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NOTICE TO APPLICANTS

GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS FOR HUMAN USE AUTHORISED BY THE UNION

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[1] OJ L 299 of 27.10.2012, p.1.
[2] OJ L 316 of 14.11.2012, p. 38

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Legal framework **3**
Purpose **4**
Section A - Labelling **5**
1. **The text of the labelling** 5
2. **Language** 5
3. **Additional labelling information required by some Member States** 6
4. **Legal status** 7
5. **Marketing authorisation number** 7
6. **Optional information under Article 62 of the Directive** 7
7. **Blind and partially-sighted patients** 8
8. **Control of the conformity of the labelling with the Directive** 8
9. **Changes to the labelling** 9

Section B - Package leaflet **10**
1. **The text of the package leaflet** 10
2. **Language** 10
3. **Optional information under Article 62 of the Directive** 11

Local representative 11
5. **Blind and partially-sighted patients** 12
6. **Control of the conformity of the package leaflet with the Directive** 12
7. **Changes to the package leaflet** 12

Section C - Presentation of the medicinal product **14**
1. **Pack sizes** 14
2. **Pack design (logo, colour, etc.)** 14

ANNEX **15**

Legal framework

Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[3] (hereinafter "the Regulation") lays down a centralised Union procedure for the authorisation of medicinal products. This means that 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.

The Regulation provides that an application for the authorisation of a medicinal product for human use should specifically and completely include the particulars and documents as referred in particular in Article 8(3)(j) of Directive 2001/83/EC which provides that:

"*The application [for a marketing authorisation] shall be accompanied by the following particulars and documents* […]: […] *a mock-up of the outer packaging, containing the details provided for in Article 54, and of the immediate packaging of the medicinal product, containing the details provided for in Article 55, together with a package leaflet in accordance with Article 59*".

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 use[4] (hereinafter "the Directive") contains, in Title V 'Labelling and Package Leaflet', provisions on the text of the label and package leaflet of medicinal products placed on the EU market.

Article 60 of the Directive provides that "*Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Title*".

Article 57 of the Directive provides that:

"*Notwithstanding Article 60, Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:*

— the price of the medicinal product,

— the reimbursement conditions of social security organizations,

— the legal status for supply to the patient, in accordance with Title VI,

— authenticity and identification in accordance with Article 54a(5).

For medicinal products authorised under Regulation (EC) No 726/2004, Member States shall, when applying this Article, observe the detailed guidance referred to in Article 65 of this Directive".

Article 65(f) of the Directive provides that:

"*In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular* […] *harmonised provisions for the implementation of Article 57*".

[3] OJ L 136, 30.04.2004, p. 1
[4] OJ L 311, 28.11.2001, p. 67

Article 62 of the Directive provides that:

"*The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information mentioned in Articles 54 and 59(1) and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature*".

Purpose

The purpose of this guideline is to describe how the above mentioned provisions of the Directive , apply in the case of a marketing authorisation to be granted by the Commission.

In particular, this guideline provide information on the items required by some Member States under Article 57 of the Directive and also on the additional items included in the labelling pursuant to Article 62 of the Directive in order to ensure that these are in conformity with the legislative provisions and are correctly presented.

This shall assist applicants and marketing authorisation holders when drawing up the labelling and package leaflet and preparing the mock-up and specimens of the sales presentation[5].

Guidelines and other interpretative documents to which references may be included within this document represent the views of their authors.

[5] 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).

Section A - Labelling

1. The text of the labelling

The Union authorisation of a medicinal product includes the labelling text which is the same throughout the Union.

Article 9, paragraph 4 (d) of the Regulation provides that must be in annex of the favourable CHMP opinion the draft text of the labelling proposed by the applicant and presented in accordance with title V of the Directive.

Article 54 of the Directive lists the particulars that must appear on the outer packaging of medicinal product or, where there is no outer packaging, on the immediate packaging.

Article 61(2) of the Directive provides that the labelling must comply with the provisions of title V and the particulars listed in the summary of products characteristics. For products authorised by the Union there is a single summary of product characteristics agreed at EU level, which forms part of the Commission Decision granting the marketing authorisation.

However, Article 63(3) of the Directive provides that "*Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet.[…]*" Such requests for exemption regarding particulars must be addressed to EMA.

Furthermore, Member States may require further information, see below point 3 and some information may be added at the initiative of the applicant/marketing authorisation holder, see below point 6.

Article 56 of the Directive provides that the particulars in the labelling shall be easily legible, clearly comprehensible and indelible. For these aspects, reference is made to the Guideline on the readability of the labelling and package leaflet of medicinal products for human use[6].
Reference is also made to Product information templates and reference documents prepared by the Quality Review of Documents group and published by the EMA.

2. Language

Article 63(1), 1st and 2nd sub-paragraph of the Directive provides that

"*The particulars for labelling listed in Articles 54, 59 and 62 shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.*

[6] Revision 1 of 12 January 2009 (ENTR/F/2/SF/jr (2009)D/869).

The first subparagraph shall not prevent these particulars from being indicated in several languages, provided that the same particulars appear in all the languages used".

This means that each Member State where the medicinal product is placed on the market decide the official language in which the labelling must be presented. 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 the content of all language versions must be identical and the overall readability should not be adversely affected. . It is recommended to group different text elements for each language, where appropriate.

However, in case of certain orphan medicinal products, Article 63(1), 3d sub-paragraph of the Directive provides that "[…] *the particulars listed in Article 54 may, on reasoned request, appear in only one of the official languages of the Community*". Such request for exemption should be addressed to EMA.

In addition, article 63(3) of the Directive provides that "*Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant […] a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State."* Such requests for exemption regarding language should be addressed to concerned national competent authorities.

3. Additional labelling information required by some Member States

Article 60 of the Directive provides that Member States may not prohibit or impede the placing on the market of a medicinal product which labelling and package leaflet comply with requirements of Title V of the Directive.
However in accordance with article 57, Member States may require the use of certain forms of labelling in order to ascertain:

- the price of the medicinal product,
- the reimbursement conditions of social security organizations,
- the legal status for supply to the patient, in accordance with Title VI of the Directive,
- authenticity and identification in accordance with Article 54a(5).

Annex I of this document lists, by Member State, these national requirements.

The information specific to a Member State should be accommodated on the label in a single boxed area (the so-called 'blue box'[7]), 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,, this box will contain different information relevant for each Member State. Assembling different information for different Member States in the 'blue box' could be achieved in practice

[7] The "blue box" is a boxed area included in the labelling, with a blue border, aimed at containing information specific to each Member State.

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, several 'blue boxes' are required for the different Member States; they should ideally have the same dimensions and appear on the same side of the pack.

4. Legal status

In accordance with Article 9(4)(b) and 10(1) of the Regulation, the CHMP scientific opinion and the Commission decision on the marketing authorisation must respectively include "details of any conditions or restrictions which should be imposed on the supply or use of the medicinal product concerned, including the conditions under which te medicinal product may be made available to patients, in accordance with the criteria laid down in Title VI of Directive 2001/83/EC".

Therefore the Commission decision may include one, or more, of the sub-categories listed in Article 70 of the Directive as well as other conditions or restrictions on the supply which are deemed necessary from a public health perspective.

Whenever these conditions or restrictions are added to the primary classification as subject or not subject to medical prescription they have to be implemented nationally using the available instruments of the legal framework.

In addition to appearing in Annex II of the Commission decision granting the marketing authorisation, the legal supply status may also appear on the labelling text which is included in Annex III A of the Commission decision.

According to Article 57 of the Directive Member States may require further information on the legal supply status to be included on the label. This may concern either one, or a combination, of the sub-categories listed in Article 70 of the Directive, or a specific mode of conveying particular information on the legal status. Obviously, this information must be in accordance with the legal supply status in the Commission decision granting the marketing authorisation. This implies that a sub-category in the sense of Article 70 of the Directive may not be specified if this is not done in the Commission decision granting the marketing authorisation.

Furthermore, in accordance with Article 57 of the Directive, symbols may be used in some Member States to express the legal supply status on the labelling. These are provided in the Annex of this document.

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 above, point 3).

6. Optional information under Article 62 of the Directive

The labelling may include symbols or pictograms designed to clarify certain information and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature. it is recommended that proposals for such inclusionare discussed with the EMA in advance (e.g at the pre-submission meeting or when submitting mock-ups).

In some Member States certain expressions, including symbols and pictograms have become established for expressing certain items of information. As these particulars are only known or relevant in some Member States, they should appear in the corresponding 'blue box' referred to above (see point 4). These are listed in the Annex of this document.

Local representative

Article 1, point 18a of the Directive defines the representative of the marketing authorisation holder as "*the person, commonly known as local representative, designated by the marketing authorisation holder to represent him in the Member State concerned*".

"Local Representative" should be taken to mean any natural or legal person established in the Union charged, through a contract under private law with the marketing authorisation holder, to represent him in a defined (geographical) area. This agreement excludes any transfer of any responsibility imposed on the marketing authorisation holder by Union law and by national law, regulation and administrative action implementing such Union law.

Article 54(k) of the Directive provides that must appear on the labelling "*the name and address of the marketing authorisation holder and, where applicable, the name of the representative appointed by the holder to represent him*".

The designation of a local representative is not obligatory[8].

The 'local representative' may be indicated in the 'blue box' on the labelling 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 text which must mandatory appear on the outer packaging).

Local representatives should be able to address queries in the local official EEA language(s) of the country for which they are designated.

7. Blind and partially-sighted patients

Article 56a of the Directive requires the name of the medicinal product (as referred to in Article 54(a)) to be expressed in Braille format on the packaging.

For these aspects, reference is made to the Guideline on the readability of the label and package leaflet of medicinal products for human use[9].

8. Control of the conformity of the labelling with the Directive

Article 12(1), 2nd sub-paragraph of the Regulation provides that "*Authorisation shall* […] *be refused if […] the labelling […] proposed by the applicant are not in accordance with Title V of Directive 2001/83/EC*".

[8] ECJ T-179/00 of 3.07.2002.
[9] Revision 1 of 12 January 2009 (ENTR/F/2/SF/jr (2009)D/869).

The labelling of the medicinal product forms part of the authorisation. To this end the CHMP, in accordance with Article 8(3)(j) of the Directive, and Articles 6(1), 7(a) and 9(4)(d) of the Regulation, provides the Commission with its opinion whether the labelling is in compliance with Title V of the Directive.

The proposed outer and immediate packaging and package leaflet will be reviewed for compliance with the requirements provided in the Directive, during the scientific assessment and linguistic review of the application. In addition, the EMA will perform a general check of mock-ups and specimens from the viewpoint of readability in order to contribute to the safe use of medicines (e.g. lay-out and design, font-sizes, differentiation between strengths, etc).

In the case of a favourable opinion, the text of the labelling is attached to the CHMP opinion, to be annexed to the Commission decision granting the marketing authorisation.

Whilst most of the information referred to under point 3 (price, reimbursement conditions, identification number) will not be available at the time of the adoption of the Commission Decision, a clear indication on how this information will eventually be presented shall be submitted with the application, as provided for in Article 8 (3) (j) and in Article 61 (1) of the Directive through mock-ups of the outer packaging and of the immediate packaging.
The requirements for mock-up and specimen submissions and details of the EMA check are set-out in specific guidelines available on EMA website.

9. Changes to the labelling

Article 61(3) of the Directive provides that: "*All proposed changes to an aspect of the labelling or the package leaflet covered by this Title and not connected with the summary of product characteristics shall be submitted to the authorities competent for authorizing marketing. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect*". 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, which is not linked to a modification of the SmPC, he must first notify this change to the EMA, who shall inform him if the proposed change is not accepted within 90 days following the introduction of the request. If necessary, the EMA should inform the Commission, who should amend the decision granting the marketing authorisation.
Where a change in the labelling is a consequence of a modification of the summary product characteristics as part of a variation or renewal it will be dealt with under the procedure laid down for that purpose.

Where a change to the labelling impacts only on the overall lay-out, design or readability and not on the actual labelling text (in the Commission decision granting the marketing authorisation), the need for an EMA review of the proposed changes by means of the provision of mock-ups and specimens, should be discussed with the EMA on a case-by-case basis, as outlined in specific guidelines available on EMA website.

Section B - Package leaflet

The inclusion in the packaging of all medicinal products of a package leaflet is obligatory unless all information required is directly conveyed on the labelling.

1. The text of the package leaflet

The Union authorisation of a medicinal product includes the text of the package leaflet, which is the same throughout the Union.

Article 9, paragraph 4 (d) of the Regulation provides that must be in annex of the favourable CHMP opinion the draft text of the package leaflet proposed by the applicant and presented in accordance with title V of the Directive.

Articles 59(1) and 61(2) of the Directive provide that the package leaflet must comply with the provisions of title V and the particulars listed in the summary of products characteristics. For products authorised by the Union there is a single summary of product characteristics agreed at EU level, which forms part of the Commission Decision granting the marketing authorisation.

However Article 63(3) of the Directive provides that "Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant an exemption to the obligation that certain particulars should appear on the labelling and in the package leaflet […]"; Such requests for exemption regarding particulars must be addressed to EMA.

Furthermore, some information may be added at the initiative of the applicant/marketing authorisation holder, see below point 4.

Article 59 (3) of the Directive 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".

Article 63(2), 1st sub-paragraph of the Directive provides 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. […]*".

For these aspects, reference is made to the guideline on the readability of the labelling and package leaflet of medicinal products for human use[10].

Reference is also made to Product information templates and reference documents prepared by the Quality Review of Documents group and published by the EMA .

2. Language

Article 63 (2), 1st and 2nd sub-paragraph of the Directive provides that:

"[…] *The package leaflet must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State*

[10] Revision 1 of 12 January 2009 (ENTR/F/2/SF/jr (2009)D/869).

The first subparagraph shall not prevent the package leaflet from being printed in several languages, provided that the same information is given in all the languages used".

This means that each Member States where the medicinal product is placed on the market decide the official language in which the package leaflet must be presented. The package leaflet must therefore 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 the content of all languages versions must be identical and the overall readability of the package leaflet should not be adversely affected.

However, article 63(3) of the Directive provides that "*Where the medicinal product is not intended to be delivered directly to the patient, or where there are severe problems in respect of the availability of the medicinal product, the competent authorities may, subject to measures they consider necessary to safeguard human health, grant […] full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State."* Such requests for exemption regarding language should be addressed to the concerned national competent authorities.

3. Optional information under Article 62 of the Directive

Package leaflet may include symbols or pictograms designed to clarify certain information and other information compatible with the summary of the product characteristics which is useful to the patient, to the exclusion of any element of a promotional nature. It is recommended that proposals for such inclusion are discussed with the EMA in advance (e.g at the pre-submission meeting or when submitting mock-ups).

Local representative

For the concept see point 6 of section A on labelling.

Article 59(1) f) vi) of the Directive provides that the package leaflet should include "*the name and address of the marketing authorisation holder and, where applicable, the name of his appointed representatives in the Member States*".

Designation of a local representative is not obligatory[11] . 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.

More than one local representative per Member State may be designated and listed in the package leaflet, but this should not entail the risk of confusion for patients and, as such, poses a risk to public health and that provided that the company can ensure the same level and quality of service will be provided by all local representatives.

The 'local representative' may be indicated by name, telephone number and/or electronic e-mail address and logo (optional). Postal address may be included if space permits (should not interfere with the legibility of the text that must mandatory appear on the packaging 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 aboard, an alternative international number may have to be added).

[11] ECJ T-179/00 of 3.07.2002.

Local representatives should be able to address queries in the local official EEA language(s) of the country for which he/she is designated.

5. Blind and partially-sighted patients

Article 56a of the Directive provides that "*the marketing authorisation 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*". Marketing authorisation holders are therefore encouraged to include a statement at the end of the package leaflet informing about the availability of such alternative formats.

6. Control of the conformity of the package leaflet with the Directive

Article 12(1) of the Regulation provides that "*Authorisation shall* […] *be refused if […] the […] package leaflet proposed by the applicant are not in accordance with Title V of Directive 2001/83/EC*".

The package leaflet of the medicinal product forms part of the authorisation. To this end the CHMP, in accordance with Articles 7(a) and 9(4)(d) of the Regulation, provides the Commission with its opinion whether the package leaflet is in compliance with Title V of Directive 2001/83.

The proposed outer and immediate labelling and package leaflet will be reviewed for compliance with the requirements provided in the Directive, during the scientific assessment and linguistic review of the application. In addition, the EMA will perform a general check of mock-ups and specimens from the viewpoint of readability in order to contribute to the safe use of medicines (e.g. lay-out and design, font-sizes, differentiation between strengths, etc).

In the case of a favourable opinion, the text of the package leaflet is attached to the CHMP opinion, to be annexed to the Commission Decision granting the marketing authorisation.

The requirements for mock-up and specimen submissions and details of the EMA check are set-out in the specific guidelines available on EMA website.

7. Changes to the package leaflet

Article 61 (3) of the Directive provides that "*All proposed changes to an aspect of […] the package leaflet covered by this title and not connected with the summary of product characteristics shall be submitted to the authorities competent for authorizing marketing. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect*".

Therefore, if a marketing authorisation holder wishes either to introduce any additional information to the package leaflet annexed to the Commission decision granting the marketing authorisation or to change any aspect of the package leaflet, which is not linked to a modification of the SmPC, he must first notify this change to the EMA, who shall inform him if the change is not accepted within 90 days following the introduction of the request. If necessary, the EMA 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 as part of a variation or renewal it will be dealt with under the procedure laid down for that purpose.

Where a change to the package leaflet impacts only on the overall lay-out, design or readability and not on the actual labelling text (in the Commission decision granting the marketing authorisation), the need for an EMA review of the proposed changes by means of the provision of mock-up and specimens should be discussed with the EMA Medical Information Sector on a case-by-case basis, as outlined in specific guidelines available on EMA website.

Section C - 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 EU marketing authorisation is valid throughout the EU, 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.*

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 should be identical for all the versions of packs of that medicinal product throughout the Union.

However, Article 82(3) of the Regulation provides that "W*ithout prejudice to the unique, Community nature of the content of the documents referred to in Article 9(4)(a), (b), (c) and (d) and in Article 34(4)(a) to (e), this regulation shall not prohibit the use of two or more commercial designs for a given medicinal product covered by a single marketing authorisation*".

Applicants/marketing authorisation holders wishing to make use of this provision can contact the EMA to discuss its practical application and to review the proposed designs in advance of marketing.

3. Pack composition

The descriptions below provide examples of presentations, that may be covered by marketing authorisation(s), and do not reflect marketing possibilities.

Multi packs: these packs are composed of several single packs of the same strength of a medicinal product.

Treatment initiation pack: these packs are composed of different strengths of a medicinal product. These presentations aim at giving to patients in once all strengths of a medicinal product for the duration of their initiation, as the dosage may change during this period.

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;
- "apothekenpflichtig" = available only in pharmacies;
- If the supply is not restricted to pharmacies, this has to be declared appropriately.

Radiopharmaceuticals :

- "Rezeptpflichtig. Abgabe nur an Inhaber einer Bewilligung für den Umgang mit radioaktiven Stoffen gemäß Strahlenschutzgesetz" = available only on prescription for authorised personnel

For vaccines and blood derivatives:

- „Charge staatlich freigegeben" = Batch released by OMCL
- „Charge verkehrsfähig" = Batch marketable; in case an exemption from the requirement for batch release has been granted

Information in accordance with Article 57 of Directive 2001/83/EC:

Identification and authenticity

The EAN code is accepted on the label, but not required.

For vaccines and blood derivates: 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.

Information under Article 62 of Directive 2001/83/EEC:

Symbols or pictograms

A pictogram for medicines which may reduce the ability to drive and operate machines by causing for example tiredness or dizziness:

“Achtung: dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen.”

“Der Gruene Punkt” or other recycling symbols are accepted on the label, but not required.
Additional Requirements for the Package Leaflet

- Anti-doping warning (if applicable):

"Die Anwendung des Arzneimittels kann bei Dopingkontrollen zu positiven Ergebnissen führen." = The administration of the medicinal product may result in positive doping controls.

BELGIUM

Legal status

The legal status is required on the label:

in the case of medicinal products that are subject to medical prescription only
“Geneesmiddel op medisch voorschrift.” /“Op medisch voorschrift”.
« Médicament sur prescription médicale. » / « Sur prescription médicale »
“Verschreibungspflichtig”

in the case of medicinal products that are not subject to medical prescription
Vrije aflevering
Délivrance libre
Freie Abgabe

The major narcotic or psychotropic drugs, subject to special medical prescription, require the following labelling: • a number/code assigned by the Minister of Public Health •

Identification and authenticity

The EAN code (bar code) is accepted but not required on the labelling.
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 labelling. 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

Section / Explanation	**French, Dutch and German text required on the labelling**	**Example of pictogram**	**English translation**
For medicinal products intended for external application, it is highly	French: usage externe – Dutch:		external application

recommended to print ' external application ' in black letters on a red-orange background in the three national languages. It is also highly recommended to deliver all packaging containing those medicinal products for external application with a warning symbol in relief, recognisable by touch. (the specifications of the triangle are as follows: This sign is an equilateral triangle with an 18 mm (+/- 0.2 mm) side. The width of the side is 1.7 mm (+/- 0,2 mm). Approximately 2 mm above the triangle, there is point with a diameter of 1.7 mm (+/- 0.2 mm). All these elements must have a relief (height) of 0.25 to 0.5 mm. For small packagings, a scaled down size is provided: side 9 mm (+/- 1 mm), width 1 mm (+/- 0.2 mm). The height remains unchanged: 0.25 to 0.5 mm. The sign will in principle be put at a height of maximum 50 mm from the basis of the packaging, and at whichever point for the scaled down size (on small packagings).	uitwendig gebruik – German: äusserliche anwendung	 	

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.

CROATIA

Price

The price of medicinal product is not required on the label.

Reimbursement

The reimbursement conditions are not required on the label.

Legal status

The following are the specific requirements for the expression of the legal status in the boxed area:
• “Lijek se izdaje na recept.” = Medicinal product subject to medical prescription.
• “Lijek se izdaje bez recepta.” = Medicinal product not subject to medical prescription.

Identification and authenticity

The EAN code is accepted on the label, but not required.

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

The legal status is required on the labelling the following text has to be used:

Section / Explanation	Czech text required on the labelling	English translation
For medicinal products subject to medical prescription	Výdej léčivého přípravku vázán na lékařský předpis.	Medicinal product subject to medical prescription.
For medicinal products not subject to medical prescription	Výdej léčivého přípravku možný bez lékařského předpisu.	Medicinal product not subject to medical prescription.

Identification and authenticity

The EAN bar codes are required on the label.

Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products

Section / Explanation	Czech text required on the labelling	English translation
On the outer packaging the following text has to be included	Nepoužitelné léčivo vraťte do lékárny.	„Any unused medicinal product should be returned to the pharmacy.“

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, traditional herbal medicinal products 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 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 outer labelling of all medicinal products, except radiopharmaceuticals, certain vitamin and mineral products, homeopathic and traditional herbal medicinal products. 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

There is no requirement for the price to appear on the label.

Reimbursement

There is no requirement for the reimbursement to appear on the label.

Legal status

The legal status and other related specific warnings are required on the labelling for prescription-only products. The following details must appear in the blue box:

1- for all prescription-only products

Active substances are classified in France in 2 categories based on whether or not the supply to the patient may be repeated without a new prescription :

- List I (non renewable delivery)
- List II (renewable delivery)

This classification must appear on the label with details as follow:

- an empty frame with:
  - A red border for list I products
  - A green border for list II products

Recommended format for the empty frame :

There is no minimum size for the coloured border.

- below this frame, written in dark characters on a red rectangular background:

French text required on the labelling	**English translation**
"respecter les doses prescrites"	Respect the prescribed dose

- then following mentions:

French text required on the labelling	**English translation**
• «Liste I » or «Liste II» • «Uniquement sur ordonnance» • «Ne pas avaler» (if appropriate)	• List I or List II • prescription only • do not swallow (if appropriate)

2- For products subject to special or restricted prescription

Other information or additional information regarding prescription, supply or use may apply and are required on the label.
The following restrictions or information may especially apply, on a case by case basis (non exhaustive list) :

2.1 - for medicinal product subject to special medical prescription (narcotics) :

Section / Explanation	**French text required on the labelling**	**English translation or explanation**
	"stupéfiant"	**narcotic**
	« prescription sur ordonnances sécurisées »	**prescription on a specific paper**
	"prescription limitée à x jours de traitement"	**prescription limited to x days of treatment**
If applicable:	"délivrance fractionnée par périodes de x jours"	**divided supply to the patient, for x days of treatment**

2.2 - for medicinal products subject to restricted medical prescription:

Section / Explanation	**French text required on the labelling**	**English translation**
a) In case of medicinal product for hospital use only, the following must be stated:	"médicament réservé à l'usage hospitalier"	Medicinal product subject to hospital use only
b) In case of medicinal product subject to hospital prescription only, the following must be stated:	"médicament soumis à prescription hospitalière"	Medicinal product subject to hospital prescription only

c) In case of medicinal product subject to initial hospital prescription the following must be stated: The duration of the prescription can be specified (e.g. 3 or 6 months or one year).	"médicament soumis à prescription initiale hospitalière"	Medicinal product subject to initial hospital prescription only
d) In case of medicinal product subject to specialist prescription only, the following must be stated: The concerned specialists must be listed. The duration of the prescription can be specified (e.g. 3 or months or one year).	"médicament à prescription réservée aux spécialistes en … »	Medicinal product subject to specialist prescription only
e) 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"	Medicinal product subject to special supervision throughout the treatment
f) In case of medicinal product restricted to professional use the following must be stated:	"médicament réservé à l'usage professionnel selon l'article R.5121-80 du code de la santé publique ».	Medicinal product subject to professional use only, as referred to article R. 5121-80 of the French Public Health Code
g) In case of medicinal product subject to restricted medical prescription (as mentioned to a), b), c) and d) above), but not restricted in emergency situation, the following could be added:	"Usage en situation d'urgence selon l'article R 5121-96 du code de la santé publique".	Emergency situation use as referred to article R. 5121-96 of the French Public Health Code
h) others restrictions or information may apply on a case by case basis		

Identification and authenticity

All packaging must include the EAN 128 syntax (combined with ECC.200 data matrix marking) as per the EAN.UC.

All presentations (pack sizes) of medicinal products are identified by a national administrative number called “code CIP” ; this code must also appear on the label.

Section / Explanation	French text required on the labelling	English translation
It is required that the following sentence is mentioned	“Médicament autorisé n° ….” (+ code CIP)	**medicinal product authorised under n°…**

In case of medicinal products derived from blood, there are specific requirements:

Section / Explanation	French text required on the labelling	English translation
Identification of the nature of the product : mention of the following statement:	“Médicament dérivé du sang humain”	**Human blood-derived medicinal product**

Moreover, for these medicinal products derived from blood, three removable stickers must be placed on the packaging; the entire name of the medicinal product (including name, strength and pharmaceutical form), the name of the firm which operates the placing of this product on the French market, the batch number and the corresponding bar code must be printed on these stickers.

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

1. Products which may reduce the ability to drive or operate machines must have a pictogram (warning triangle). Its size is adapted to fit the label.

Three categories of pictogram have been identified for specific active substances (listed in a ministerial decree) in relation with the effect on the ability to drive:

French text required on the labelling	English translation
	Be careful **Don’t drive before reading the leaflet**
	Be very careful **Don’t drive without an healthcare professional opinion**
	Warning, danger : do not drive **Don’t drive again without a doctor opinion**

Active substances with this kind of effect but not yet listed by ministerial decree must have a pictogram without mention of the risk level:

All pictograms and information on the risk level classification (1, 2 or 3) are available on the ANSM website: www.ansm.sante.fr

2. Products with teratogenic or foetotoxic effects mentioned in the SPC must have a pictogram and a corresponding warning message on the external packaging.
Three categories of pictograms apply, based on whether the medicinal product is contra-indicated during pregnancy or not (case 1 or 2), or it contains valproate or related substances (case 3); the associated warning message should specify the scope of the recommendation (female adolescent or woman of childbearing potential without effective method of contraception, pregnant woman, pregnant woman from the *Xth* month of pregnancy):

	French text required on the labelling	**English translation**
1		XXX + PREGNANCY = DANGER Do not use for [mention here the concerned population], unless there is no alternative treatment
2		XXX + PREGNANCY = PROHIBITED Do not use for [mention here the concerned population]
3		XXX + PREGNANCY = DANGER Do not use in female children, in female adolescents, in women of childbearing potential and pregnant women unless alternative treatments are ineffective

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 sentence and legal status code is required to be expressed in the boxed area of the label.

Section/Explanation	Hungarian texts required on the labelling
Medicinal product not subject to medical prescription.	Orvosi rendelvény nélkül is kiadható gyógyszer (VN).
Medicinal product subject to medical prescription.	Orvosi rendelvényhez kötött gyógyszer (V).
Medicinal product subject to restricted medical prescription, intended for outpatients after a diagnosis made by a specialist or in a hospital.	Orvosi rendelvényhez kötött gyógyszer (J).
Medicinal product subject to restricted medical prescription, requiring special supervision by a specialist throughout the treatment after a diagnosis made by a specialist or in a hospital.	Orvosi rendelvényhez kötött gyógyszer (Sz).
Medicinal product subject to restricted medical prescription, reserved for treatments which can only be followed in a hospital environment.	Orvosi rendelvényhez kötött gyógyszer (I).
Medicinal product containing a substance classified as a narcotic or a psychotropic substance subject to special medical prescription written in two copies.	Orvosi rendelvényhez kötött gyógyszer (V/J/Sz,KP).
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.	Orvosi rendelvényhez kötött gyógyszer (V/J/Sz, H).
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.	Orvosi rendelvényhez kötött gyógyszer (V/J/Sz, Ú).

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
The "Pharmazentralnummer" (PZN), has to be indicated on the labelling. The PZN can be requested at:
Informationsstelle für Arzneispezialitäten – IFA GmbH
Postfach 15 02 61
D-60062 Frankfurt am Main
Phone: +4969/97 99 19-0
Fax: +4969/97 99 19-39
E-mail: ifa@ifaffm.de
Internet: http://www.ifaffm.de
The reimbursement conditions are required on the label:
- concerning the "N"-classification please see the attachements of the "Packungsgrößenverordnung-PackungsV vom 22.06.2004 (BGBl. I S. 1318)" in the current version
- •
- "Klinikpackung" for the hospital packsize
- "Unverkäufliches Muster" in the case of a sample pack size

The reimbursement conditions are not relevant for products sold directly to hospital units.
Co-Promotion
Name and address of the Co-Promotor

Legal status
The legal status is required on the label:
- "Verschreibungspflichtig" = to appear in the boxed area in the case of medicinal products that are subject to medical prescription only
- "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.
- In respect of sera, particulars on the type of living organism from which the sera were obtained shall be indicated.
- In respect of virus vaccines, particulars of the host system which was used for the multiplication of the virus shall be indicated.

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

The official pictogram in case of radiopharmaceuticals.

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:
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 »
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»
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

The legal status for supply is required on the labelling

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 labelling for medicinal products supplied without prescription.

If a medicinal product is supplied on medicinal prescription, the price should be printed on the pharmacy labelling.

Reimbursement
The reimbursement conditions are accepted but not required on the labelling.

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 a medicinal product is available without medical prescription, there are three routes of supply for a medicinal product.

Section / Explanation	Dutch text required on the labelling	English translation
If supply is restricted to pharmacy, this has to be expressed in the blue box areas a	"UA" "U.A." "Uitsluitend apotheek"	"Only pharmacy"
If supply is restricted to pharmacy and chemist's (drugstore), this has to be expressed in the blue box areas as	"UAD" "U.A.D." "Uitsluitend apotheek en drogist"	"Only pharmacy and chemist's
If supply is allowed in pharmacy, chemist's (drugstore) and general sales, this has to be expressed in the blue box areas as	"AV" "A.V." "Algemene verkoop"	"General sale"

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. The EAN code (bar code) is accepted but not required on the labelling.
QR (quick response) codes are accepted but not required. The QR code should be in line with the QR code policy (see http://www.cbg-meb.nl/NR/rdonlyres/AB9A053A-CFCA-460A-BF4E-63614C9FBCCD/0/1410BeleidQRcodeEN.pdf)

POLAND

Price
The price is not required and not wanted on the labelling.

Reimbursement
The reimbursement conditions are not required and not wanted on the labelling.

Legal Status
The legal status is required on the labelling.
The following are the specific requirements for the expression of the legal status in the boxed area:

Section / Explanation	Polish text required on the labelling*	English translation
Medicinal product not subject to medical prescription	OTC – Lek wydawany bez recepty or OTC*	OTC - Medicinal product not subject to medical prescription
Medicinal product subject to medical prescription	Rp – Lek wydawany na receptę or Rp*	Rp - Medicinal product subject to medical prescription
Medicinal product subject to restricted medical prescription	Rpz – Lek wydawany na receptę or Rpz*	Rpz - Medicinal product subject to medical prescription
Medicinal product subject to special medical prescription (e.g. narcotic)	Rpw – Lek wydawany na receptę or Rpw*	Rpw - Medicinal product subject to medical prescription
Medicinal product only for hospital use	Lz – Lek stosowany w lecznictwie zamkniętym or Lz*	Lz - Medicinal product only for hospital use

*** if justified description of legal category may be limited to abbreviation**

Identification and Authenticity
The EAN code (bar code) is required on the labelling.

Information under Article 62 of Directive 2001/83/EC: symbols or pictograms
The symbols and pictograms, which are recommended but are not required on the labelling:

- the road sign, symbol of prohibition to entry (Θ) – 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(Δ) – 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 and Reimbursement

The need of reference to the price and reimbursement on the labelling should be done accordingly with the latest update of the specific national legislation.
In case of regulatory actions regarding Price, the sentence "PVP, se aplicável e de acordo com os critérios e legislação em vigor" should be included within the boxed area.
However, this sentence will be replaced by the relevant information on the printed materials.

Legal status

According to the national legislation, the legal status should be stated on the labelling.

The indication of the legal status is required, within the Blue Box, and it should be one of the following:

Legal Status	Portuguese text to appear in the Blue Box
Medicinal product subject to medical prescription	Medicamento sujeito a receita médica*
Medicinal product not subject to medical prescription	Medicamento não sujeito a receita médica*
Medicinal product subject to special medical prescription	Medicamento de receita médica especial
Medicinal product subject to restricted medical prescription	Medicamento de receita médica restrita, de utilização reservada a certos meios especializados
Medicinal product on medical prescription for renewable delivery	Medicamento de receita médica renovável

* These expressions must only be included in the Blue box, if not previously presented on the labelling.

Identification and authenticity

A digital code, a bar code and the national identification (or registration) number must appear on the label to identify the product.

Information under Article 62 of Directive 2001/83/EC: symbols or pictograms

•Products for external use should state “Uso externo” on a red background area.

Other relevant information to appear on the labelling:

- The abbreviation MG should be used to identify generic medicinal products, in accordance with the national requirements.

- The expressions “Amostra gratuita” and “Proibida a venda ao público” or other similar expressions should be added when applicable, as per the conditions expressed in the national legislation.

- For medicinal products on special medical prescription containing narcotic substances or psychotropic substances (tables I and II of national legislation: Decreto-Lei 15/93, de 22 de Janeiro) a double red line should be included in the immediate packaging only.

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 which is retained by the pharmacy:
Medicament eliberat pe bază de prescripţie medicală – PRF

For medicinal products supplied in pharmacy based on medical prescription valid for 6 months (the supply prescribed may be repeated)
Medicament eliberat pe bază de prescripţie medicală – P6L

For medicinal products supplied in pharmacy based on special medical prescription (narcotics and psychotropics):
Medicament eliberat pe bază de prescripţie medicală specială – PS

For medicinal products subject to restricted prescription (use in hospital only, use in certain specialised areas, ambulatory use but the prescription must be done only by a specialist and special follow up measures are necessary due to safety concerns).
Medicament eliberat pe bază de prescripţie medicală restrictivă – PR

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:

Medicinal products containing inflammable material must bear the international warning symbol:

Radiopharmaceutical products must bear the international warning symbol:

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

The following are the specific requirements for the expression of the legal status in the boxed area:

- Výdaj lieku je viazaný na lekársky predpis. = Medicinal products subject to medical prescription.
- Výdaj lieku nie je viazaný na lekársky predpis. = Medicinal product not subject to medical prescription.
- Výdaj lieku je viazaný na osobitné tlačivo so šikmým modrým pruhom. = Medicinal product subject to special medical prescription with skew blue stripe.
- Výdaj lieku je viazaný na lekársky predpis s obmedzením predpisovania.= Medicinal product subject to restricted medical prescription.

Identification and authenticity

The EAN code is required. Bar codes are accepted on the label, but are not required.

Information under Article 62 of Directive 2001/83/EC: symbols or pictograms

In the case of radiopharmaceuticals an international symbol for radioactivity and the amount of radioactivity should be stated.

For the outer packaging
Section 10
Nepoužitý liek vráťte do lekárne. = The unused medicinal product returns to the pharmacy.

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

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

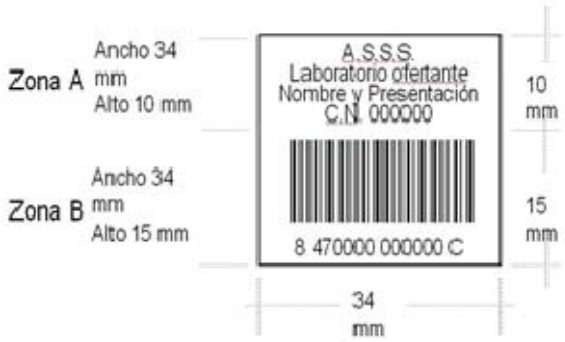
Price

The price can be included in the labelling in a voluntary basis (not mandatory).

Reimbursement

The reimbursement conditions should be included on a perforated detachable section that will need to be reviewed for its acceptance by the following department of the Spanish Ministry of Health:"Dirección General de Cartera Básica de Servicios del Sistema Nacional de Salud y Farmacia".

An example of this perforated detachable section is included below for reference:



Legal status

These statements should be included in a visible place and using big enough font size to ensure adequate readability. The corresponding acronyms (except for 'EFG') should be included in the upper right corner of the package, between the national product number and the symbols.

Section / Explanation	Spanish text required on the labelling: acronyms	English translation
Medicinal products subject to medical prescription	**MEDICAMENTO SUJETO A PRECRIPCIÓN MEDICA** (uppercase and bold format)	Medicinal products subject to medical prescription
Medicinal products to be used in the hospital	"Uso hospitalario": "H"	Hospital use
Medicinal products for diagnosis performed in hospital	"Diagnóstico hospitalario": "DH"	Hospital diagnosis
Medicinal products to be used under supervision by a specialized physician	"Especial control medico": "ECM"	Special medical control
Medicinal products with hospital package	"Envase clínico. Prohibida su venta al detalle"	Hospital package. Not to be sold separately
Medicinal products free samples	"Muestra gratuita. Prohibida su venta"	Free sample. Not to be sold
Generic medicinal products approved on the basis of Directive 2001/83/EC Art. 10.1	"Medicamento genérico": "EFG"	Generic medical product: EFG
Medicinal products to be used long term	Tratamiento de larga duración: "TLD"	Long term treatment

Legal status symbols: These symbols should be included in the upper right corner, following the national product number and the legal status acronyms, as appropriate.

Section / Explanation	Symbol in the labelling
For medicinal products subject to medical prescription	O
For psychotropic medicinal products in list I- IV	◐
For psychotropic medicinal products in annex II	◑
For narcotic medicinal products	●

Identification and authenticity

The national product number consists of a code composed of seven digits assigned by the Spanish National Competent Authority (i.e. AEMPS). The national product number or national code should be included in the upper right corner of the package, followed by the corresponding symbols and acronyms.

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

Additional symbols/pictograms should be included when (is) required according to the national legislation.

These symbols/pictograms are listed, described and their characteristics are clearly defined within the corresponding national legislation. (i.e RD 1345/2007 annex IV).

1. **Special storage conditions**: For those medicinal products to be stored in a refrigerator)the inclusion of the following symbol is required:

*****

[to be included in the upper right corner, following the national product number and the applicable legal status acronyms].

2. **Driving:** Those active substances affecting the ability to drive or use machines (SmPC Section 4.7) and listed by the AEMPS on its website, should include the following pictogram: [to be included together with a specific statement]

Conducción: ver prospecto
[*Driving: See package leaflet*]

3. **Radioactive material:** the inclusion of the following pictogram is required: [to be included together with a specific statement]

Material radioactivo
[*Radioactive material*]

4. **Combustion-producing medicinal gas:** the inclusion of the following pictogram is required (Símbolo de gas medicinal comburente)

5. **Flammable medicinal gas:** the inclusion of the following pictogram is required (Símbolo de gas medicinal inflamable)

6. The symbol of any Integrated System of Residues Treatment authorized in Spain should be included for medicinal products that are dispensed in pharmacies. There is no established place to include it but adequate readability should be guaranteed.

E.g.: (Símbolo Sigre)

SWEDEN

Identification and authenticity

Nordic commodity number required (exception radiopharmaceuticals and herbal medicines). Written as Vnr XX XX XX. A bar code or 2D- code is accepted on the label but not required.

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.

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: