use, where such risks are not immediately obvious without adequate warnings, and to take precautions against those risks.

The presence of warnings does not exempt any person from compliance with the other requirements laid down in this Directive.

Within the limits of their respective activities, producers shall adopt measures commensurate with the characteristics of the products which they supply, enabling them to:

(a) be informed of risks which these products might pose;

(b) choose to take appropriate action including, if necessary to avoid these risks, withdrawal from the market, adequately and effectively warning consumers or recall from consumers.

The measures referred to in the third subparagraph shall include, for example:

(a) an indication, by means of the product or its packaging, of the identity and details of the producer and the product reference or, where applicable, the batch of products to which it belongs, except where not to give such indication is justified and

(b) in all cases where appropriate, the carrying out of sample testing of marketed products, investigating and, if necessary, keeping a register of complaints and keeping distributors informed of such monitoring.

Action such as that referred to in (b) of the third subparagraph shall be undertaken on a voluntary basis or at the request of the competent authorities in accordance with Article 8(1)(f). Recall shall take place as a last resort, where other measures would not suffice to prevent the risks involved, in instances where the producers consider it necessary or where they are obliged to do so further to a measure taken by the competent authority. It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.

2. Distributors shall be required to act with due care to help to ensure compliance with the applicable safety requirements, in particular by not supplying products which they know or should have presumed, on the basis of the information in their possession and as professionals, do not comply with those requirements. Moreover, within the limits of their respective activities, they shall participate in monitoring the safety of products placed on the market, especially by passing on information on product risks, keeping and providing the documentation necessary for tracing the origin of products, and cooperating in the action taken by producers and competent authorities to avoid the risks. Within the limits of their respective activities they shall take measures enabling them to cooperate efficiently.

3. Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof under the conditions laid down in Annex I, giving details, in particular, of action taken to prevent risk to the consumer.

The Commission shall, in accordance with the procedure referred to in Article 15(3), adapt the specific requirements relating to the obligation to provide information laid down in Annex I.

4. Producers and distributors shall, within the limits of their respective activities, cooperate with the competent authorities, at the request of the latter, on action taken to avoid the risks posed by products which they supply or have supplied. The procedures for such cooperation, including procedures for dialogue with the producers and distributors concerned on issues related to product safety, shall be established by the competent authorities.

CHAPTER IV

Specific obligations and powers of the Member States

Article 6

1. Member States shall ensure that producers and distributors comply with their obligations under this Directive in such a way that products placed on the market are safe.

2. Member States shall establish or nominate authorities competent to monitor the compliance of products with the general safety requirements and arrange for such authorities to have and use the necessary powers to take the appropriate measures incumbent upon them under this Directive.

3. Member States shall define the tasks, powers, organisation and cooperation arrangements of the competent authorities. They shall keep the Commission informed, and the Commission shall pass on such information to the other Member States.

Article 7

Member States shall lay down the rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member

States shall notify those provisions to the Commission by 15 January 2004 and shall also notify it, without delay, of any amendment affecting them.

Article 8

1. For the purposes of this Directive, and in particular of Article 6 thereof, the competent authorities of the Member States shall be entitled to take, inter alia, the measures in (a) and in (b) to (f) below, where appropriate:

(a) for any product:

(i) to organise, even after its being placed on the market as being safe, appropriate checks on its safety properties, on an adequate scale, up to the final stage of use or consumption;

(ii) to require all necessary information from the parties concerned;

(iii) to take samples of products and subject them to safety checks;

(b) for any product that could pose risks in certain conditions:

(i) to require that it be marked with suitable, clearly worded and easily comprehensible warnings, in the official languages of the Member State in which the product is marketed, on the risks it may present;

(ii) to make its marketing subject to prior conditions so as to make it safe;

(c) for any product that could pose risks for certain persons:

to order that they be given warning of the risk in good time and in an appropriate form, including the publication of special warnings;

(d) for any product that could be dangerous:

for the period needed for the various safety evaluations, checks and controls, temporarily to ban its supply, the offer to supply it or its display;

(e) for any dangerous product:

to ban its marketing and introduce the accompanying measures required to ensure the ban is complied with;

(f) for any dangerous product already on the market:

(i) to order or organise its actual and immediate withdrawal, and alert consumers to the risks it presents;

(ii) to order or coordinate or, if appropriate, to organise together with producers and distributors its recall from consumers and its destruction in suitable conditions.

2. When the competent authorities of the Member States take measures such as those provided for in paragraph 1, in particular those referred to in (d) to (f), they shall act in accordance with the Treaty, and in particular Articles 28 and 30 thereof, in such a way as to implement the measures in a manner proportional to the seriousness of the risk, and taking due account of the precautionary principle.

In this context, they shall encourage and promote voluntary action by producers and distributors, in accordance with the obligations incumbent on them under this Directive, and in particular Chapter III thereof, including where applicable by the development of codes of good practice.

If necessary, they shall organise or order the measures provided for in paragraph 1(f) if the action undertaken by the producers and distributors in fulfilment of their obligations is unsatisfactory or insufficient. Recall shall take place as a last resort. It may be effected within the framework of codes of good practice on the matter in the Member State concerned, where such codes exist.

3. In particular, the competent authorities shall have the power to take the necessary action to apply with due dispatch appropriate measures such as those mentioned in paragraph 1, (b) to (f), in the case of products posing a serious risk. These circumstances shall be determined by the Member States, assessing each individual case on its merits, taking into account the guidelines referred to in point 8 of Annex II.

4. The measures to be taken by the competent authorities under this Article shall be addressed, as appropriate, to:

(a) the producer;

(b) within the limits of their respective activities, distributors and in particular the party responsible for the first stage of distribution on the national market;

(c) any other person, where necessary, with a view to cooperation in action taken to avoid risks arising from a product.

Article 9

1. In order to ensure effective market surveillance, aimed at guaranteeing a high level of consumer health and safety protection, which entails cooperation between their competent authorities, Member States shall ensure that approaches employing appropriate means and procedures are put in place, which may include in particular:

(a) establishment, periodical updating and implementation of sectoral surveillance programmes by categories of products or risks and the monitoring of surveillance activities, findings and results;

(b) follow-up and updating of scientific and technical knowledge concerning the safety of products;

(c) periodical review and assessment of the functioning of the control activities and their effectiveness and, if necessary, revision of the surveillance approach and organisation put in place.

2. Member States shall ensure that consumers and other interested parties are given an opportunity to submit complaints to the competent authorities on product safety and on surveillance and control activities and that these complaints are followed up as appropriate. Member States shall actively inform consumers and other interested parties of the procedures established to that end.

Article 10

1. The Commission shall promote and take part in the operation in a European network of the authorities of the Member States competent for product safety, in particular in the form of administrative cooperation.

2. This network operation shall develop in a coordinated manner with the other existing Community procedures, particularly RAPEX. Its objective shall be, in particular, to facilitate:

(a) the exchange of information on risk assessment, dangerous products, test methods and results, recent scientific developments as well as other aspects relevant for control activities;

(b) the establishment and execution of joint surveillance and testing projects;

(c) the exchange of expertise and best practices and cooperation in training activities;

(d) improved cooperation at Community level with regard to the tracing, withdrawal and recall of dangerous products.

CHAPTER V

Exchanges of information and rapid intervention situations

Article 11

1. Where a Member State takes measures which restrict the placing on the market of products - or require their withdrawal or recall - such as those provided for in Article 8(1)(b) to (f), the Member State shall, to the extent that such notification is not required under Article 12 or any specific Community legislation, inform the Commission of the measures, specifying its reasons for adopting them. It shall also inform the Commission of any modification or lifting of such measures.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall notify the measures concerned insofar as they involve information likely to be of interest to Member States from the product safety standpoint, and in particular if they are in response to a new risk which has not yet been reported in other notifications.

In accordance with the procedure laid down in Article 15(3) of this Directive, the Commission shall, while ensuring the effectiveness and proper functioning of the system, adopt the guidelines referred to in point 8 of Annex II. These shall propose the content and standard form for the notifications provided for in this Article, and, in particular, shall provide precise criteria for determining the conditions for which notification is relevant for the purposes of the second subparagraph.

2. The Commission shall forward the notification to the other Member States, unless it concludes, after examination on the basis of the information contained in the notification, that the measure does not comply with Community law. In such a case, it shall immediately inform the Member State which initiated the action.

Article 12

1. Where a Member State adopts or decides to adopt, recommend or agree with producers and distributors, whether on a compulsory or voluntary basis, measures or actions to prevent, restrict or impose specific conditions on the possible marketing or use, within its own territory, of products by reason of a serious risk, it shall immediately notify the Commission thereof through RAPEX. It shall also inform the Commission without delay of modification or withdrawal of any such measure or action.

If the notifying Member State considers that the effects of the risk do not or cannot go beyond its territory, it shall follow the procedure laid down in Article 11, taking into account the relevant criteria proposed in the guidelines referred to in point 8 of Annex II.

Without prejudice to the first subparagraph, before deciding to adopt such measures or to take such action, Member States may pass on to the Commission any information in their possession regarding the existence of a serious risk.

In the case of a serious risk, they shall notify the Commission of the voluntary measures laid down in Article 5 of this Directive taken by producers and distributors.

2. On receiving such notifications, the Commission shall check whether they comply with this Article and with the requirements applicable to the functioning of RAPEX, and shall forward them to the other Member States, which, in turn, shall immediately inform the Commission of any measures adopted.

3. Detailed procedures for RAPEX are set out in Annex II. They shall be adapted by the Commission in accordance with the procedure referred to in Article 15(3).

4. Access to RAPEX shall be open to applicant countries, third countries or international organisations, within the framework of agreements between the Community and those countries or international organisations, according to arrangements defined in these agreements. Any such agreements shall be based on reciprocity and include provisions on confidentiality corresponding to those applicable in the Community.

Article 13

1. If the Commission becomes aware of a serious risk from certain products to the health and safety of consumers in various Member States, it may, after consulting the Member States, and, if scientific questions arise which fall within the competence of a Community Scientific Committee, the Scientific Committee competent to deal with the risk concerned, adopt a decision in the light of the result of those consultations, in accordance with the procedure laid down in Article 15(2), requiring Member States to take measures from among those listed in Article 8(1)(b) to (f) if, at one and the same time:

(a) it emerges from prior consultations with the Member States that they differ significantly on the approach adopted or to be adopted to deal with the risk; and

(b) the risk cannot be dealt with, in view of the nature of the safety issue posed by the product, in a manner compatible with the degree of urgency of the case, under other procedures laid down by the specific Community legislation applicable to the products concerned; and

(c) the risk can be eliminated effectively only by adopting appropriate measures applicable at Community level, in order to ensure a consistent and high level of protection of the health and safety of consumers and the proper functioning of the internal market.

2. The decisions referred to in paragraph 1 shall be valid for a period not exceeding one year and may be confirmed, under the same procedure, for additional periods none of which shall exceed one year.

However, decisions concerning specific, individually identified products or batches of products shall be valid without a time limit.

3. Export from the Community of dangerous products which have been the subject of a decision referred to in paragraph 1 shall be prohibited unless the decision provides otherwise.

4. Member States shall take all necessary measures to implement the decisions referred to in paragraph 1 within less than 20 days, unless a different period is specified in those decisions.

5. The competent authorities responsible for carrying out the measures referred to in paragraph 1 shall, within one month, give the parties concerned an opportunity to submit their views and shall inform the Commission accordingly.

CHAPTER VI

Committee procedures

Article 14

1. The measures necessary for the implementation of this Directive relating to the matters referred to below shall be adopted in accordance with the regulatory procedure provided for in Article 15(2):

(a) the measures referred to in Article 4 concerning standards adopted by the European standardisation bodies;

(b) the decisions referred to in Article 13 requiring Member States to take measures as listed in Article 8(1)(b) to (f).

2. The measures necessary for the implementation of this Directive in respect of all other matters shall be adopted in accordance with the advisory procedure provided for in Article 15(3).

Article 15

1. The Commission shall be assisted by a Committee.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at 15 days.

3. Where reference is made to this paragraph, Articles 3 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

4. The Committee shall adopt its rules of procedure.

CHAPTER VII

Final provisions

Article 16

1. Information available to the authorities of the Member States or the Commission relating to risks to consumer health and safety posed by products shall in general be available to the public, in accordance with the requirements of transparency and without prejudice to the restrictions required for monitoring and investigation activities. In particular the public shall have access to information on product identification, the nature of the risk and the measures taken.

However, Member States and the Commission shall take the steps necessary to ensure that their officials and agents are required not to disclose information obtained for the purposes of this Directive which, by its nature, is covered by professional secrecy in duly justified cases, except for information relating to the safety properties of products which must be made public if circumstances so require, in order to protect the health and safety of consumers.

2. Protection of professional secrecy shall not prevent the dissemination to the competent authorities of information relevant for ensuring the effectiveness of market monitoring and surveillance activities. The authorities receiving information covered by professional secrecy shall ensure its protection.

Article 17

This Directive shall be without prejudice to the application of Directive 85/374/EEC.

Article 18

1. Any measure adopted under this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal or recall must state the appropriate reasons on which it is based. It shall be notified as soon as possible to the party concerned and shall indicate the remedies available under the provisions in force in the Member State in question and the time limits applying to such remedies.

The parties concerned shall, whenever feasible, be given an opportunity to submit their views before the adoption of the measure. If this has not been done in advance because of the urgency of the measures to be taken, they shall be given such opportunity in due course after the measure has been implemented.

Measures requiring the withdrawal of a product or its recall shall take into consideration the need to encourage distributors, users and consumers to contribute to the implementation of such measures.

2. Member States shall ensure that any measure taken by the competent authorities involving restrictions on the placing of a product on the market or requiring its withdrawal or recall can be challenged before the competent courts.

3. Any decision taken by virtue of this Directive and involving restrictions on the placing of a product on the market or requiring its withdrawal or its recall shall be without prejudice to assessment of the liability of the party concerned, in the light of the national criminal law applying in the case in question.

Article 19

1. The Commission may bring before the Committee referred to in Article 15 any matter concerning the application of this Directive and particularly those relating to market monitoring and surveillance activities.

2. Every three years, following 15 January 2004, the Commission shall submit a report on the implementation of this Directive to the European Parliament and the Council.

The report shall in particular include information on the safety of consumer products, in particular on improved traceability of products, the functioning of market surveillance, standardisation work, the functioning of RAPEX and Community measures taken on the basis of Article 13. To this end the Commission shall conduct assessments of the relevant issues, in particular the approaches, systems and practices put in place in the Member States, in the light of the requirements of this Directive and the other Community legislation relating to product safety. The Member States shall provide the Commission with all the necessary assistance and information for carrying out the assessments and preparing the reports.

Article 20

The Commission shall identify the needs, possibilities and priorities for Community action on the safety of services and submit to the European Parliament and the Council, before 1 January 2003, a report, accompanied by proposals on the subject as appropriate.

Article 21

1. Member States shall bring into force the laws, regulations and administrative provisions necessary in order to comply with this Directive with effect from 15 January 2004. They shall forthwith inform the Commission thereof.

When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the provisions of national law which they adopt in the field covered by this Directive.

Article 22

Directive 92/59/EEC is hereby repealed from 15 January 2004, without prejudice to the obligations of Member States concerning the deadlines for transposition and application of the said Directive as indicated in Annex III.

References to Directive 92/59/EEC shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex IV.

Article 23

This Directive shall enter into force on the day of its publication in the Official Journal of the European Communities.

Article 24

This Directive is addressed to the Member States.

Done at Brussels, 3 December 2001.

For the European Parliament

The President

N. Fontaine

For the Council

The President

F. Vandenbroucke

(1) OJ C 337 E, 28.11.2000, p. 109 and OJ C 154 E, 29.5.2000, p. 265.

(2) OJ C 367, 20.12.2000, p. 34.

(3) Opinion of the European Parliament of 15.11.2000 (OJ C 223, 8.8.2001, p. 154), Council Common Position of 12.2.2001 (OJ C 93, 23.3.2001, p. 24) and Decision of the European Parliament of 16.5.2001 (not yet published in the Official Journal). Decision of the European Parliament of 4.10.2001 and Council Decision of 27.9.2001.

(4) OJ L 228, 11.8.1992, p. 24.

(5) OJ L 184, 17.7.1999, p. 23.

(6) OJ L 210, 7.8.1985, p. 29. Directive as amended by Directive 1999/34/EC of the European Parliament and of the Council (OJ L 141, 4.6.1999, p. 20).

(7) OJ L 204, 21.7.1998, p. 37. Directive amended by Directive 98/48/EC (OJ L 217, 5.8.1998, p. 18).

ANNEX I

REQUIREMENTS CONCERNING INFORMATION ON PRODUCTS THAT DO NOT COMPLY WITH THE GENERAL SAFETY REQUIREMENT TO BE PROVIDED TO THE COMPETENT AUTHORITIES BY PRODUCERS AND DISTRIBUTORS

1. The information specified in Article 5(3), or where applicable by specific requirements of Community rules on the product concerned, shall be passed to the competent authorities appointed for the purpose in the Member States where the products in question are or have been marketed or otherwise supplied to consumers.

2. The Commission, assisted by the Committee referred to in Article 15, shall define the content and draw up the standard form of the notifications provided for in this Annex, while ensuring the effectiveness and proper functioning of the system. In particular, it shall put forward, possibly in the form of a guide, simple and clear criteria for determining the special conditions, particularly those concerning isolated circumstances or products, for which notification is not relevant in relation to this Annex.

3. In the event of serious risks, this information shall include at least the following:

(a) information enabling a precise identification of the product or batch of products in question;

(b) a full description of the risk that the products in question present;

(c) all available information relevant for tracing the product;

(d) a description of the action undertaken to prevent risks to consumers.

ANNEX II

PROCEDURES FOR THE APPLICATION OF RAPEX AND GUIDELINES FOR NOTIFICATIONS

1. RAPEX covers products as defined in Article 2(a) that pose a serious risk to the health and safety of consumers.

Pharmaceuticals, which come under Directives 75/319/EEC(1) and 81/851/EEC(2), are excluded from the scope of RAPEX.

2. RAPEX is essentially aimed at a rapid exchange of information in the event of a serious risk. The guidelines referred to in point 8 define specific criteria for identifying serious risks.

3. Member States notifying under Article 12 shall provide all available details. In particular, the notification shall contain the information stipulated in the guidelines referred to in point 8 and at least:

(a) information enabling the product to be identified;

(b) a description of the risk involved, including a summary of the results of any tests/analyses and of their conclusions which are relevant to assessing the level of risk;

(c) the nature and the duration of the measures or action taken or decided on, if applicable;

(d) information on supply chains and distribution of the product, in particular on destination countries.

Such information must be transmitted using the special standard notification form and by the means stipulated in the guidelines referred to in point 8.

When the measure notified pursuant to Article 11 or Article 12 seeks to limit the marketing or use of a chemical substance or preparation, the Member States shall provide as soon as possible either a summary or the references of the relevant data relating to the substance or preparation considered and to known and available substitutes, where such information is available. They will also communicate the anticipated effects of the measure on consumer health and safety together with the assessment of the risk carried out in accordance with the general principles for the risk evaluation of chemical substances as referred to in Article 10(4) of Regulation (EEC) No 793/93(3) in the case of an existing substance or in Article 3(2) of Directive 67/548/EEC(4) in the case of a new substance. The guidelines referred to in point 8 shall define the details and procedures for the information requested in that respect.

4. When a Member State has informed the Commission, in accordance with Article 12(1), third subparagraph, of a serious risk before deciding to adopt measures, it must inform the Commission within 45 days whether it confirms or modifies this information.

5. The Commission shall, in the shortest time possible, verify the conformity with the provisions of the Directive of the information received under RAPEX and, may, when it considers it to be necessary and in order to assess product safety, carry out an investigation on its own initiative. In the case of such an investigation, Member States shall supply the Commission with the requested information to the best of their ability.

6. Upon receipt of a notification referred to in Article 12, the Member States are requested to inform the Commission, at the latest within the set period of time stipulated in the guidelines referred to in point 8, of the following:

(a) whether the product has been marketed in their territory;

(b) what measures concerning the product in question they may be adopting in the light of their own circumstances, stating the reasons, including any differing assessment of risk or any other special circumstance justifying their decision, in particular lack of action or of follow-up;

(c) any relevant supplementary information they have obtained on the risk involved, including the results of any tests or analyses carried out.

The guidelines referred to in point 8 shall provide precise criteria for notifying measures limited to national territory and shall specify how to deal with notifications concerning risks which are considered by the Member State not to go beyond its territory.

7. Member States shall immediately inform the Commission of any modification or lifting of the measure(s) or action(s) in question.

8. The Commission shall prepare and regularly update, in accordance with the procedure laid down in Article 15(3), guidelines concerning the management of RAPEX by the Commission and the Member States.

9. The Commission may inform the national contact points regarding products posing serious risks, imported into or exported from the Community and the European Economic Area.

10. Responsibility for the information provided lies with the notifying Member State.

11. The Commission shall ensure the proper functioning of the system, in particular classifying and indexing notifications according to the degree of urgency. Detailed procedures shall be laid down by the guidelines referred to in point 8.

(1) OJ L 147, 9.6.1975, p. 13. Directive as last amended by Commission Directive 2000/38/EC (OJ L 139, 10.6.2000, p. 28).

(2) OJ L 317, 6.11.1981, p. 1. Directive as last amended by Commission Directive 2000/37/EC (OJ L 139, 10.6.2000, p. 25).

(3) OJ L 84, 5.4.1993, p. 1.

(4) OJ 196, 16.8.1967, p. 1/67. Directive as last amended by Commission Directive 2000/33/EC (OJ L 136, 8.6.2000, p. 90).

ANNEX III

PERIOD FOR THE TRANSPOSITION AND APPLICATION OF THE REPEALED DIRECTIVE

(REFERRED TO IN THE FIRST SUBPARAGRAPHE OF ARTICLE 22)

ANNEX IV

CORRELATION TABLE

(REFERRED TO IN THE SECOND SUBPARAGRAPH OF ARTICLE 22)

9.3.3. Bundesgesetz über die Haftung für ein fehlerhaftes Produkt (Product Liability Act)

BGBl I Nr. 99/1988, Latest version per 16.8.2012
(www.ris.bka.gv.at) German version only.

Haftung

§ 1. (1) Wird durch den Fehler eines Produkts ein Mensch getötet, am Körper verletzt oder an der Gesundheit geschädigt oder eine von dem Produkt verschiedene körperliche Sache beschädigt, so haftet für den Ersatz des Schadens

1. der Unternehmer, der es hergestellt und in den Verkehr gebracht hat,

2. der Unternehmer, der es zum Vertrieb in den Europäischen Wirtschaftsraum eingeführt und hier in den Verkehr gebracht hat (Importeur).

(2) Kann der Hersteller oder - bei eingeführten Produkten - der Importeur (Abs. 1 Z 2) nicht festgestellt werden, so haftet jeder Unternehmer, der das Produkt in den Verkehr gebracht hat, nach Abs. 1, wenn er nicht dem Geschädigten in angemessener Frist den Hersteller beziehungsweise - bei eingeführten Produkten - den Importeur oder denjenigen nennt, der ihm das Produkt geliefert hat.

§ 2. Der Schaden durch die Beschädigung einer Sache ist nur zu ersetzen,

1. wenn ihn nicht ein Unternehmer erlitten hat, der die Sache überwiegend in seinem Unternehmen verwendet hat, und

2. überdies nur mit dem 500 Euro übersteigenden Teil.

Hersteller

§ 3. Hersteller (§ 1 Abs. 1 Z 1) ist derjenige, der das Endprodukt, einen Grundstoff oder ein Teilprodukt erzeugt hat, sowie jeder, der als Hersteller auftritt, indem er seinen Namen, seine Marke oder ein anderes Erkennungszeichen auf dem Produkt anbringt.

Produkt

§ 4. Produkt ist jede bewegliche körperliche Sache, auch wenn sie ein Teil einer anderen beweglichen Sache oder mit einer unbeweglichen Sache verbunden worden ist, einschließlich Energie.

Fehler

§ 5. (1) Ein Produkt ist fehlerhaft, wenn es nicht die Sicherheit bietet, die man unter Berücksichtigung aller Umstände zu erwarten berechtigt ist, besonders angesichts

1. der Darbietung des Produkts,

2. des Gebrauchs des Produkts, mit dem billigerweise gerechnet werden kann,

3. des Zeitpunkts, zu dem das Produkt in den Verkehr gebracht worden ist.

(2) Ein Produkt kann nicht allein deshalb als fehlerhaft angesehen werden, weil später ein verbessertes Produkt in den Verkehr gebracht worden ist.

Inverkehrbringen

§ 6. Ein Produkt ist in den Verkehr gebracht, sobald es der Unternehmer, gleich auf Grund welchen Titels, einem anderen in dessen Verfügungsmacht oder zu dessen Gebrauch übergeben hat. Die Versendung an den Abnehmer genügt.

Beweislastumkehr

§ 7. (1) Behauptet ein Hersteller oder ein Importeur, die Sache nicht in den Verkehr gebracht oder nicht als Unternehmer gehandelt zu haben, so obliegt ihm der Beweis.

(2) Behauptet ein in Anspruch Genommener, daß das Produkt den Fehler, der den Schaden verursacht hat, noch nicht hatte, als er es in den Verkehr gebracht hat, so hat er dies als unter Berücksichtigung der Umstände wahrscheinlich darzutun.

Haftungsausschlüsse

§ 8. Die Haftung kann nicht durch den Mangel eines Verschuldens, sondern nur durch den Nachweis ausgeschlossen werden, dass

1. der Fehler auf eine Rechtsvorschrift oder behördliche Anordnung zurückzuführen ist, der das Produkt zu entsprechen hatte,

2. die Eigenschaften des Produkts nach dem Stand der Wissenschaft und Technik zu dem Zeitpunkt, zu dem es der in Anspruch Genommene in den Verkehr gebracht hat, nicht als Fehler erkannt werden konnten oder

3. - wenn der in Anspruch Genommene nur einen Grundstoff oder ein Teilprodukt hergestellt hat - der Fehler durch die Konstruktion des Produkts, in welches der Grundstoff oder das Teilprodukt eingearbeitet worden ist, oder durch die Anleitungen des Herstellers dieses Produkts verursacht worden ist.

§ 9. Die Ersatzpflicht nach diesem Bundesgesetz kann im voraus weder ausgeschlossen noch beschränkt werden.

Solidarhaftung

§ 10. Trifft die Haftpflicht mehrere, so haften sie zur ungeteilten Hand. Ihre Haftung wird nicht dadurch gemindert, daß auch andere nach anderen Bestimmungen für den Ersatz desselben Schadens haften.

Mitverschulden des Geschädigten

§ 11. Trifft den Geschädigten oder jemanden, dessen Verhalten er zu vertreten hat, ein Verschulden, so ist § 1304 ABGB sinngemäß anzuwenden.

Rückgriff

§ 12. (1) Hat ein Ersatzpflichtiger Schadenersatz geleistet und ist der Fehler des Produkts weder von ihm noch von einem seiner Leute verursacht worden, so kann er vom Hersteller des fehlerhaften Endprodukts, Grundstoffs oder Teilprodukts Rückersatz verlangen. Sind mehrere rückersatzpflichtig, so haften sie zur ungeteilten Hand.

(2) Haben mehrere Haftende den Fehler mitverursacht, so richtet sich das Ausmaß des Anspruchs desjenigen, der den Schaden ersetzt hat, auf Rückersatz gegen die übrigen nach den Umständen, besonders danach, wie weit der Schaden von dem einen oder dem anderen Beteiligten verschuldet oder durch die Herbeiführung eines Fehlers des Produkts verursacht worden ist.

(3) Kann ein nach Abs. 1 oder 2 Rückersatzpflichtiger nicht festgestellt werden, so ist jeder Unternehmer rückersatzpflichtig, der das Produkt vor dem Rückersatzberechtigten in den Verkehr gebracht hat, wenn er nicht diesem in angemessener Frist den Hersteller oder denjenigen nennt, der ihm das Produkt geliefert hat.

Erlöschung
§ 13. Sofern nach diesem Bundesgesetz bestehende Ersatzansprüche nicht früher verjähren, erlöschen sie zehn Jahre nach dem Zeitpunkt, zu dem der Ersatzpflichtige das Produkt in den Verkehr gebracht hat, es sei denn, der Geschädigte hat seinen Anspruch inzwischen gerichtlich geltend gemacht.

Anwendung des ABGB
§ 14. Soweit in diesem Bundesgesetz nicht anderes bestimmt ist, ist auf die darin vorgesehenen Ersatzansprüche das Allgemeine bürgerliche Gesetzbuch anzuwenden.

Sonstige Ersatzansprüche
§ 15. (1) Bestimmungen des Allgemeinen bürgerlichen Gesetzesbuchs und anderer Vorschriften, nach denen Schäden in weiterem Umfang oder von anderen Personen als nach diesem Bundesgesetz zu ersetzen sind, bleiben unberührt.
(2) Dieses Bundesgesetz gilt nicht für Schäden durch ein nukleares Ereignis, die in einem von EFTA-Staaten und EG-Mitgliedstaaten ratifizierten internationalen Übereinkommen erfasst sind.

Deckungsvorsorge
§ 16. Hersteller und Importeure von Produkten sind verpflichtet, in einer Art und in einem Ausmaß, wie sie im redlichen Geschäftsverkehr üblich sind, durch das Eingehen einer Versicherung oder in anderer geeigneter Weise dafür Vorsorge zu treffen, daß Schadenersatzpflichten nach diesem Bundesgesetz befriedigt werden können.

Beachte für folgende Bestimmung
Die Überschrift ist seit der Änderung durch die Novelle BGBl. Nr. 95/1993 gegenstandslos.

Zuschläge
§ 17. Als Importeur im Sinn des § 1 Abs. 1 Z 2 gilt überdies derjenige Unternehmer, der das Produkt zum Vertrieb von einem EFTA-Staat in die Europäische Wirtschaftsgemeinschaft oder von der Europäischen Wirtschaftsgemeinschaft in einen EFTA-Staat oder von einem EFTA-Staat in einen anderen EFTA-Staat eingeführt und hier in den Verkehr gebracht hat. Dies gilt ab dem Tag, an dem das Luganer Übereinkommen vom 16. September 1988 über die gerichtliche Zuständigkeit und die Vollstreckung gerichtlicher Entscheidungen in Zivil- und Handelssachen für einen EG-Mitgliedstaat oder einen EFTA-Staat in Kraft tritt, nicht mehr für diejenigen Staaten, die das Übereinkommen ratifiziert haben, insoweit auf Grund dieser Ratifikationen ein zugunsten des Geschädigten erwirktes nationales Urteil gegen den Hersteller oder den Importeur im Sinn des § 1 Abs. 1 Z 2 vollstreckbar ist.

Übergangsbestimmung, Vollziehung
§ 18. Dieses Bundesgesetz tritt mit 1. Juli 1988 in Kraft.

§ 19. Dieses Bundesgesetz ist auf Schäden durch Produkte, die vor seinem Inkrafttreten in den Verkehr gebracht worden sind, nicht anzuwenden.

§ 19a. (1) § 1 Abs. 1 Z 2, § 2, § 9, § 13, § 15 Abs. 2 und § 17 in der Fassung des Bundesgesetzes BGBl. Nr. 95/1993 treten zu demselben Zeitpunkt in Kraft wie das Abkommen über den Europäischen Wirtschaftsraums *).
(2) Die Neufassung dieser Bestimmungen ist auf Schäden durch Produkte, die vor dem im Abs. 1 genannten Zeitpunkt in Verkehr gebracht worden sind, nicht anzuwenden.
(3) Die §§ 4 und 8 in der Fassung des Bundesgesetzes BGBl. I Nr. 185/1999 treten mit 1. Jänner 2000 in Kraft. Die Neufassung dieser Bestimmungen ist auf Produkte, die vor dem 1. Jänner 2000 in Verkehr gebracht worden sind, nicht anzuwenden.
(3) Die §§ 2 und 19a in der Fassung des Bundesgesetzes BGBl. I Nr. 98/2001 treten mit 1. Jänner 2002 in Kraft. § 2 ist in dieser Fassung auf Schäden durch Produkte, die vor diesem Tag in Verkehr gebracht worden sind, nicht anzuwenden.

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*) Die Kundmachung des Abkommens und seines Inkrafttretens wird zu einem späteren Zeitpunkt erfolgen.

§ 20. Mit der Vollziehung dieses Bundesgesetzes ist der Bundesminister für Justiz betraut.

Artikel IV
Umsetzung
(*Anm.: Zu BGBl. Nr. 99/1988*)
Mit diesem Bundesgesetz werden die Richtlinie 97/7/EG über den Verbraucherschutz bei Vertragsabschlüssen im Fernabsatz, ABl. Nr. L 144 vom 4. Juni 1997, S 19, die Richtlinie 97/55/EG zur Änderung der Richtlinie 84/450/EWG über irreführende Werbung zwecks Einbeziehung der vergleichenden Werbung, ABl. Nr. L 290 vom 23. Oktober 1997, S 18, die Richtlinie 98/27/EG über Unterlassungsklagen zum Schutz der Verbraucherinteressen, ABl. Nr. L 166 vom 11. Juni 1998, S 51, und die Richtlinie 99/34/EG zur Änderung der Richtlinie 85/374/EWG des Rates zur Angleichung der Rechts- und Verwaltungsvorschriften der Mitgliedstaaten über die Haftung für fehlerhafte Produkte umgesetzt.

9.3.4. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States concerning liability for defective products

Official Journal L 210 , 07/08/1985 P. 0029 - 0033
Finnish special edition: Chapter 15 Volume 6 P. 0239
Spanish special edition: Chapter 13 Volume 19 P. 0008
Swedish special edition: Chapter 15 Volume 6 P. 0239
Portuguese special edition Chapter 13 Volume 19 P. 0008

THE COUNCIL OF THE EUROPEAN

COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas approximation of the laws of the Member States concerning the liability of the producer for damage caused by the defectiveness of his products is necessary because the existing divergences may distort competition and affect the movement of goods within the common market and entail a differing degree of protection of the consumer against damage caused by a defective product to his health or property;

Whereas liability without fault on the part of the producer is the sole means of adequately solving the problem, peculiar to our age of increasing technicality, of a fair apportionment of the risks inherent in modern technological production;

Whereas libility without fault should apply only to movables which have been industrially produced; whereas, as a result, it is appropriate to exclude liability for agricultural products and game, except where they have undergone a processing of an industrial nature which could cause a defect in these products; whereas the liability provided for in this Directive should also apply to movables which are used in the construction of immovables or are installed in immovables;

Whereas protection of the consumer requires that all producers involved in the production process should be made liable, in so far as their finished product, component part or any raw material supplied by them was defective; whereas, for the same reason, liability should extend to importers of products into the Community and to persons who present themselves as producers by affixing their name, trade mark or other distinguishing feature or who supply a product the producer of which cannot be identified;

Whereas, in situations where several persons are liable for the same damage, the protection of the consumer requires that the injured person should be able to claim full compensation for the damage from any one of them;

whereas, to protect the physical well-being and property of the consumer, the defectiveness of the product should be determined by reference not to its fitness for use but to the lack of the safety which the public at large is entitled to expect; whereas the safety is assessed by excluding any misuse of the product not reasonable under the circumstances;

Whereas a fair apportionment of risk between the injured person and the producer implies that the producer should be able to free himself from liability if he furnishes proof as to the existence of certain exonerating circumstances;

Whereas the protection of the consumer requires that the liability of the producer remains unaffacted by acts or omissions of other persons having contributed to cause the damage; whereas, however, the contributory negligence of the injured person may be taken into account to reduce or disallow such liability;

Whereas the protection of the consumer requires compensation for death and personal injury as well as compensation for damage to property; whereas the latter should nevertheless be limited to goods for private use or consumption and be subject to a deduction of a lower threshold of a fixed amount in order to avoid litigation in an excessive number of cases; whereas this Directive should not prejudice compensation for pain and suffering and other non-material damages payable, where appropriate, under the law applicable to the case;

Whereas a uniform period of limitation for the bringing of action for compensation is in the interests both of the injured person and of the producer;

Whereas products age in the course of time, higher safety standards are developed and the state of science and technology progresses; whereas, therefore, it would not be reasonable to make the producer liable for an unlimited period for the defectiveness of his product; whereas, therefore, liability should expire after a reasonable length of time, without prejudice to claims pending at law;

Whereas, to achieve effective protection of consumers, no contractual derogation should be permitted as regards the liability of the producer in relation to the injured person;

Whereas under the legal systems of the Member States an injured party may have a claim for damages based on grounds of contractual liability or on grounds of non-contractual liability other than that provided for in this Directive; in so far as these provisions also serve to attain the objective of effective protection of consumers, they should remain unaffected by this Directive; whereas, in so far as effective protection of consumers in the sector of pharmaceutical products is already also attained in a Member State under a special liability system, claims based on this system should similarly remain possible;

Whereas, to the extent that liability for nuclear injury or damage is already covered in all Member States by adequate special rules, it has been possible to exclude damage of this type from the scope of this Directive;

Whereas, since the exclusion of primary agricultural products and game from the scope of this Directive may be felt, in certain Member States, in view of what is expected for the protection of consumers, to restrict unduly such protection, it should be possible for a Member State to extend liability to such products;

Whereas, for similar reasons, the possibility offered to a producer to free himself from liability if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered may be felt in certain Member States to restrict unduly the protection of the consumer; whereas it should therefore be possible for a Member State to maintain in its legislation or to provide by new legislation that this exonerating circumstance is not admitted; whereas, in the case of new legislation, making use of this

derogation should, however, be subject to a Community stand-still procedure, in order to raise, if possible, the level of protection in a uniform manner throughout the Community;

Whereas, taking into account the legal traditions in most of the Member States, it is inappropriate to set any financial ceiling on the producer's liability without fault; whereas, in so far as there are, however, differing traditions, it seems possible to admit that a Member State may derogate from the principle of unlimited liability by providing a limit for the total liability of the producer for damage resulting from a death or personal injury and caused by identical items with the same defect, provided that this limit is established at a level sufficiently high to guarantee adequate protection of the consumer and the correct functioning of the common market;

Whereas the harmonization resulting from this cannot be total at the present stage, but opens the way towards greater harmonization; whereas it is therefore necessary that the Council receive at regular intervals, reports from the Commission on the application of this Directive, accompanied, as the case may be, by appropriate proposals;

Whereas it is particularly important in this respect that a re-examination be carried out of those parts of the Directive relating to the derogations open to the Member States, at the expiry of a period of sufficient length to gather practical experience on the effects of these derogations on the protection of consumers and on the functioning of the common market,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The producer shall be liable for damage caused by a defect in his product.

Article 2

For the purpose of this Directive 'product' means all movables, with the exception of primary agricultural products and game, even though incorporated into another movable or into an immovable. 'Primary agricultural products' means the products of the soil, of stock-farming and of fisheries, excluding products which have undergone initial processing. 'Product' includes electricity.

Article 3

1. 'Producer' means the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person who, by putting his name, trade mark or other distinguishing feature on the product presents himself as its producer. 2. Without prejudice to the liability of the producer, any person who imports into the Community a product for sale, hire, leasing or any form of distribution in the course of his business shall be deemed to be a producer within the meaning of this Directive and shall be responsible as a producer.

3. Where the producer of the product cannot be identified, each supplier of the product shall be treated as its producer unless he informs the injured person, within a reasonable time, of the identity of the producer or of the person who supplied him with the product. The same shall apply, in the case of an imported product, if this product does not indicate the identity of the importer referred to in paragraph 2, even if the name of the producer is indicated.

Article 4

The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage.

Article 5

Where, as a result of the provisions of this Directive, two or more persons are liable for the same damage, they shall be liable jointly and severally, without prejudice to the provisions of national law concerning the rights of contribution or recourse.

Article 6

1. A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account, including:

(a) the presentation of the product;

(b) the use to which it could reasonably be expected that the product would be put;

(c) the time when the product was put into circulation.

2. A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation.

Article 7

The producer shall not be liable as a result of this Directive if he proves:

(a) that he did not put the product into circulation; or

(b) that, having regard to the circumstances, it is probable that the defect which caused the damage did not exist at the time when the product was put into circulation by him or that this defect came into being afterwards; or

(c) that the product was neither manufactured by him for sale or any form of distribution for economic purpose nor manufactured or distributed by him in the course of his business; or

(d) that the defect is due to compliance of the product with mandatory regulations issued by the public authorities; or

(e) that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered; or

(f) in the case of a manufacturer of a component, that the defect is attributable to the design of the product in which the component has been fitted or to the instructions given by the manufacturer of the product.

Article 8

1. Without prejudice to the provisions of national law concerning the right of contribution or recourse, the liability of the producer shall not be reduced when the damage is caused both by a defect in product and by the act or omission of a third party.

2. The liability of the producer may be reduced or disallowed when, having regard to all the circumstances, the damage is caused both by a defect in the product and by the fault of the injured person or any person for whom the injured person is responsible.

Article 9

For the purpose of Article 1, 'damage' means:

(a) damage caused by death or by personal injuries;

(b) damage to, or destruction of, any item of property other than the defective product itself, with a lower threshold of 500 ECU, provided that the item of property:

(i) is of a type ordinarily intended for private use or consumption, and

(ii) was used by the injured person mainly for his own private use or consumption.

This Article shall be without prejudice to national provisions relating to non-material damage.

Article 10

1. Member States shall provide in their legislation that a limitation period of three years shall apply to proceedings for the recovery of damages as provided for in this Directive. The limitation period shall begin to run from the day on which the plaintiff became aware, or should reasonably have become aware, of the damage, the defect and the identity of the producer.

2. The laws of Member States regulating suspension or interruption of the limitation period shall not be affected by this Directive.

Article 11

Member States shall provide in their legislation that the rights conferred upon the injured person pursuant to this Directive shall be extinguished upon the expiry of a period of 10 years from the date on which the producer put into circulation the actual product which caused the damage, unless the injured person has in the meantime instituted proceedings against the producer.

Article 12

The liability of the producer arising from this Directive may not, in relation to the injured person, be limited or excluded by a provision limiting his liability or exempting him from liability.

Article 13

This Directive shall not affect any rights which an injured person may have according to the rules of the law of contractual or non-contractual liability or a special liability system existing at the moment when this Directive is notified.

Article 14

This Directive shall not apply to injury or damage arising from nuclear accidents and covered by international conventions ratified by the Member States.

Article 15

1. Each Member State may:

(a) by way of derogation from Article 2, provide in its legislation that within the meaning of Article 1 of this Directive 'product' also means primary agricultural products and game;

(b) by way of derogation from Article 7 (e), maintain or, subject to the procedure set out in paragraph 2 of this Article, provide in this legislation that the producer shall be liable even if he proves that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of a defect to be discovered.

2. A Member State wishing to introduce the measure specified in paragraph 1 (b) shall communicate the text of the proposed measure to the Commission. The Commission shall inform the other Member States thereof.

The Member State concerned shall hold the proposed measure in abeyance for nine months after the Commission is informed and provided that in the meantime the Commission has not submitted to the Council a proposal amending this Directive on the relevant matter. However, if within three months of receiving the said information, the Commission does not advise the Member State concerned that it intends submitting such a proposal to the Council, the Member State may take the proposed measure immediately.

If the Commission does submit to the Council such a proposal amending this Directive within the aforementioned nine months, the Member State concerned shall hold the proposed measure in abeyance for a further period of 18 months from the date on which the proposal is submitted.

3. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect that rulings by the courts as to the application of Article 7 (e) and of paragraph 1

(b) of this Article have on consumer protection and the functioning of the common market. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal Article 7 (e).

Article 16

1. Any Member State may provide that a producer's total liability for damage resulting from a death or personal injury and caused by identical items with the same defect shall be limited to an amount which may not be less than 70 million ECU.

2. Ten years after the date of notification of this Directive, the Commission shall submit to the Council a report on the effect on consumer protection and the functioning of the common market of the implementation of the financial limit on liability by those Member States which have used the option provided for in paragraph 1. In the light of this report the Council, acting on a proposal from the Commission and pursuant to the terms of Article 100 of the Treaty, shall decide whether to repeal paragraph 1.

Article 17

This Directive shall not apply to products put into circulation before the date on which the provisions referred to in Article 19 enter into force.

Article 18

1. For the purposes of this Directive, the ECU shall be that defined by Regulation (EEC) No 3180/78 (1), as amended by Regulation (EEC) No 2626/84 (2). The equivalent in national currency shall initially be calculated at the rate obtaining on the date of adoption of this Directive.

2. Every five years the Council, acting on a proposal from the Commission, shall examine and, if need be, revise the amounts in this Directive, in the light of economic and monetary trends in the Community.

Article 19

1. Member States shall bring into force, not later than three years from the date of notification of this Directive, the laws, regulations and administrative provisions necessary to comply with this Directive. They shall forthwith inform the Commission thereof (1).

2. The procedure set out in Article 15 (2) shall apply from the date of notification of this Directive.

Article 20

Member States shall communicate to the Commission the texts of the main provisions of national law which they subsequently adopt in the field governed by this Directive.

Article 21

Every five years the Commission shall present a report to the Council on the application of this Directive and, if necessary, shall submit appropriate proposals to it.

Article 22

This Directive is addressed to the Member States. Done at Brussels, 25 July 1985.

For the Council

The President J. POOS

(1) OJ No C 241, 14. 10. 1976, p. 9 and OJ No C 271, 26. 10. 1979, p. 3.

(2) OJ No C 127, 21. 5. 1979, p. 61.

(3) OJ No C 114, 7. 5. 1979, p. 15.

(1) OJ No L 379, 30. 12. 1978, p. 1.

(2) OJ No L 247, 16. 9. 1984, p. 1.

(1) This Directive was notified to the Member States on 30 July 1985.

9.3.5. A Guideline on Summary of Product Characteristics (SmPC) Volume 2C Noticeto Applicants of the Rules Governing Medicinal Products in the European Union, Eudralex, Revision 2, September 2009

MODULE 1.3 SUMMARY OF PRODUCT CHARACTERISTICS

Article 8(3)(j) of Directive 2001/83/EC and Article 6(1) of Regulation (EC) 726/2004 require that, in order to obtain a marketing authorisation, a Summary of Product Characteristics (SmPC) in accordance with Article 11 of Directive 2001/83/EC must be included in the application1. In accordance with Directive 2001/83/EC, when the marketing authorisation is issued, the Marketing Authorisation Holder shall be informed, by the competent authorities of the Member States concerned, of the SmPC as approved by it. For decisions concerning centralised marketing authorisations, according to Article 10 of Regulation (EC) No 726/2004, the final Commission decision with the SmPC is addressed and notified to the Marketing Authorisation Holder. Thus, the SmPC forms an intrinsic and integral part of the marketing authorisation.

The SmPC sets out the agreed position of the medicinal product as distilled during the course of the assessment process. As such the content cannot be changed except with the approval of the originating competent authority.

The SmPC is the basis of information for healthcare professionals on how to use the medicinal product safely and effectively. The Package Leaflet (PL) shall be drawn up in accordance with the SmPC. The *Guideline on excipients in the label and package leaflet of medicinal products for human use* is also applicable to the SmPC.

It is not in the remit of the SmPC to give general advice on the treatment of particular medical conditions. On the other hand specific aspects of the treatment related to use of the medicinal product or its effects should be mentioned. Similarly, general advice on administration procedures should not be included but any advice specific to the concerned medicinal product should be included.

This guideline provides advice on the principles of presenting information in the SmPC. Applicants should maintain the integrity of each section of the document by only including information in each section which is relevant to the section heading. However, some issues may need to be addressed in more than one section of the SmPC and in such situations the individual statements may cross-refer to other sections when these contain relevant additional information.

This guideline should be read in conjunction with any other specific guidance document related to the SmPC (e.g. on benzodiazepines, antibiotics, vaccines, pegylated proteins, or plasma-derived medicinal products).

Separate SmPCs are required for each pharmaceutical form and strength by the European Commission and certain Member States. Limited references to other strengths or pharmaceutical forms of the same medicinal product may be necessary in a SmPC if the dosage regimen is based on the use of several strengths or pharmaceutical forms. For the purposes of giving information to prescribers, the SmPCs of different pharmaceutical forms and strengths may be combined for appropriate products within the same range.

This guidance shall apply as from 1 May 2010. However, submissions may also be done on the basis of this guidance prior to that date.

SUMMARY OF PRODUCT CHARACTERISTICS: Principles of presenting information

- The SmPC should be worded in clear and concise language.
- Each section of the SmPC should first deal with those issues that apply to the core population for whom the medicine is indicated followed - when necessary – by specific information for any relevant special population (e.g. children or elderly).
- Public Assessment Reports provide detailed information on medicinal products and are available on the website of the European Medicines Agency, of Heads of medicines Agencies or other National Competent Authorities. A link to the relevant website should be included in SmPCs when a public assessment report is available.
- Consistent medical terminology should be used throughout the SmPC. For example, the use of MedDRA as described in the annex for section 4.8 should be applied though the SmPC, in particular for sections 4.3 and 4.4 and 4.8.
- The SmPC provides information on a particular medicinal product; therefore it should not include reference to other medicinal products (e.g. through statement such as "Like other medicines of the same class …") except when it is a class warning recommended by a competent authority.
- The principles set-out in this guideline are applicable to all medicinal products. The application of those principles for a particular medicinal product will depend on the scientific knowledge on the medicinal product, the legal basis of a marketing authorisation and public health needs. Deviation from this guideline should therefore be justified in the relevant Overview or Summary in the marketing authorisation application.
- Practical advice on how to draw up the SmPC is provided to the applicant in the form of templates developed by the Quality Review of Documents (QRD) group, for centralised, decentralised and mutual recognition procedures.

1 NAME OF THE MEDICINAL PRODUCT

The (invented) name should be followed by both the strength and the pharmaceutical form. However, when otherwise referring to the medicinal product throughout the SmPC text, the strength and the pharmaceutical form do not have to be mentioned in the name. The International Non-proprietary Name (INN) or the usual common name of the active substance should be used when referring to properties of the active substance(s) rather than those of the product.
The use of pronouns (e.g. "it") is encouraged whenever possible.

Strength
The strength should be the relevant quantity for identification and use of the product and should be consistent with the quantity stated in the quantitative composition and in the posology. Different strengths of the same medicinal product should be stated in the same way, e.g. 250 mg, 500 mg, 750 mg. The use of decimal points should be avoided where these can be easily removed (e.g. 250 microgram, not 0.25 mg). However, where a range of medicinal products of the same pharmaceutical form includes strengths of more than one unit (e.g. 250 microgram, 1 mg and 6 mg), it may be more appropriate in certain cases to state the strengths in the same unit for the purpose of comparability (e.g. 0.25 mg, 1 mg and 6 mg). For safety reasons, micrograms and millions (e.g. for units) should always be spelled out in full rather than be abbreviated.

Pharmaceutical form
The pharmaceutical form of a medicinal product should be described by a single full Standard Term of the European Pharmacopoeia using the plural form if appropriate (e.g. tablets) (see section 3). If an appropriate standard term does not exist, a new term may be constructed from a combination of

standard terms in accordance with the document "Standard Terms, Introduction and Guidance to use".

Should this not be possible, the competent authority should be asked to request a new Standard Term from the European Department for the Quality of Medicines (EDQM) of the Council of Europe. No reference should be made to the route of administration or container unless these elements are part of the standard term or where there is a particular safety reason for their inclusion or where there are identical products, which may be distinguished only by reference to the route of administration or to the container.
For the expression of the name and strength of (traditional) herbal medicinal products the declaration should be in accordance with existing quality guidelines on herbal medicinal products.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Full details of the qualitative and quantitative composition in terms of the active substance(s) and excipients, knowledge of which are essential for proper administration of the medicinal product, should be provided in section 2 and as appropriate in section 4.3 or 4.4. For example, excipients listed in the Annex to the "*Guideline on the excipients in the label and package leaflet of medicinal product for human use*" should be stated here under a separate subheading qualitatively, and, quantitatively.
The following standard statement should be included at the end of the section, i.e. 'for full list of excipients, see section 6.1'.
If a diluent is part of the medicinal product, information should be included in the relevant sections (usually sections 3, 6.1, 6.5 and 6.6).

Qualitative declaration
The active substance should be declared by its recommended INN, accompanied by its salt or hydrate form if relevant, or the European Pharmacopoeial name if that name represents an established name in Europe. If no INN exists, the European Pharmacopoeia name should be used or if the substance is not in the pharmacopoeia, the usual common name should be used. In the absence of a common name, the exact scientific designation should be given. Substances not having an exact scientific designation should be described by a statement on how and from what they were prepared. References to the pharmacopoeial quality should not be included.
Where the medicinal product is a (traditional) herbal medicinal product, the qualitative declaration should be in accordance with the existing quality guidelines on herbal medicinal products.
When the medicinal product is a radiopharmaceutical kit, the qualitative declaration should clearly indicate that the radioisotope is not part of the kit.

Quantitative declaration
The quantity of the active substance should be expressed per dosage unit (for metered dose inhalation products, per delivered dose and/or per metered dose), per unit volume, or per unit of weight and should be related to the declaration of strength in section 1.
Quantity should be expressed in internationally recognised standard term which could be complemented with another term if more meaningful to healthcare professionals.

Salts and hydrates
Where the active substance is present in the form of a salt or hydrate, the quantitative composition should be expressed in terms of the mass (or biological activity in International (or other) units where appropriate) of the active moiety (base, acid or anhydrous material), e.g. '60 mg toremifene (as citrate)' or toremifene citrate equivalent to 60 mg toremifene'.
Where a salt is formed *in situ* during the preparation of the finished product (i.e. formed during the

mixture of a solvent and powder), the quantity of the active moiety should be stated, with a reference to the *in situ* formation of the salt.
In the case of established active substances in medicinal products where the strength has traditionally been expressed in the form of a salt or hydrate, the quantitative composition may be declared in terms

of the salt or hydrate, e.g. '60 mg diltiazem hydrochloride'. This may also apply when the salt is formed *in situ.*

Esters and pro-drugs
If the active substance is an ester or pro-drug, the quantitative composition should be stated in terms of the quantity of the ester or pro-drug. When the active moiety is an active substance of an already approved medicinal product, the quantitative composition should also be stated in terms of the quantity of this active moiety (e.g. 75 mg of fosphenytoin is equivalent to 50 mg of phenytoin).

Oral powders for solution or suspension
The quantity of active substance should be stated per unit dose if the product is a single-dose preparation or otherwise per unit dose volume after reconstitution; a reference to the molar concentration may also be appropriate in some cases.

Parenterals excluding powders for reconstitution
For single-dose parenterals, where the total contents of the container are given in a single dose ('total use'), the quantity of active substance(s) should be stated per presentation (e.g. 20 mg etc.) not including any overages or overfill. The quantity per ml and the total labelled volume should also be given.
For single-dose parenterals, where the amount to be given is calculated on the basis of the patient's weight or body surface or other variable ('partial use'), the quantity of active substance(s) should be stated per ml. The quantity per total labelled volume should also be given. Overages or overfills should not be included.
For multi-dose and large volume parenterals, the quantity of active substance(s) should be stated per ml, per 100 ml, per 1000 ml, etc. as appropriate, except for multidose vaccines containing 'n' doses of the same dose. In this case, the strength should be expressed per dose volume. Overages or overfills should not be included.
Where appropriate, e.g. for X-ray contrast media, and parenterals containing inorganic salts, the quantity of active substance(s) should also be indicated in millimoles. For X-ray contrast media with iodine-containing actives substances, the quantity of iodine per ml should be stated in addition to the quantity of the active substance.

Powders for reconstitution prior to parenteral administration
When the product is a powder to be reconstituted prior to administration, the total quantity of active substance in the container should be stated not including overages or overfills, as well as the quantity per ml when reconstituted, unless there are several means of reconstituting, or different quantities used, which result in different final concentrations.

Concentrates
The quantity should be stated as the content per ml in the concentrate and as the total content of the active substance. The content per ml when diluted as recommended should also be included unless the concentrate is to be diluted to within a range of different final concentrations.

Transdermal patches

The following quantitative details should be given: the content of active substance(s) per patch, the mean dose delivered per unit time, and the area of the releasing surface, e.g. 'Each patch contains 750 micrograms of estradiol in a patch size of 10 cm2, releasing a nominal 25 micrograms of estradiol per 24 hours'.

Multidose solid or semi-solid products
Quantity of active substance should be stated, where possible, per unit dose, otherwise per gram, per 100 g or percentage, as appropriate.

Biological medicinal products
Expression of strength.
The quantity of biological medicinal products should be expressed in terms of mass units, units of biological activity, or International Units as appropriate for the particular product, and reflecting *European Pharmacopoeia* usage where relevant. For pegylated proteins, the CHMP *Guideline on the Description of Composition of Pegylated (Conjugated) Proteins in the SmPC* should be referred to.
The biological origin of the active substance.
The origin of the active substance should be defined briefly. Thus, the nature of any cellular system(s) used for production and, if relevant, the use of recombinant DNA technology should be specified. The entry should take the form: "produced in XXX cells <by recombinant DNA technology>". The following are examples of the application of this principle:
"produced in human diploid (MRC-5) cells",
"produced in *Escherichia coli* cells by recombinant DNA technology",
"produced in chick-embryo cells",
"produced from the plasma of human donors",
"produced from human urine",
"produced from <animal>blood",
"produced from porcine pancreatic tissue",
"produced from porcine intestinal mucosa".
Special provisions for normal immunoglobulins.
In the case of normal immunoglobulins, the IgG subclass distribution should be stated in terms of percent of total IgG present. The upper limit of the IgA content should follow.
Special provisions for vaccines.
In the case of vaccines, the content of active substance per dose unit (e.g. per 0.5 ml) should be stated.
Adjuvants, if present, should be stated qualitatively and quantitatively.
Residues that are of special relevance (e.g. ovalbumin in egg derived vaccines) should be specified.
Additional specific guidance is available in CHMP guidelines on biotechnological medicinal products, e.g. the CHMP Guideline on the Pharmaceutical Aspects of the Product Information for Human Vaccines.

Herbal medicinal products
The quantitative declaration should be in accordance with the existing quality guidelines on herbal medicinal products.

3 PHARMACEUTICAL FORM

The pharmaceutical form should be described by a full standard term of the European Pharmacopoeia (see section 1) using the singular form. The term used in this section should be the same as the term used in section 1. However, where a short standard term of the European Pharmacopoeia is used on small immediate packaging material, the short term should be added in brackets in this section.

A visual description of the appearance of the product (colour, markings, etc.) should be given, in a separate paragraph to the standard term, including information on the actual size of a solid oral formulation, e.g. '*Tablet - White, circular flat bevelled-edge tablets of 5 mm marked '100' on one side'*. In case of tablets designed with a score line, information should be given on whether or not reproducible dividing of the tablets has been shown. e.g. 'the scoreline is only to facilitate breaking for ease of swallowing and not to divide into equal doses', 'the tablet can be divided into equal halves'.
Information on pH and osmolarity should be provided, as appropriate.
In case of products to be reconstituted before use, the appearance before reconstitution should be stated in this section. Appearance of the product after reconstitution should be stated in sections 4.2 and 6.6.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

The indication(s) should be stated clearly and concisely and should define the target disease or condition distinguishing between treatment (symptomatic, curative or modifying the evolution or progression of the disease), prevention (primary or secondary) and diagnostic indication. When appropriate it should define the target population especially when restrictions to the patient populations apply.
Study endpoints should not normally be included, unless such mention is specified as being appropriate for the indication in CHMP Guidelines. The objective of a prevention indication may be mentioned in general terms only. This should also be done for the target population.
Where results from subsequent studies provide further definition or information on an authorised indication, such information, provided it does not itself constitute a new indication, may be considered for inclusion in section 5.1.
Mandatory conditions of product usage not covered more appropriately in other parts of the SmPC may also be included when relevant, e.g. concomitant dietary measures, lifestyle changes, or other therapy.
It should be stated in which age groups the product is indicated, specifying the age limits, e.g. 'X is indicated in <adults><neonates><infants><children> <adolescents> <aged x to y <years, months>>.
If the product's indication depends on a particular genotype or the expression of a gene or a particular phenotype, this should be stated in the indication.

4.2 Posology and method of administration

In case of restricted medical prescription, this section should be started by specifying the conditions.
In case of specific safety need, any recommended restriction to a particular setting should also be stated (e.g. "*restricted to hospital use only*" or "*appropriate resuscitation equipment should be availa*ble").

Posology

The dosage should be clearly specified for each method/route of administration and for each indication, as appropriate.
Where appropriate, a reference to official recommendations should be made (e.g. for primary vaccination and antibiotics as well as for booster dose).
Dose recommendations (e.g. mg, mg/kg, mg/m2) should be specified per dose interval for each category where appropriate (specify age/weight/body surface area of subsets of the population as appropriate). Frequency of dosing should be expressed using time units (e.g. once or twice daily or every 6 hour) and, to avoid confusion, abbreviations e.g. OD or BID should not be used.
Where appropriate, the following points should be addressed:

• the maximum recommended single, daily and/or total dose,
• the need for dose titration,
• the normal duration of use and any restrictions on duration and, if relevant, the need for tapering off, or advice on discontinuation,
• advice on action to be taken if one or more dose(s) is (are) missed, or e.g. in case of vomiting (the advice should be as specific as possible, taking into consideration the recommended frequency of dosing and relevant pharmacokinetic data)
• advice on preventive measures to avoid certain adverse drug reactions (e.g. administration of antiemetics) with cross-reference to section 4.4,
• the intake of the product in relation to drink and food intake, together with a cross-reference to section 4.5 in case of specific interaction e.g. with alcohol, grapefruit or milk,
• advice regarding repeat use, with any information on intervals to be observed between courses of treatment, as appropriate,
• interactions requiring specific dose adjustments with cross-reference to other appropriate sections of the SmPC (e.g. 4.4, 4.5, 4.8, 5.1, 5.2), and
• it may also be relevant to recommend not to prematurely discontinue a treatment in case of specific non-serious adverse reaction(s) that are frequent but transient or manageable with dosetitration.
Where relevant to the particular product, the following should appear 'The potency of this medicinal product is expressed in <invented name> units. These units are not interchangeable with the units used to express the potency of other <active substance name> preparations'.

Special populations
Dosage adjustments or other posology related information in specific patient groups should be stated where necessary, in well-defined sub-sections ordered by importance, e.g. regarding:
• elderly population; it should be made clear whether or not any dosage adjustment is necessary in any subsets of the elderly population, with cross-reference to other sections providing information in elderly, e.g. 4.4, 4.5, 4.8 or 5.2.
• renal impairment; the dose recommendation should relate as precisely as possible to the cut-off values for biochemical markers of renal impairment in clinical studies and to the results of these studies;
• hepatic impairment, specified according to the patients included in studies, for instance 'alcohol-related cirrhosis' and the definitions used in the studies, for instance Child-Pugh score/grade of the patients;
• patients with a particular genotype; with cross-reference to other relevant sections for further detail as appropriate;
• other relevant special population (e.g. patients with other concomitant disease or overweight patients).
Advice relevant for dosage adjustment e.g. from monitoring of clinical symptoms and signs, and/or laboratory investigations, including blood concentrations of the medicinal product should be mentioned when appropriate with cross-reference to other sections where appropriate.

Paediatric population
The specific sub-section 'paediatric population' should always be included and the information given should cover all subsets of the paediatric population, using a combination of the possible situations presented below as appropriate.
If the product is indicated in the paediatric population, posology recommendations should be given for each of the relevant subsets. The age limits should reflect the benefit-risk assessment of the available documentation for each subset.
If the posology is the same in adults and children, then a statement to this effect is sufficient; the

posology does not need to be repeated.
Dose recommendations (e.g. mg, mg/kg, mg/m2) should be specified per dose interval for the paediatric subsets where the product is indicated. Different subsets may require different dosing information. If necessary, recommendations in preterm newborns should be presented taking into account the more appropriate age e.g. gestational age or the post-menstrual age.
Depending on the subset, the clinical data and available formulations, the dose will be expressed according to weight or body surface area, e.g. "*children aged 2-4 years, 1 mg/kg bodyweight twice a day*". When appropriate, information on timing of intake of the product should consider children's daily life, e.g. school or sleep.
Where a product is indicated in children and no adequate paediatric formulation can be developed, detailed instructions on how to obtain an extemporaneous preparation shall be included in section 6.6 with a cross-reference in section 4.2.
Doses and method of administration in the various subsets may be presented in a tabulated format.
If there is no indication for the product in some or all subsets of the paediatric population, no posology recommendation can be made, but available information should be summarised using the following standard statements (one or combination of several as appropriate):
• The <safety> <and> <efficacy> of X in children aged x to y <months, years> <*or any other relevant subsets e.g. weight, pubertal age, gender*> <has><have> not <yet> been established.
One of the following statements should be added:
– <No data are available>. or
– <Currently available data are described in section <4.8><5.1><5.2> but no recommendation on a posology can be made >
• X should not be used in children aged x to y <years, months><*or any other relevant subsets e.g. weight, pubertal age, gender*> because of <safety> <efficacy> concern(s) <*concern(s) to be stated* with cross-reference to sections detailing data (e.g. 4.8 or 5.1) >.
• There is no relevant use of X in <the paediatric population><in children aged x to y><years, months>><*or any other relevant subsets e.g. weight, pubertal age, gender*> in the indication(s) <specify indication(s)>.
• X is contraindicated in children aged x to y <years, months> <*or any other relevant subsets e.g. weight, pubertal age, gender*> <in the indication …> (cross-reference to section 4.3).
If there are more appropriate strength(s) and/or pharmaceutical form(s) for administration in some or all subsets of the paediatric population (e.g. oral solution for infants), these can be mentioned in section 4.2 of the SmPC of the less appropriate one(s).
E.g.: Other pharmaceutical forms/strengths may be more appropriate for administration to this population.

Method of administration
Any special precautions related to the manipulation or administration of the product (e.g. cytotoxic products) by healthcare professionals (including pregnant healthcare professionals), the patient or carers should be mentioned here under a specific sub-heading (<*Precaution to be taken before manipulating or administering the product*>), with a cross-reference to section 6.6 (or 12).
The route of administration and concise relevant instruction for correct administration and use should be given here. Information on instructions for preparation or reconstitution should be placed in section 6.6 'Special precautions for disposal of a used medicinal product and other handling of the product' (or in section 12 if appropriate) and cross-referenced here.
When supportive data are available, information on alternative method(s) to facilitate administration or acceptability should be given as explicitly as possible (e.g. possibility of crushing tablet, cutting tablet or transdermal patch, pulverising tablet, opening capsules, mixing with food, dissolution in drinks – specifying if a proportion of the dose can be given) particularly for administration via feeding

tubes.
Any specific recommendation for use related to the pharmaceutical form should be explained, e.g.:
- “the coated tablet should not be chewed because of <bad taste>,
- “the enteric-coated tablet should not be crushed because coating prevents <pH sensitive degradation><irritant effects> on the gut”,
- “the coated tablet should not be broken because the coating is intended to ensure a prolonged release (see 5.2)”.
For parenteral formulations, information on the rate or speed of injection or infusion should be provided.
For parenteral formulations - in children, especially newborns in whom quite often fluids have to be restricted - it would be useful to have information on maximal concentration that can be safely administered (e.g. "*no more than X mg of Y/ml of solution*").

4.3 Contraindications
Situations where the medicinal product must not be given for safety reasons, i.e. contraindications, are the subject of this section. Such circumstances could include a particular clinical diagnosis, concomitant diseases, demographic factors (e.g. gender, age) or predispositions (e.g. metabolic or immunological factors, a particular genotype and prior adverse reactions to the medicine or class of medicines). The situations should be unambiguously, comprehensively and clearly outlined.
Other medicines or classes of medicine, which must not be used concomitantly or consecutively should be stated, based on either data or strong theoretical reasons. If applicable a cross-reference to section 4.5 should be made.
In general, patient populations not studied in the clinical trial programme should be mentioned in section 4.4 and not in this section unless a safety issue can be predicted (e.g. use of renally eliminated substances with narrow therapeutic margin in renal failure patients). If, however, patients have been excluded from studies due to a contraindication on grounds of safety, they should be mentioned in this section. If applicable a cross-reference to section 4.4 should be made.
Only if pregnancy or breastfeeding is contraindicated, should it be mentioned here. In section 4.6, a cross-reference should be made and further background information provided.
Hypersensitivity to the active substance or to any of the excipients or residues from the manufacturing process should be included, as well as any contraindication arising from the presence of certain excipients (see *Guideline on excipients in the label and package leaflet of medicinal products for Human Use*).
For herbal medicinal products, hypersensitivity extended to other plants of the same family or to other parts of the same plant should be labelled as a contraindication, where applicable.
Lack of data alone should not lead to a contraindication. Where for safety reasons, the product should be contraindicated in a specific population, e.g. paediatric or a subset of the paediatric population, it should appear in this section with a cross-reference to the section giving detailed information on the safety issue. A contraindication in the paediatric population should be listed without a sub-heading.

4.4 Special warnings and precautions for use
The order of warnings and precautions should in principle be determined by the importance of the safety information provided.
The exact content of this section will be different for each product and the therapeutic conditions it is intended to treat. It is however suggested that the following items should be included where relevant to the specific product.
Information on a specific risk should be given in section 4.4 only when the risk leads to a precaution

for use or when healthcare professionals have to be warned of this risk. Patient groups in which use of the medicinal product is contraindicated should be mentioned in section 4.3 only and not to be repeated here.

The following should be described:

• The conditions, in which the use of the medicinal product could be acceptable, provided that special conditions for use are fulfilled. In particular, specific risk minimisation measures requested as part of a Risk Management Plan to ensure safe and effective use should be described in this section. (*For example; "Liver function should be monitored before initiation of treatment and monthly thereafter", "Patients should be advised to immediately report any symptoms of depression and/or suicidal ideation",* "*Women of childbearing potential should use contraception", ...)*

• Special patient groups that are at increased risk or are the only groups at risk of experiencing product or product class-related adverse reactions (usually serious or common), e.g. elderly, children, patients with renal or hepatic impairment (including the degree of impairment, e.g. mild, moderate or severe), patients having an anaesthesic or patients with cardiac failure (including in this case the NYHA Classification for example). Cross-reference to section 4.8 on the differential effects in terms of frequency and severity of the specified adverse reaction should be provided.

• Serious adverse reactions to which healthcare professionals need to be alerted, the situations in which these may occur and the action that may be required, e.g. emergency resuscitation.

• If there are particular risks associated with starting the medicinal product (e.g. first dose effects) or stopping it (e.g. rebound, withdrawal effects), these should be mentioned in this section, together with the action required for prevention.

• Any measures which can be taken to identify patients at risk and prevent the occurrence, or detect early the onset or worsening of noxious conditions. If there is a need for awareness of symptoms or signs representing early warning of a serious adverse reaction, a statement should be included.

• Any need for specific clinical or laboratory monitoring should be stated. Recommendation for monitoring should address why, when and how the monitoring should be conducted in clinical practice. If dose reduction or other posology is recommended in such circumstances or conditions, this should be included in section 4.2 and cross-referenced here.

• Any warnings necessary for excipients or residues from the manufacturing process.

• For herbal preparations containing alcohol, information about the ethanol content in the medicinal product should be included in accordance with the Guideline on excipients in the label and package leaflet of medicinal products for human use.

• Any warnings necessary with respect to transmissible agents (e.g. Warning of Transmissible Agents in SmPCs and Package Leaflets for Plasma-Derived Medicinal Products (CPMP/BPWG/BWP/ 561/03).

• Subjects or patients with a specific genotype or phenotype might either not respond to the treatment or be at risk of a pronounced pharmacodynamic effect or adverse reaction. These may arise because of non-functioning enzyme alleles, alternative metabolic pathways (governed by specific alleles), or transporter deficiencies. Such situations should be clearly described if known.

• Any particular risk associated with an incorrect route of administration (e.g. necrosis risk with extravasation of intravenous formulation, or neurological consequences of intravenous use instead of intramuscular use), should be presented, with advice on management if possible.

In exceptional cases, especially important safety information may be included in bold type within a box.

Any adverse reactions described in this section or known to result from conditions mentioned here should also be included in section 4.8.

Specific interference with laboratory tests should be mentioned when appropriate, e.g. Coombs test and Beta-lactams. They should be clearly identified with a subheading, e.g. "*Interference with serological testing*".

In general, descriptions of warnings and precautions regarding pregnancy and breast-feeding, ability to drive and use machines, and other aspects of interactions should be dealt with in sections 4.6, 4.7 and 4.5, respectively. However in specific cases of major clinical importance it might be more appropriate to describe specific precautionary measures in this section, e.g. contraception measures, or when concomitant use of another medicine is not recommended, and with cross reference to section 4.5, 4.6, or 4.7.

Paediatric population

When the product is indicated in one or more subsets of the paediatric population and there are warnings and precautions for use that are specific to the paediatric population or any subset of the paediatric population, they should be identified under this subheading. Any necessary warning or precaution in relation to long-term safety (e.g. on growth, neuro-behavioural development or sexual maturation) or specific monitoring (e.g. growth) in the paediatric population should be described.

When long-term safety data are necessary but not yet available, it should be stated in this section.

Warnings should be included in case of possible significant or long-lasting impact on children's daily activities, such as learning ability or physical activities, or in case of impact on appetite or sleep pattern.

If measures are requested that are specific to the paediatric population for which the product is indicated (e.g. as part of a Risk Management Plan), these measures should be described in this section.

4.5 Interaction with other medicinal products and other forms of interaction

This section should provide information on the potential for clinically relevant interactions based on the pharmacodynamic properties and *in vivo* pharmacokinetic studies of the medicinal product, with a particular emphasis on the interactions, which result in a recommendation regarding the use of this medicinal product. This includes *in vivo* interaction results which are important for extrapolating an effect on a marker ('probe') substance to other medicinal products having the same pharmacokinetic property as the marker.

Interactions affecting the use of this medicinal product should be given first, followed by those interactions resulting in clinically relevant changes on the use of others.

Interactions referred to in other sections of the SmPC should be described here and cross-referenced from other sections.

The order of presentation should be contraindicated combinations, those where concomitant use is not recommended, followed by others.

The following information should be given for each clinically relevant interaction:

a. Recommendations: these might be

• contraindications of concomitant use (cross-refer to section 4.3),

• concomitant use not recommended (cross-refer to section 4.4), and

• precautions including dose adjustment (cross-refer to sections 4.2 or 4.4, as appropriate),

mentioning specific situations where these may be required.

b. Any clinical manifestations and effects on plasma levels and AUC of parent compounds or active metabolites and/or on laboratory parameters.

c. Mechanism, if known. For example, interaction due to inhibition or induction of cytochrome P450 should be presented as such in this section, with a cross-reference to 5.2 where *in vitro* results on inhibition or induction potential should be summarised.

Interactions not studied *in vivo* but predicted from *in vitro* studies or deducible from other situations or studies should be described if they result in a change in the use of the medicinal product, crossreferring to sections 4.2 or 4.4.

This section should mention the duration of interaction when a medicinal product with clinically important interaction (e.g., enzyme inhibitor or inducer) is discontinued. Adjustment of dosing may be

required as a result. The implication for the need for a washout period when using medicines consecutively should also be mentioned.
Information on other relevant interactions such as with herbal medicinal products, food, alcohol, smoking, or pharmacologically active substances not used for medical purpose, should also be given.
With regard to pharmacodynamic effects where there is a possibility of a clinically relevant potentiation or a harmful additive effect, this should be stated.
In vivo results demonstrating an absence of interaction should only be mentioned here if this is of major importance to the prescriber (e.g. in therapeutic area where potentially problematic interactions have been identified such as with anti-retroviral medicines).
If no interaction studies have been performed, this should be clearly stated.

Additional information on special populations
If there are patient groups in which the impact of an interaction is more severe, or the magnitude of an interaction is expected to be larger e.g., patients with decreased renal function (in case the parallel pathway is renal excretion), paediatric patients, elderly etc, this information should be given here.
If interactions with other medicinal products depend on polymorphisms of metabolising enzymes or certain genotypes, this should be stated.

Paediatric population
Information specific to a subset of the paediatric population should be given here if there is an indication for the particular age group.
The resulting exposure and clinical consequences of a pharmacokinetic interaction can differ between adults and children, or between older and younger children. Therefore;
• Any identified treatment recommendations should be given in relation to concomitant use in the paediatric subset(s) (e.g. dose adjustment, extra-monitoring of clinical effect marker/adverse reactions, therapeutic drug monitoring),
• If the interaction studies have been performed in adults, the statement 'Interaction studies have only been performed in adults' should be included.
• If the extent of an interaction is known to be similar in a paediatric age group to that in adults, this should be stated.
• If this is not known, this should also be stated.
The same applies to pharmacodynamic drug interactions.
In cases of food interaction leading to a recommendation on co-administration with a meal or specific food, it should be specified whether this is relevant for paediatric use (especially newborns and infants) whose diet is different (100 % milk in newborns).
Overall, section 4.5 should be presented in the simplest possible way to highlight the interactions resulting in a practical recommendation regarding the use of the medicinal product. Presentation in a tabulated format may help where interactions are numerous and various, such as with anti-viral products.

4.6 Fertility, pregnancy and lactation

General principles
Efforts should be made by the Marketing Authorisation Applicant or Holder to provide the reasons for the recommendations for use in pregnant or lactating women and in women of childbearing potential. This information is important for the healthcare professionals informing the patient.
In the overall assessment, all available knowledge should be taken into account, including clinical studies and post-marketing surveillance, pharmacological activity, results from non-clinical studies, and knowledge about compounds within the same class.

Efforts should be made to update the recommendations for use during pregnancy and lactation on the basis of increasing human experience in exposed pregnancies which eventually supersede the animal data.
In case of contraindication, this should be included in section 4.3.
The following should be mentioned:

Women of childbearing potential / Contraception in males and females
Recommendations on the use of the medicinal product in women of childbearing potential should be given when appropriate including the need for pregnancy test or contraceptive measures. Where an effective contraception is required for patients or partners of patients during treatment or for a defined period before starting or after ending treatment, the rationale should be included in this section. If contraceptive measures are recommended, there should also be a cross-reference to section 4.5 (and possibly 4.4) in case of interaction with oral contraceptives.

Pregnancy
In general, clinical and non-clinical data should be followed by recommendations.
With respect to non-clinical data,
• only conclusions of the reproductive toxicity studies should be included in this section. Further details should be provided in section 5.3.
With respect to clinical data,
• the section should include comprehensive information on relevant adverse events reported in the embryo, the fetus, neonates and pregnant women, when appropriate. The frequency of such events (for example the frequency of birth defects) should be specified when available.
• the section should specify the extent of the human experience if no adverse events have been reported in pregnancy.
With respect to the recommendations:
a) Recommendations on the use of the medicinal product during the different periods of gestation, including the reason(s) for these recommendations, should be given.
b) Recommendations for the management of exposure during pregnancy when appropriate (including relevant specific monitoring such as fetal ultrasound, specific biological or clinical surveillance of the fetus or the neonate) should be given.
Cross-references can be included in sections 4.3, 4.4 and 4.8, as appropriate.
Examples of wording for this section are annexed to the CHMP/SWP guideline on reproduction and lactation.

Breastfeeding
If available, clinical data should be mentioned (exposed breastfed infants) as the conclusions of kinetic studies (plasma concentrations in breastfed infants, transfer of the active substance and/or its metabolite(s) into human milk…). Information on adverse reactions in nursing neonates should be included if available.
Conclusions from non-clinical studies on the transfer of the active substance and/or its metabolite(s) into milk should be given only if no human data are available.
Recommendations should be given to stop or continue breastfeeding and/or to stop or continue the treatment in cases where treatment or breastfeeding discontinuation is recommended, and the reason should be provided.
Examples of wordings for this section are annexed to the CHMP/SWP guideline on reproduction and lactation.

Fertility
The main information on the possible effects of the medicinal product on male and female fertility should be included in section 4.6.
This section should include:
a) Clinical data if available.
b) Relevant conclusions from nonclinical toxicity studies, if available. Further details should be included in section 5.3.
c) Recommendations for the use of the medicinal product when pregnancy is planned but fertility might be affected by treatment.
Cross-references could be included in section 4.3, if appropriate.
If there are no fertility data at all, then this should be clearly stated.

4.7 Effects on ability to drive and use machines
On the basis of the pharmacodynamic and pharmacokinetic profile, reported adverse reactions and/or specific studies in a relevant target population addressing the performance related to driving and road safety or using machines, specify whether the medicinal product has a) no or negligible influence b) minor influence, c) moderate influence or d) major influence on these abilities. Other important factors that affect the ability to drive and use machines should be considered if known, e.g. duration of the impairing effect and the development of tolerance or adverse reactions with continued use.
For situations c and d, special warnings/precautions for use should be mentioned here (and also in section 4.4 for situation d).

4.8 Undesirable effects
This section should include all adverse reactions from clinical trials, post-authorisation safety studies and spontaneous reporting for which, after thorough assessment, a causal relationship between the medicinal product and the adverse event is at least a reasonable possibility, based for example, on their comparative incidence in clinical trials, or on findings from epidemiological studies and/or on an evaluation of causality from individual case reports. Adverse events, without at least a suspected causal relationship, should not be listed in the SmPC.
The content of this section should be justified in the Clinical Overview of the marketing authorisation application based upon a best-evidence assessment of all observed adverse events and all facts relevant to the assessment of causality, severity and frequency. This section should be regularly reviewed and, if necessary, updated with the aim to ensure appropriate information to health care professionals on the safety profile of the product. In addition, the whole section could be revised at the renewal of the marketing authorisation, where the safety profile of most products is likely to be well established, and thereafter at each of the three-yearly PSUR.
It is important that the whole section is worded in concise and specific language and does not include information such as claims regarding the absence of specific adverse reactions, comparative frequency statements other than as described below, or statements of general good tolerability such as “well tolerated”, “adverse reactions are normally rare”, etc. Statements on lack of proof of causal association should not be included.

In order to provide clear and readily accessible information, section 4.8 should be structured according to the following recommendations:
a. Summary of the safety profile
b. Tabulated summary of adverse reactions
c. Description of selected adverse reactions
d. <Paediatric population>
e. <Other special population(s)>

a. ***Summary of the safety profile***

The summary of the safety profile should provide information about the most serious and/or most frequently occurring adverse reactions.

If known, it may be helpful to indicate the timing when adverse reactions occur. For example, in order to prevent early discontinuation of a treatment, it may be important to inform about non-serious adverse reactions that are frequent in the beginning of the treatment but may disappear with its continuation. Another example would be to inform about adverse reaction associated with long-term use. Frequencies of cited adverse reactions should be stated as accurately as possible. This summary of the safety profile should be consistent with the important identified risks mentioned in the Safety Specification of the Risk Management Plan. The information should be consistent with the Table of Adverse Reactions (see section b). Cross-reference should be made to section 4.4 if relevant risk minimisation measures have been proposed in that section.

An example of an acceptable statement is given below:

'At the beginning of the treatment, epigastric pain, nausea, diarrhoea, headache or vertigo may occur; these reactions usually disappear within a few days even if treatment is continued. The most commonly reported adverse reactions during treatment are dizziness and headache, both occurring in approximately 6% of patients. Serious acute liver injury and agranulocytosis may occur rarely (less than 1 case per 1,000 patients)'

b. ***Tabulated list of adverse reactions***

A single table (or structured listing) should list all adverse reactions with their respective frequency category. In some cases for common or very common reactions, and when it is necessary for the clarity of the information, frequency figures may be presented in the table.

Separate tables are acceptable in exceptional cases where the adverse reaction profiles markedly differ depending on the use of the product. For example, it might be the case for a product used for different indications (e.g. an oncology and a non-oncology indication) or at different posologies.

The table should be introduced with a short paragraph stating the source of the safety database (e.g. from clinical trials, post-authorisation safety studies or spontaneous reporting).

The table should be presented according to the MedDRA system organ classification. The system organ class (SOC) should be presented in the order shown in the annex. Adverse reactions descriptions should be based on the most suitable representation within the MedDRA terminology. This will usually be at the Preferred Term (PT) Level, although there may be instances where the use of Lowest Term Level or exceptionally group terms, such as High Level Terms may be appropriate. As a general rule, any adverse reactions should be assigned to the most relevant SOC related to the target organ. For example, PT '*Liver function test abnormal*' should be assigned to the SOC '*Hepatobiliary disorders*' rather than to the SOC '*Investigations*'. Within each system organ class, the adverse reactions should be ranked under headings of frequency, most frequent reactions first. Within each frequency grouping, adverse reactions should be presented in the order of decreasing seriousness. The names used to describe each of the frequency groupings should follow standard terms established in each official language using the following convention: Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000).

In exceptional cases, if a frequency cannot be estimated from the available data, an additional category frequency 'not known' may be used. In case the expression *"Frequency not known"* is used, the following text should be added in the list of terms explaining the frequency categories: *"not known (cannot be estimated from the available data)"*. The expressions isolated/single cases/reports should not be used.

Where additional details about an adverse reaction are described in section c), the reaction concerned should be highlighted, for example with an asterisk, and, "see section c)" should be included as a

footnote.
Guidance on how to estimate the frequency of an adverse reaction is provided at the end of this chapter of the guideline.

c. ***Description of selected adverse reactions***
This section should include information characterising specific adverse reaction which may be useful to prevent, assess or manage the occurrence of an adverse reaction in clinical practice.
This section should include information characterising individual serious and/or frequently occurring adverse reactions, or those where there have been reports of particularly severe cases. The information should provide frequency and may describe for example reversibility, time of onset, severity, duration, mechanism of the reaction (if of clinical relevance), dose relationship, relationship with duration of exposure or risk factors. Measures to be taken to avoid specific adverse reactions or actions to be taken if specific reactions occur should be mentioned under section 4.4 and cross-referenced here.
Information on the occurrence of withdrawal reactions may be mentioned here with cross-reference to section 4.2 in case of need for tapering off or advice on discontinuation of the product.
Mention should be made here of any differences between different dosage forms in respect of adverse reactions.
In the case of combination products, information should be included in this sub-section pointing out which particular adverse reactions are usually attributable to which active substance of the combination, where known.
Any adverse reactions resulting directly from an interaction should be mentioned here and crossreferenced
to section 4.5.
This section should also inform on adverse reactions with very low frequency or with delayed onset of symptoms which may not have been observed in relation to the product, but which are considered to be related to the same therapeutic, chemical or pharmacological class. The fact that this is a class attribution should be mentioned.
Any adverse reaction specific to excipients or residues from the manufacturing process should be included.

d. **<*Paediatric population*>**
A paediatric sub-section should always be included (unless irrelevant).
The extent and age characteristics of the safety database in children should be described (e.g. from clinical trials or pharmacovigilance data). Uncertainties due to limited experience should be stated.
If the observed safety profile is similar in children and adults this could be stated: e.g. "Frequency, type and severity of adverse reactions in children are <expected> to be the same as in adults".
Similarly, it is appropriate to state whether the safety profiles in the different paediatric subsets are similar or not.
Any clinically relevant differences (i.e. in nature, frequency, seriousness or reversibility of adverse reactions) between the safety profiles in adult and paediatric populations, or in any relevant age groups, should be described and presented by age group. If there is a need for specific monitoring, this should be highlighted by cross-referencing to section 4.4. For clinically relevant differences, a separate table listing such adverse reactions by frequency can be added and presented by relevant age groups if appropriate. If some paediatric adverse reactions are considered common (≥1/100 to <1/10) or very common (≥1/10), the frequencies should be provided in parentheses. In case of major difference with the safety profile in adults, a summary of the safety profile in children could be presented to facilitate the presentation of the information. Available information, from any source scientifically validated, on

long-term safety in children (e.g. on growth, mental development and sexual maturation) should also be summarised, whether positive or negative, with cross-reference to section 5.1 if appropriate. Any risk factors such as duration of treatment or period at risk should be specified.
If relevant, symptoms of neonatal withdrawal should be listed in a separate paragraph with cross reference with 4.6.

e. <Other special populations>
This section may include information on any clinically relevant differences (i.e. in nature, frequency, seriousness or reversibility of adverse reactions, or need for monitoring) specifically observed in other special populations such as elderly, patients with renal impairment, patients with hepatic impairment, patients with other diseases or a specific genotype. Cross-reference to other sections such as 4.3, 4.4 or 4.5 may be added as appropriate.
Adverse reactions may also be related to genetically determined product metabolism. Subjects or patients deficient in the specific enzyme may experience a different rate or severity of adverse reactions. This should be mentioned and where relevant correlated with data from clinical trials.

Further guidance on the estimation of frequency of adverse reactions
The estimation of the frequency of an adverse reaction depends on the data source (i.e. clinical trial, post-authorisation safety study or spontaneous reporting), the quality of data collection and causality evaluation. If the choice of the frequency category is based on different sources, the category representing the highest frequency should be chosen unless a more specific method has been applied and thus resulted in an estimate of clearly higher validity, e.g. a pooled analysis across suitable studies. Sources of data should use population exposed to the doses and treatment duration as recommended in the SmPC.
Reactions that are reported under different terms but represent the same phenomenon (e.g., sedation, somnolence, drowsiness) should ordinarily be grouped together as a single adverse reaction to avoid diluting or obscuring the true effect. Similarly, reactions that represent a syndrome complex should ordinarily be grouped together under an appropriate heading to avoid obscuring the full range of respective symptoms.
Adverse reactions from clinical trials
Safety data from several studies should be pooled to increase the precision of adverse reaction rates as appropriate without introducing bias (e.g. major difference in population characteristics or exposure to the product).
The frequency of adverse reactions should be derived from pooled placebo-controlled studies if these data are available and the databases are sufficiently large to be informative. If these data are unavailable or not sufficiently informative, active-controlled data or possibly single-arm or add-on trials databases could be used to estimate frequencies.
Frequency should represent crude incidence rates (and not differences or relative risks calculated against placebo or other comparator).
When a common, very common or serious adverse reaction (e.g. suicide) also occurs in the placebo group with a relevant frequency, both incidence rates can be stated to put the risk into perspective (e.g. in subsection c).
Adverse reactions from safety studies
The choice of the frequency category to which any adverse reaction will be assigned is based on the point estimate of the crude incidence rate derived from a study designed in such a way that specific adverse events occurring in patients within a defined observation period would have been detected and reasonably attributed to the medicinal product. In this situation, it is possible to calculate a point estimate of the crude incidence rate using standard statistical methods. In cases where the original

information is expressed as an incidence density (denominator expressed as person-time), an appropriate transformation into an incidence proportion should be performed for choosing the frequency category. Normally, incidence proportions for the most representative exposure period (e.g. 1 week, 3 months, 1 year) should be used to derive the frequency category. However, this may not be appropriate if the hazard function increases over time; in this case, the adverse reaction and its frequency pattern, when clinically relevant, should be properly described in section c).
The frequency category to be chosen for each adverse reaction should not be based on differences calculated against a comparator. However, when data are derived from a study with a non-exposed group and the rate difference attributed to the medicinal product is smaller than the baseline or background incidence rate, and if the adverse reaction is considered important, the background incidence may be provided (e.g. in section c).
Adverse reactions from spontaneous reporting
The number of spontaneous reports should not be stated because the number can quickly become outdated. Frequencies based on reporting rates from a spontaneous reporting system should not be used to assign frequency category. In case of an unexpected adverse reaction detected from spontaneous reporting, each adequately designed study where this adverse reaction could have been detected should be reviewed to choose a frequency category. If the adverse reaction has never been observed in clinical trials, then the upper limit of the 95% confidence interval is not higher than 3/X, with X representing the total sample size summed up across all relevant clinical trials and studies (e.g. those with a follow-up long enough to detect the adverse reaction). For example, if a particular adverse reaction has not been observed among 3600 subjects exposed to the product in clinical trials and studies, then the upper limit of the 95% confidence interval for the point estimate is 1/1200 or less and the frequency category should be "rare", based on worst value of the point estimate. The rationale for the frequency category for that particular reaction could be explained in sub-section c).

4.9 Overdose
Describe acute symptoms and signs and potential sequelae of different dose levels of the medicinal product based on all available information including accidental intake, mistakes and suicide attempts by patients.
Taking into account all relevant evidence, describe management of overdose in man, e.g. in relation to monitoring or use of specific agonists/antagonists, antidotes or methods to increase elimination of the medicinal product such as dialysis. However, there should not be any dosage recommendation of other medicinal products (e.g. antidotes) as it could create conflict with the SmPCs of those other products. If applicable, counteractive measures based on genetic factors should be described.

Additional information on special populations
Information specifically observed in special populations such as elderly, patients with renal impairment, patients with hepatic impairment, other concomitant diseases etc.

Paediatric population
If there are specific paediatric considerations, there should be a sub-section entitled ‘paediatric population’.
Special mention should be made of those medicinal products/strength of formulation for which ingestion of only one dose unit by children can cause fatal poisoning.

5. PHARMACOLOGICAL PROPERTIES

Sections 5.1 – 5.3 should normally mention information, which is relevant to the prescriber and to other health-care professionals, taking into account the approved therapeutic indication(s) and the

potential adverse drug reactions. Statements should be brief and precise.
The sections should be updated regularly when new information becomes available, especially in relation to the paediatric population.

5.1 Pharmacodynamic properties
Describe:
• Pharmacotherapeutic group and ATC code:
Inclusion of the therapeutic subgroup (2nd level of WHO classification) with the 3rd (pharmacological subgroup) or 4th (chemical subgroup) level is recommended.
If an ATC code is not yet available, this should be mentioned as 'not yet assigned'.
In case of medicinal product authorised as similar biological medicinal product, the following statement will be included:
<< (Invented) Name> is a biosimilar medicinal product. Detailed information is available on the European Medicines Agency website; www.emea.europa.eu>
• Mechanism of action (if known)
• Pharmacodynamic effects.
• Clinical efficacy and safety
It may be appropriate to provide limited information, relevant to the prescriber, such as the main results (statistically compelling and clinically relevant) regarding pre-specified end points or clinical outcomes in the major trials, and giving the main characteristics of the patient population. Such information on clinical trials should be concise, clear, relevant and balanced, and should summarise evidence from relevant studies supporting the indication. The magnitude of effects should be described using absolute figures. (Relative risks or odd ratio should not be presented without absolute figures).
In the exceptional cases when clinically relevant information from subgroup or post-hoc analyses is presented, it should be identified as such in a balanced manner reflecting the limited robustness of both positive and negative secondary observations.
Any relevant pharmacogenetic information from clinical studies may be mentioned here. This should include any data showing a difference in benefit or risk depending on a particular genotype or phenotype.

Paediatric population
The results of all pharmacodynamic (clinically relevant) or efficacy studies conducted in children should be presented under this sub-heading.
Information should be updated when new relevant information becomes available.
Results should be presented by age or relevant subsets.
When there are data available, but there is no authorised paediatric indication, data should be presented and a cross-reference should always be made to section 4.2and, as appropriate to 4.3. In presenting results of studies, particular attention should be given to include the relevant safety data.
For exploratory studies, the results of the main endpoints should be given with the main characteristics of the population studied and the doses used.
When they are available, information and results of confirmatory studies should usually supersede and replace those of exploratory studies. For confirmatory studies, the objectives, the study duration, the doses used (and the formulation used if different from the marketed one), the main characteristics of the patient population studied (including age and numbers of patient), and the main results regarding pre-specified endpoints should be provided, whether positive or negative. If data are considered inconclusive, this should be stated.
The objective and the main results or the conclusion of any specific clinical safety study should also be given.
[If the EMEA has waived or deferred a paediatric development, the information should be given as

follows:]
-For waivers applying to all subsets:
"The European Medicines Agency has waived the obligation to submit the results of studies with <name of the product> in all subsets of the paediatric population in <condition as per PIP decision, in the granted indication>. See 4.2 for information on paediatric use."
- For deferrals applying to at least one subset:
"The European Medicines Agency has deferred the obligation to submit the results of studies with <name of the product> in one or more subsets of the paediatric population in <condition, as per PIP decision in the granted indication>. See 4.2 for information on paediatric use.
[For products approved under 'conditional approval' in the centralised procedure, include the following statement:]
<This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. The European Medicines Agency (EMEA) will review new information on the product every year and this SmPC will be updated as necessary.>
[For products approved under 'exceptional circumstances', include the following statement:]
<This medicinal product has been authorised under 'Exceptional Circumstances'. This means that <due to the rarity of the disease> <for scientific reasons> <for ethical reasons> it has not been possible to obtain complete information on this medicinal product. The {name of Agency} will review any new information which may become available every year and this SmPC will be updated as necessary.>

5.2 Pharmacokinetic properties
Pharmacokinetic properties of the active substance(s) relevant for the advised dose, strength and the pharmaceutical formulation marketed should be given in this section. If these are not available, results obtained with other administration routes, other pharmaceutical forms or doses can be given as alternative.
Basic primary pharmacokinetic parameters, for instance bioavailability, clearance and half-life, should be given as mean values with a measure of variability.
Pharmacokinetics items, which could be included in this section when relevant, are given below.
a. General introduction, information about whether the medicinal product is a pro-drug or whether there are active metabolites, chirality, solubility, information on the population in which general pharmacokinetic data were obtained, etc.
b. General characteristics of the active substance(s) after administration of the medicinal product formulation to be marketed.
• **Absorption:** complete or incomplete absorption; absolute and/or relative bioavailability; first pass effect; Tmax; the influence of food; in case of locally applied medicinal product the systemic bioavailability; involvement of transport proteins. If available, information on the site of absorption in the gastro-intestinal tract should be stated (as it may be important for administration by enteral feeding tubes).
• **Distribution:** plasma protein binding; apparent volume of distribution per kilogram body weight (l/kg); tissue and/or plasma concentrations; pronounced multi-compartment behaviour; involvement of transport proteins.
• **Biotransformation:** degree of metabolism; which metabolites; activity of metabolites and contribution to effect and toxicity; enzymes involved in metabolism; site of metabolism; results from in vitro interaction studies that indicate whether the new compound can induce/inhibit metabolic enzymes.
• **Elimination:** elimination half-lives, total clearance; inter and/or intra-subject variability in total clearance; excretion routes of the unchanged substance and the metabolites including the relative portion of the hepatic and renal eliminated fraction, involvement of transport proteins.

• **Linearity/non-linearity:** linearity/non-linearity of the pharmacokinetics of the active substance with respect to dose and/or time; if the pharmacokinetics are nonlinear with respect to dose and/or time, the underlying reason for the non-linearity should be presented.
Additional relevant information should be included here.
c. Characteristics in specific groups of subjects or patients
• Variations with respect to factors such as age, weight, gender, smoking status, polymorphic metabolism and concomitant pathological situations such as renal failure, hepatic disease, including degree of impairment. If the influence on pharmacokinetics is considered to be clinically relevant, it should be described here in quantitative terms (cross-reference to section 4.2 when applicable).
d. Pharmacokinetic/pharmacodynamic relationship(s)
• Relationship between dose/concentration/pharmacokinetic parameter and effect (either true endpoint, validated surrogate endpoint or side effect).
• The population studied should be described.

Paediatric population
Results of pharmacokinetic studies in the different paediatric age groups should be summarised, with a comparison to adults if available. If appropriate, the dose producing similar product exposure as in adults could be given. The pharmaceutical form(s) used for pharmacokinetic studies in children should be stated. Uncertainties due to limited experience should be stated.

5.3 Preclinical safety data
Information should be given on any findings in the non-clinical testing which could be of relevance for the prescriber, in recognising the safety profile of the medicinal product used for the authorised indication(s), and which is not already included in other relevant sections of the SmPC.
If the results of the non-clinical studies do not add to the information needed by the prescriber, then the results (either positive or negative) need not be repeated in the SmPC.
The findings of the non-clinical testing should be described in brief with qualitative statements as outlined in the following example:
• Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential and toxicity to reproduction and development.
• Effects in non-clinical studies were observed only at exposures considered sufficiently in excess of the maximum human exposure indicating little relevance to clinical use.
• Adverse reactions not observed in clinical studies, but seen in animals at exposure levels similar to clinical exposure levels and with possible relevance to clinical use were as follows.
Findings of non-clinical studies relevant for use in the paediatric population, including juvenile animals and peri- or post- natal studies, should be presented with a discussion of their clinical relevance, under a sub-heading if necessary.
<Environmental Risk Assessment (ERA)>
Where relevant, conclusions on the environmental risk assessment of the product should be included, with reference to section 6.6.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
A list should be given of the excipients, expressed qualitatively only. All excipients, which are present in the product, should be included, even those present in small amounts, such as printing inks. Further details on the excipients to be declared may be found in the section on definitions and examples in the *Guideline on the Excipients in the Label and Package Leaflet of Medicinal Products for Human Use*.

For transdermal patches, all ingredients of the patch (including the adhesive, release liner and backing film) should be mentioned.
The active substance itself, residues of substances used during manufacture of the finished product (for example, solvents, head-space gases or antibiotics in vaccine manufacture), lubricants for prefilled syringes and constituents of capsule shells for inhalation powders not intended to be taken should not be included.
However, certain residues such as residues of antibiotic or other antimicrobial agents used in production that are known allergens with a potential for inducing undesirable effects should be mentioned in section 4.3 or 4.4 as appropriate.
Excipients should be referred to by their recommended INN if existing, accompanied by the salt or hydrate form if relevant or by their European Pharmacopoeia name. If an excipient has neither an INN nor European Pharmacopoeia name, it should be described by its usual common name. References to the pharmacopoeial quality should not be included. E numbers should be given along with the common name of the excipient where they exist and when necessary for proper use, e.g. when the excipient is listed in the Guideline on the excipients in the label and package leaflet of medicinal products for human use (as having recognised action or effect).
The ingredients in excipient mixtures should be listed individually. In cases where the full composition of a flavour or fragrance is not known to the applicant or is too complex, it may be declared in general terms (e.g. 'orange flavour', 'citrus perfume'). However, any of the components, which are known to have a recognised action or effect, should be included.
Ingredients that may or may not be added for the pH adjustment should be followed by the parenthesis '(for pH-adjustment)'
Invented names or general descriptive names such as 'printing ink' should not be used in place of the common name of an ingredient or of a mixture of ingredients but may be used in conjunction with the name(s) of the ingredient(s), so long as it is clear which ingredients are described by the name.
Chemically modified excipients should be declared in such a way as to avoid confusion with the unmodified excipients, e.g. 'pregelatinised starch'.
In the case of a product containing a covert marker for the purpose of tracking, tracing and authentication, a general term such as "authentication factor" should be included in the list of excipients instead of the name of the excipient, unless the excipient is one that is known to have a recognised action or effect.
For clarity, it is recommended that each excipient be listed on a separate line. It can be useful to list excipients according to the different parts of the product, e.g. tablet core/coat, capsule contents/shells, etc. For products that are presented in more than one container or in dual-chamber containers, the excipients should be listed per container or per chamber.
Abbreviations for excipients should not be used. However, where justified for space considerations, abbreviations for excipient names may appear on the labelling, on condition that these abbreviations are designated in section 6.1.

6.2 Incompatibilities

Information on physical and chemical incompatibilities of the medicinal product with other products with which it is likely to be mixed or co-administered should be stated. This is particularly important for medicinal products to be reconstituted and/or diluted before parenteral administration. Significant interaction problems, e.g. sorption of products or product components to syringes, large volume parenteral containers, tubing, in-line filters, administration sets, etc. should be stated.
Statements concerning compatibility of the product with other medicinal products or devices should not be included in this section but in section 6.6. Statements concerning pharmacological and chemical/physical incompatibilities with food should be included in section 4.5. If appropriate, the standard statement, 'Not applicable', should be included.

For certain pharmaceutical forms, e.g. parenterals, either of the following standard statements should be included as appropriate:

• *'In the absence of compatibility studies, this medicinal product must not be mixed with other medicinal products.'*

• *'This medicinal product must not be mixed with other medicinal products except those mentioned in section 6.6.'*

6.3 Shelf life

The shelf life should be given for the medicinal product as packaged for sale and, if appropriate, after dilution or reconstitution or after first opening.

A clear statement of the shelf life should be given, in an appropriate unit of time.

For statements to be included regarding in-use shelf lives of sterile products, consult the *Note for Guidance on maximum shelf life for sterile products for human use after first opening or following reconstitution.* An in-use shelf life may need to be stated for other medicinal products if development studies have found it to be necessary.

Additionally, if different concentrations need to be prepared, e.g. for use in children, the physicochemical stability throughout the entire concentration range should be stated; e.g. *"The stability has been demonstrated between x mg/ml and y mg/ml for t hours/days at 25 ºC and 2-8 ºC"*.

In case of a paediatric indication, if no age appropriate formulation is available for children but an extemporaneous formulation could be prepared from an existing formulation, relevant physicochemical data on storage and stability should be included here with a cross-reference in sections 6.4 and 6.6."

In case of specific temporary storage conditions need to be provided to healthcare professionals or patients, e.g. for the purpose of ambulatory use (e.g. shelf-life 24 months at 2-8°C of which 3 months could be below 25°C), specific additional guidance should be provided as appropriate. Such information should always be based on stability data. In particular, the recommended temperature range and maximum duration of temporary storage should be specified. This guidance may also include the action to be taken after the product has been stored under the temporary storage conditions (e.g. discard immediately).

Statements such as "These data are not recommendations for storage" should not be used.

No reference should be made to the container unless there are different shelf lives for different containers. Storage conditions should not be included, except for the storage conditions after opening (see the corresponding guideline). Statements such as 'Do not use after the expiry date' should not be included.

When a device is supplied together with a medicinal product, the in-use shelf-life of the device should be given where applicable.

6.4 Special precautions for storage

Storage warnings should use one or more of the standard statements from the *Note for Guidance on declaration of storage conditions in the product information of medicinal products.* When such a standard statement is used, an explanation specifying whether the product is sensitive to light and/or moisture should be added.

For storage of sterile products that have been opened, diluted or reconstituted, a cross-reference should be made to section 6.3.

Note that if a specific storage warning is required, the warning should be consistent between the SmPC, label and PL.

A warning to keep the product out of the reach and sight of children should not be included in the SmPC.

6.5 Nature and contents of container

Reference should be made to the immediate container using the European Pharmacopoeia standard term; the material of construction of the immediate container should be stated ('glass vials', 'PVC/Aluminium blisters', 'HDPE bottles'); and any other component of the product should be listed, e.g. needles, swabs, measuring spoons, syringes inhaler devices, desiccant. The graduation on measuring devices should be explained. The container of any solvent provided with the medicinal product should also be described. Excessive detail, e.g., concerning the colour of the stopper, the nature of the heat-seal lacquer, should usually not be included. For parenteral preparations, when enclosure colour is used to differentiate between the presentations of a product, this should be stated here.

If appropriate, it should be indicated if the container closure is child-resistant.

Examples on the text in this section:

'<Volume> ml suspension in a pre-filled syringe (glass) with plunger stopper (chlorobutyl rubber) with or without needle in pack sizes of 5 or 10.' 'HDPE bottle with a child-resistant closure and a silica gel desiccant. Pack-sizes of 30, 60 or 90 film-coated tablets.'

All pack sizes should be listed. Pack sizes mentioned should include the number of units, number of doses (for e.g. multi-dose vaccines, inhalers, etc.), total weight or volume of the immediate container, as appropriate, and the number of containers present in any outer carton. If appropriate, a standard statement, 'Not all pack sizes may be marketed', should be included, in order to alert health professionals to the fact that not all listed pack sizes may be available for prescribing or dispensing.

Multiple unit packs for distribution purposes only do not constitute new pack sizes for marketing of the product and should therefore not be included in this section.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product2

Instructions for disposal should be included here, if appropriate for the product.

Where special precautions for the handling and disposal of certain products such as cytotoxics and some biological products or waste material derived from it are advised, e.g. in the case of products containing live organisms, these should be stated in this section, as should, where relevant, the disposal of items which come into contact with the product, such as nappies, or spoons used to administer oral vaccines. If relevant, a cross-reference to conclusions on the environmental risk assessment described in section 5.3 can be included.

If applicable, e.g. for cytotoxics, the following standard statement should be included, 'Any unused product or waste material should be disposed of in accordance with local requirements.'

If there are no special use or handling instructions for the pharmacist or other healthcare professionals, the standard statement, 'No special requirements.' should be included.

Any directions necessary for the accurate preparation of certain products such as cytotoxics and some biological products and/or necessary for the protection of persons including parents or carers preparing or handling the product should be stated.

In section 4.2, instructions on handling of the product by the doctor, other health personnel, or patient should be included, as well as general information concerning the administration of the product (whether administered by the patient or the health personnel). If instructions for use/handling are needed where the medicinal product has to be prepared before use, e.g. where it must be suspended or diluted, this information has to be given here.

For clarity, a cross-reference in section 4.2 to the relevant information in section 6.6 could be included, e.g. 'For instructions on dilution of the product before administration, see section 6.6.' It is recommend that only information necessary for the pharmacist or other health personnel to prepare the product for administration to the patient should be included here.

Information on the preparation (e.g. the suspension of a powder for injection, or preparing a dilution) of the medicinal should be included in section 6.6, regardless of who prepares the product (e.g. pharmacist, doctor, other health personnel, patient, parents or carers). In the case of products for reconstitution, the appearance of the product after reconstitution should be stated.
Statements concerning compatibility of the product with other medicinal products or devices can be given here provided the data have been provided in the dossier.
In the exceptional cases where a product is indicated in children and where no adequate paediatric formulation can be developed (based on duly justified scientific grounds), information on extemporaneous formulation should appear under a sub-heading "*Use in the paediatric population*" and should cross-refer to the section 4.2. Detailed instructions for the preparation of the extemporaneous formulation from the appropriate "adult" or other "older children" dosage form and additional information on extemporaneous formulations for use in younger children shall be provided and, where appropriate, the maximum storage time during which such preparation will conform to its specifications. When necessary, the required packaging material and storage conditions should be stated here.
Any specific warnings for the handling of the product should be in section 4.4.
Information on risks due to occupational exposure should be included in this section, with reference to section 4.4 or 4.8 if there is information in that section.

7 MARKETING AUTHORISATION HOLDER

Name and permanent address or registered place of business of the Marketing Authorisation Holder. Telephone, fax numbers or e-mail addresses may be included (not websites or emails linking to websites).

8 MARKETING AUTHORISATION NUMBER(S)

Item to be completed by the competent authority or by the Marketing Authorisation Holder once the Marketing Authorisation has been granted. For medicinal products for which the European Commission is the Competent Authority, the number to be included in this section is the number in the Community Register.

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Item to be completed by the competent authority or by the Marketing Authorisation Holder once the Marketing Authorisation has been granted or renewed. Both the date of first authorisation and, if the authorisation has been renewed, the date of the (last) renewal should be stated in the format given in the following example:
Date of first authorisation: 3 April 1985
Date of latest renewal: 3 April 2000

10 DATE OF REVISION OF THE TEXT
Leave blank in case of a first Marketing Authorisation.
For medicinal products for which the European Commission is the Competent Authority: date of approval of latest variation or transfer, e.g. the latest Commission Decision amending the SmPC, implementation date of the Urgent Safety Restriction or date of (EMEA) notification amending the annexes to the Marketing Authorisation.
For products for which Member States are the Competent Authorities: date of approval of latest variation or implementation date of the Urgent Safety Restriction resulting in a revision of the SmPC.

Item to be completed by the competent authority or by the Marketing Authorisation Holder at time of printing the SmPC.

11 DOSIMETRY (IF APPLICABLE)

Full details of internal radiation dosimetry should be included in this section for radiopharmaceuticals. For all other products, this section should be excluded.

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)

For radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform to its specifications.
Special instructions relating to the disposal of containers and unused contents should also be included

ANNEX
THE MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES TERMINOLOGY (MedDRA)

All ADRs should be grouped according to the following order based on the MedDRA system organ classes (SOC). As a general rule, MedDRA terms should be classified according to the most relevant SOC related to the target organ.
A pragmatic approach to the location of terms should be taken in order to make the identification of adverse reactions simpler and clinically appropriate for the reader. For example, it may be helpful on some occasions – solely in the context of the SmPC - to use secondary SOC locations of some MedDRA Preferred Terms (PT), or sometimes to use locations that do not strictly accord with the MedDRA architecture. For example, if the PT '*Liver function test abnormal*', '*Hepatitis*' and '*Hepatic encephalopathy*' are to be included in an SmPC, it would be acceptable to include them all under the SOC '*Hepatobiliary disorders*' instead of distributing the reactions among the SOCs '*Hepatobiliary disorders*', '*Nervous system disorders*' and '*Investigations*' as dictated by their primary location in MedDRA.

SOC LIST
• Infections and infestations
• Neoplasms benign, malignant and unspecified (including cysts and polyps)
• Blood and lymphatic system disorders
• Immune system disorders
• Endocrine disorders
• Metabolism and nutrition disorders
• Psychiatric disorders
• Nervous system disorders
• Eye disorders
• Ear and labyrinth disorders
• Cardiac disorders
• Vascular disorders
• Respiratory, thoracic and mediastinal disorders
• Gastrointestinal disorders

• Hepatobiliary disorders
• Skin and subcutaneous tissue disorders
• Musculoskeletal and connective tissue disorders
• Renal and urinary disorders
• Pregnancy, puerperium and perinatal conditions
• Reproductive system and breast disorders
• Congenital, familial and genetic disorders
• General disorders and administration site conditions
• Investigations
• Injury, poisoning and procedural complications
• Surgical and medical procedures
• Social circumstances

Adverse reaction descriptions should be based on the most suitable representation within the MedDRA terminology. This will usually be at the PT level, although there may be instances where the use of Lowest Level Terms (LLT) or group terms, such as high-level terms (HLT) may be appropriate. It is acceptable to adapt the names of the MedDRA group terms if this makes their meaning more transparent to the reader of the SmPC; e.g. the use of the suffixes NEC and NOS are not appropriate for inclusion in the SmPC. The adverse reaction term should be expressed in natural word order, e.g. 'Interstitial pneumonia' in preference to 'Pneumonia interstitial'. It may be appropriate to modify MedDRA terms in other ways in the interests of comprehensibility. The most widely recognised term for a particular condition should be used, e.g. the use of 'Churg Strauss syndrome' might be more appropriate than the use of 'Allergic granulomatous angiitis'.

Within each MedDRA SOC, adverse reactions should be classified according to their frequency of occurrence. Prior to estimating frequency of occurrence of adverse events from systematic studies (clinical trials or other sources), appropriate levels of the MedDRA hierarchy should be used in order to group together clinically related conditions in a meaningful way. For example, if 'postural dizziness', 'exertional dizziness' and 'unspecified dizziness' were each reported by 2% of patients, this might reasonably be represented in the SmPC as 'Dizziness' occurring in 6% of patients (assuming that only one report of dizziness applied to each patient). It may also be appropriate to use *ad hoc* groupings of terms, or to adapt MedDRA group terms if the established MedDRA group terms are not completely suitable, e.g. reports of adverse reactions represented as 'Diarrhoea', 'Diarrhoea aggravated', 'Loose stools', 'Stools watery', 'Intestinal hypermotility' or other might all reasonably be represented as the single term 'Diarrhoea' in the interest of making the SmPC relevant and comprehensible to patients. The total number of those cases should be used to estimate the frequency of diarrhoea.

9.3.6. Guideline on the Packaging Information of Medicinal Products for Human Use Authorised by the Community

Notice to Applicants Volume 2C of the Rules governing Medicinal Products in the European Community, Revision 13, February 2008

Introduction

Legal framework

Council Regulation (EEC) No 2309/93 lays down a centralised Community procedure for the authorisation of medicinal products, for which there is a single application, a single evaluation and a single authorisation allowing direct access to the EU market of a medicinal product bearing a single set of information.

Regulation (EEC) No 2309/93 provides that the legal status of medicinal products for human use to be authorised by the Community shall be fixed in accordance with the criteria laid down in Directive 2001/83/EC as amended as amended and that the text of their labelling and package leaflet shall be presented in accordance with Directive 2001/83/EC as amended. The legal status and the text of the label and of the leaflet form part of the Community decision, and all proposed changes to any aspect of the labelling or package leaflet shall be submitted to the competent authority, i.e. the EMEA and the Commission.

Directive 2001/83/EC as amended contains provisions on the text of the label and package leaflet and Article 60 therein require that Member States may not prohibit or impede the marketing of medicinal products within their territory on grounds relating to the labelling or package leaflet if these comply with the provisions of this directive. However, Article 57 provides that, notwithstanding Article 60, Member States may require the use of certain forms of labelling making it possible to indicate: the price of the medicinal product, the reimbursement conditions, the legal status and the identification. Furthermore, Article 62 provides that the labelling may include symbols or pictograms and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature.

Purpose

This guideline has been prepared in order to describe how the provisions of Directive 2001/83/EC as amended, including the optional provisions in Articles 62 and 57, apply in the case of an authorisation to be granted by the Community.

As provided in Article 8 (3) (j) of Directive 2001/83/EC as amended and in Article 61 (1) of Directive 2001/83/EC as amended an application for a Community marketing authorisation must include one or more specimens or mock-ups of the outer packaging and of the immediate packaging of the medicinal product, together with the draft package leaflet.

Once the Community marketing authorisation has been issued specimens of the finalised outer and immediate packaging and of the package leaflet should be submitted for each Member State to the EMEA, before the actual commercialisation of the product. This mechanism ensures that any changes introduced during the decision making process have been incorporated and that the information on the label required by some Member States under Article 57 of Directive 2001/83/EC as amended and the

additional information included in the label pursuant to Article 62 are in conformity with the legislative provisions and are correctly presented.

Section A – Label

1. Conformity with the summary of product characteristics

Article 9 (3) c) of Council Regulation 2309/93 requires that the label text must be in accordance with Directive 2001/83/EC as amended, which in turn requires the label text to be in accordance with the summary of products characteristics. For products authorised by the Community there is a single summary of product characteristics agreed at Community level, which forms part of the Community decision.

2. The label text

The Community authorisation for a medicinal product includes the label text which is identical for all packs of that medicinal product throughout the Community, except as indicated under 4 below.

In accordance with Article 56 and 63 (1) of Directive 2001/83/EC as amended, the particulars in the label shall be easily legible, clearly comprehensible and indelible. Applicants should refer in this respect to the Guideline on the readability of the label and package leaflet of medicinal products for human use.

3. Language

In accordance with Article 56 and 63 (1) of Directive 2001/83/EC as amended, the labelling must be presented at least in the language or languages of the Member State(s) where the product is placed on the market. If more than one language is used, then all of the text must be in each language and the overall readability should not be adversely affected. The content of all language versions must be identical. It is recommended to group different text elements for each language, where appropriate.

4. Additional labelling information required by some Member States

Article 57 of Directive 2001/83/EC as amended provides that, notwithstanding Article 60, Member States may require the use of certain forms of labelling making it possible to indicate :

- the price of the medicinal product,
- the reimbursement conditions of social security organisations,
- the legal status for supply to the patient, in accordance with Directive 2001/83/EC as amended,
- identification and authenticity.

The information currently required by the Member States is outlined in the Annex.

The information specific to a Member State should be accommodated on the label in a boxed area (the so-called ‘blue box’), to appear on one side of the pack. Each ‘blue box’ should only be presented in the official language or languages of the Member State concerned and should state the name of that Member State. The location of the ‘blue box’ on the package should ideally be the same for all Member States. When one pack is intended for marketing in several Member States, it is preferable to have only one ‘blue box’ on the pack. This box will contain different information relevant for each Member State. This could be achieved in practice for instance by printing a blank ‘blue box’ on this pack onto which a sticker with the appropriate Member State information can be securely affixed. When in exceptional circumstances, this cannot be achieved, each ‘blue box’ should ideally have the same dimensions and appear on the same side of the pack.

As far as the legal status is concerned, it should be noted that the main categories, "medicinal product subject to medical prescription" or “medicinal product not subject to medical prescription”, are already included in the labelling. Hence, the ‘blue box’ may only contain the symbol and/or the expression used in the Member State to denote the legal status. See also Section B hereafter. The symbols used for the legal status on the label in some Member States are given in the Annex.

5. Marketing authorisation number

This is the marketing authorisation number consisting of "EU" followed by a nine- digit number (e.g. "EU/1/96/000/000"). .

This number must appear on the package, whilst the (national) identification number, if any, can only appear (once) in the ‘blue box’ (see paragraph 4).

6. Optional information under Article 62 of Directive 2001/83/EC as amended

Article 62 of Directive 2001/83/EC as amended provides that, apart from the particulars required under Article 54, the labelling may include symbols or pictograms and other information compatible with the summary of the product characteristics which is useful for health education, to the exclusion of any element of a promotional nature. It is recommended that proposals for inclusion of such symbols or pictograms be discussed with the EMEA in advance.

In some Member States certain expressions, including symbols and pictograms have become established for expressing certain items of information. These items are outlined in the Annex.

As these particulars are only known or relevant in some Member States, they should appear in the corresponding ‘blue box’ referred to under paragraph 4. Even if it is not mentioned on Directive 2001/83/EC as amended, the additional use of label information in Braille is possible.

For the “local representative” see section C- Package leaflet paragraph 5.

7. Control of the conformity of the labelling with Directive 2001/83/EC as amended

The labelling of the medicinal product, including the particulars referred to under paragraphs 4 and 6 above, forms part of the authorisation and must therefore beapproved by the competent authority, i.e. the EMEA and the Commission (or the Council, as the case may be) where the authorisation is granted by the Community.

Indeed Article 9 of Regulation (EEC) No 2309/93 provides that the CPMP opinion will be negative if the labelling of the product is not in compliance with Directive 2001/83/EC as amended. Furthermore, in the case of a favourable opinion, the text of the labelling will be attached to the opinion, and will later on be annexed to the Community decision.

Whilst most of the information referred to under paragraph 4 (price, reimbursement conditions, identification number) will not be available at the time that the Community decision is being drafted, a clear indication of the way this information will eventually be presented shall be given in the application, as provided for in Article 8 (3) (j) and in Article 61 (1) of Directive 2001/83/EC as amended. Thus mock-ups of the outer packaging and of the immediate packaging should be provided. A mock-up is a copy of the flat artwork design in full colour providing a replica of both the outer and immediate packaging and of the labelling text of the medicinal product. It is generally referred to as a “paper copy” or “computer generated version”.

8. Changes to the labelling

Article 61 (3) of Directive 2001/83/EC as amended requires that any changes to the label which are not connected with the summary of product characteristics shall be notified to the competent authority. Therefore, if a marketing authorisation holder wishes either to introduce any label text additional to that in the decision or to change any aspect of the labelling he must first (in accordance with Article 61

of Directive 2001/83/EC as amended) notify this change to the EMEA, who shall inform the marketing authorisation holder whether the proposed change is accepted or not. If necessary, the EMEA shall inform the Commission, who shall amend the decision granting the marketing authorisation.

Where a change in the labelling is a consequence of a modification of the summary product characteristics it will be dealt with under the procedure laid down for that purpose (see Regulation 1085/2003/EC).

Section B - Legal Status

1. Articles 9 (3) b) and 13 (3) of Council Regulation 2309/93

In accordance with Article 9 (3) b) of Council Regulation 2309/93 the Community decision on the marketing authorisation must include "*...details of any conditions or restrictions which could be imposed on the supply or use of the medicinal product concerned including the conditions under which the medicinal product may be made available to patients, having regard to the criteria laid down in Council Directive 92/26/EEC of 31 March 1992* (now Articles 1 (19) and 70 to 75 of Directive 2001/83/EC as amended) *concerning the classification for the supply of medicinal products for human use without prejudice to the provisions of Article 3 (4) of that Directive* (now Article 71 of Directive 2001/83/EC as amended)...*"*. Therefore the Community decision may include one, or more, of the sub-categories listed in Article 70 of Directive 2001/83/EC as amended. Furthermore, Article 13 (3) of Council Regulation 2309/93 provides the option to *"authorise some products only for use in hospitals or for prescription by some specialists"*.

These terms, for additional restrictions on the legal status of medicinal products subject to medical prescription, are not well understood and are subject to different interpretations. The particular interpretation applicable to a medicinal product should always be clarified with reference to the summary of product characteristics. For medicinal products authorised by the Community, the following interpretations for these terms may be used:

• *use in hospital / use in certain specialised areas*, may be taken to include use within a framework providing hospital-type care;

• *prescription by some specialists / restricted medical prescription*, may be taken to include that the prescription, or the initial prescription only, must be by a specialist. The designation of the specialist shall take into account the progress made under Directive 93/16/EEC in harmonising Member States' terminology for medical specialists;

• *renewable/non-renewable prescription may be taken to mean* that on the basis of one medical prescription, the supply prescribed may/may not be repeated.

• *special medical prescription* this includes medicinal products containing narcotics and psychotropics.

The legislation in some Member States does not provide for certain sub-categories.

However, these Member States should use the means available, within their existing administrative framework, to fulfil all of the conditions laid down in the Community decision granting the marketing authorisation. Therefore, when one of the subcategories of legal status is in Annex II of the Community decision, this shall be applied, to the extent to which this can be possible done, within the existing administrative framework in each Member State.

2. Legal Status on the label

In addition to appearing in Annex II of the Community decision, the main legal status must also appear in the label text which is included in Annex III A of the Community decision. However, the expression of the legal status in the label text in the Commission decision is limited, at present, to one of the main classifications under Article 70 of Directive 2001/83/EC as amended "medicinal product subject to medical prescription" or "medicinal product not subject to medical prescription" which are common to all Member States.

3. Additional Member States' requirements for legal status on the label

A Member State may require further information on the legal status, to be included on the label. This may concern either one, or a combination, of the sub-categories listed in Article 70 of Directive 2001/83/EC as amended, or a specific mode of conveying particular information on the legal status. Obviously, this information must be in accordance with the legal status in the Community decision (i.e. a sub-category in the sense of Article 70 of Directive 2001/83/EC as amended may not be specified if this is not done in the Community decision). Furthermore, symbols are used in some Member States to express the legal status on the label and these are provided in the Annex.

If this further information on legal status is to be accommodated on the label it must only appear in the so-called 'blue box' referred to in Section A (concerning the label).

Section C - Package leaflet

1. Conformity with the SPC

Article 9 (3) c) of Council Regulation 2309/93 requires that the text of the leaflet must be in accordance with Directive 2001/83/EC as amended which in turn requires the leaflet text to be in accordance with the summary of products characteristics. For products authorised by the Community there is a single summary product characteristics agreed at Community level, and which forms part of the Community decision.

2. The text of the leaflet

The Community authorisation of a medicinal product includes the text of the leaflet, which is the same throughout the Community.

In accordance with Article 63(2) of Directive 2001/83/EC as amended, the package leaflet must be written in clear and understandable terms for the patient and be clearly legible. Applicants should refer in this respect to the guideline on the readability of the label and package leaflet of medicinal products for human use. In particular, applicants should consider using the "model leaflet" annexed to that guideline. Product information templates and various reference documents prepared by the Quality Review of Documents group and published by the EMEA on the EMEA Website, should also be taken into account.

3. Language

In accordance with Article 63 (2) of Directive 2001/83/EC as amended, the package leaflet must be presented at least in the language or languages of the Member State(s) where the product is placed on the market. When more than one language is used, then all the text must be in each language, and the overall readability of the label should not be adversely affected. The content of all language versions must be identical.

4. Additional package leaflet text not connected with the SPC

As provided by Article 62 of Directive 2001/83/EC as amended, the package leaflet may include: "...other information compatible with the summary of product characteristics which is useful for health education, to the exclusion of any element of a promotional nature."

5. Local representative

"Local Representative" shall be taken to mean any private *or* legal person established in the Community charged, through a civil contract with the marketing authorisation holder, with representing him in a defined (geographical) area, this contract excluding any transfer of any

responsibility imposed on the marketing authorisation holder by Community law and by national law, regulation and administrative action implementing such Community law.
Designation of a local representative cannot be a requirement but, when the marketing authorisation holder wishes to identify a local representative, in the leaflet, all of the Community must be covered so that the consumer in each Member State and EEA country has equivalent access to a local representative.

The 'local representative' may be indicated:
• in the leaflet by name and telephone number and/or electronic e-mail address. Post address may be added space permitting and
• in the ‘blue box' on the label (referred to in Section A), by name, telephone number and/or e-mail address and logo (optional). Postal address may be included if space permits (should not interfere with the legibility of the EU text on the outer packaging), and if mentioned in the leaflet.
All telephone numbers should be accessible when dialled from abroad (e.g. when a tollfree number is given which is not accessible from aboard, an alternative international number may have to be added).
When mentioned in the leaflet, the local representative of the marketing authorisation holder can in addition be mentioned in the ‘blue box’ area on the mock-up/specimen.
However, it is not compulsory to mention a local representative in the ‘blue box’.
If the marketing authorisation holder wishes to mention local representatives, they can be mentioned under the relevant heading of the package leaflet, but where used a local representative shall be indicated for all Member States and EEA countries. However, a local representative may be designated for more than one Member State or EEA country and may also be the marketing authorisation holder where no other local representative is indicated.
Local representatives should be able to address queries in the local official EEA language(s) of the country for which he/she is designated. References to Website addresses are not alowed, neither for the marketing authorisation holder nor for the local representatives.
There has been some confusion with regard to terms such as 'exploitant', 'technical director', 'distributor' etc. Since there is neither a commonly agreed understanding of these terms nor equivalent legal definitions of these terms amongst the Member States, and in the absence of any reference or definition in Community law, reference to such terminology will not be accepted for a medicinal product authorised by the Community.
It must be recalled that, under the case-law of the EC Court of Justice, Member States may not require that a local representative of the marketing authorisation holder be appointed for their territory. Therefore, the arrangements outlined above are purely optional for holders of Community marketing authorisations.

6. Application of Article 59 (2) of Directive 2001/83/EC as amended

Article 59 (2) of Directive 2001/83/EC as amended provides that "the competent authorities may decide that certain therapeutic indications shall not be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient".
This clause was introduced to avoid circumstances where a patient might not have been informed of the diagnosis (cancer, for instance) and would learn about it when reading the leaflet of the medicinal products which has been prescribed. Such a fundamental departure from the principle that the package leaflet should be in accordance with the summary of product characteristics and that patients should be fully and correctly informed about the medicinal products they are using should obviously only occur in exceptional circumstances.
Article 9 (3) c) of Regulation (EEC) No 2309/93 refers expressly to Article 59 of Directive 2001/83/EC as amended. There is therefore no doubt that the Community may avail itself of the

derogation in Article 59 (2) of Directive 2001/83/EC as amended (see also Commission answer to written questions No 813/96 and 814/96 of Mr van Dijk, MEP).

7. Control of the conformity of the package leaflet with Directive 2001/83/EC as amended

The text of the package leaflet forms part of the authorisation and must therefore be approved by the competent authority, i.e. the EMEA and the Commission where the authorisation is granted by the Community. Indeed Article 9 of Regulation (EEC) No 2309/93 provides that the CPMP opinion will be negative if the package leaflet of the product is not in compliance with Directive 2001/83/EC as amended. Furthermore, in the case of a favourable opinion, the text of the labelling and package leaflet will be attached to the opinion, and will later on be annexed to the Community decision.

8. Changes to the package leaflet

Article 61 (3) of Directive 2001/83/EC as amended requires that any changes to the package leaflet which are not connected with the summary of product characteristics shall be notified to the competent authority. Therefore, if a marketing authorisation holder wishes either to introduce any additional information to the package leaflet annexed to the decision or to change any aspect of the package leaflet he must first (in accordance with Article 61 of Directive 2001/83/EC as amended) notify this change to the EMEA, who shall inform the marketing authorisation holder whether the change is accepted or not. If necessary, the EMEA shall inform the Commission, who shall amend the decision granting the marketing authorisation. Where a change in the package leaflet is a consequence of a modification of the summary of product characteristics it will be dealt with under the procedure laid down for that purpose (see Regulation (EEC) No 542/95).

Section D - Presentation of the medicinal product

1. Pack sizes

When presenting a range of pack sizes for a medicinal product it is important that the principles of rational use of medicinal products are taken into consideration. As a Community marketing authorisation is valid throughout the Community, every pack size covered by the authorisation may be available in any Member State. Therefore, the appropriate range of pack sizes should be chosen in accordance with the duration(s) of treatment and in accordance with the posology in the summary of product characteristics, and **not** in accordance with local traditions or prescription habits.

For example, there could be :

- *one pack size for a short course of treatment,*
- *one pack size for a monthly course of treatment*
- *and one pack size for each multiple of the above.*

In any case, pack sizes should not be too close to one another. For example, pack sizes of both 28 dose units and 30 dose units and/or of 56 dose units and 60 dose units would not be considered acceptable.

2. Pack design (logo, colour, etc.)

For practical and linguistic reasons marketing authorisation holders are likely to present the medicinal product packaging in several linguistic and/or "national" versions (i.e. with the relevant boxed areas). In such cases, the logo, format, layout, style, colour scheme and if possible also the pack dimensions must be identical for all the versions of packs of that medicinal product throughout the Community.

In accordance with Article 61 of Directive 2001/83/EC as amended, all proposed changes to any aspect of the presentation shall be submitted to the EMEA, who will inform the Commission where relevant.

ANNEX

'Blue box'
Label information which may be required by Member States (under 57 of Directive 2001/83/EC as amended) Label information which has become established in Member States (allowed under Article 62 of Directive 2001/83/EC as amended).

AUSTRIA (last update March 2010) www.basg.gv.at

Price
The price is not required and not wanted on the label.

Reimbursement
The reimbursement conditions are not required and not wanted on the label.

Legal status
The following are the specific requirements for the expression of the legal status in the boxed area:
• "rezept- und apothekenpflichtig" = available only on prescription and only in pharmacies; not applicable for hospital
• "apothekenpflichtig" = available only in pharmacies;
• If the supply is not restricted to pharmacies, this has to be declared appropriately.

Identification and authenticity
The EAN code is accepted on the label, but not required.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
A pictogram for medicines which cause tiredness:

"Achtung: dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen."

"Der Gruene Punkt"  or other recycling symbols are accepted on the label, but not required.

Anti doping Note: if applicable only in the PL:
"Die Anwendung des Arzneimittels [name of the product] kann bei Dopingkontrollen zu positiven Ergebnissen führen". In case of misuse of the medicinal product for doping purposes the corresponding risks should be stated.

Legal requirements for vaccines and blood products
For Blood derivates or vaccines: in order to allow traceability from patient back to biological starting material (e.g. blood donation), the Austrian legislation requires attachment of a self-adhesive label – stating the name, expiry date and batch number – to each primary package of blood derivates or vaccines for human use. "Jede Verabreichung soll mittels beigefügter Selbstklebeetikette in der Krankengeschichte oder Impfpass dokumentiert werden." ("Each application should be documented in patient history or vaccination document using the self-adhesive label attached.")

BELGIUM

Price

The following statements are required for the price on the label:

• the price for ordinary reimbursement*,

• the price to be paid by those in certain social circumstances*.

*If the reimbursement is subject to a specific authorisation, the price should be mentioned between brackets. The price is required only on products which are not restricted to hospital use.

Reimbursement

The reimbursement conditions are required on the label and can be classified in five categories which are indicated using the following letter designation: “A”, “B”, “C”, “Cx” or “Cs”, which must appear in red on a white background with a black border.

- If those medicinal products are reimbursed only when used in hospitals, the abovementioned letter designations must be followed by the letter “h”.
- If their reimbursement is subject to a specific authorisation the above-mentioned letter designations must be followed by the letter “f”.

Legal status

The major narcotic or psychotropic drugs, subject to special medical prescription, require the following labels:

- a number/code assigned by the Minister of Public Health
- a double red line which must be as large as the largest characters on the label. These double red lines must be parallel, 1-3cms apart and with an angel of 45° starting from the left lower corner to the right upper corner of the label.

Identification and authenticity

For all medicinal products, a national code (possibly presented as a bar code) is accepted on the label, but not required.

For reimbursed medicinal products (except containers with oxygen gas) a unique numerical bar code, printed in black with a white background, must appear on the label.

An irremovable sticker may be used as well. The unique numerical bar code is required only on products, which are not restricted to hospital use.

Optional information under Article 62 of Directive 2001/83/EEC: symbols or pictograms

For medicinal products intended for external application, 'external application' should be printed in black letters on a red-orange background in the three national languages: French, Dutch and German (usage externe - uitwendig gebruik - äusserliche anwendung). All packaging containing those medicinal products for external application should be delivered with a warning symbol in relief, recognisable by touch.

BULGARIA

Price

There is no requirement for the price to appear on the label.

Reimbursement

There is no requirement for the reimbursement conditions to appear on the label.

Legal Status
The requirements with respect to legal status are as follows:
− For medicinal products not subject to medical prescription, the following expression should appear:
Без лекарско предписание
− For medicinal products subject to medical prescription, the following expression should appear:
По лекарско предписание
− For medicinal products subject to restricted medical prescription, the following expression should appear:
По ограничено лекарско предписание
− For medicinal products reserved for treatments which can only be followed in a hospital environment due to limited experience or in the interests of public health, the following expression should appear:
За болнична употреба
− For pack size/sizes which is/are not intended to be delivered to a particular patient but used in a hospital environment for several patients or several treatment courses of one patient, the following expression should appear:
Болнична опаковка
− For medicinal products subject to special medical prescription, the following expression should appear:
По специално лекарско предписание, and
1. a double red line positioned diagonally on the package labels – for medicinal products containing narcotic substances,
2. a double blue line positioned diagonally on the package labels - for medicinal products containing psychotropic substances.

Identification and authenticity
The EAN code (bar code) is accepted but not required on the label.

Symbols or pictograms
Symbols for separate disposal and recycling in compliance with the Law on Waste Management are required on the outer packaging label of a medicinal product.
The labelling may include symbols or pictograms as well as other information consistent with the Summary of Product Characteristics and useful for the patient, excluding any element of advertising.

Invented name
Invented name written in Bulgarian language to appear on the outer packaging.

International nonproprietary name (INN) or common name
INN or common name written in English language to appear on the outer packaging.

CYPRUS

Price
There is no requirement for the price to appear on the label. Nevertheless, according to National Provisions, the price will be placed locally on the outer packaging (blue box) by the retailer (pharmacist).

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
A bar code is accepted on the label but not required.

CZECH REPUBLIC

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal Status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
The EAN bar codes are required on the label.

Information under Article 62 of Directive 2001/83/EC: symbols or pictograms
Recycling symbols are accepted on the label.

DENMARK

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
There is no specific requirement in respect of the legal status.

Identification and authenticity
The Nordic number is required on the outer label of all medicinal products, except radio-pharmaceuticals, certain vitamins and mineral products, homeopathic and herbal remedies. It may be written as “Vnr XX XX XX”.
A bar code is accepted on the label but not required.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Products containing inflammable material must bear the international warning symbol. Products which may reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

ESTONIA

Identification and authenticity
Code of the medicinal product is required.

FINLAND

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as "Vnr XX XX XX". A bar code is accepted on the label but not required.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Products containing inflammable material must bear the international warning symbol. Products which may reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

FRANCE

Price
The price is required only on products which are not restricted to hospital use and are reimbursable by the social security. The information on price must appear in the form of a sticker.

Reimbursement
The reimbursement conditions are required on the label. They must appear on the same sticker as the price. The sticker is coloured:
• white if the reimbursement rate is 65%
• blue if the reimbursement rate is 35%
• white with a cross through it "X" if the reimbursement rate is 100%
• white and surrounded by a green coloured line for the so called 'drug of exception' (very expensive medicinal products prescribed in specific indications)
The sticker must have "* vignette" on it and this must be on the sticker of the smallest or the single pack size. Moreover, on the sticker, it should be mentioned:
"vignette" or "vign." ; but with an "*" if the sticker is on the smallest or the single pack size of a medicinal product (i.e. "*vignette" or "*vign.").
- the bar code corresponding in particular to the administrative identification number (« code CIP » see below), the price and the reimbursement conditions of the medicinal product.

Legal status

The legal status is required to be expressed on the label for prescription-only products. The following details must appear in the blue box:

- an empty frame with:
• A red border for list I products,
• A green border for list II products,
- below this frame, written in dark characters on a red rectangular background:
• “respecter les doses prescrites“,
- then following mentions:
• «Liste I / Liste II»
• «Uniquement sur ordonnance»
• «Ne pas avaler» (if appropriate)

Below: recommended format:
List I products: red border
List II products: green border
There is no minimum size for the red border.
Respecter les doses prescrites (Red background / Dark characters)
Liste I / Liste II
Uniquement sur ordonnance
Ne pas avaler (if appropriate)

The following restrictions may apply and are required on the label:
1 - for medicinal products subject to special medical prescription:
• “stupéfiant“
• “prescription limitée à 7, 14, 28 jours“
If applicable:
• “délivrance fractionnée en (x fractions) “
2 - In addition, for medicinal products subject to restricted prescription:
a) In case of medicinal product for use only in hospital, the following must be stated:
“médicament réservé à l’usage hospitalier”
b) In case of medicinal product subject to initial prescription only in hospital, the following must be stated:
“médicament à prescription initiale hospitalière“

Identification and authenticity

- It is required that the following sentence is mentioned: “Médicament autorisé n° + code CIP“
- A bar code is accepted but not required.

In case of medicinal products derived from blood, there are specific requirements
- mention of the following statement : “Médicament dérivé du sang humain”
-follow-up called “traceability“ from the manufacturing to the administration which is mandatory in France. Consequently, 3 detachable labels should be put on the outer packaging with the following mentions:
- the name of the medicinal product
- the marketing holder or the local representative
- the batch number
- the corresponding bar code

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Products which may reduce the ability to drive or operate machines must have a warning triangle. It is an equilateral red triangle in which a black car is located on a white background. Its size is adapted to fit the label (pictogram available on Afssaps site www.afssaps.fr).

HUNGARY

Price
The price is not required and not wanted on the label.

Reimbursement
The reimbursement conditions are not required and not wanted on the label.
Legal status
The relevant legal status code is required to be expressed in the boxed area of the label.

Blue box code Applicable to
VN Medicinal product not subject to medical prescription.
V Medicinal product subject to medical prescription.
KP Medicinal product containing a substance classified as a narcotic or a psychotropic substance subject to special medical prescription written in two copies
H Medicinal product subject to special medical prescription written in two copies, likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes.
Ú Medicinal product subject to special medical prescription written in two copies, containing a substance the activity and/or adverse reactions of which, by reason of its novelty, require further investigation.
J Medicinal product subject to medical prescription, intended for outpatients after a diagnosis made by a specialist or in a hospital.
Sz Medicinal product subject to medical prescription, requiring special supervision by a specialist throughout the treatment after a diagnosis made by a specialist or in a hospital.
I Medicinal product subject to medical prescription prescribed for or delivered to those providing medical services.

Identification and authenticity
The EAN code (bar code) is accepted on the label, but not required.

GERMANY

Price
The marketing authorisation holder is not required to put the price on the label.

Reimbursement
A bar code must appear on the label. This is the Pharmazentralnummer. It is a 7 digit number, which is printed in figures and as a bar code (code 39). The reimbursement conditions are required on the label:
• “N1” for the small pack size
• “N2” for the medium pack size
• “N3” for the large pack size
• “Klinikpackung” for the hospital packsize
“der Grüne Punkt”, or other recycling symbol

The reimbursement conditions N1, N2 etc are not relevant for products sold directly to hospital units.

Legal status
The legal status is required on the label:
"Apothekenpflichtig" = to appear in the boxed area in the case of medicinal products that are not subject to medical prescription but are only available in pharmacies. (No statement in the case of products which are neither prescription only nor pharmacy only)

Identification and authenticity
In the case of active substances manufactured by genetechnological means, the active substance and the designation of the genetechnologically modified microorganism or cell lines.

GREECE

Price
The price is required on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
If any of the sub-categories appear in the decision they are to be stated on the label. Other, more specific requirements are outlined hereunder.
Specific national provisions (defined by EOF or by the Ministry of Health and Welfare in compliance with SPC requirements and concerning either medicinal products subject to special medical prescription or medicinal products subject to restricted prescription) must appear on the label.
- For instance, medicinal products subject to special medical prescription (narcotics) must have a letter/code assigned by the Ministry of Health and Welfare with special colour (red or green) according to the assigned classification.
For medicinal products classified as narcotics according to Greek Law 1729/87 as modified, the following text must appear on the label:
a. Products belonging to List B must mention in red letters "B, to be dispensed with special prescription for narcotics":
« Β,χορηγείται με ειδική συνταγή Ναρκωτικών »
b. Products belonging to the exceptions of list B must mention in green letters "ΒΣ, to be dispensed with prescription of Law 1729/87":
« ΒΣ, χορηγείται με συνταγή του Ν.1729/87»
c. Products belonging to list Γ must mention in red letters "Γ, to be dispensed with special prescription for narcotics":
«Γ, χορηγείται με ειδική συνταγή Ναρκωτικών»
d. Products belonging to the exceptions of list Γ must mention in green letters "ΓΣ, to be dispensed with prescription of Law 1729/87":
«ΓΣ, χορηγείται με συνταγή του Ν.1729/87»
e. Products belonging to list Δ must mention in green letters "Δ, to be dispensed with prescription of Law 1729/87":
«Δ, χορηγείται με συνταγή του Ν. 1729/87»
- Another instance relates to medicinal products restricted to hospital use. These products must state "only for hospital use" on the label:
«μόνο για νοσοκομειακή χρήση »

Identification and authenticity
All medicinal products must be identified by a safety coded sticker on the outer package. This sticker is issued by EOF (National Organisation for Medicines) free of charge to companies. It is produced by a special aquarelled paper; the national emblem and the name of EOF are visible only by U.V. The sticker is 27mm x 24mm and the following are typed by EOF: name of the company, production year and sticker number. The company is obliged to type the following: product name, pharmaceutical form and strength, code number (assigned by EOF and unique to the product) and the retail price.
Greek safety and authenticity requirements related to radiopharmaceuticals: the safety coded stickers which are described in the Greek requirements for the blue box (Guideline on Packaging Information for Community Authorized Products) are not implemented in radiopharmaceuticals.

IRELAND

Price
The price is not required on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
The non-prescription status of certain medicinal products, containing certain active substances, must be stated. These active substances include: acyclovir, diclofenac diethylammonium, famotidine, hydrocortisone, hydrocortisone acetate, ibuprofen, ketoprofen, naproxen, nicotine, nicotine resinate, oxethazine and piroxicam, when contained in medicinal products specifically authorised for sale without a prescription. (Other medicinal products containing any of these active substances remain subject to prescription control.)
The designation “POM” (for prescription-only medicines) is in common use and would be in the boxed area.

Identification and authenticity
Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label, but are not required.

ITALY

Price
The price is required on the label.

Reimbursement
Should a medicinal product be considered reimbursable by the National Health Service (S.S.N.), the Company should insert within the blue box a peelable sticker containing the following information, in compliance with the Decree of Ministry of Health 2 Agosto 2001:
• Bar code
• Name of the medicinal product (including strength, pharmaceutical form, units)
• National Identification Number
• Name of the Marketing Authorisation Holder
The following wording, printed in the area underneath the sticker, must appear once the latter has been removed: “Confezione dispensata dal SSN”

Legal status

The requirements in respect of the legal status are the following:

A) For medicinal products not subject to medical prescription one of the following is required:

1 “Medicinale di automedicazione” (medicinal products for self-medication)

2 “Medicinale non soggetto a prescrizione medica” (medicinal product not subject to medical prescription)

B) For medicinal products subject to medical prescription the following is required:

1 “Da vendersi dietro presentazione di ricetta medica” (prescription-only medicinal product)

C) For medicinal products subject to non renewable medical prescription the following is required:

1 “Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta”

D) For medicinal products on restricted medical prescription, the specification of the restricted authorised prescriber [hospital department(s) or specialist(s)] has to be added to the cases B1 and C1:

1 “Da vendersi dietro presentazione di ricetta medica rilasciata dallo specialista (o dal centro specializzato)” [Specialist(s) to be specified]

2 “Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta rilasciata dallo specialista (o dal centro specializzato)” [Specialist(s) to be specified]

E) For medicinal products to be used only in hospitals, the following is required:

1 “Uso riservato agli ospedali.<alle cliniche e alle case di cura [where appropriate]>Vietata la vendita al pubblico.” (Hospital use only, not to be sold to the public)(OSP 1)

2 “Uso riservato agli ospedali.<alle cliniche e alle case di cura [where appropriate]> <o in ambito extraospedaliero [where appropriate] >” (in compliance with the requirements of Determinazione 25 Luglio 2005 issued by Agenzia Italiana del Farmaco) “Vietata la vendita al pubblico” (Hospital use only, not to be sold to the public)(OSP 2)

3 “Utilizzabile esclusivamente in ambito ospedaliero da specialisti identificati [where appropriate]” (in compliance with the requirements of Determinazione 25 Luglio 2005 issued by Agenzia Italiana del Farmaco) “Vietata la vendita al pubblico” (Hospital use only, not to be sold to the public)(OSP L)

F) For medicinal products to be used only by specialist(s), the following is required:

1 “Uso riservato allo specialista. Vietata la vendita al pubblico. [Specialist(s) to be specified]”

G) For psychotropic and narcotic medicinal products falling within the scope of a specific

Italian law (D.P.R. 9 Ottobre n. 309 as amended) the following is required (in compliance with the Decree of Ministry of Health 26 Marzo 1979):

1 “Soggetto alla disciplina del DPR 309/90 Tabella II <A><B><C><D><E>” For psychotropic and narcotic medicinal products belonging to Table II, section A referred to in D.P.R. 9 Ottobre n. 309 as amended, the statement must be marked with a red double line as described below (in compliance with the Decree of Ministry of Health 26 Marzo 1979):

Soggetto alla disciplina del DPR 309/90 Tabella II A

Identification and authenticity

National Identification Number must appear on any part of the label as well as on the peelable sticker.

Particular information and statements

Statement: “Medicinale Equivalente”, in compliance with the requirements of the Italian Law 26 Luglio 2005 n 149, Art. 1 bis (for generic products only) Statement: “Controindicato l’uso contemporaneo di bevande alcoliche”, where appropriate, in compliance with the requirements of the Italian Law 30 Marzo 2001 n 125, Art.7;

Statement: “Può alterare la capacità di guidare veicoli e di usare macchinari”, where appropriate, in compliance with the requirements of the Italian Law 30 Marzo 2001 n 125, Art.7 Medicinal products for intravenous use, containing ≥ 1 mEq/ml potassium.

In the outer package: in red characters, the chemical symbol “K” followed by the statement “Diluire prima della somministrazione: mortale se infuso non diluito.”

Pictograms
Doping pictogram: in compliance with the requirements of the Decree of Ministry of Health 19 Maggio 2005 (implementing the Italian Law 14 Dicembre 2000 n 376 as amended);
pictogram size: Ø17 mm
Smile pictogram: for non prescription medicinal products in compliance with the requirements of the Decree of Ministry of Health 1 Febbraio 2002;
pictogram size: Ø17 mm

LATVIA

Price
The price is not required on the label.

Reimbursement
The reimbursement conditions are not required on the label.

Legal status
There is no specific requirement in respect of the legal status.

Identification and authenticity
The bar code is accepted on the label, but not required.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Any symbols and pictograms can be used (but it is not obligatory) on the label, if there are no elements of advertising.
For example:
Products which may reduce the ability to drive or operate machines can have a warning triangle. (A red triangle on a white background.)
Products containing inflammable material can have the international warming symbol
Product containing the active substances manufactured by genetical-tehnological means or the active substance and the designation of the genetical tehnologically modified microorganism or cell lines can have special phrases:
“Šī produkta sastāvā ir ģenētiski modificētie organismi(ĢMO)”
“Šī produkta satāvā var būt ģenētiski modificētie organismi(ĢMO)”

LITHUANIA

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
A bar code is accepted on the label but not required.

LUXEMBOURG

There are no additional requirements

MALTA

No further information is required in the blue box.

THE NETHERLANDS

Price
The price is not required on the label for medicinal products supplied without prescription.
If a medicinal product is supplied on medicinal prescription, the price should be printed on the pharmacy label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
"If a medicinal product is only available on medical prescription, the legal status is required to be expressed in the blue box area as "UR", or "U.R." or "uitsluitend recept". If supply of a medicinal product available without prescription is restricted to pharmacy, this has to be expressed in the blue box areas as "UA", "U.A." or "uitsluitend apotheek"

Identification and authenticity
Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label, but are not required.

POLAND

Price
The price is not required and not wanted on the label.

Reimbursement
The reimbursement conditions are not required and not wanted on the label.

Legal status
The following are the specific requirements for the expression of the legal status in the boxed area:
• Lek wydaje się na specjalnie oznakowaną receptę (Rp.w). = available only on special prescription (eg. narcotica)
• Lek dostępny wyłącznie w lecznictwie zamkniętym (Lz) = only for hospital use

Identification and authenticity
The EAN code is required on the label.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
The symbols and pictograms, which are recommended but are not required on the label:
• the road sign, symbol of prohibition to entry (□) – the pharmaceutical product which strongly influence the psychophysical coordination and have the information that prohibits to drive and operate the mechanical equipment for 24 hours after taking;
• the road sign, symbol of warning (□) – the pharmaceutical product when prescribed dosage or road of administration indicates that the product may impair the psychophysical coordination and necessity of special caution while driving or operating the mechanical equipment should be indicated to the patient;
• radioactivity pictogram – the pharmaceutical product which contains radionuclids

PORTUGAL

Price
The price is required on the label.
The reimbursement conditions are required on the label as a digital code.

Legal status
If applicable, the specific legal status is required to be expressed on the label as one of the following:
• "medicamento sujeito a receita médica especial" (special);
• "medicamento sujeito a receita médica não renovável" (non-renewable);
• "medicamento sujeito a receita médica renovável" (renewable);
• "medicamento de receita médica restrita" (restricted).

Identification and authenticity
A digital code, a bar code and the marketing authorisation number serve to identify the product.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
•Products for external use should state "external use" in a red boxed area on the label.

ROMANIA

Price
There is no requirement for the price to appear on the label. Nevertheless, according to national legislation, the price will be placed locally in the boxed area by the pharmacist.

Reimbursement
There is no requirement for reimbursement conditions to appear on the label.

Legal status
The legal status is required to be expressed on the label for prescription-only products. The following mentions must appear in the boxed area:
For medicinal products supplied in pharmacy based on medical prescription valid for 6 months which can be retained by the patients:
- Se eliberează pe bază de prescripţie medicală – **P-6L**
For medicinal products supplied in pharmacy based on medical prescription which is retained by the pharmacy:
- Se eliberează pe bază de prescripţie medicală – **P-RF**

For medicinal products supplied in pharmacy based on special medical prescription with raised seal (narcotics):
- Se eliberează pe bază de prescripţie medicală specială – **P-TS**
For medicinal products subject to restricted prescription:
- Se eliberează pe bază de prescripţie medicală restrictivă:
- **prescripţie întocmită de medicul specialist** (prescription by specialist doctor) – **P-RF/R**
- **numai pentru utilizare în spital** (for hospital use only) – **S**

Identification and authenticity
The bar code is accepted on the label, but not required.

Information under Article 62 of Directive 2001/83/EEC: symbols and pictograms
Medicinal products contraindicated to vehicle drivers must have a distinctive sign – an equilateral triangle with the top up, of white color, with red sides and with the length of 10 mm and the thickness of 1,5 mm, having in the center an exclamation mark of black color, triangle framed in a square of white color with the side of 15 mm.

SLOVAK REPUBLIC

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal Status
There are no additional requirements.

Identification and authenticity
The EAN code is required.

Information under Article 62 of Directive 2001/83/EC: symbols or pictograms
There is no requirement for pictograms to appear on the label.

SLOVENIA

Price
The price of medicinal product is not recommended on the label.

Reimbursement
The reimbursement conditions are not recommended on the label.

Legal status
The following requirements on the legal status for supply to the patient are to be stated in the boxed area: For medicinal products, reserved for treatments, which can only be followed in a hospital environment, the following information is required: "H - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah."
For medicinal products, reserved for treatments, which can only be followed in institutions/health care centers with adequate facilities, the following information is required": ZZ - Zdravilo se izdaja le na

recept, uporablja pa se samo v javnih zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost".
For medicinal products, reserved for treatment of conditions which must be diagnosed in a hospital environment, although administration and follow-up may be carried out elsewhere, the following information is required: "H/Rp - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah. Izjemoma se lahko uporablja pri nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju".
For medicinal products intended for outpatients, but which may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision through the treatment, the following information is required: Rp/Spec. – "Zdravilo se izdaja le na recept, uporablja pa se po navodilu in pod posebnim nadzorom zdravnika specialista ali od njega pooblaščenega zdravnika".
For medicinal products not subject to medical prescription and supplied in pharmacies only, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah."
For medicinal products not subject to medical prescription and supplied either in pharmacies or non pharmacy outlets, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah in specializiranih prodajalnah."
If there is insufficient space on the label, only abbreviations can be used (i.e. H, ZZ, H/Rp or Rp/Spec.)

Identification and authenticity
The Slovenian EAN code on the label is required.
In case of medicinal products derived from blood or plasma, there are some additional specific requirements: country of origin of blood/plasma must be stated substance and the designation of the genetically modified microorganisms or cell lines.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Δ Medicinal products which may reduce the ability to drive or operate machines must have a warning triangle (an empty triangle in the colour of the text) ▲ Medicinal products which significantly reduce the ability to drive or operate machines must have a warning triangle (a full triangle, red colour)
§ Narcotics must be marked with (§) in the colour of the text
! Limited quantity that may be dispensed at one time; the sign (!) in the colour of the text

SPAIN

Price
The price should be expressed as "PVP" and "PVP + IVA".

Reimbursement
The reimbursement conditions are shown on a perforated detachable section of the blue box which shall include:
• The abbreviation "A.S.S.S." if the product is reimbursable and the symbol " " on the left side of "A.S.S.S.", if the patient's contribution is of the 10% of the price,
• the symbol " σ " on the right side of "A.S.S.S." if the medicinal product is also one of the so-called "hospital diagnostic",
• the national product number (e.g. "C.N. 914317"),
• the bar code,
This perforated detachable section should have a black line around it for medicinal products which are subject to a special control as regards reimbursement.

Legal status
The legal status is shown on the blue box as follows:
• for products available without medical prescription, the expression “sin receta” or the abbreviation EFP, if the product can be advertised is required,
• for prescription-only products, the symbol: “ ”,
• for products on restricted medical prescription the restrictions will be expressed as follows:
– hospital use: “USO HOSPITALARIO” (H), both words and abbreviation,
– Diagnosis performed in hospital: “DIAGNOSTICO HOSPITALARIO” (DH) both words and abbreviation,
– specialist supervision: “ESPECIAL CONTROL MEDICO” with the abbreviation “ECM”, which should be placed on the right side of “ASSS” (on the perforated detachable section),
• for products available on a renewable prescription the abbreviation “TLD” is required, it should be placed on the right side of “ASSS” (on the perforated detachable section);
• for psychotropic medicinal products the symbols “ ” and “ ” are required,
• for narcotic medicinal products the symbol “ ” is required.

Identification and authenticity
A bar code is required. The national product number (e.g. “C.N. 914317”) is also required; it is a six digit number code.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
• The symbol “ ” for products which must be stored between 2-8° C.
• The symbol “ " for products which have a shelf life less than 5 years.
Hospital pack : “Envase clínico prohibida su venta al detalle”.
It is possible to use any symbol belonged to any Integrated System of Residues treatment, authorised in the country. The symbol should be added in the blue box.

SWEDEN

Price
There is no requirement for the price to appear on the label.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the label.

Legal status
There is no requirement for the legal status to appear on the label.

Identification and authenticity
A bar code is accepted on the label but not required. Nordic commodity number required (exception radiopharmaceuticals and herbal medicines). Written as Vnr XX XX XX.

UNITED KINGDOM

Price
There is no requirement for price to appear on the label.

Reimbursement
There is no requirement for reimbursement conditions to appear on the label.

Legal status
The legal status is required to be expressed in the boxed area as one of the following:
– if the medicinal product is available on prescription-only:
– if the medicinal product is available without prescription, but through registered pharmacies only:

Identification and authenticity
Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label, but are not required.

EFTA STATES

ICELAND

Price
No requirement for price on the label.

Reimbursement
No requirement for reimbursement conditions on the label.

Legal status
No requirement for legal status on the label.

Identification and authenticity
Nordic commodity number required (exception: radiopharmaceuticals and herbal medicines). Written as Vnr XX XX XX. Bar code is accepted.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms
Products which reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

NORWAY

Price
No requirement for price on the label.

Reimbursement
No requirement for reimbursement conditions on the label.

Legal status
No requirement for legal status on the label.

Identification and authenticity
Nordic commodity number required (exception: radiopharmaceuticals and herbal medicines). Written as “Vnr XX XX XX”. Bar code is accepted.

Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms

Products which reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

9.3.7. Guideline on the Readability of the Package Leaflet of Medicinal Products for Human Use Revision 1, 12 Janary 2009

Legal framework

All medicinal products placed on the Community market are required by Community law to be accompanied by labelling and package leaflet which provide a set of comprehensible information enabling the use of the medicinal product safely and appropriately.

According to Article 54, Article 55 and Article 59 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use1 (hereinafter: "**Directive 2001/83/EC**") medicinal products must be accompanied by outer and/or immediate packaging information (labelling) and a package leaflet.

Article 58 of Directive 2001/83/EC allows for the omission of a package leaflet where all the required information can be directly conveyed on the packaging.

Article 56 of Directive 2001/83/EC requires that the particulars to be included in the labelling shall be easily legible, clearly comprehensible and indelible.

Article 56a of Directive 2001/83/EC requires the name of the medicinal product (as referred to in Article 54(a)) to be expressed in Braille format on the packaging, and the marketing authorisation holder to ensure that the package leaflet is made available on request from patients' organisations in formats appropriate for the blind and partiallysighted.

Article 59(3) of Directive 2001/83/EC provides that the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.

Articles 61(1) and 8(3)(j) of Directive 2001/83/EC specify that one or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the draft package leaflet, shall be submitted to the competent authority at the time of marketing authorisation application. The results of assessments carried out in cooperation with target patient groups shall also be provided.

Article 63(1) of Directive 2001/83/EC requires that the labelling and package leaflet shall appear in the official language or languages of the Member State where the product is placed on the market. Additional languages can be included provided the information presented is the same in all languages.

Article 63(2) of Directive 2001/83/EC requires that the package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals. The package leaflet must be clearly legible in the official language or languages of the Member State(s) in which the medicinal product is placed on the market.

Purpose of this guideline

The main purpose of this document is to provide guidance on how to ensure that the information on the labelling and package leaflet is accessible to and can be understood by those who receive it, so that they can use their medicine safely and appropriately.

This guideline is written to assist applicants and marketing authorisations holders when drawing up the labelling and package leaflet and preparing the mock-ups or specimens of the sales presentations (A mock-up is a copy of the flat artwork design in full colour, presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging so that the three dimensional presentation of the labelling text is clear. This mock-up is generally referred to as a paper copy and not necessarily in the material of the sales presentation. A specimen is a sample of the actual printed out outer and immediate packaging materials and package leaflet (i.e. the sales presentation).

The guidance gives advice on the presentation of the content of the labelling and package leaflet (required in accordance with Title V of the Directive) and on the design and layout concepts which will aid the production of quality information. It includes guidance on consultations with target patient groups for the package leaflet.

The guideline also includes information on how the requirements for Braille can be met, as well as how to make the package leaflet available in formats suitable for the blind and partially-sighted patients.

Finally, the guideline includes an example of a way of undertaking a test of a package leaflet.

This guideline is published in accordance with Article 65(c) of Directive 2001/83/EC, which provides for the development of guidelines concerning the legibility of particulars on the labelling and package leaflet.

The guideline is intended to apply to all marketing authorisation procedures and to all medicinal products, including those available without prescription.

Chapter 1 Readability of the package leaflet and the labelling

SECTION A RECOMMENDATIONS FOR THE PACKAGE LEAFLET GENERAL CONSIDERATIONS

The package leaflet is intended for the patient/user. If the package leaflet is well designed and clearly worded, this maximises the number of people who can use the information, including older children and adolescents, those with poor literacy skills and those with some degree of sight loss. Companies are encouraged to seek advice from specialists in information design when devising their house style for the package leaflet to ensure that the design facilitates navigation and access to information.

The following guidance sets out recommendations on various aspects related to the preparation of package leaflets. It is aimed at helping applicants/marketing authorisation holders to fully comply with the legal requirements and is based on experience where it has been shown that using these techniques optimises the usability of the package leaflet.

Additional requirements may apply in particular Member States. Applicants should check details of those requirements in the Notice to Applicants, Volume 2A, chapter 7.

1. TYPE SIZE AND FONT

Choose a font which is easy to read. Stylised fonts which are difficult to read should not be used. It is important to choose a font in which similar letters/numbers, such as “i”, “l” and “1” can be easily distinguished from each other.

The type size should be as large as possible to aid readers. A type size of 9 points, as measured in font ‘Times New Roman’, not narrowed, with a space between lines of at least 3 mm, should be considered as a minimum. However, for marketing authorisation applications until 1 February 2011, a type size of 8 points, as measured in font ‘Times New Roman’, not narrowed, with a space between lines of at least 3 mm, should be acceptable as absolute minimum.

Consideration should be given to using different text sizes to enable key information to stand out and to facilitate navigation in the text (for example, for headings).
Consideration should be given to using larger type size where a medicinal product is especially intended for an indication linked to visual impairment (see also Chapter 2 section 6).
The widespread use of capitals should not be used. The brain recognises words in written documents by the word shape, so choose lower case text for large blocks of text.
However, capitals may be useful for emphasis.
Do not use italics and underlining as they make it more difficult for the reader to recognise the word-shape. Italics, however, may be considered when using Latin terms.

2. DESIGN AND LAYOUT OF THE INFORMATION

The use of "justified" text (that is text aligned to both left hand and right hand margins) should in principle not be used.
Line spaces should be kept clear. The space between lines is an important factor influencing the clarity of the text. As a general rule the space between one line and the next should be at least 1.5 times the space between words on a line, where practical.
Contrast between the text and the background is important. Factors like paper weight, colour of the paper, size and weight of the type, colour of the type and the paper itself should be considered. Too little contrast between the text and the background adversely affects the accessibility of the information. Therefore, background images should in principle not be placed behind the text since they may interfere with the clarity of the information making it harder to read.
A column format for the text can help the reader navigate the information. The margin between the columns should be large enough to adequately separate the text. If space is limited a vertical line to separate the text may be used. Related information should be kept together so the text flows easily from one column to the next. Consideration should be given to using a landscape layout which can be helpful to patients. Where a multilingual leaflet is proposed there should be a clear demarcation between the different languages used; all the information provided in each language should be assembled.

3. HEADINGS

Headings are important and can help patients navigate the text if used well. Therefore, bold type face for the heading or a different colour, may help make this information stand out. The spacing above and below the headings should be consistently applied throughout the leaflet. Same level headings should appear consistently (numbering, bulleting, colour, indentation, font and size) to aid the reader.
The use of multiple levels of headings should be considered carefully, as more than two levels may make it difficult for readers to find their way around the leaflet. However, where complex information has to be communicated multiple levels of headings may be needed.
Using lines to separate the different sections within the text can also be helpful as a navigational tool.
Include all main section headings covered by Article 59(1) of Directive 2001/83/EC within the leaflet.
Sub-headings and associated text within the leaflet should only be included if these are relevant for the particular medicine. For example if there is no information in relation to excipients of known effect this section may be omitted from the package leaflet.

4. PRINT COLOUR

Accessibility is not only determined by print size. Characters may be printed in one or several colours allowing them to be clearly distinguished from the background. A different type size or colour is one way of making headings or other important information clearly recognisable.
The relationship between the colours used is as important as the colours themselves. As a general rule dark text should be printed on a light background. But there may be occasions when reverse type (light

text on a dark background) could be considered to highlight for instance particular warnings. In such circumstances the quality of the print will need careful consideration and may require the use of a larger type size or bold text. Similar colours should not be used for the text and background as legibility is impaired.

5. SYNTAX

Some people may have poor reading skills, and some may have poor health literacy. Aim to use simple words of few syllables. Long sentences should not be used. It is better to use a couple of sentences rather than one longer sentence, especially for new information.

Long paragraphs can confuse readers, particularly where lists of side effects are included. The use of bullet points for such lists is considered more appropriate. Where possible, no more than five or six bullet points in a list are recommended.

When setting out the side effects it is particularly important to consider the order in which they are given so the patients/users may maximise the use of the information. In general, setting out the side effects by frequency of occurrence, starting with the highest frequency, is recommended to help communicate the level of risk to individuals.

Frequency terms should be explained in a way patients/users can understand – for example "very common" (more than 1 in 10 patients). However, where a serious side effect exists which would require the patient/user to take urgent action this should be afforded greater prominence and appear at the start of the section. Setting side effects by organ/system/class is not recommended since patients/users are in general not familiar with these classifications.

6. STYLE

When writing, an active style should be used, instead of passive. For example:

- '*take 2 tablets'* instead of *'2 tablet should be taken','*
- '*you must....'* is better than *'it is necessary ...*'

When telling patients what action to take, reasons should be provided. Instructions should come first, followed by the reasoning, for example: 'take care with X if you have asthma – it may bring on an attack'.

"Your medicine, this medicine, etc." should be used rather than repeating the name of the product, as long as the context makes clear what is being referred to.

Abbreviations and acronyms should not usually be used unless these are appropriate.

When first used in the text, the meaning should be spelled out in full. Similarly scientific symbols (e.g. > or <) are not well understood and should not be used. Medical terms should be translated into language which patients can understand. Consistency should be assured in how translations are explained by giving the lay term with a description first and the detailed medical term immediately after. On a case by case basis the most appropriate term (lay or medical) may then be used thereafter throughout the package leaflet in order to achieve a readable text. Make sure that the language used alerts the reader to all the information relevant to him/her, and gives sufficient detail on how to recognise possible side effects and understand any action which may be necessary.

7. PAPER

The paper weight chosen should be such that the paper is sufficiently thick to reduce transparency which makes reading difficult, particularly where the text size is small.

Glossy paper reflects light making the information difficult to read, so the use of uncoated paper should be considered. Make sure that when the leaflet is folded the creases do not interfere with the readability of the information.

8. USE OF SYMBOLS AND PICTOGRAMS

The legal provisions within Article 62 of Directive 2001/83/EC permit the use of images, pictograms and other graphics to aid comprehension of the information, but these exclude any element of a promotional nature. Symbols and pictograms can be useful provided the meaning of the symbol is clear and the size of the graphic makes it easily legible. They should only be used to aid navigation, clarify or highlight certain aspects of the text and should not replace the actual text. Evidence may be required to ensure that their meaning is generally understood and not misleading or confusing. If there is any doubt about the meaning of a particular pictogram it will be considered inappropriate. Particular care will be needed when symbols are transferred or used in other language versions of the leaflet and further user testing of these may be necessary.

9. ADDITIONAL INFORMATION

9.1. Product ranges

There should, in principle, be a separate leaflet for each strength and pharmaceutical form of a medicinal product. On a case-by-case basis national competent authorities or the European Commission may however agree to allow the use of combined package leaflets for different strengths and/or different pharmaceutical forms (e.g. tablets and capsules), for instance where achieving a recommended dose necessitates a combination of different strengths, or when the dose varies from day to day depending on the clinical response.(combined package leaflets for different strengths for medicines authorised through the centralised procedure, applicants may wish to consult guidance provided by the EMEA at http://www.emea.europa.eu/htms/human/qrd/qrdplt/2509002.pdf)

Simple reference to other strengths and pharmaceutical forms of the same medicine is always possible if necessary for the therapy. For instance, referring to a different strength, or referring in the package leaflet of a tablet which is unsuitable for children to the availability of an oral solution for children.

9.2. Products administered by a healthcare professional or in a hospital

For a product administered by a healthcare professional, information from the summary of product characteristics for the healthcare professional (e.g. the instructions for use) could be included at the end of the patient leaflet e.g. in a tear-off portion, to be removed prior to giving the leaflet to the patient. Alternatively the complete summary of product characteristics could be provided in the pack along with the package leaflet.

For a product administered in hospital additional package leaflets (in addition to the one provided in the pack) may be made available on request to ensure that every patient receiving the medicine has access to the information.

10. TEMPLATES FOR THE PACKAGE LEAFLET

The templates provided in all EEA languages on the EMEA Website (http://www.emea.europa.eu/htms/human/qrd/qrdtemplate.htm) reflect the particulars which must appear on the labelling and package leaflet of medicinal products according to Directive 2001/83/EC. They will help to ensure that the information appears as intended by the Directive, and to ensure consistency in the information provided across a number of different medicines and across Member States.

For the purpose of regulatory submissions to national competent authorities/EMEA, the text version of the product information is to be presented in the format and lay-out (see “QRD convention” on the EMEA Website at http://www.emea.europa.eu/htms/human/qrd/qrdplt/qrdconvention.pdf) using the electronic product information templates.

When using these templates, reference should be made to relevant Community Guidelines, QRD Guidance and the “Annotated QRD Template”, which provides detailed guidance on how to complete each section and which can be found on the EMEA Website

(http://www.emea.europa.eu/htms/human/qrd/qrdplt/AnnotatedTemplate-H.pdf) and the Heads of Agencies Website
(http://www.hma.eu/uploads/media/QRD_annotated_template_CMDh.pdf).
Having used the templates provided, marketing authorisation applicants/holders will still need to format the resulting text into the relevant full colour mock-ups or specimens of the package leaflet. Also applicants should remember that using the template does not guarantee compliance with Article 59(3) of the directive and consultations with target patient groups will still have to be carried out on the full colour mock-up or specimen of the package leaflet.

SECTION B RECOMMENDATIONS FOR THE LABELLING
GENERAL CONSIDERATIONS

Labelling covers both outer packaging and inner packaging. Although inner packaging may include a lesser set of particulars, many of the principles outlined in relation to outer packaging will apply equally to the labelling of blister packs or other small package units. Labelling ensures that the critical information necessary for the safe use of the medicine is legible, easily accessible and that users of medicines are assisted in assimilating this information so that confusion and error are minimised.
Those involved in the design of labelling should consider the following sections prior to submission to the competent authority. The recommendations given in relation to the package leaflet (section A) may be applicable to labelling and should be borne in mind in designing and laying out the required information on labels. The particulars appearing on the label of all medicinal products should be printed in characters of at least 7 points (or of a size where the lower case "x" is at least 1.4 mm in height), leaving a space between lines of at least 3 mm.
In particular the information presented on small packs will need careful consideration so that the text is presented in as large a type size as possible to reduce the likelihood of medication error.
According to Article 57 of Directive 2001/83/EC, additional labelling requirements may apply in particular Member States in respect of price, reimbursement conditions, legal status for supply and identification and authenticity. Applicants should check details of those requirements in the Notice to Applicants, Volume 2A, chapter 7.
Labelling must contain all elements required by Article 54 of Directive 2001/83/EC or a lesser set of elements where the provisions of Article 55 of the same Directive apply.
Nevertheless, of the information items listed in Article 54 of Directive 2001/83/EC, certain items are deemed critical for the safe use of the medicine. These items are:
· name of the medicine;
· strength and, where relevant, total content;
· route of administration.
Where possible these should be brought together using a sufficiently large type size on the labelling. Having these items together in the same field of view should be considered in order to aid users.

1. NAME OF THE MEDICINE
Article 54(a) of Directive 2001/83/EC sets out what is required in relation to the name of the medicinal product. The full name of the medicinal product, with its strength and its pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults, should appear on the outer packaging and on the immediate packaging to aid accurate identification of the medicinal product.
Where the medicinal product contains up to three active ingredients, the INN/common name(s) of these active ingredient(s) should be stated after the full name on the outer packaging and the immediate packaging, unless the INN/common name(s) is part of the name. The INN should be

afforded due prominence for safety reasons. Where space is at premium the shortened term for pharmaceutical form, as stated in the in the list of EDQM "Standard Terms" may be used on small immediate packaging.
For requirements concerning Braille, see Chapter 2.

2. STRENGTH AND TOTAL CONTENT
In some cases the packaging may need to contain information on both the quantity per unit volume and on the total quantity per total volume. The total quantity per total volume can be particularly important for safety reasons for injectable products and other medicines available in solution or suspension.
Different strengths of the same medicinal product should be expressed in the same manner: for example 250 mg, 500 mg, 750 mg, 1000 mg and NOT 1 g. Trailing zeros should not appear (2.5 mg and NOT 2.50 mg). The use of decimal points (or comma) should be avoided where these can be removed (i.e. 250 mg is acceptable whereas 0.25 g is not). For safety reasons it is important that micrograms is spelt out in full and not abbreviated. However, in certain instances where this poses a practical problem which cannot be solved by using a smaller type size then abbreviated forms may be used, if justified and if there are no safety concerns.

3. ROUTE OF ADMINISTRATION
This should be as registered in the summary of product characteristics (SPC) only according to the standard terms. Negative statements should not be used: for example "Not for intravenous use". In principle only standard abbreviations may be acceptable (i.v., i.m., s.c.,). In addition, a list of other, non-standard abbreviations which can be used in SPC and labelling is published on the EMEA website (http://www.emea.europa.eu/htms/human/qrd/docs/listnonstandard.pdf). Other nonstandard routes of administration should be spelled out in full. Some routes of administration will be unfamiliar to patients and may need to be explained within the package leaflet. This is particularly important when medicinal products are made available for self-medication.

4. DESIGN AND LAYOUT
Applicants and marketing authorisation holders should make best use of the space available to ensure that the important information is clearly mentioned on prime spaces on the outer and immediate packaging, presented in a sufficiently large type size. Company logos and pictograms (if accepted in accordance with Article 62) may be presented, where space permits, on the outer packaging and on immediate packaging, provided they do not interfere with the legibility of the mandatory information.
Use of a large type size will be appropriate, although other factors may also be important in making the information legible. Consideration should be given to the line-spacing and use of white space to enhance the legibility of the information provided. For some small view. The use of any innovative technique in packaging design to aid in the identification and selection of the medicinal product is encouraged. It is also encouraged where space is at a premium.
Colours should be chosen to ensure a good contrast between the text and the background to assure maximum legibility and accessibility of the information. Highly glossy, metallic or reflective packaging should be avoided, as this affects the legibility of the information.
Different colours in the name of the product are discouraged since they may negatively impact on the correct identification of the product name. The use of different colours to distinguish different strengths is strongly recommended.
Similarity in packaging which contributes to medication error can be reduced by the judicious use of colour on the pack. The number of colours used on packs will need careful consideration as too many colours could confuse. Where colour is used on the outer pack it is recommended that it is carried onto primary packaging to aid identification of the medicine.

Where a multi-lingual outer and/or immediate packaging is proposed there should be a clear demarcation between different languages where space permits.
All outer packaging must include space for the prescribed dose to be indicated and/or "blue box" 4 information as required by Member States (see section 6)

5. TEMPLATES FOR LABELLING

The templates provided in all EEA languages on the EMEA Website
http://www.emea.eu.int/htms/human/qrd/qrdtemplate.htm reflect the particulars which must appear on the labelling and package leaflet of medicinal products according to Directive 2001/83/EC. They will help to ensure that the information appears as intended by the Directive, and to ensure consistency in the information.
For the purpose of regulatory submissions to national competent authorities/EMEA, the text version of the product information is to be presented in the mandatory format and lay-out (see "QRD convention" on the EMEA Website at
http://www.emea.europa.eu/htms/human/qrd/qrdplt/qrdconvention.pdf) using the electronic product information templates.
When using these templates, reference should be made to relevant Community Guidelines, QRD Guidance and the "Annotated QRD Template", which provides detailed guidance on how to complete each section and which can be found on the EMEA Website
(http://www.emea.europa.eu/htms/human/qrd/qrdplt/AnnotatedTemplate-H.pdf) and the Heads of Agencies Website (http://www.hma.eu/uploads/media/QRD_annotated_template_CMDh.pdf).
Having used the templates provided, marketing authorisation holders will still need to format the resulting text into the relevant full colour mock-ups and specimens of the packaging.

6. OTHER INFORMATION

As foreseen by Article 57 of Directive 2001/83/EC, a Member State may ask for additional information to appear on the packaging concerning identification and authenticity of product, the legal category for supply and the price. National rules will apply in these circumstances and details on the requirements for the "blue box" in mutual recognition and decentralised procedures are given in the Notice to Applicants, Volume 2A, chapter 7. The "blue box" requirements in the centralised procedure are set out in the Notice to Applicants Volume 2C, "Guideline on the packaging information of medicinal products for human use authorised by the Community".

7. BLISTER PACK PRESENTATIONS

For blister pack presentations it is important that the particulars remain available to the user up to the point at which the last dose is removed. Often it will not be possible to apply all the information over each blister pocket, consequently where a random display of the information is proposed it should frequently appear across the pack. In all cases it will be acceptable to apply the batch number and expiry date to the end of the blister strip. If technically possible, applying this information to both ends of each strip should be considered. Where a unit-dose blister presentation is proposed all the information required for blister packs must appear on each unit dose presentation.
In addition, blister foils should be printed to ensure maximum legibility of the information using a sufficiently large font.
Colour for the text and the font style, should be chosen carefully as the legibility of the text on the foil is already impaired due to the nature of the material. Where possible, nonreflective material or coloured foils should be considered to enhance the readability of the information presented and the correct identification of the medicine.

8 SMALL CONTAINERS

Where the labelling particulars set out in article 54 of Directive 2001/83/EC cannot be applied in full to the labelling of small containers, as a minimum the particulars set out in Article 55(3) of the directive should be applied. Other information required in Article 54 may be added as appropriate, where space permits. The criteria for small container status would normally apply to containers of nominal capacity of 10ml or less. However, other factors may need to be taken into account such as the amount of information which has to be included and the font size necessary to ensure the legibility of the information. Innovative pack design is encouraged where space is at a premium (e.g. the use of wraparound or concertina labels). Paper labels are recommended to increase the legibility of the information applied to, for example, ampoules.

Chapter 2 Specific recommendations for blind and partiallysighted patients

Directive 2004/27/EC amending Directive 2001/83/EC included changes to the label and package leaflet requirements. This guidance interprets the requirements for Braille on the packaging, and the requirements for the package leaflet to be made available in formats for the blind and partially-sighted according to Article 56a.

1. LEGAL TEXT

Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 56(a)

"The name of the medicinal product, as referred to in Article 54, point (a) must also be expressed in Braille format on the packaging. The marketing authorization holder shall ensure that the package information leaflet is made available on request from patients' organisations in formats appropriate for the blind and partially-sighted."

Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 54(a)

"The name of the medicinal product, followed by its strength and pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults;

where the product contains up to three active substances, the international nonproprietary name (INN) shall be included, or, if one does not exist, the common name."

2. IMPLEMENTATION

The provision of Article 56a will apply after the end of the implementation period – 30 Oct 2005 – to all medicinal product approved after this date. It will not apply immediately to products authorized before 30 October 2005.

Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible. For specific implementation requirements reference is made to the relevant national legislation and EMEA guidance for Centrally Authorised Products.

3. BRAILLE

Braille is the internationally widespread reading and writing system for blind and partiallysighted people. The system was founded in 1825 by Louis Braille (1809 –1852), who lived in France and himself was blind. Braille is not a language, it is just another way to read and write a language.

Braille consists of arrangements of dots which make up the letters of the alphabet, numbers and punctuation marks. The basic Braille symbol is called the Braille cell.

Due to the reason that there are differences in Braille in different countries, the type of Braille letter (size of Braille cell) has to be standardized. The use of Marburg Medium is highly recommended.

The uncontracted Braille system should be used. In this system every Braille character (Braille cell) makes up the letter of the alphabet, punctuation mark, numbers, etc. The contracted Braille system

with letter-combinations should not be used, except in small volume packaging (up to 10 ml volume) – see paragraph below under “Scope”.

4. SCOPE

“The name of the medicinal product, as referred to in Article 54a” should be interpreted in a way which allows clear identification for blind people. According to the definition in
Article 1(20) of Directive 2001/83/EC as amended “the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder”, the (invented) name of the medicinal product followed by its strength should be put in Braille on the packaging of the product.
For medicinal products authorised only in a single strength, it is acceptable that only the invented name in Braille is put on the packaging.
This interpretation does not prevent companies to express further information (pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults, etc) in Braille on bigger volume packages on a voluntary basis. Also the inclusion of the expiry date in Braille would be welcome, although it is acknowledged that this may not always be feasible.
For Herbal Medicinal Products the Braille requirement will be restricted to the invented name of the Medicinal Product only. Where the name consists of the active substance(s), information could be limited to the plant name (+ plant part in those cases where several parts are available), plus the type of preparation and the strength in those cases where several strengths exist.
In case of small volume packages (up to 10 ml) with limited space capacity, alternative means of providing Braille information may be considered, eg. use of contracted Braille system or certain defined abbreviations or addition of supplementary “tab” label.
Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, eg. certain eye drop preparations.
In case of multilingual packaging, the name in Braille has to be printed in all the different languages concerned. Companies are encouraged to use the same invented name for the same medicinal product.
There is no need to put the name in Braille on the packaging of products which are only intended for administration by health care professionals, for example it is not required to put the name in Braille for vaccines.

5. PACKAGING

The name in Braille does not have to be printed on the immediate packaging - such as blisters, ampoules and bottles it only has to appear on the outer/secondary packaging, which is normally a carton. In case where there is no secondary packaging, e.g. large volume bottles (500 ml, 1000 ml, etc.), it is possible to fix an adhesive Braille label around the bottle during the manufacturing process.
On a voluntary basis companies can put the name in Braille on all packaging components.
Affixing an adhesive Braille label at the point of sale/dispensing of the medicinal product on request is not recommended, due to the risk of affixing the wrong Braille label and confusion.
Concerning the location of the Braille on the outer packaging there is no need to put the Braille dots on an empty space of the packaging, but the underlying printed text has to be easily legible.
Where Braille is present on the (outer) packaging of a medicinal product, parallel importer/parallel distributor should ensure that the same Braille text is provided in the language(s) of the member state of destination and that the original Braille text will not cause confusion.

6. PACKAGE INFORMATION LEAFLET FOR BLIND AND PARTIALLY-SIGHTED

On request from patients' organisations the package leaflet should be provided for partially-sighted people in a suitable print, taking into consideration all aspects determining the readability (eg. fontsize: Sans serif typefaces, 16 - 20 point, contrast: black letters on white paper, word spacing, text

alignment, line spacing, layout, paper quality). For blind people the text has to be provided in an appropriate format, it is recommended to provide the text in a format perceptible by hearing (CD-ROM, audiocassette, etc.). In certain cases the appropriate format may be the package leaflet available in Braille.
Choice of the appropriate medium should be made by the marketing authorisation holder in consultation with representatives of organizations for the blind and partially sighted. It is the responsibility of the marketing authorization holder to provide the package leaflet on request from patients' organizations in an appropriate format and to ensure that the current version is supplied.
These requirements concerning the package leaflet for blind and partially-sighted persons also fully apply to parallel importers/distributors.

Chapter 3 Guidance concerning consultations with target patient groups for the package leaflet

1. INTRODUCTION
According to Articles 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC new requirements apply to the package leaflet. Article 59(3) as amended requires that consultation with target patient groups ('user consultation') be carried out to demonstrate the readability and usefulness of the package leaflet to patients.
Article 59(3) reads:
"The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use."
Article 61(1) states that:
"*The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.*"
Article 63(2) states that:
"The package leaflet must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals."
In addition Article 28(2) and (3) of Directive 2001/83/EC requires that products authorised through the mutual recognition and decentralised procedures will result in a harmonised package leaflet between Member States.

2. SCOPE
For all marketing authorisations granted after 30 October 2005, all the requirements set out in Directive 2001/83/EC as amended apply. Therefore all package leaflets included in Community or national marketing authorisations have to be checked accordingly and the information about the patient consultation must be included in the application dossier.
For changes to existing marketing authorisations, the need for user consultation covers in principle situations where significant changes are made to the package leaflet, either through a variation or a procedure according to Article 61(3) of Directive 2001/83/EC.

3. FORMS OF PATIENT CONSULTATION
Articles 59(3) and 61(1) of Directive 2001/83 require that the package leaflet reflects the results of consultations with target patient groups to ensure that it is legible, clear and easy to use and that these results of assessments carried out in cooperation with target patient groups are also provided to the competent authority.
They do not define the precise method to be used. As a consequence, these provisions permit user testing as well as other appropriate forms of consultation.

3.1 User testing

One of the possible ways of complying with Article 59(3) is by performing a 'user testing' of the package leaflet. User testing means to test the readability of a specimen with a group of selected test subjects. It is a development tool which is flexible and aims to identify whether or not the information as presented, conveys the correct messages to those who read it. Testing itself does not improve the quality of the information but it will indicate where there are problem areas which should be rectified. The user testing should be part of Module 1 of the application dossier.

Care should be taken that user testing is performed on the basis of the package leaflet as it is actually supplied with the product. This will require the use of a full mock-up of the leaflet in the colours and style and on the paper as used for the leaflet in the marketed pack. In particular, in the case of multilingual package leaflets, colour, style (including type size) and paper of the language version subject to user testing should be identical to the package leaflet as supplied with the marketed pack.

3.2 Other methods

Other methods than user testing may be acceptable provided that the outcome ensures that the information is legible, clear and easy to use so that patients can locate important information within the package leaflet, understand it and enables the user to act appropriately. Such alternative methodology will have to be justified by the applicant/marketing authorisation holder and will be considered on a case-by-case basis.

4. DEMONSTRATION OF PATIENT CONSULTATIONS

In general, performing the user testing or another justified consultation method will be essential prior to granting or varying any marketing authorisation under either the centralised, mutual recognition, decentralised or national procedures.

Member States and the European Medicines Agency agreed on harmonised Quality Review of Documents (QRD) templates for the package leaflet to ensure that the statutory information appears as intended by the Directive 2001/83/EC. Compliance with the QRD templates does not exempt from the obligation to undertake a user test or other form of user consultation.

4.1 New consultation for a medicinal product

In the following situations a user consultation is always required:

· First authorisation of a medicinal product with a new active substance,
· Medicinal products which have undergone a change in legal status,
· Medicinal products with a new presentation,
· Medicinal products with particular critical safety issues.

4.2 Reference to already approved package leaflets according to Article 59(3) and Article 61(1) of Directive 2001/83/EC

The evidence from tests on similar package leaflets may be used where appropriate.

Examples of when this may be considered acceptable based on a sound justification by the applicant/marketing authorisation holder are:

• extensions for the same route of administration e.g. intravenous/intramuscular or oropharyngeal/ laryngopharyngeal,
• same safety issues identified,
• same class of medicinal product.

It may be appropriate for an applicant/marketing authorisation holder to refer to a representative sample of package leaflets for medicinal products which comply with the new legislative requirements. The types of package leaflets should be chosen carefully to be representative of one or more of the following considerations:

• recently approved package leaflets for a corresponding medicinal product,
• reflect complex issues of risk communication which may need careful handling,
• medical terminology which requires detailed explanation .

However, certain package leaflets may require further user consultation to provide reassurance that patients will benefit from the information provided. This is e.g. the case where user consultation concentrates on one particular aspect of a leaflet which may need particular patient attention, e.g. expression of risk of side effects or complex instructions how to administer the medicinal product.

Member States, in the framework of the CMD(h), have issued additional guidance in the CMD(h)/QRD document "Consultation with Target Patient Groups – meeting the requirements of Article 59(3) without the need for a full test – Recommendations for Bridging".

5. TESTING OF MULTIPLE LANGUAGE VERSIONS

The package leaflet should be legible, clear and easy to read in all EEA languages. As a matter of principle it is normally sufficient to undertake patient consultation in one EEA language. Results of such consultation should be presented in English for the centralised, decentralised and mutual recognition procedure, or in the national language for national procedures to permit the assessment of the test to be undertaken by competent authority responsible for granting the marketing authorisation.

In the centralised, decentralised and mutual recognition procedure, only the English language version of the package leaflet will be agreed during the scientific assessment.

The quality of translation should be the focus of a thorough review by the applicant/marketing authorisation holder once the original package leaflet has been properly tested and modified.

During the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way. It is important that the outcome of the user consultation is then correctly translated into the other languages. Strict literal translations from the original language may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand. Therefore, different language versions of the same package leaflet should be 'faithful' translations allowing for regional translation flexibility, whilst maintaining the same core meaning.

Following the grant of the marketing authorisation, the responsibility for the production of faithful translations will rest with the marketing authorisation holder in consultation with the Member States/European Medicines Agency.

If user consultation has been performed on a package leaflet in the old QRD template, there is no need to be retested when updating according to the new QRD template.

6. PRESENTATION OF RESULTS

The presentation of results should be summarised5 explaining how the consultation was executed and how the resulting package leaflet accommodated any need for change. The summary should be in Module 1.3.4 of the application and should have the following structure:

1. Product description
2. Consultation or test details, such as:

· Method used
· Explanation on the choice of population consulted
· Language(s) tested

3. Questionnaire (including instructions and observation forms)
4. Original and revised package leaflets
5. Summary and discussion of results (subjects' answers, problems identified and revisions made to relevant package leaflet section)
6. Conclusion

All other details should be available on demand.

7. APPROVAL BY THE COMPETENT AUTHORITY

In approving package leaflets the competent authorities will look for evidence that people who are likely to rely on the package leaflet can understand it and act appropriately. Any consultation submitted in support of a package leaflet will need to cover the following:

• Data gathered from users under defined conditions

• The people who are likely to rely on the package leaflet for a particular medicine will depend upon a number of factors and may include carers (e.g. parents, partners, friends, as well as nursing assistants) rather than patients if the medicine is generally intended for administration by someone other than the patient.

• In order to ensure that those involved can understand and apply the information, the evidence presented must demonstrate that they can pick out the relevant information, interpret this and describe the action they would take as a result.

• The key information will need to be defined prior to the consultation by the marketing authorisation holder and is likely to include significant side effects, warnings, what the medicine is for and how to take/use the product.

ANNEX - ILLUSTRATION - ONE WAY OF UNDERTAKING A TEST OF A PACKAGE LEAFLET

This information is included for illustrative purposes only and is an example of a method that could be used for consultation with target patient groups.

The method described covers one-to-one, face-to-face, structured sets of interviews, involving at least 20 participants reflecting the population for whom the medicine is intended. As indicated above, other performance-based methods are equally valid, and competent authorities will judge applications on a case by case basis.

1. PERFORMING THE TEST

Testing of package leaflets may be done by the Marketing Authorisation holder or by a company contracted to carry out such testing on its behalf. It should be carried out by an experienced interviewer with good interview, observational and listening skills.

Ideally the person writing the package leaflet should help draw out the questionnaire and occasionally accompany the interviewer during testing, to enable direct transfer of learning. In addition, it may be useful to involve patient associations or ‘expert patients’ in the design of the test.

A full colour mock-up or specimen of the package leaflet intended for the market place must be used for testing.

2. RECRUITING PARTICIPANTS

Ensure a range of different types of people who are able to imagine needing to use the medicine. People selected should be representative of the population to be treated. For most medicines this criteria will be sufficient since the leaflet information will need to be accessible to all newly diagnosed patients. However, for some medicines you will need to involve carers.

Be sure to exclude people who are directly involved with medicines such as doctors, nurses and pharmacists.

Remember that information which can be used by the least able will be beneficial for all users. Try and include:

· particular age groups such as young people and older people – especially if the medicine is particularly relevant to their age group;

· new users or people who do not normally use medicines, particularly for information provided with new medicines likely to be used by a wide range of people (e.g. analgesics or antihistamines);
· people who do not use written documents in their working life;
· people who find written information difficult.
Recruit participants from wherever is most relevant and practical. For example you could use: older people's meeting points, self-help groups, patient support groups, community centres, parent and toddler groups.

3. SUGGESTED TESTING PROCEDURE
Only small numbers of participants are needed. The aim is to meet the success criteria in a total of 20 participants (excluding the pilot test). The important thing is not to re-test participants whom you have already tested. You can achieve this by undertaking:
· a pilot of around 3-6 participants is recommended to test that the questions will work in practice; as you gain experience, you may be able to use just two or three participants in the pilot test or move straight to the main testing phase;
· during testing review the results and make any necessary amendments to the package leaflet;
· repeat tests until you have satisfactory data from a group of 10 participants;
· a final test of a further 10 to see if the success criteria are also met in this further 10 (i.e. in 20 participants in total on the final proposed package leaflet).

4. PREPARING FOR THE TEST
You are advised to:
· draw up a new protocol for each medicine;
· include questions that reflect all the important and difficult issues, and use rigorous assessment criteria;
· make sure the questions cover finding, understanding and the participants ability to act appropriately;
· include a set of expected correct answers;
· design the test to last no more than 45 minutes, to avoid tiring participants.
Ensure that the questions reflect any specific issues for safe and effective use and compliance issues related to the medicine being tested. Testing is most beneficial when the questions relate to areas where patients' fears are greatest, such as side effects. Avoiding serious safety issues with a medicine during user testing of the package leaflet is not recommended.

The interviewer should:
· reassure the participants that it is the document which is being tested not them;
· allow the participant to read the whole of the leaflet if they wish;
· use a written set of questions for reference;
· ask the questions orally;
· adopt a conversational manner, allowing ample opportunity for interaction with the participant;
· ask participants, once they have located the required information, not to read it directly from the leaflet but to put it into their own words where appropriate.
As well as recording the answers to the questions, observe how each participant handles the leaflet and searches for information, noting, for example, whether people become lost or confused. This will yield valuable information about how to improve the structure of the package leaflet.

The questions should:
· adequately cover any critical safety issues with the medicine;
· be kept to a minimum; usually 12 -15 will be enough, though more may be required in special cases, e.g. if there are significant safety issues to be investigated;

· cover a balance of general and specific issues; a general issue might be what to do if a dose is missed, while a specific issue might relate to a side effect that occurs particularly with that medicine;
· be phrased differently from the text of the leaflet to avoid participants providing answers based merely on identifying groups of words;
· appear in a random order (i.e. not in the order the information appears in the leaflet);
· cover the preparation/handling instructions for products with complex administration devices; the use of dummy containers and active demonstration by participants is encouraged.
Copies of the protocol(s) including the questions asked, the responses offered, the interviewer's written observations and the different versions of the package leaflet tested must be submitted in module m-1-3-4 of the application dossier to the competent authority for review. Information on how to present the results is set out in Chapter 3, section 6.

5. SUCCESS CRITERIA

The purpose of user testing is to achieve a legible, clear and easy to use package leaflet and as such all suggestions from the user testing should be taken into consideration or otherwise justified. Questions asked within the test should be drafted carefully in order to test properly that key messages for safe use specific to the medicine can be understood and found within the text. Drafting easy or trivial questions simply with an aim of ensuring success must not occur.
A satisfactory test outcome for the method outlined above is when the information requested within the package leaflet can be found by 90% of test participants, of whom 90% can show that they understand it. That means to have 16 out of 20 participants able to find the information and answer each question correctly and act appropriately.
However, it need not be the same 16 participants in each case. The success criteria will need to be achieved with each question. Results cannot be aggregated. If you use a different performance based method, different success criteria may be appropriate. Competent authorities will consider these on a case-by-case basis.

9.3.8. Guidance concerning the Braille Requirements for Labelling and the Package Leaflet ENTR/F2 D(2005 (Article 56a of Directive 2001/83/EC as amended)

Directive 2004/27/EC – amending Directive 2001/83/EC - includes changes to the label and package leaflet requirements. This guidance interprets the requirements for Braille on the packaging, and the requirements for the package leaflet to be made available in formats for the blind and partially sighted according to Article 56a.

Legal text:
Directive 2001/83/EC as amended by Directive 2004/27/EC, Article 56 a The name of the medicinal product, as referred to in Article 54 a must also be expressed in Braille format on the packaging.
The marketing authorization holder shall ensure that the package information leaflet is made available on request from patients organisations in formats appropriate for the blind and partially-sighted. Directive 2001/83/EC as amended by Directive 2004/27/EC, Article54 a. The name of the medicinal product, followed by its strength and pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults; where the product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name.

Implementation
The provision of Article 56a will apply after the end of the implementation period – 30 Oct 2005 – to all medicinal product approved after this date. It will not apply immediately to products authorized before 30 October 2005. Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible. For specific implementation requirements reference is made to the relevant national legislation and EMEA guidance for Centrally Authorised Products.

Braille
Braille is the internationally widespread reading and writing system for blind and partially sighted people. The system was founded in 1825 by Louis Braille (1809 – 1852), who lived in France and himself was blind. Braille is not a language, it is just another way to read and write a language. Braille consists of arrangements of dots which make up the letters of the alphabet, numbers and punctuation marks. The basic Braille symbol is called the Braille cell. Due to the reason that there are differences in Braille in different countries, the type of Braille letter (size of Braille cell) has to be standardized. The use of Marburg Medium is highly recommended The uncontracted Braille system should be used. In this system every Braille character (Braille cell) makes up the letter of the alphabet, punctuation mark, numbers, etc. The contracted Braille system with letter-combinations should not be used, except in small volume packaging (up to 10 ml volume) – see paragraph below under “Scope”.

Scope
“The name of the medicinal product, as referred to in Article 54a” should be interpreted in a way which allows clear identification for blind people. According to the definition in Article 1.20 of Directive 2001/83/EC as amended “the name, which may be either an invented name not liable to confusion with the common name, or a common or scientific name accompanied by a trade mark or the name of the marketing authorization holder”, the (invented) name of the medicinal product followed by its strength should be put in Braille on the packaging of the product.
For medicinal products authorised only in a single strength, it is acceptable that only the invented name in Braille is put on the packaging. This interpretation does not prevent companies to express

further information (pharmaceutical form, and if appropriate, whether it is intended for babies, children or adults, etc) in Braille on bigger volume packages on a voluntary basis. Also the inclusion of the expiry date in Braille would be welcome, although it is acknowledged that this may not always be feasible. For Herbal Medicinal Products the Braille requirement will be restricted to the invented name of the Medicinal Product only. Where the name consists of the active substance(s), information could be limited to the plant name (+ plant part in those cases where several parts are available), plus the type of preparation and the strength in those cases where several strengths exist.
In case of small volume packages (up to 10 ml) with limited space capacity, alternative means of providing Braille information may be considered, eg. use of contracted Braille system or certain defined abbreviations or addition of supplementary "tab" label. Particular consideration should be given to medicinal products likely to be used by a high visually impaired target population, eg. certain eye drop preparations. In case of multilingual packaging, the name in Braille has to be printed in all the different languages concerned. Companies are encouraged to use the same invented name for the same medicinal product. There is no need to put the name in Braille on the packaging of products which are only intended for administration by health care professionals, for example it is not required to put the name in Braille for vaccines.

Packaging
The name in Braille does not have to be printed on the immediate packaging - such as blisters, ampoules and bottles, it only has to appear on the outer/secondary packaging, which is normally a carton. In case where there is no secondary packaging, eg. Large volume bottles (500 ml, 1000 ml, etc.), it is possible to fix an adhesive Braille label around the bottle during the manufacturing process.
On a volunteer basis companies can put the name in Braille on all packaging components. Affixing an adhesive Braille label at the point of sale/dispensing of the medicinal product on request is not recommended, due to the risk of affixing the wrong Braille label and confusion. Concerning the location of the Braille on the outer packaging there is no need to put the Braille dots on an empty space of the packaging, but the underlying printed text has to be easily legible. Where Braille is present on the (outer) packaging of a medicinal product, parallel importer/parallel distributor should ensure that the same Braille text is provided in the language(s) of the member state of destination and that the original Braille text will not cause confusion.

Package information leaflet for blind and partially sighted
On request the package leaflet should be provided for partially sighted people in a suitable print, taking into consideration all aspects determining the readability (eg. Fontsize: Sans serif typefaces, 16 - 20 point, contrast: black letters on white paper, word spacing, text alignment, line spacing, layout, paper quality). For blind people the text has to be provided in an appropriate format, it is recommended to provide the text in a format perceptible by hearing (CD-ROM, audiocassette, etc.). In certain cases the appropriate format may be the package leaflet available in Braille. Choice of the appropriate medium should be made by the MAH in consultation with representatives of organizations for the blind and partially sighted. It is the responsibility of the marketing authorization holder to provide the package leaflet on request from patient organizations in an appropriate format and to ensure that the current version is supplied. This provision of Article 56a will apply after the end of the implementation period – 30 October 2005 – to all medicinal product marketing authorization applications approved after this date. It will not apply immediately to products authorized before 30 October 2005. Nevertheless companies are encouraged to apply the provision to all medicinal products as soon as possible. For specific implementation requirements reference is made to the relevant national legislation and EMEA guidance for Centrally Authorised Products. These requirements concerning the package leaflet for blind and partially sighted persons also fully apply to parallel importers/ distributors.

9.3.9. Operational Procedure on Handling of "Consultation with Target Patient Groups" on Package Leaflets (PL) for Centrally Authorised Products for Human Use Doc. Ref. EMEA/277378/2005

1. Introduction

Articles 59(3) and 61(1) of Directive 2001/83, as amended, require that the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use and that the results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

The articles do not define the precise method to be used. As a consequence, these provisions permit 'user testing' as well as other appropriate forms of consultation.

This is addressed in the draft EU guidance document published on the website of the European Commission for consultation:

(http://pharmacos.eudra.org/F2/pharmacos/docs/Doc2005/08_05/USERTESTING_20050817.pdf).

To guide applicants/MAH as to how 'consultation with target patient groups' will be handled and reviewed in the centralised procedure, some practical/operational issues are addressed below.

This guidance applies to centralised procedure applications concerning new medicinal products for human use, as of 20 November 2005. For ongoing applications, which are before day 120 on 20 November 2005, the required information needs to be provided by Day 121. For all other ongoing applications for which a marketing authorisation will be granted as of 20 November 2005, submission and review of the required information needs to be discussed with the EMEA on a case-by-case basis.

Where significant changes are made to the package leaflet of authorised medicinal products, 'user consultation' should be considered on a case-by-case basis.

2. Submission and assessment of information on 'target patient group (user) consultation'

Pre-Submission

During the pre-submission phase the applicant may discuss how to address 'user consultation' with EMEA and (Co-) Rapporteur, if necessary. This discussion may indicate whether new 'user consultation' would be necessary or whether a justification for its absence or 'focused' user testing could be acceptable.

DAY 1-120

At the time of the submission of the application the issue of 'user consultation' should be addressed in Module 1.3.4. In the Day 80 Assessment Reports (AR) sent to the CHMP members and to the applicant a comment shall be included on whether 'user consultation' of the PL has been performed or is foreseen, or whether the justification for its absence or 'focused' user testing is acceptable.

In case a 'user consultation' of the PL has been performed and is included in the application, the (Co-) Rapporteur will include the assessment of the results of 'user consultation' in their Day 80 Assessment Reports (AR), as well as a conclusion on the overall readability of the PL and outline possible deficiencies. By Day 100 CHMP members should also review the Rapporteur's position on the requirement for 'user consultation' and his/her assessment of the 'user consultation' results experts for the assessment of the 'user consultation' information and PL readability.

DAY 120-121

Within the clock-stop time, the applicant may undertake initial or further ‘user consultation’ to take account of questions on the ‘user consultation’ performed or on the readability of the package leaflet included in the CHMP List of Questions (LoQ).

DAY 121-150

If not included in the initial submission the results of ‘user consultation’ or any further clarification, as requested, will be submitted as part of the answers to the LoQ at Day 121.

In the Day 150 Joint AR the (Co-)Rapporteur will include the assessment of the results of ‘user consultation’ or of any further clarification submitted, as well as a conclusion on the overall readability of the PL and forward it to the applicant and to the CHMP members.

Module 1.3.4 ‘user consultation’ results and the (Co-)Rapporteur’s assessment of the results and the PL readability will also be forwarded to the QRD Group, as useful information when reviewing the draft product information around Day 160.

DAY 180

By Day 180 CHMP may identify outstanding issues, which may include remarks on the PL and ‘user consultation’ carried out.

9.3.10. Guidance concerning consultations with target patient groups for the package leaflet

May 2006, Article 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC

1. INTRODUCTION

According to Articles 59(3) and 61(1) of Directive 2001/83/EC as amended by Directive 2004/27/EC new requirements apply to the package leaflet. Article 59(3) as amended requires that consultation with target patient groups ('user consultation') be carried out to demonstrate the readability and usefulness of the package leaflet to patients.

Article 59(3) reads:

"The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use."

Article 61(1) states that

"*The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.*"

Article 63(2) states that:

"The package leaflet must be written and designed to be clear and understandable, enabling the user to act appropriately"

In addition Article 28(2) and (3) of Directive 2001/83/EC requires that products authorised through the mutual recognition and decentralised procedures will result in a harmonised package leaflet between Member States.

2. SCOPE

For all marketing authorisations granted after 30 October 2005, all the requirements set out in Directive 2001/83/EC as amended apply. Therefore all package leaflets included in Community or national marketing authorisations have to be checked accordingly and the information about the patient consultation must be included in the application dossier. Further guidance is given in section 8 of this guideline.

For changes to existing marketing authorisations, the need for user consultation covers in principle situations where significant changes are made to the package leaflet, either through a variation or a procedure according to Article 61(3) of Directive 2001/83/EC.

3. FORMS OF PATIENTS CONSULTATION

Articles 59(3) and 61(1) of Directive 2001/83 require that the package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use and that these results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.

They do not define the precise method to be used. As a consequence, these provisions permit user testing as well as other appropriate forms of consultation.

3.1 User Testing

One of the possible ways of complying with the new legal requirement is by performing a 'user testing' of the package leaflet.

User testing means to test the readability of a specimen with a group of selected test subjects. It is a development tool which is flexible and aims to identify whether or not the information as presented, conveys the correct messages to those who read it. Testing itself does not improve the quality of the

information but it will indicate where there are problem areas which should be rectified. The user testing should be part of Module 1 of the application dossier.

3.2 Other methods

Other methods than user testing may be acceptable provided that the outcome ensures that the information is legible, clear and easy to use so that patients can locate important information within the package leaflet, understand it and enables the user to act appropriately. Such alternative methodology will have to be justified by the applicant/marketing authorisation holder and will be considered on a case-by-case basis.

4. DEMONSTRATION OF PATIENTS CONSULTATION

In general, performing the user testing or another justified consultation method will be essential prior to granting or varying any marketing authorisation under either the centralised, mutual recognition, decentralised or national procedures.

Member States and the European Medicines Agency agreed on harmonised Quality Review of Documents (QRD) templates for the package leaflet to ensure that the statutory information appears as intended by the Directive 2001/83/EC as amended. Compliance with the QRD templates does not exempt from the obligation to undertake a user test or other form of user consultation.

a) New consultation for a medicinal product

In the following situations a user consultation is always required: First authorisation of a medicinal product with a new active substance,

• Medicinal products which have undergone a change in legal status,
• Medicinal products with a new presentation,
• Medicinal products with particular critical safety issues.

b) Reference to already approved package leaflets according to Article 59(3) and Article 61(1) of Directive 2001/83/EC

The evidence from tests on similar package leaflets may be used where appropriate. Examples of when this may be considered acceptable based on a sound justification by the applicant/marketing authorisation holder are:

• extensions for the same route of administration e.g. intravenous/intramuscular or oropharyngeal/ laryngopharyngea,
• same safety issues identified,
• same class of medicinal product.

It may be appropriate for an applicant/marketing authorisation holder to refer to a representative sample of package leaflets for medicinal products which comply with the new legislative requirements. The types of package leaflets should be chosen carefully to be representative of one or more of the following considerations:

• recently approved package leaflets for a corresponding medicinal product,
• reflect complex issues of risk communication which may need careful handling,
• medical terminology which requires detailed explanation .

However, certain package leaflets may require further user consultation to provide reassurance that patients will benefit from the information provided. This is e.g. the case where user consultation concentrates on one particular aspect of a leaflet which may need particular patient attention, e.g. expression of risk of side effects or complex instructions how to administer the medicinal product.

5. TESTING OF MULTIPLE LANGUAGE VERSIONS

The package leaflet should be legible, clear and easy to read in all EEA languages. As a matter of principle it is normally sufficient to undertake patient consultation in one EEA language. Results of such consultation should be presented in English for the centralised, decentralised and mutual recognition procedure, or in the national language for national procedures to permit the assessment of the test to be undertaken by competent authority responsible for granting the marketing authorisation.

In the centralised, decentralised and mutual recognition procedure, only the English language version of the package leaflet will be agreed during the scientific assessment.

The quality of translation should be the focus of a thorough review by the applicant/marketing authorisation holder once the original package leaflet has been properly tested and modified. During the drafting of the original package leaflet every effort should be made to ensure that the package leaflet can be translated from the original to the various national languages in a clear and understandable way. It is important that the outcome of the user consultation is then correctly translated into the other languages. Strict literal translations from the original language may lead to package leaflets which contain unnatural phrases resulting in a package leaflet which is difficult for patients to understand. Therefore, different language versions of the same package leaflet should be 'faithful' translations allowing for regional translation flexibility, whilst maintaining the same core meaning.

Following the grant of the marketing authorisation, the responsibility for the production of faithful translations will rest with the marketing authorisation holder in consultation with the Member States/European Medicines Agency.

If user consultation has been performed on a package leaflet in the old QRD template, there is no need to be retested when updating according to the new QRD template.

6. PRESENTATION OF RESULTS

The presentation of results should be shortened to a summary explaining how the consultation was executed and how the resulting package leaflet accommodated any need for change. The summary should be in Module 1.3.4 of the application and should have the following structure:

1. Product description
2. Consultation or test details, such as:

· Method used

· Explanation on the choice of population consulted

· Language(s) tested

3. Questionnaire (including instructions and observation forms)
4. Original and revised package leaflets
5. Summary and discussion of results (subjects' answers, problems identified and revisions made to relevant package leaflet section)
6. Conclusion

All other details should be available on demand.

The report and the results of the consultation should be presented in English for the centralised, decentralised and mutual recognition procedure or in the national language for national procedures.

7. APPROVAL BY THE COMPETENT AUTHORITY

In approving package leaflets the competent authorities will look for evidence that people who are likely to rely on the package leaflet can understand it and act appropriately. Any consultation submitted in support of a package leaflet will need to cover the following:

• Data gathered from users under defined conditions

• The people who are likely to rely on the package leaflet for a particular medicine will depend upon a number of factors and may include carers (e.g. parents, partners, friends, as well as nursing assistants)

rather than patients if the medicine is generally intended for administration by someone other than the patient.

• In order to ensure that those involved can understand and apply the information, the evidence presented must demonstrate that they can pick out the relevant information, interpret this and describe the action they would take as a result.

• The key information will need to be defined prior to the consultation by the marketing authorisation holder and is likely to include significant side effects, warnings, what the medicine is for and how to take/use the product.

8. OTHER ISSUES FOR CONSIDERATION

The Member States or the European Medicines Agency will have considered other aspects in relation to consultation or user testing and usability of package leaflets and additional guidance is available or under development concerning:

• Timing of user consultation, submission and assessment within the evaluation procedure;

• Guidance in relation to usability and presentation of information;

• Guidance on how user testing should be carried out and what alternative methods are acceptable.

9.3.11. Procedure for Review of Information on Medicinal Products by patients´and Consumers´Organisations EMA/174255/2010 Rev. 2

Introduction

The European Medicines Agency (EMA) is responsible for providing information about medicines authorised via the centralised procedure which includes information directed to the patient and the public. During the preparation of this information, the Agency interacts with patients' and consumers' organisations to ensure that it is adequately formulated and comprehensible to the target audience.
The package leaflet (PL) is supplied to the patient in the package in which the medicinal product is contained, and provides information related to the use of the medicine.
The EPAR summary is a lay-language document, available on the EMA website, which contains general information about the medicine. It also provides a summary of the grounds on which the EMA based its recommendation for the medicine to receive a marketing authorisation.
These documents are initially prepared during the course of the procedure for evaluating the marketing-authorisation application for a medicine; they follow specific deadlines and are confidential during the evaluation. The review procedure described herein also includes the review of PLs at the time of their renewal.
Safety communications refer to documents which are specifically addressed to the public once a medicinal product has been authorised and which conveys an important (emerging) message relating to the product. For example, informing patients when a product is withdrawn or suspended from the market for safety reasons, has a new contraindication or warning, or where there is a product defect or supply shortage.
As expressed in the 'Framework on the Interaction between the EMA and Patients' and Consumers' Organisations' (EMEA/354515/2005) the EMA should ensure adequate consultation with patients' and consumers' organisations (PCOs) so that the information provided by the Agency fulfils patients' and the general public's expectations.
This document describes the procedures for involving PCOs during the EMA review of PLs and EPAR summaries and in the preparation and dissemination of Agency safety communications. These procedures are managed by the EMA Medical Information Sector (MIS) as part of its responsibilities for interacting with PCOs.

Background

Articles 78(1) and 78(2) of Council Regulation (EC) No 726/2004 provide a mandate for the EMA to develop interaction with PCOs:
1. *"The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission."*
2. *"The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article, shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an*

advisory basis, establish contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned."

The EMA/CHMP Working Group with Patients Organisations (forerunner of the Patients' and Consumers' Working Party) recommended that feedback be sought from patients on the readability of information contained in package leaflets, public statements and similar materials intended for the public.

Proposed scope of interaction

The purpose of the consultation between the EMA and PCOs on these documents is not to rewrite them but to ensure that the information is clear and understandable by the target audience, and that it fulfils their needs in terms of information content.
The consultation of PCOs on safety communications includes several different types of important material to be addressed to the public, such as question-and-answer documents relating to emerging safety information, withdrawal or suspension of a product from the market for safety reasons, shortage in supply or new contraindications or warnings. PCOs will also systematically be involved in the preparation of communications when they have previously been involved in the benefit/risk evaluation of the product.

Procedural principles for the interaction

Organisations and experts to be involved

Any organisation that is consulted must fulfil the 'Criteria to be fulfilled by Patients' and Consumers' Organisations' (EMA/14610/04/Final) and be listed in the EMA's approved list of eligible organisations (See: http://www.ema.europa.eu/Patients/organisations.htm).
The 'Rules of involvement of member(s) of Patients' and/or Consumers' Organisations in Committees related activities' (EMA/161660/2005) will apply. Since patients will act as experts in these procedures, they will have to adhere to the same rules as all other experts participating in EMA activities, especially with regard to confidentiality undertaking and the EMA Code of Conduct.

Since the documents to be reviewed are in English, experts should be fluent in English. In addition, they should have access to appropriate information-technology equipment and to the Internet.
With regards to the participation in the preparation and dissemination of safety communications, the experts involved should also have a good understanding of the specific therapeutic area in question.

Identification of a list of experts

Every organisation fulfilling the criteria for involvement in EMA activities will be invited to designate experts for participation. After consideration, the EMA can nominate them as EMA experts and they will be included in the Agency's European expert database. Thereafter additional experts may be proposed and nominated whenever necessary.
As far as possible, for consistency and efficiency reasons, each organisation should nominate one of their members as a coordinator. This coordinator will be the initial reference contact point between the EMA and the organisation and will have the responsibility of ensuring that experts from their organisation adhere to the above-mentioned rules, in particular with regard to confidentiality undertakings and declarations of interests.

The EMA will prepare a list of nominated PCO experts, identifying the coordinator for each organisation, as well as the area of expertise of each expert, if relevant.
This list will be updated according to organisations' proposals, as necessary.

Consultation process

For each document to be produced, the EMA will consult an organisation(s) that specialises in the therapeutic area of the product, from the above-mentioned list. If there is no specialised organisation available, a general organisation will be consulted. If there is more than one organisation having expertise in the field, the EMA will select which organisation(s) to consult. Experts who have participated in specific training organised by the EMA will have preference.
The EMA will send the request for review to the coordinator.
When providing comments to the EMA, the coordinator should identify the expert(s) having participated to the review.
The EMA will organise only one round of consultation and will ensure processing of the comments as part of EMA procedures. The final version will be circulated for information to the organisation having participated.
The EMA will monitor the PCOs' input in these reviews and will provide regular feedback to the Patients' and Consumers' Organisations Working Party (PCWP).

Training

All nominated experts will be invited to attend training sessions at the EMA, currently held on an annual basis, to introduce the procedure. Preference for attending the training sessions will be given to those recently added to the list of experts. Outside of the training sessions, all training material will be provided to new experts.

Confidentiality

All documents subject for review and covered in this procedure are confidential (i.e. PLs, EPAR summaries and safety communication material) until they are made public. All experts must have signed confidentiality undertaking at the time of being involved in the review.

Implementation

The specific procedures for each type of review mentioned above are annexed hereafter.

Annex I

Procedure for review of PL

Package Leaflet

The Package Leaflet (PL) is part of the product information that is approved at the time of marketing authorisation by the regulatory authority. It is initially prepared by the applicant (pharmaceutical company), when requesting a marketing authorisation. The PL is prepared in accordance with legal requirements, as well as with EMA templates and guidance.
For centrally authorised medicines, the EMA reviews the PL proposed by the company at the time of initial evaluation for marketing authorisation and after the commercialisation of the product. During

EMA reviews, scientific and linguistic amendments are proposed by assessors, and the quality and content of the PL are deeply scrutinised prior to finalisation of the product information by the EMA's relevant scientific committee; the Committee for Medicinal Products for Human Use (CHMP).

Initial marketing-authorisation procedure

The EMA is responsible for the centralised procedure. This procedure results in a single marketing authorisation that is valid across the European Union, as well as in Iceland, Liechtenstein and Norway. The marketing-authorisation applicant (pharmaceutical company) will submit a consolidated dossier on the medicine to be authorised, including a proposal for the English version of the PL. This dossier is evaluated by the Agency's relevant scientific committee (CHMP) within 210 days, at the end of which the committee adopts an opinion on whether the medicine should be marketed or not. This opinion is then transmitted to the European Commission, which issues a formal decision on the authorisation of the product.
In parallel to the scientific assessment, the EMA and its Quality Review of Documents (QRD) group perform a linguistic review of the English version of the PL between Days 121-165 of the assessment procedure (before the CHMP gives a final opinion).
Upon receipt from the company of an EN PL at Day 121, the EMA forwards it to all QRD members for comments (via written procedure) within 15 days. The consolidated comments are sent to the company by Day 157 for implementation. The procedure foresees the possibility of a meeting at the EMA around Day 165 (EMA QRD sub-group meeting) with EMA, QRD representatives, with the participation of company representatives, if necessary.

Renewal procedure

A Community marketing authorisation is initially valid for five years and may be renewed after this period on the basis of a re-evaluation of the risk-benefit balance by the CHMP. To this end, the marketing-authorisation holder (pharmaceutical company) will submit a consolidated dossier on the medicine, including a revised proposal for PL. This dossier must be assessed within 90 to 120 days by the CHMP before the marketing authorisation expires. This procedure is called the 'renewal procedure'.
In parallel to the scientific assessment, the EMA and its QRD group perform a linguistic review of the English version of the product information. Linguistic comments are consolidated and sent to the pharmaceutical company by Day 75 of the procedure.

PCO experts review

The purpose of the consultation and interaction between the EMA and PCOs is not to rewrite the document, but to confirm that the information is clear and understandable by the target audience, and that it fulfils the public's needs in terms of information content. It is acknowledged that the PL of every medicine undergoes a readability testing by target patient groups during the evaluation procedure (Articles 59(3) and 61(1) of Council Directive 2001/83/EC, as amended by Directive 2004/27/EC). The current procedure does not intend to be a repetition of it. Specific comments are recommended rather than general ones.

Review of PLs at the time of initial evaluation for marketing authorisation

PCOs experts perform the review in parallel to QRD members; thereafter the comments will be compiled for both groups (QRD members and PCO experts) simultaneously and sent to the company.

At the request of the EMA, and depending on the comments received and the issues to be discussed, PCO experts may be invited to participate in an EMA QRD sub-group meeting.
The documentation will be exchanged by e-mail (via a secure system called Eudralink), and comments should be made clear by using track changes mode (without modifying the original text).

The procedure for evaluating new PLs is as follows:

. Start of the evaluation procedure.
. EMA Medical Information Sector (MIS) will contact the coordinator(s) of the selected organisation(s) requesting availability for the review of a specific PL giving a response deadline of 5 days.
. Once an organisation has responded, MIS will provide the PL for review.
. The coordinator will organise the review and send back comments to MIS within 10 days after receipt of the document.
. QRD will validate comments and transmit them to the applicant, without naming the organisation.
. PCO experts will be informed if their participation is requested at an EMA QRD sub-group meeting.
. The CHMP will adopt the PL as part of its opinion.
. The final PL will be sent to the coordinator of the reviewing organisation for information.

Review of PLs at the time of the renewal of a marketing authorisation

The procedure for evaluating renewal PLs is the same as for new applications (above), apart from the overall application timeline (days) which are shorter, but which does not affect the review time for the PL.

Annex II

Procedure for review of EPAR summary

EPAR summary
When a marketing authorisation is granted for a medicine, the EMA publishes a European public assessment report (EPAR). The EPAR provides a comprehensive summary of available data on the quality, safety and efficacy of the product, justifying its marketing authorisation. The EPAR also includes a summary written in a manner that is understandable to the public.
The EPAR and the EPAR summary have to be prepared within 70 days of a CHMP positive opinion being adopted, to be available at the time of the marketing authorisation.
The first draft of the EPAR summary is prepared by the EMA, within the Medical Information Sector (MIS), immediately after the CHMP opinion. According to the internal procedure for the preparation of EPAR summaries, the first draft prepared by the Medical Information Sector is sent for consultation first to CHMP and EMA project managers (10 days), and then to the applicant (5 days). The EPAR summary is finalised within about one month, and has to be adopted by the CHMP as part of the full EPAR. Finally, the EPAR summary has to be translated into all official EU languages before publication.

PCO experts review
The purpose of the consultation and interaction between EMA and PCOs is not to rewrite the document, but to ensure that the information is clear and understandable by the target audience, and that it fulfils their needs in terms of information content.

PCOs will be consulted at the same time as the CHMP Rapporteur/Co-Rapporteur and EMA project managers, i.e. the 10-day consultation that takes place following the CHMP opinion.
The documentation will be exchanged by e-mail (via a secure system called Eudralink), and comments should be made clear by using track changes mode (without modifying the original text).

The procedure is as follows:

. Following an adopted opinion, the MIS will prepare a draft EPAR summary.
. The MIS will provide the draft EPAR Summary to be reviewed to the coordinator of the selected organisation.
. The coordinator will organise the review and send back comments within 10 days after receipt of the document.
. The MIS will implement the comments together with those received from other parties.
. The final EPAR summary, together with some general feedback, will be sent to the coordinator of the reviewing organisation for information.

Annex III

Procedure for review of safety communications

Communication tools
The Agency uses several different tools to communicate with the public, such as European Public Assessments Reports, press releases, question-and-answer documents (Q&A), summaries of opinion, monthly reports and public statements. For "safety announcements" the methods used tend to be Q&As and press releases.
Press releases are stand-alone documents which are essentially prepared by the Agency's press office and are intended for the media to help them prepare news stories.
Q&As are prepared by the Medical Information Sector (MIS), in collaboration with internal and external expertise and are written for the general public, including patients. They concern authorised medicinal products and tend to relate to major safety issues: withdrawal or suspension of a product from the market, shortage in supply or new contraindications or warnings, restriction of use or product defect for safety reasons.
Preparation of these communications (especially risk-based) implies short timelines with limited predictability but at the same time need to take into account views of many stakeholders. The procedure involves multiple stages of review and input from internal and external experts and once finalised they are published on the Agency website (as PDF files). The final version may differ substantially from the initial draft reviewed.
The selected expert(s) may discuss the document with other experts within their organisation, however all experts consulted must have signed the confidentiality undertaking in advance.
It is not initially proposed to include the review of withdrawals or refusals of applications unless patients or consumers have been involved within the medicine's benefit/risk evaluation (during evaluation).

PCO experts review
The purpose of the consultation and interaction between EMA and PCOs on safety communications is to ensure that the message to be conveyed is clear and comprehensible to its targeted audience and fulfils its needs in terms of information content.
PCOs will be consulted at the same time as the CHMP Rapporteur/Co-Rapporteur and EMA experts, the documentation will be exchanged by e-mail (secure system - Eudralink), and comments should be clearly defined using track changes mode (without modifying the original text).

The procedure is as follows:

. As soon as MIS is aware of an upcoming safety communication, they will contact the coordinator(s) of the selected organisation(s) requesting availability for the review of the document, indicating the nature of the communication and, when possible, the expected timelines.

. As soon as a draft document is available it will be forwarded to the selected expert(s), usually giving 12-24 hours to provide comments on the text, however in some urgent cases only 3-4 hours may be available for consultation.

The expert(s) are welcome to contact the EMA MIS for further discussion or clarification on the specific issues and in some cases, particularly when timelines are tight, comments may be given via telephone.

The coordinator of the relevant organisation(s) will receive a link to the final document at the time of publication and is responsible for disseminating it within the organisation and to any other interested parties - no confidentiality applies at this stage, as the document is published on the EMA website.