~~May~~ July 202~~3~~

CMDh/258/2012, Rev.~~25~~26

"Blue – Box" requirements

Additional information on labelling/package leaflet that may be required nationally in accordance with Articles 57 and 62 of Directive 2001/83/EC as amended is outlined below.

These requirements apply to products authorised via a National, Mutual Recognition or Decentralised Procedure only.

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AUSTRIA (AT)

Additional Requirements for the Labelling

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

Section / Explanation	Austrian text required on the labelling	English translation
For medicinal products subject to medical prescription. If the supply is not restricted to pharmacies, this has to be declared appropriately.	"rezept- und apothekenpflichtig"	available only on prescription and only in pharmacies
For medicinal products not subject to medical prescription. If the supply is not restricted to pharmacies, this has to be declared appropriately.	"apothekenpflichtig"	available only in pharmacies
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 derivates official batch release is required.	„Charge staatlich freigegeben"	Batch released by OMCL
For vaccines and blood derivatives that usually require official batch release, but have been granted an exemption from this requirement.	„Charge verkehrsfähig"	Batch marketable.

Identification and Authenticity
The EAN code (bar code) is accepted, but not required on the labelling.

The marketing authorisation number is required on the labelling (Z.Nr.: …).

Symbols and Pictograms

Section / Explanation	Austrian text required on the labelling	English translation
Required warning statement and symbol* 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."	 "Caution: This medicine might compromise reactivity and ability to drive."
Recycling symbols are accepted on the labelling, but not required.	"Der Grüne Punkt" 	"Der Grüne Punkt"  or other.
Radiopharmaceuticals		
For Blood derivates or vaccines: self-adhesive label	[Selbstklebeetikette] < Product name > Verw. bis: Ch.B.:	[self-adhesive label] < Product name > EXP: LOT:

Additional Requirements for the Package Leaflet

Identification and authenticity

Section / Explanation	Austrian text required in the package leaflet	English translation
The marketing authorisation number is required on the package leaflet.	Z.Nr.: ……	MA-No. ……
Anti doping Note (if applicable)	"Die Anwendung des Arzneimittels kann bei Dopingkontrollen zu positiven Ergebnissen führen." In case of misuse of the medicinal product for doping purposes	The administration of the medicinal product may result in positive doping controls.

	the corresponding risks should be stated.	

Symbols and Pictograms:

Section / Explanation	**Austrian text required in the package leaflet**	**English translation**
Required warning statement and optional symbol* 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."	 "Caution: This medicine might compromise reactivity and ability to drive."

*Symbol based on the "danger sign" according to the Austrian Road Traffic Act without having to comply with the colour requirements

BELGIUM (BE)

Additional Requirements for the Labelling

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 is accepted but not required on the labelling. Reimbursed OTC medicinal products must carry a two-dimensional barcode containing an unique identifier as described in Commission Delegated Regulation (EU) 2016/161 of 2 October 2015. Reimbursed OTC products for hospital use only are exempted.

Symbols and 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 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	French: usage externe – Dutch: uitwendig gebruik – German: äusserliche anwendung		external application

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).			

Additional Requirements for the Package Leaflet

Section / Explanation	French, Dutch and German text required in the package leaflet	English translation
Section 3, If you <take> <use> more X than you should	French : Si vous avez utilisé ou pris trop de X, prenez immédiatement contact avec	If you have taken/used too much X, contact your doctor, pharmacist or the poison centre (tel. 070/245 245)

	votre médecin, votre pharmacien ou le centre Antipoison (070/245.245). Dutch : Wanneer u teveel van X heeft gebruikt of ingenomen, neem dan onmiddellijk contact op met uw arts, apotheker of het Antigifcentrum (070/245.245). German: Wenn Sie eine größere Menge von X haben angewendet, kontaktieren Sie sofort Ihren Arzt, Ihren Apotheker oder das Antigiftzentrum (070/245.245).	
Section 6, Contents of the pack and other information: Supply classification of the medicinal product Mention the MA number of the medicinal product	<...> BExxxxxx	<...> MA-No. ……

BULGARIA (BG)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status

Section / Explanation	Bulgarian text required on the labelling	English translation
For medicinal products not subject to medical prescription	Без лекарско предписание	Not subject to medical prescription
For medicinal products subject to medical prescription	По лекарско предписание	Subject to medical prescription
For medicinal products on restricted medical prescription for hospital use only	За болнична употреба	For hospital use
For medicinal products on special medical prescription containing psychotropic substances	По специално лекарско предписание *The outer packaging has to be marked with a double blue line positioned diagonally*	Subject to special medical prescription
For medicinal products on special medical prescription containing narcotic substances	По специално лекарско предписание *The outer packaging has to be marked with a double red line positioned diagonally*	Subject to special medical prescription
For pack sizes not intended to be delivered to a single patient but to be used in a hospital environment for several patients /treatment courses	Болнична опаковка	Hospital pack

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

Symbols and Pictograms
Symbols for separate disposal and recycling in compliance with the Law on Waste Management are required on the outer packaging.

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.

Specific types of medicinal products:

- Sera: the species from which the serum is obtained has to be specified on the outer packaging and the package leaflet.
- Viral vaccines: the host system used for viral reproduction has to be specified on the outer packaging and the package leaflet.
- Radiopharmaceuticals: immediate packaging labelling (additional requirements to the Ph Eur monograph 0125):
  - MA number, designation or chemical symbol of the radionuclide;
  - International radioactivity symbol;

Section / Explanation	Bulgarian text required on the labelling	English translation
For homeopathic medicinal products	Хомеопатичен лекарствен продукт	Homeopathic medicinal products
For traditional herbal medicinal products	Традиционен растителен лекарствен продукт	Traditional herbal medicinal product

CROATIA (HR)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status
The legal status is required on the labelling:

Section / Explanation	Croatian text required on the labelling	English translation
For medicinal products subject to medical prescription	Lijek se izdaje na recept.	Medicinal product subject to medical prescription.
For medicinal products not subject to medical prescription	Lijek se izdaje bez recepta.	Medicinal product not subject to medical prescription.

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

Additional Requirements for the Package Leaflet

Legal Status
Above the heading "This leaflet was last revised in" the following requirements describing the legal status for supply to the patient are to be stated under the title "Način i mjesto izdavanja lijeka" (English translation: "Classification for supply"):

Section / Explanation	Croatian text required in the package leaflet	English translation
For medicinal products subject to medical prescription supplied in pharmacy the following information is required:	Lijek se izdaje na recept, u ljekarni.	Medicinal product subject to medical prescription supplied in pharmacy.
For medicinal products not subject to medical prescription supplied in pharmacy the following information is required:	Lijek se izdaje bez recepta, u ljekarni.	Medicinal product not subject to medical prescription supplied in pharmacy.
For medicinal products not subject to medical prescription supplied in	Lijek se izdaje bez recepta, u ljekarni i specijaliziranim	Medicinal product not subject to medical prescription

pharmacy and specialised retail stores the following information is required:	prodavaonicama za promet na malo lijekovima.	supplied in pharmacy and specialised retail stores.

Local representative
Below the heading "Marketing authorisation holder and manufacturer" the following information on local representative (when appointed by marketing authorisation holder) is to be stated under the heading "Predstavnik nositelja odobrenja za Republiku Hrvatsku" (English translation: "Representative of the marketing authorisation holder for the Republic of Croatia"):

name,
address
telephone number

CYPRUS (CY)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status
The legal status is accepted but not required on the labelling.

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

Additional Requirements for the Package Leaflet

No specific requirements.

CZECH REPUBLIC (CZ)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status
The legal status is accepted but not required on the outer labelling.

Identification and Authenticity

In case that identification of the medicinal product is not ensured via the unique identifier as part of the safety features, the internationally recognized identification standard (e.g. the EAN code or 2D code) is required on the outer labelling. The code allocated by the SÚKL (so-called "SÚKL code") is required on the printed version of outer packaging.

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 if relevant	Nepoužitelné léčivo vraťte do lékárny.	„Any unused medicinal product should be returned to the pharmacy.“

In addition to the above mentioned Blue Box requirements there may be additional requirements that are required under national legislation or as specified by the SÚKL.

Additional Requirements for the Package Leaflet

There may be additional requirements that are required under national legislation or as specified by the SÚKL.

DENMARK (DK)

Additional Requirements for the Labelling

Price
There is no requirement for the price to appear on the labelling.

Reimbursement
There is no requirement for the reimbursement conditions to appear on the labelling.

Legal Status
There is no specific requirement in respect of the legal status.

Identification and Authenticity
The Nordic number is required on the outer labelling of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic, herbal and traditional herbal medicinal products. It may be written as "Vnr XX XX XX".
A bar code is accepted but not required on the labelling.

Symbols and 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 labelling; its sides are as minimum 10 mm long and the width of the frame is usually 2 mm:

Other requirements
Other warnings to be included in the labelling are listed in section 29(3-5) and section 31(2-6) of the Danish executive order no 869 of 21 July 2011, as amended on labelling etc. of medicinal products (Danish title: "Bekendtgørelse nr. 869 af 21. juli 2011 med senere ændringer om mærkning m.m. af lægemidler).

Additional Requirements for the Package Leaflet

Section / Explanation	Danish text required in the package leaflet	English translation
Section 2, What you need to know before you <take> <use> X	Lægen kan have foreskrevet anden anvendelse eller dosering end angivet i denne information. Følg altid lægens anvisning og oplysningerne på doseringsetiketten.	Please notice that your doctor may have prescribed the medicinal product for a different therapeutic indication and/or at a different dosage than stated in the package leaflet. Always follow the doctor's prescription and the instructions on the dosage label.

Section 2, Driving and using machines -*Only for products which carry the red warning triangle*	Pakningen er forsynet med en rød advarselstrekant. Det betyder, at "X" virker sløvende, og at det kan påvirke arbejdssikkerheden og evnen til at færdes sikkert i trafikken. *eller* Pakningen er forsynet med en rød advarselstrekant. Det betyder, at "X" kan give bivirkninger, som kan påvirke arbejdssikkerheden og evnen til at færdes sikkert i trafikken. *eller* Pakningen er forsynet med en rød advarselstrekant. Det betyder, at "X" især i begyndelsen af behandlingen og ved stigning i dosis virker sløvende, og at det kan påvirke arbejdssikkerheden og evnen til at færdes sikkert i trafikken.	The package contains a red warning triangle. This means that "X" can be sedating and can reduce the ability to drive and use machines. *or* The package contains a red warning triangle. This means that "X" can cause side effects that can reduce the ability to drive and use machines. *or* The package contains a red warning triangle. This means that "X" can be sedating and can reduce the ability to drive and use machines. This usually occurs at the beginning of treatment and when the dose is increased.
Section 3, If you <take> <use> more X than you should	Kontakt lægen, skadestuen eller apoteket, hvis De/du har taget mere af "X", end der står i denne information, eller mere end lægen har foreskrevet (og De/du føler Dem/dig utilpas).	Contact your doctor, hospital or pharmacy if you have taken more "X" than prescribed in this information or by your doctor (and you do not feel well).

Other requirements

Section 2, Warnings and precautions, must include any warnings listed in Schedule 2 of the Danish executive order no 869 of 21 July 2011, as amended on labelling etc. of medicinal products (Danish title: "Bekendtgørelse nr. 869 af 21. juli 2011 med senere ændringer om mærkning m.m. af lægemidler)pursuant to section 35(1) (4d).

ESTONIA (EE)

Additional Requirements for the Labelling

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

FINLAND (FI)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status
The legal status is accepted but not required on the labelling.

Identification and Authenticity
The Nordic number is required on the outer labelling of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic, herbal and traditional herbal medicinal products. It is written as "Vnr XX XX XX".
The EAN code (bar code) is accepted but not required on the labelling.

Symbols and 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 labelling; its sides are as minimum 10 mm long and the width of the frame is usually 2 mm:

Additional Requirements for the Package Leaflet

~~The following text should appear in the Package Leaflet. For readability reasons we suggest that the text below should appear in separate paragraphs under the adequate headings.~~

Section 1
The text in the table below should appear at the end of section in Package Leaflet shared with Sweden in case inclusion of corresponding Blue box is required by the Swedish Medical Products Agency. This text may also be included if seen relevant for the product in question. In general, this text should not be included in Package Leaflets for non-prescription products.

~~Section / Explanation~~	Text in Finnish ~~text required in the package leaflet~~PL	Text in Swedish ~~text required in the package leaflet~~PL	English translatio

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~~Under heading number 1~~	~~(Lääkeainetta),~~{Vaikuttavaa ainetta*}, jota ~~(~~{Kauppanimi~~)~~} sisältää, voidaan joskus käyttää myös muiden kuin tässä pakkausselosteessa mainittujen sairauksien hoitoon. Kysy neuvoa lääkäriltä, apteekkihenkilökunnalta tai muulta terveydenhuollon ammattilaiselta tarvittaessa ja noudata aina heiltä saamiasi ohjeita.	~~(~~{Aktiv substans~~)~~} som finns i ~~(produktnamn)~~ {Produktnamn} kan också vara godkänd för att behandla andra sjukdomar som inte nämns i denna produktinformation. Fråga läkare, apotek eller annan hälsovårdspersonal om du har ytterligare frågor och följ alltid deras instruktion.	~~(~~{Active ~~Substance) which is contained~~substance} included in ~~(product)~~{Product name} may sometimes also be ~~authorised~~used to treat other ~~illnesses,~~conditions which are not mentioned in this leaflet. ~~Ask your~~If necessary, consult a doctor, pharmacist or other healthcare professional ~~if you have further questions~~ and always follow their instructions.

~~For products which may reduce the ability to drive or operate machines the following text should be included under the heading "Driving and using machines"~~	~~Lääke voi heikentää kykyä kuljettaa moottoriajoneuvoa tai tehdä tarkkaa keskittymistä vaativia tehtäviä. On omalla vastuullasi arvioida, pystytkö näihin tehtäviin lääkehoidon aikana. Lääkkeen vaikutuksia ja haittavaikutuksia on kuvattu muissa kappaleissa. Lue koko pakkausseloste opastukseksesi. Keskustele lääkärin tai apteekkihenkilökunnan kanssa, jos olet epävarma.~~	~~Du är själv ansvarig för att bedöma om du är i kondition att framföra motorfordon eller utföra arbeten som kräver skärpt uppmärksamhet. En av faktorerna som kan påverka din förmåga i dessa avseenden är användning av läkemedel på grund av deras effekter och/eller biverkningar. Beskrivning av dessa effekter och biverkningar finns i andra avsnitt. Läs därför all information i denna bipacksedel för vägledning. Diskutera med din läkare eller apotekspersonal om du är osäker.~~	~~You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines. Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you~~

			are unsure about anything.
Under the heading "If you take more X than you should"	Jos olet ottanut liian suuren lääkeannoksen tai vaikkapa lapsi on ottanut lääkettä vahingossa, ota aina yhteyttä lääkäriin, sairaalaan tai Myrkytystietokeskuksen (puh. 0800 147 111 [Suomessa, 112 Ruotsissa]*) riskien arvioimiseksi ja lisäohjeiden saamiseksi.	Om du fått i dig för stor mängd läkemedel eller om t.ex. ett barn fått i sig läkemedlet av misstag kontakta läkare, sjukhus eller Giftinformationscentralen (tel. [112 i Sverige,]*0800 147 111 [i Finland]*) för bedömning av risken samt rådgivning.	If you have taken more X than you should, or if children have been taking medicine by accident, please contact your doctor, the hospital or Myrkytystietokeskus (tel. 0800 147 111 [in Finland, 112 in Sweden]*) to get an opinion of the risk and advice on action to be taken.

* square brackets if needed

* Please note that in Finnish text the name of active substance should be inflected as appropriate.

Section 2

The text in the table below should appear under the subheading "Driving and using machines" in Package Leaflet shared with Sweden in case inclusion of corresponding Blue box is required by the Swedish Medical Products Agency. This text may also be included if seen relevant by the applicant.

Text in Finnish PL	Text in Swedish PL	English translation
Lääkkeet voivat heikentää kykyä kuljettaa moottoriajoneuvoa tai suorittaa erityistä tarkkaavaisuutta vaativia tehtäviä. On omalla vastuullasi arvioida, pystytkö näihin tehtäviin lääkehoidon aikana. Lääkkeen vaikutuksia ja haittavaikutuksia on kuvattu muissa kappaleissa. Lue koko pakkausseloste opastukseksesi. Keskustele lääkärin tai	Du är själv ansvarig för att bedöma om du är i kondition att framföra motorfordon eller utföra arbeten som kräver skärpt uppmärksamhet. En av faktorerna som kan påverka din förmåga i dessa avseenden är användning av läkemedel på grund av deras effekter och/eller biverkningar. Beskrivning av dessa effekter och biverkningar finns i andra avsnitt. Läs därför all information i denna	Medicines may impair the ability to drive a motor vehicle or perform tasks that require particular attention. It is your responsibility to assess whether you are able to perform these tasks. Description of effects and adverse effects of the medicine can be found in other sections. Read all the information in this leaflet for guidance. If in doubt, discuss with a doctor or pharmacist.

apteekkihenkilökunnan kanssa, jos olet epävarma.	bipacksedel för vägledning. Diskutera med din läkare eller apotekspersonal om du är osäker.	

Section 3

The text in the table below should appear under the subheading "If you <take> <use> more X than you should".

Text in Finnish PL	**Text in Swedish PL**	**English translation**
Jos olet ottanut liian suuren lääkeannoksen tai vaikkapa lapsi on ottanut lääkettä vahingossa, ota aina yhteyttä lääkäriin, sairaalaan tai Myrkytystietokeskukseen (puh. 0800 147 111 <Suomessa, 112 Ruotsissa>*) riskien arvioimiseksi ja lisäohjeiden saamiseksi.	Om du fått i dig för stor mängd läkemedel eller om t.ex. ett barn fått i sig läkemedlet av misstag kontakta läkare, sjukhus eller Giftinformationscentralen (tel. <112 i Sverige,>* 0800 147 111 <i Finland>*) för bedömning av risken samt rådgivning.	If you have taken more medicine than you should or if e.g. a child has taken medicine by accident, always contact a doctor, hospital or Poison Information Center (tel. 0800 147 111 <in Finland, 112 in Sweden>*) for risk assessment and advice on action to be taken.

* Text within "< >" applicable only in case of a shared Package Leaflet with Sweden (not mandatory in Finnish PL).

For readability reasons it is recommended that the above-mentioned Blue box texts under PL sections 1, 2 and 3 appear as separate paragraphs.

FRANCE (FR)

Additional Requirements for the Labelling

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:

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 7x 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.	"médicament à prescription réservée aux spécialistes en … »	**Medicinal product subject to specialist prescription only**

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

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/EC: 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.

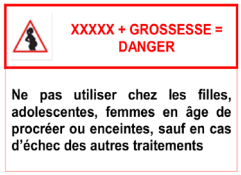
French text required on the labelling	English translation
	**Be careful** **Don't drive before reading the leaflet**
	**Be very careful** **Don't drive without an healthcare professional opinion**
	**Warning, danger : do not drive** **Don't drive again without a doctor opinion**

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

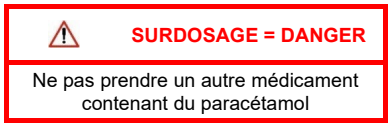
3. Some products with phototoxic effects mentioned in the SPC must have, decided on a case-by-case basis, a pictogram and a corresponding warning message on the external packaging.

French text required on the labelling	English translation
	"Do not expose yourself to the sun, even veiled, nor to U.V.A"

4. Paracetamol-containing products (alone or in association) must have hepatotoxicity warnings on the outer packaging as follows:

	French text required on the labelling	English translation

1. Paracetamol-containing products only	<u>On the front side of the packaging</u> ⚠ **SURDOSAGE = DANGER** Dépasser la dose peut détruire le foie	"OVERDOSE = DANGER Exceed the dose could destroy liver"
	<u>On the back side</u> • **500 mg** **ATTENTION** - Réservé à l'adulte et à l'enfant à partir de 27 kg (à partir d'environ 8 ans). - Enfants de 27 à 40 kg (environ 8 à 13 ans) : espacer les prises d'au moins 6 heures et ne pas dépasser 4 [*comprimés*] [*gélules*] par jour. - Adultes et enfants de plus de 40 kg : espacer les prises d'au moins 4 heures. Ne pas dépasser 6 [*comprimés*] [*gélules*] par jour sans avis médical. - Ne pas prendre un autre médicament contenant du paracétamol. • **1000 mg** **ATTENTION** - Réservé à l'adulte et à l'enfant de plus de 50 kg (soit à partir d'environ 15 ans). - Prendre 1 seul [comprimés] [gélules] à la fois. - Espacer les prises d'au moins 4 heures. - Ne pas dépasser 3 [comprimés] [gélules] par jour sans avis médical. - Ne pas prendre un autre médicament contenant du paracétamol.	• **500 mg** "WARNING - For adult and children over 27 kg only (from about 8 years old) - Children weighing 27 to 40 kg (about 8 to 13 years old): Leave at least 6 hours before taking another dose and do not take more than 4 [*tablets*] [*capsules*] a day. - Adults and children over 40 kg: Leave at least 4 hours before taking another dose. Do not take more than 6 [*tablets*] [*capsules*] a day without medical advice. - Do not take any other paracetamol-containing product." • **1000 mg** "WARNING - For adult and children over 50 kg only (from about 15 years old). - Take only 1[*tablet*] [*capsule*] at a time. - Leave at least 4 hours before taking another dose. - Do not take more than 3 [*tablets*] [*capsules*] a day without medical advice. - Do not take any other paracetamol-containing product."

2. Paracetamol-containing products in association with another active substance	<u>On the front side of the packaging</u>  	"OVERDOSE = DANGER Do not take any other paracetamol-containing product"

GERMANY (DE)

Additional Requirements for the Labelling

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
Hamburger Allee 26-28
60486 Frankfurt am Main
GERMANY

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 labelling:
- 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 pack size
- "Unverkäufliches Muster" in the case of a sample pack size

The reimbursement conditions are not relevant for products sold directly to hospital units.

Legal Status
The legal status is required on the labelling:

Section / Explanation	German text required on the labelling	English translation
In the case of medicinal products that are not subject to medical prescription but are only available in pharmacies	"Apothekenpflichtig"	available only in pharmacies
In the case of medicinal products that are subject to medical prescription only	"Verschreibungspflichtig"	available only on prescription

Identification and Authenticity
- In the case of active substances manufactured by gene technological means, the active substance and the designation of the gene technologically modified microorganism or cell line.

- 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.

Symbols and Pictograms

- the official pictogram in case of radiopharmaceuticals.

GREECE (EL)

Additional Requirements for the Labelling

Price
The price is required on the labelling.

Reimbursement
The reimbursement conditions are not required on the labelling.

Legal Status
If any of the sub-categories appear in the decision they are to be stated on the labelling.
Specific national provisions [defined by the National Organization for Medicines (EOF) or by the Ministry of Health and Welfare in compliance with SmPC requirements and concerning either medicinal products subject to special medical prescription or medicinal products subject to restricted prescription] must appear on the labelling.
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 3459/2006 as amended:

Section / Explanation	Greek text required on the labelling	English translation
Products belonging to List B must be mentioned in red letters	Β, χορηγείται με ειδική συνταγή Ναρκωτικών	B, to be dispensed with special prescription for narcotics
Products belonging to the exceptions of list B must be mentioned in green letters	ΒΣ, χορηγείται με συνταγή του Ν. 3459/2006	BΣ, to be dispensed with prescription of Law 3459/2006
Products belonging to list Γ must be mentioned in red letters	Γ, χορηγείται με ειδική συνταγή Ναρκωτικών	Γ, to be dispensed with special prescription for narcotics
Products belonging to the exceptions of list Γ must be mentioned in green letters	ΓΣ, χορηγείται με συνταγή του Ν. 3459/2006	ΓΣ, to be dispensed with prescription of Law 3459/2006
Products belonging to list Δ must be mentioned in green letters	Δ, χορηγείται με συνταγή του Ν. 3459/2006	Δ, to be dispensed with prescription of Law 3459/2006

For medicinal products restricted to hospital use:

Section / Explanation	Greek text required on the labelling	English translation

For medicinal products restricted to hospital use the following text must appear	Με περιορισμένη ιατρική συνταγή : Μόνο για νοσοκομειακή χρήση.	Medicinal product subject to restricted medical prescription: only for hospital use

In addition to the above mentioned Blue Box requirements there may be other restrictions/provisions to medicinal products according to current National Decisions. Referring to medicinal products subject to restricted prescription, the relevant sub-categories should be defined and adopted by EOF.

Identification and Authenticity
All medicinal products must be identified by a safety coded sticker (authenticity sticker) on the outer package. This sticker is of a size of 27mm x 24 mm approx, it is issued by EOF (National Organisation for Medicines) and distributed free of charge to the companies. Information printed : company name, product name, pharmaceutical form, strength, packaging, as well as a product-specific number and a package-specific, unique, serial number (both numbers in both numerical and barcode form). The authenticity sticker is printed on a special paper and carries invisible thread marks as well, so that it is not copied.

The authenticity sticker requirements apply for all categories of pharmaceutical products, with the exception of the radiopharmaceuticals.

HUNGARY (HU)

Additional Requirements for the Labelling

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

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

Legal Status

Section / Explanation	Hungarian text 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 but not required on the labelling.

Local Representative
The local representative is accepted but not required on the labelling.

Additional Requirements for the Package Leaflet

Marketing Authorisation Number(s)
The marketing authorisation number(s) should be stated in the form of OGYI-T-XXXXX/XX

Local Representative
The local representative is accepted but not required in the package leaflet.

ICELAND (IS)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the package.

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

Legal Status

Section / Explanation	Icelandic text required on the labelling	English translation
The legal status is required on the labelling for packages intended for dose dispensing	Þessi pakkning er eingöngu ætluð til skömmtunar	For dose dispensing only

Identification and Authenticity
The Nordic Article Number is required on the outer package of all medicinal products, except radiopharmaceuticals, homeopathic products and traditional herbal medicinal products. It is written as “Vnr xx xx xx”.
The EAN code (bar code) is accepted but not required on the package.

Symbols and 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 labelling; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

Additional Requirements for the Package Leaflet

Section / Explanation	Icelandic text required in the package leaflet	English translation
BEFORE YOU <TAKE> <USE> X	Verið getur að læknirinn hafi ávísað lyfinu við öðrum sjúkdómi eða í öðrum skömmtum en tiltekið er í þessum fylgiseðli. Ávallt skal fylgja fyrirmælum læknis og leiðbeiningum á merkimiða frá lyfjabúð.	Please notice that your doctor may have prescribed the medicinal product for a different therapeutic indication and/or at a different dosage that is stated in the package leaflet. Always follow the doctor’s prescription and the instructions on the pharmacy label.

Driving and using machines	Hver og einn verður að leggja mat á getu sína til aksturs og starfa sem krefjast óskertrar árvekni. Eitt af því sem getur haft áhrif á slíkt er lyf, vegna verkunar sinnar eða aukaverkana. Lýsing á verkun og aukaverkunum er í öðrum köflum fylgiseðilsins. Lesið því allan fylgiseðilinn. Ef þörf er á skal ræða þetta við lækni eða lyfjafræðing.	You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these things safely is your use of medicines. Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor or pharmacist if you are unsure about anything.
If you <take> <use> more X than you should	Ef of stór skammtur af lyfinu hefur verið notaður, eða ef barn hefur í ógáti tekið inn lyfið skal hafa samband við lækni, sjúkrahús eða eitrunarmiðstöð (sími 543 2222).	Contact your doctor, the hospital or "Eitrunarmiðstöð" (sími 543 2222) if you have taken more X than you should or if children have been taking medicine by accident.

IRELAND (IE)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Legal Status
The non-prescription status of certain medicinal products, containing certain active substances, must be stated.
These active substances include: aciclovir, diclofenac diethylammonium, diclofenac sodium, famotidine, flurbiprofen, 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
The EAN code (bar code) is accepted but not required on the labelling.

Other
In addition to the above mentioned Blue Box requirements there may be additional requirements that are required under Irish national legislation or as specified by the HPRA.

Additional requirements for Package Leaflet

There may be additional requirements that are required under Irish national legislation or as specified by the HPRA.

ITALY (IT)

Additional Requirements for the Labelling

Price
The price for the public (art. 73(1r) D.Lvo 219/2006) should be reported as: "Prezzo: Euro xxx" or "Prezzo: € xxx".
For medicinal products reimbursed by the National Health Service (NHS), the price should be the one reported in the AIFA Determination including the price reductions provided for in AIFA Determinations 3 July 2006 and 27 September 2006, published, respectively, in the Official Journal of the Italian Republic General Series n. 156 7 July 2006 and n. 227 of September 2006.
For medicinal products not subject to medical prescription (SOP and OTC) the price is not required on the labelling (art. 1(801) Law n. 296 of 27 December 2006).
For radiopharmaceuticals ready to use, radionuclide generators and precursors (notwithstanding the classification for reimbursement by NHS) if the price is reported as "Euro xxx" this is meant to be the price per pack. Otherwise, the reference unit should be stated, e.g. price per activity unit: "Euro xxx/MBq", etc.

Authenticity/Traceability
For all medicinal products (subject or not -SOP e OTC- to medical prescription and notwithstanding the classification for reimbursement by NHS) a peelable sticker issued by the Printing and State Mint (Istituto poligrafico e zecca dello stato) carrying the unique identifier in human-readable format and as two-dimensional barcode, should be applied (art. 54o Directive 2001/83; art. 73.1p-bis D.Lvo 219/2006 implemented by Decree of the Ministry of Health 30 May 2014 "Numerazione progressiva dei bollini apposti sulle confezioni dei medicinali immessi in commercio in Italia", artt. 4 and 5 Delegated Regulation 2016/161 of 2 October 2015 which supplements the Directive 2001/83/CE). National identification number ("numero di AIC") in human-readable format must appear on the outer label (or immediate label if the outer one is lacking) as well as on the peelable sticker.
Radiopharmaceuticals which release/contain radioactive isotopes (thus excluding the kit for radiopharmaceutical preparations) are exempted from the application of the peelable sticker (art. 73.3 D.Lvo 219/2006). Homeopathic medicinal products are exempted considering the provision of art. 52.17 of the Law 289 of 27 December 2002.

Reimbursement
For medicinal products reimbursed by NHS as per AIFA determinazione, the following text "Confezione dispensata dal SSN" printed in the area underneath the sticker, should appear once the latter has been removed (art. 73(1s) D.Lvo 219/2006).

Classification for supply
Art. 73(1q) and artt. 88, 89, 90, 91, 92, 93, 94, 96 D.Lvo 219/2006

	Type of medical prescription	**Text to be reported**
a. medicinal products not subject to medical	OTC	Medicinale di automedicazione. (+ pictogram - see point 11. a)

	SOP	Medicinale non soggetto a prescrizione medica (+ pictogram - see point 11.a)
b.	medicinal products subject to medical prescription (RR) (art. 88 D.Lvo 219/2006)	Da vendersi dietro presentazione di ricetta medica.
c.	medicinal products subject to medical prescription to be renewed each time (RNR) (art. 89 D.Lvo 219/2006)	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta.
d. medicinal products subject to restrictive medical prescription (art. 91 D.Lvo 219/2006)	medicinal products to be used only in hospital setting or in similar facilities (OSP) (art. 92 D.Lvo 219/2006) radiopharmaceuticals: medicinal products to be used only in hospital setting or in similar facilities (OSP) (art. 92 D.Lvo 219/2006)	Uso riservato agli ospedali o alle cliniche e alle case di cura *[if expressly specified in the AIFA determinazione]*>. Vietata la vendita al pubblico. "Uso riservato ad ospedali, alle cliniche e alle case di cura autorizzati all'impiego di radiofarmaci. Vietata la vendita al pubblico
	medicinal products to be dispensed on prescription from hospital centers or specialists (RRL) (art. 93 D.Lvo 219/2006)	Da vendersi dietro presentazione di ricetta medica su prescrizione di centri ospedalieri o di specialisti *[indicate the type of facility or specialist authorized for the prescription]*
	medicinal products to be dispensed on prescription to be renewed each time from hospital centers or specialists (RNRL) (art. 93 D.Lvo 219/2006)	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta su prescrizione di centri ospedalieri o di specialisti *[indicate the type of facility or specialist authorized for the prescription]*
	medicinal products to be used only by the specialist (USPL) (art. 94 D.Lvo 219/2006)	Uso riservato allo specialista *[indicate the specialist authorized for the prescription]*. Vietata la vendita al pubblico.
e. medicinal products containing narcotic and psychotropic substances (DPR 309/1990 as	medicinal products subject to special medical prescription (art. 90 D.Lvo 219/2006; DPR 309/1990 as amended)	Da vendersi dietro presentazione di ricetta ministeriale a ricalco

	Medicinal products containing narcotic and psychotropic substances (DPR. 309/1990 as amended).	Medicinale soggetto alla disciplina del DPR 309/90 e s.m.i. <Tabella medicinali sezione <A><B><C><D><E>> <Allegato III bis> The text must be marked with a double red line as in the example shown above (Decree of the Ministry of Health 26 March 1979)

5 - Local representative optional and only if mentioned in the package leaflet[2]
The following information may be reported if the readability of mandatory text on the label is not compromised: "Rappresentante locale: name, phone and/or e-mail address, logo, postal address."

6 - Distributor/who, on the basis of a specific agreement with the Marketing Authorisation Holder, manages the actual marketing of the medicinal product in Italy (art. 73(2) D.Lvo 219/2006), optional and subject to notification to AIFA:
The following information should be reported: "Concessionario di vendita: *name, phone and/or e-mail address, logo [optional]"*

7 - For equivalent medicinal products (biosimilars are considered excluded) (Law July 26, 2005, No. 149) the following statement should be reported.: "medicinale equivalente" .

8 - If relevant, the following statement should be reported: "Non assumere contemporaneamente bevande alcoliche" (art. 65 Directive 2001/83, art. 73(1)g D.Lvo 219/2006)

9 - If relevant, the following statement should be reported: "Può alterare la capacità di guidare veicoli e di usare macchinari" (art. 65 Directive 2001/83, art. 73(1)g D.Lvo 219/2006)

10 - For medicinal products for intravenous use containing potassium amount equal or above 1 mEq/ ml:

- the following statement: "Potassio (K), diluire prima della somministrazione: mortale se infuso non diluito", in red font, should be reported in the outer package (AIFA determinazione 11 November 2005)
- the following statement: "Potassio (K): mortale se non diluito", in red font should be reported, in the immediate package (AIFA determinazione 11 November 2005)

Pictograms
a. for medicinal products NOT subject to medical prescription (SOP and OTC) the following pictogram should be reported (Decree of the Ministry of Health of 1 February 2002):

Diameter: Ø17 mm

Homeopathic medicinal products are exempted.

b. for medicinal products containing the active substances listed in decrees amending Law 376/2000 which are issued annually by the Ministry of Health (see also World Anti-Doping Agency https://www.wada-ama.org/en/what-we-do/the-prohibited-list), the following pictogram should be reported (Decree Ministry of Health 19 May 2005 as amended):

Diameter: Ø17 mm

For medicinal products **NOT** to be used **exclusively** in hospital setting or in similar facilities (OSP) (art. 92 D.Lvo 219/2006) and containing one or more of the following opioids: buprenorphine; codeine; dihydrocodeine; fentanyl; hydrocodone; hydromorphone; methadone; morphine; oxycodone; oxymorphone; sufentanyl; tapentadol, tramadol; petidine (https://www.aifa.gov.it/documents/20142/847366/comunicazione_nuove_avvertenze_etichette_oppioidi_22.06.2020.pdf/1af21a63-a563-9108-faf4-fb1631871992), the following statement in the following format should be included**:**

Contiene·OPPIOIDE¶
Può·dare·dipendenza¶

Additional Requirements for the Package Leaflet

1. For equivalent medicinal products (biosimilars are considered excluded) (Law July 26, 2005, No. 149) the following statement should be reported: "medicinale equivalente".

2. For medicinal products containing the active substances listed in decrees amending Law 376/2000 which are issued annually by the Ministry of Health (see also World Anti-Doping Agency https://www.wada-ama.org/en/what-we-do/the-prohibited-list), the following statement should be reported (Ministry of Health Decree 19 May 2005 as amended):

"Per chi svolge attività sportiva: l'uso del farmaco senza necessità terapeutica costituisce doping e può determinare comunque positività ai test antidoping" .

- For medicinal products containing the active substances belonging to class S5 – plasma expanders the following statement should be reported; "Attenzione per chi pratica attività sportiva: il principio attivo contenuto in questa preparazione è incluso nella lista delle sostanze vietate per doping"

- For topically applied locally acting medicinal products belonging to class S5- S6 the following statement should be reported: "Attenzione per chi svolge attività sportive: il prodotto contiene sostanze vietate per doping. È vietata un'assunzione diversa, per schema posologico e per via di somministrazione, da quelle riportate".

3. For medicinal products for intravenous use containing potassium amount equal or above 1 mEq/ ml, the following statement: "**diluire prima della somministrazione: mortale se infuso non diluito**", in bold, should be reported (AIFA Determinazione 11 November 2005).

- Distributor/who, on the basis of a specific agreement with the MAH, manages the actual marketing of the medicinal product in Italy (art. 73(2) D.Lvo 219/2006) optional and subject to notification to AIFA:
  The following information should be reported: "Concessionario di vendita: *name, phone and/or e-mail address, logo [optional]"*

[2]NOTICE TO APPLICANTS - GUIDELINE ON THE PACKAGING INFORMATION OF MEDICINAL PRODUCTS OR HUMAN USE AUTHORISED BY THE UNION: "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)."

LATVIA (LV)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling.

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

Symbols and Pictograms
Symbols and pictograms are accepted but not required on the labelling, 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:

Latvian text required on the labelling	**Text in English**
"Šo zāļu sastāvā ir ģenētiski modificēti organismi (ĢMO)"	This medicinal product contains genetically modified organisms.
"Šo zāļu sastāvā var būt ģenētiski modificēti organismi (ĢMO)"	This medicinal product may contain genetically modified organisms.

LIECHTENSTEIN (LI)

Additional Requirements for the Labelling

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

LITHUANIA (LT)

Additional Requirements for the Labelling

Legal Status
The legal status is required on the labelling.

Additional Requirements for the Package Leaflet

No specific requirements.

LUXEMBOURG (LU)

Additional Requirements for the Labelling

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

MALTA (MT)

Additional Requirements for the Labelling

No specific requirements.

Additional Requirements for the Package Leaflet

No specific requirements.

NETHERLANDS (THE) (NL)

Additional Requirements for the Labelling

Price
The price is accepted but not required on the labelling for medicinal products supplied without prescription.
If a medicinal product is supplied on medicinal prescription, the price could be printed on the pharmacy labelling (but it is not mandatory).

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

Legal Status
In case the legal status is "prescription only" the following abbreviation should be included on the labelling: "UR or "Uitsluitend Recept".
There are three routes of supply for a medicinal product, available without medical prescription.

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 as	"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 restricted to 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 regarding the identification and authenticity is accepted but not required on the labelling.
The EAN code (bar code) is accepted but not required on the labelling.

Symbols and Pictograms
See national guidance as included in the MEB's policy document Labelling of pharmaceutical products (MEB 6) Annex 5: Positive List of Pictograms.

Additional Requirements for the Package Leaflet

Section / Explanation	Dutch text required on the labelling	English translation
If not all indications can be mentioned in the product information because of patent law, the following sentence should be added in section 1 'What X is and what it is used for'	Product bevat als werkza(a)m (e) bestandde(e)l(en) <na(a)m(en) van werkza(a)m(e) bestandde(e)l(en)>, dat (die) ook is (zijn) goedgekeurd voor andere aandoeningen die niet in deze bijsluiter staan vermeld. Vraag uw arts of apotheker als u nog nadere vragen heeft.	**Product contains as active ingredient (s) <name of actieve ingredient(s)>, approved for other disorders not mentioned in this package leaflet. Ask your doctor or pharmacist if you have further questions.**

In the section 'Marketing Authorisation Holder and Manufacturer' the national marketing authorisation number in the Netherlands (RVG-number) should be stated.

NORWAY (NO)

Additional Requirements for the Labelling

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

Reimbursement
No reimbursement conditions should appear on the label.

Identification and Authenticity
The Nordic number is required on the outer labelling of all medicinal products (written as "Vnr XX XX XX").
The 2 D matrix code is accepted but not required on the labelling for medicinal products which do not need to bear the safety features according to regulation (EU) 2016/161.

Symbols and Pictograms

Section / Explanation	Norwegian text required on the labelling	English translation
Products containing inflammable material must bear the international warning symbol 	Brannfarlig + symbol	Inflammable + symbol

Medicinal products which reduce the ability to drive or operate machines must have a warning triangle on the outer and inner packaging. The medicinal products concerned are defined by the Norwegian Medicines Agency. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the labelling; its sides are usually 10 mm long and the width of the frame is usually 2 mm.

Additional Requirements for the Package Leaflet

No specific requirements.

Additional Requirements Regarding OTC for the Package Leaflet and Labelling

As the legal status may differ between MS there is a need for the possibility to make additional amendments and/or delete information about indications, dosage and also important warnings approved for OTC.

POLAND (PL)

Additional Requirements for the Labelling

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	OTC - Medicinal product not subject to medical prescription.
Medicinal product subject to medical prescription	Rp – Lek wydawany na receptę	Rp - Medicinal product subject to medical prescription.
Medicinal product subject to restricted medical prescription	Rpz – Lek wydawany na receptę	Rpz - Medicinal product subject to medical prescription.
Medicinal product subject to special medical prescription (e.g. narcotic)	Rpw – Lek wydawany na receptę	Rpw - Medicinal product subject to medical prescription.
Medicinal product only for hospital use	Lz – Lek stosowany w lecznictwie zamkniętym	Lz - Medicinal product only for hospital use

Identification and Authenticity
The GTIN number is required on the labelling.

Symbols and 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 (PT)

Additional Requirements for the Labelling

Price and Reimbursement
The need of reference to the price and reimbursement in the labelling should be done accordingly with the latest update of the specific national legislation.
For regulatory actions regarding Price the sentence "PVP, se aplicável e de acordo com os critérios e legislação em vigor" should be included.

Legal Status
The legal status is required on the labelling for prescription and non-precription medicinal products.

Section / Explanation	Portuguese text required on the labelling	English translation
For medicinal products not subject to medical prescription	Medicamento não sujeito a receita médica	Not subject to medical prescription
For medicinal products subject to medical prescription	Medicamento sujeito a receita médica	Subject to medical prescription
For medicinal products on restricted medical prescription	Medicamento de receita médica restrita, de utilização reservada a certos meios especializados	Restricted use
For renewed prescription medicinal products	Medicamento de receita médica renovável	Medicinal product on prescription which may be renewed
For medicinal products on special medical prescription containing narcotic substances or psychotropic substances	Medicamento de receita médica especial	Subject to special medical prescription

Identification and Authenticity
A digital code, a bar code and the marketing authorisation number must appear on the label, to identify the medicinal product.

Specific types of medicinal products:

Section / Explanation	Portuguese text required on the labelling	English translation
Products for external use should state in a red boxed area on the labelling:	"Uso externo"	"External use"

For medicinal products on special medical prescription containing narcotic substances or psychotropic substances – tables I and II of Decreto-Lei n.º 15/93, de 22 de Janeiro	A double red line should be included in the immediate packaging	Only applicable to the immediate packaging
Generic medicinal products should state on the labelling:	"MG“	Generic medicinal product
For Homeopathic medicinal products	The expression “Medicamento Homeopático” must appear on blue background	Applicable to the outer, immediate packaging and Leaflet
For Traditional Herbal Medicinal Products	The expression “Medicamento tradicional à base de plantas”	Applicable to the outer, immediate packaging and Leaflet

- Radiopharmaceuticals – immediate packaging label
    - MA number, designation or chemical symbol of the radionuclide
    - Batch identification and expiry date
    - International radioactivity symbol
    - Name and address of the manufacturer
    - Radioactive activity per dose

Other relevant information to appear on the labelling:

- The name of the local representative may be added if it is mentioned on the leaflet.
- Adequate space should be left blank for the pharmacist to insert information on the dosage schedule
- For OTC products, therapeutic indications may be added.
- The expressions “Amostra gratuita” and “Proíbida a venda ao publico” can be added for samples that may be provided to healthcare professionals (in the conditions expressed in the national legislation)
- Different print colours and/or types should be used for the different pharmaceutical forms/strengths of the same medicinal product

ROMANIA (RO)

Additional Requirements for the Labelling

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:

The 'local representative' may be indicated in the package leaflet by name and telephone number and/or electronic e-mail address. Post address may be added space permitting.

SLOVAK REPUBLIC (SK)

Additional Requirements for the Labelling

Price
There is no requirement for the price to appear in the label.

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

Legal Status

Section / Explanation	Slovak text required on the labelling	English translation
Section 14, medicinal product subject to medical prescription	Výdaj lieku je viazaný na lekársky predpis.	Medicinal product subject to medical prescription.
Section 14, medicinal product not subject to medical prescription	Výdaj lieku nie je viazaný na lekársky predpis.	Medicinal product not subject to medical prescription.
Section 14, medicinal product subject to special medical prescription.	Výdaj lieku je viazaný na osobitné tlačivo so šikmým modrým pruhom.	Medicinal product subject to special medical prescription with skew blue stripe.
Section 14, medicinal product subject to restricted medical prescription	Výdaj lieku je viazaný na lekársky predpis s obmedzením predpisovania.	Medicinal product subject to restricted medical prescription.

Identification and Authenticity
The GTIN code (bar code) is required on the labelling if the medicinal product is labelled by this code.

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

For the outer packaging

Section / Explanation	Slovak text required on the labelling	English translation
Section 10	„NEPOUŽITÝ LIEK VRÁŤTE DO LEKÁRNE“	**“**THE UNUSED MEDICINAL PRODUCT RETURN TO THE PHARMACY”

Symbols and Pictograms

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

Additional Requirements for the Package Leaflet

As the legal status may differ between MS we suggest that the legal status including information about indications and dosage approved for OTC should be put in a blue box in the package leaflet.

In the case of imuno-biologic medicinal product, package leaflet shall include an information about presence of chemical substances classified as carcinogenic or mutagenic agents and of substances with toxic effect on nervous system, especially mercury (present as a thiomersal), aluminum (present in its compounds) and formaldehyde (and its compounds) and statement about their quantitative content within a single dose of dosage form.
Information about presence and quantitative content of substances used for inactivation of agens and their approved weight limits on human shall be also included.
Package leaflet shall include information about genetically modified substances.

SLOVENIA (SI)

Additional Requirements for the Labelling

Price
The price is not required and should not be present on the labelling.

Reimbursement
The reimbursement conditions are not required and should not be present on the labelling.

Legal Status
The legal status for supply is required on the labelling.
The following requirements concerning the legal status for supply to the patient are to be stated:

Section / Explanation	Slovenian text required on the labelling	English translation
For medicinal products subject to medical prescription only, the following information is required:	Rp – Predpisovanje in izdaja zdravila je le na recept.	Rp - Medicinal products prescribed and dispensed to medical prescription only.
For medicinal products that are intended exclusively for in-hospital treatment because of their properties, relative novelty or public health protection, the following information is required:	H – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v bolnišnicah.	H - Medicinal products prescribed and dispensed to medical prescription only that are intended for in-hospital treatment only.
For medicinal products that require administration and supervision by a healthcare professional, which shall be used exclusively in public health institutions and by legal entities and natural persons pursuing healthcare services, the following information is required:	ZZ – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v javnih zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost.	ZZ - Medicinal products prescribed and dispensed to medical prescription, which shall be used in public health institutions only and by legal entities and natural persons pursuing healthcare services.
For medicinal products, that are used for the treatment of diseases which must be diagnosed in a hospital or other institution with adequate	H/Rp – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v bolnišnicah. Izjemoma se lahko uporablja pri	H/Rp - Medicinal products prescribed and dispensed to medical prescription that are intended for in-hospital treatment

diagnostic facilities, although administration of the medicinal products and follow-up of the treatment may be carried out outside the hospital settings, the following information is required:	nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju.	only. Administration of the medicinal products and follow-up of the treatment may be.
For medicinal products requiring a prescription drawn up by a specialist in the relevant field of medicine or another physician authorised by that specialist and special supervision to be carried out throughout the course of treatment, the following information is required:	Rp/Spec – Predpisovanje in izdaja zdravila je le na recept zdravnika specialista ustreznega področja medicine ali od njega pooblaščenega zdravnika.	Rp/Spec - Medicinal products prescribed and dispensed to medical prescription by a specialized physician in the relevant field of medicine or another physician authorised by that specialist.
For medicinal products not subject to medical prescription and supplied in pharmacies only, the following information is required:	BRp – Izdaja zdravila je brez recepta v lekarnah.	BRp - Medicinal products not subject to medical prescription supplied in pharmacies only.
For medicinal products not subject to medical prescription and supplied either in pharmacies or non-pharmacy outlets, the following information is required:	BRp – Izdaja zdravila je brez recepta v lekarnah in specializiranih prodajalnah.	BRp - Medicinal products not subject to medical prescription supplied either in pharmacies or non-pharmacy outlets.

If there is insufficient space on the labelling, abbreviations can be used for restricted prescriptions (i.e. H, ZZ, H/Rp or Rp/Spec), however, they must be preceded by the phrase "Predpisovanje in izdaja zdravila je le na recept s posebnim režimom" (e.g. Predpisovanje in izdaja zdravila je le na recept s posebnim režimom – H).

Identification and Authenticity

- The EAN code (bar code) is required on the labelling of the medicinal products that are not obliged to bear the safety features.
- In case of medicinal products derived from blood or plasma, there is an additional specific requirement: country of origin of blood/plasma must be stated.
- In the case of active substances manufactured by gene technology, this active substance should be stated together with the designation of the genetically modified microorganisms or cell lines.

Symbols and Pictograms

Δ Medicinal products which may reduce the ability to drive or operate machines should have a warning symbol – an empty triangle in the colour of the text.

▲ Medicinal products which significantly reduce the ability to drive or operate machines should have a warning symbol – a full triangle in red colour.

§ Medicinal products on special prescription (narcoticts) should be marked with the symbol § in the colour of the text.

! Medicinal products, for which only a limited quantity may be dispensed at one time, should be marked with the exclamation mark (!) in the colour of the text.

The above mentioned markings must be printed in at least one half the size of the name of the medicinal products and be in a visible place.

Additional Requirements for the Package Leaflet

Legal Status

Above the heading "This leaflet was last approved in" the following requirements describing the legal status for supply to the patient are to be stated under the title "Način/režim predpisovanja in izdaje zdravila" (English translation: "Classification for supply"):

Section / Explanation	Slovenian text required on the labelling	English translation
For medicinal products subject to medical prescription only, the following information is required:	Rp – Predpisovanje in izdaja zdravila je le na recept.	Rp - Medicinal products prescribed and dispensed to medical prescription only.
For medicinal products that are intended exclusively for in-hospital treatment because of their properties, relative novelty or public health protection, the following information is required:	H – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v bolnišnicah.	H - Medicinal products prescribed and dispensed to medical prescription only that are intended for in-hospital treatment only.
For medicinal products that require administration and supervision by a healthcare professional, which shall be used exclusively in public health institutions and by legal entities and natural persons pursuing healthcare services, the following information is required:	ZZ – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v javnih zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost.	ZZ - Medicinal products prescribed and dispensed to medical prescription, which shall be used in public health institutions only and by legal entities and natural persons pursuing healthcare services.

For medicinal products, that are used for the treatment of diseases which must be diagnosed in a hospital or other institution with adequate diagnostic facilities, although administration of the medicinal products and follow-up of the treatment may be carried out outside the hospital settings, the following information is required:	H/Rp – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v bolnišnicah. Izjemoma se lahko uporablja pri nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju.	H/Rp - Medicinal products prescribed and dispensed to medical prescription that are intended for in-hospital treatment only. Administration of the medicinal products and follow-up of the treatment may be.
For medicinal products requiring a prescription drawn up by a specialist in the relevant field of medicine or another physician authorised by that specialist and special supervision to be carried out throughout the course of treatment, the following information is required:	Rp/Spec – Predpisovanje in izdaja zdravila je le na recept zdravnika specialista ustreznega področja medicine ali od njega pooblaščenega zdravnika.	Rp/Spec - Medicinal products prescribed and dispensed to medical prescription by a specialized physician in the relevant field of medicine or another physician authorised by that specialist.
For medicinal products not subject to medical prescription and supplied in pharmacies only, the following information is required:	BRp – Izdaja zdravila je brez recepta v lekarnah.	BRp - Medicinal products not subject to medical prescription supplied in pharmacies only.
For medicinal products not subject to medical prescription and supplied either in pharmacies or non-pharmacy outlets, the following information is required:	BRp – Izdaja zdravila je brez recepta v lekarnah in specializiranih prodajalnah.	BRp - Medicinal products not subject to medical prescription supplied either in pharmacies or non-pharmacy outlets.

SPAIN (ES)

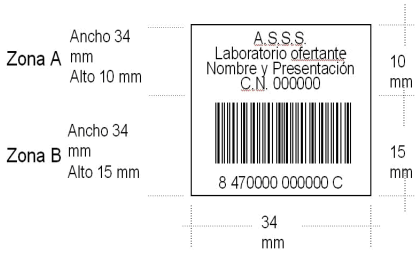
Additional Requirements for the Labelling

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.

The inclusion of the complete name of the medicinal product (name, strength and pharmaceutical form; including 'EFG' when applicable) is optional and should be included in a visible place and using big enough font size to ensure adequate readability.

Symbols and 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)

Local representative

The minimum information to be included is the name and telephone number. The inclusion of their logo is only permitted if readability is not affected, and should be included immediately after the contact information.

Manufacturer

Only the name and address should be included. The inclusion of this information is optional.

Parallel distribution

For medicinal products subject to parallel distribution the following information should be included on the packaging:

Mandatory information:

- The Marketing authorisation holder: name and address.
- The distribution responsible "Parallel distributed by": name and address.

or

- Repackage responsible "Repackaged by": name and address. (If there is product repackaging and the responsible differs from the distribution responsible).

or

- "Parallel distributed and repackaged by": name and address (when they are the same).

Optional information:

- Manufacturer: name and address.

SWEDEN (SE)

Additional Requirements for the Labelling

Price
There is no requirement for the price to appear on the labelling.

Reimbursement
There are no reimbursement conditions to appear on the labelling.

Legal Status
The legal status is accepted but not required on the labelling.

Identification and Authenticity
The Nordic number is required on the outer labelling of all medicinal products, except radiopharmaceuticals and homeopathic medicinal products. It is written as "Vnr XX XX XX". The EAN code (bar code) is accepted but not required on the labelling.

Additional Requirements for the Package Leaflet

The following text should appear in the Package Leaflet. For readability reasons we suggest that the text below should appear in separate paragraphs under the adequate headings.

Section / Explanation	Swedish text required on the labelling	English translation
Under heading number 1	(Aktiv substans) som finns i (produktnamn) kan också vara godkänd för att behandla andra sjukdomar som inte nämns i denna produktinformation. Fråga läkare, apoteks- eller annan hälso- och sjukvårdspersonal om du har ytterligare frågor och följ alltid deras instruktion.	(Active Substance) which is contained in (product) may also be authorised to treat other illnesses, which are not mentioned in this leaflet. Ask your doctor, pharmacist or other healthcare professional if you have further questions and always follow their instructions.
For products which may reduce the ability to drive or operate machines the following text should be included under the heading "Driving and using machines"	Du är själv ansvarig för att bedöma om du är i kondition att framföra motorfordon eller utföra arbeten som kräver skärpt uppmärksamhet. En av faktorerna som kan påverka din förmåga i dessa avseenden är användning av läkemedel	You alone are responsible to decide if you are in a fit condition to drive a motor vehicle or perform other tasks that demand increased concentration. Because of their effects or undesirable effects, one of the factors that can reduce your ability to do these

	på grund av deras effekter och/eller biverkningar. Beskrivning av dessa effekter och biverkningar finns i andra avsnitt. Läs därför all information i denna bipacksedel för vägledning. Diskutera med din läkare eller apotekspersonal om du är osäker.	things safely is your use of medicines. Descriptions of these effects can be found in other sections. Read all the information in this leaflet for guidance. Discuss with your doctor, nurse or pharmacist if you are unsure about anything.
Under the heading "If you take more X than you should"	Om du fått i dig för stor mängd läkemedel eller om t.ex. ett barn fått i sig läkemedlet av misstag kontakta läkare, sjukhus eller Giftinformationscentralen (tel. 112) för bedömning av risken samt rådgivning.	If you have taken more X than you should, or if children have been taking medicine by accident, please contact your doctor, the hospital or Giftinformationscentralen (tel. 112) to get an opinion of the risk and advice on action to be taken.

Additional requirements regarding OTC for the Package Leaflet and Labelling
As the legal status may differ between MS there is a need for the possibility to make additional amendments as adequate for the legal status.

UNITED KINGDOM IN RESPECT OF NORTHERN IRELAND (UK-NI)

Additional Requirements for the Labelling

Legal Status
The legal status is required on the labelling.
Labelling must include an indication of the legal status as follows:

Medicines for supply only on the prescription of a medical practitioner - the letters POM in black surrounded by a box:

POM

Medicines which may be supplied without prescription only under the supervision of a registered pharmacist - the letter P in black surrounded by a box:

P

Some additional statements are required to appear by law on the labelling and/or the package leaflet for certain medicines. The requirements are set out in current UK legislation.
The additional requirements affect medicines which contain the following substance:

- Paracetamol

Applicants whose products contain this substance should refer to UK regulations for detailed requirements.

Additional Requirements for the Package Leaflet

Some additional statements are required to appear by law on the labelling and/or the package leaflet for certain medicines placed on the UK market. The requirements are set out in current UK legislation.

The additional requirements affect medicines which contain the following substance:

- Paracetamol

Applicants whose products contain this substance should refer to UK regulations for detailed requirements.

Other warning statements for certain medicines are set out in national guidance documents which are available from the following link:

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/835489/Warning_Statements.pdf.