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## **NOTICE TO APPLICANTS**

# **GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED BY THE COMMUNITY**

**March 2005**

**This guideline is part of the Notice to Applicants Volume 2C - Medicinal Products for Human Use - Regulatory Guidelines of The Rules governing Medicinal Products in the European Community**

# 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 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 be approved 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 sub-categories 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 toll-free number is given which is not accessible from abroad, 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 allowed, 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**

##### 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 Grüne Punkt” or other recycling symbols are accepted on the label, but not required.

## 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 above-mentioned 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 angle 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.

## 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 radiopharmaceuticals, 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:



## **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“

The duration of the prescription is specified (e.g. 3 or 6 months or one year).

c) In case of “medicinal product subject to special supervision throughout the treatment“ the following must be stated:

“médicament nécessitant une surveillance particulière pendant le traitement“

Moreover, in all the three above mentioned cases (a,b,c), the prescription could be reserved for use in certain specialized areas or for prescription by some specialists, the following must be stated:

- “médicament réservé à l’usage hospitalier; prescription réservée aux spécialistes et/ou aux services spécialisés en...”
- “médicament réservé à l’usage hospitalier; prescription réservée aux spécialistes en ...”
- “médicament à prescription initiale hospitalière réservée aux spécialistes et/ou services spécialisés en...”
- “médicament à prescription initiale hospitalière réservée aux spécialistes en...”
- “médicament à prescription initiale hospitalière et renouvellement réservés aux spécialistes en...”
- “médicament nécessitant une surveillance particulière pendant le traitement.  
Prescription réservée aux spécialistes en...”
- “médicament nécessitant une surveillance particulière pendant le traitement.  
Renouvellement réservé aux spécialistes en...”

d) In case of medicinal products subject to restriction for only professional use, the following must be stated:  
“médicament réservé à l’usage professionnel“

e) In case of medicinal products for hospital use only or subject to initial prescription only in hospital, and authorised to be used outside of the hospital in emergency situations:

“Médicament réservé à l’usage hospitalier ou soumis à prescription initiale hospitalière et à l’usage en situation d’urgence selon l’article R 5143-5-7 du code de la santé publique. “

f) In case of medicinal products: derived from blood, used in dialysis or containing a narcotic substitute, the following must be added:

- “prescription autorisée aux médecins exerçant dans des établissements de transfusion sanguine”
- “prescription autorisée aux médecins exerçant dans des centres de dialyse à domicile”
- “prescription autorisée ou réservée aux médecins exerçant dans des centres spécialisés de soins aux toxicomanes”

### 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](http://www.afssaps.fr) ).



## **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 genetchnological means, the active substance and the designation of the genetchnologically 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":

« B, χορηγείται με ειδική συνταγή Ναρκωτικών »

b. Products belonging to the exceptions of list B must mention in green letters "BΣ, to be dispensed with prescription of Law 1729/87":

« BΣ, 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:

- Bar code
- Name of the medicinal product (including strength, pharmaceutical form, units)
- National Identification Number
- 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:
- "Medicinale di automedicazione" (*medicinal products for self-medication*)
  - "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:
- "Da vendersi dietro presentazione di ricetta medica" (*prescription-only medicinal product*)
- C) For medical products subject to non renewable medical prescription the following is required:
- "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:
- "Da vendersi dietro presentazione di ricetta medica rilasciata dallo *specialista (o dal centro specializzato)*" [*Specialist(s) to be specified*]
  - "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:
- "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*)
- F) For medicinal products to be used only by specialist(s), the following is required:
- "Uso riservato allo *specialista*. Vietata la vendita al pubblico. [*Specialist(s) to be specified*]
- G) Psychotropic and narcotic medicinal product fall within the scope of a specific Italian law (DPR309/90) and the following must be stated:
- "Soggetta alla disciplina del DRP 9 ottobre 1990 n. 309" *followed by the indication of the Table to which it belongs (Table number to be specified in roman numbers).*

Psychotropic and narcotic medicinal products belonging to Tables I and II referred to in Art. 13 of D.P.R. 309/90 must be marked with a red double line.

Identification and authenticity

Bar codes and national identification number are required on the label.

**LUXEMBOURG**

There are no additional requirements.

## **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.

## **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.

## 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.

### 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:



## 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: **POM**
  
- if the medicinal product is available without prescription, but through registered pharmacies only: **P**

### 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.

## **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:



## **Blue-box requirements for accession candidate countries**

Label information, which may be required by Member States (under 57 of Directive 2001/83/EC)  
Label information, which has become established in Member States (allowed under Article 62 of Directive 2001/83/EC).

### **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.

### **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.

## **ESTONIA**

### **Identification and authenticity**

Code of the medicinal product is required.

## **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.

## **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 warning symbol

Product containing the active substances manufactured by genetical-technological means or the active substance and the designation of the genetical technologically 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.

## **MALTA**

No further information is required in the blue box.

## **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 ( $\ominus$ ) – 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 ( $\Delta$ ) – 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

**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

In the case of active substances manufactured by genetical technological means, the active substance and the designation of the genetically modified microorganisms or cell lines.

### **Information under Article 62 of Directive 2001/83/EEC: symbols or pictograms**

△ 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