

## “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 derivatives 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
Medicines, which may reduce the ability to drive and operate machines by causing for example tiredness or dizziness	 <p>“Achtung: Dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen.”</p>	 <p>”Caution: This medicine might compromise reactivity and ability to drive.”</p>
Recycling symbols are accepted on the labelling, but not required.	<p>“Der Grüne Punkt”</p> 	<p>“Der Grüne Punkt”  or other.</p>
Radiopharmaceuticals		
For Blood derivatives or vaccines: self-adhesive label	<p>[Selbstklebeetikette] &lt; Product name &gt; Verw. bis: Ch.B.:</p>	<p>[self-adhesive label] &lt; Product name &gt; EXP: LOT:</p>



## 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. ....
<b>Anti doping Note</b> (if applicable)	"Die Anwendung des Arzneimittels kann bei Dopingkontrollen zu positiven Ergebnissen führen."	The administration of the medicinal product may result in positive doping controls.

	In case of misuse of the medicinal product for doping purposes the corresponding risks should be stated.	
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**Symbols and Pictograms:**

<b>Section / Explanation</b>	<b>Austrian text required in the package leaflet</b>	<b>English translation</b>
Medicines, which may reduce the ability to drive and operate machines by causing for example tiredness or dizziness	 <p>“Achtung: Dieses Arzneimittel kann die Reaktionsfähigkeit und Verkehrstüchtigkeit beeinträchtigen.”</p>	 <p>”Caution: This medicine might compromise reactivity and ability to drive.”</p>

# 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 a 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	French: usage externe – Dutch: uitwendig gebruik – German: äusserliche anwendung		external application

<p>deliver all packaging containing those medicinal products for external application with a warning symbol in relief, recognisable by touch. (the specifications of the triangle are as follows:  This sign is an equilateral triangle with an 18 mm (+/- 0.2 mm) side. The width of the side is 1.7 mm (+/- 0,2 mm). Approximately 2 mm above the triangle, there is point with a diameter of 1.7 mm (+/- 0.2 mm). All these elements must have a relief (height) of 0.25 to 0.5 mm.  For small packagings, a scaled down size is provided: side 9 mm (+/- 1 mm), width 1 mm (+/- 0.2 mm). The height remains unchanged: 0.25 to 0.5 mm.  The sign will in principle be put at a height of maximum 50 mm from the basis of the packaging, and at whichever point for the scaled down size (on small packagings).</p>			
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### 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	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

<p>should</p>	<p>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).</p>	<p>245)</p>
<p>Section 6,  Contents of the pack and other information:</p> <p>Supply classification of the medicinal product</p> <p>Mention the MA number of the medicinal product</p>	<p style="text-align: center;">&lt;...&gt;</p> <p style="text-align: center;">BExxxxxxx</p>	<p style="text-align: center;">&lt;...&gt;</p> <p style="text-align: center;">MA-No. ....</p>

# 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  <i>The outer packaging has to be marked with a double blue line positioned diagonally</i>	Subject to special medical prescription
For medicinal products on special medical prescription containing narcotic substances	По специално лекарско предписание  <i>The outer packaging has to be marked with a double red line positioned diagonally</i>	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;

<b>Section / Explanation</b>	<b>Bulgarian text required on the labelling</b>	<b>English translation</b>
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	Lijek se izdaje bez recepta, u ljekarni i	Medicinal product not subject to

prescription supplied in pharmacy and specialised retail stores the following information is required:	specijaliziranim prodavaonicama za promet na malo lijekovima.	medical prescription supplied in pharmacy and specialised retail stores.
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### **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 labelling.

However, if the legal status is stated on the labelling, than the following text has to be used:

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

### Identification and Authenticity

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

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

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

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 SUKL.

## Additional Requirements for the Package Leaflet

### Legal Status

The legal status is accepted but not required in the package leaflet.

However, if the legal status is stated in the package leaflet, than the following text has to be used:

<b>Section / Explanation</b>	<b>Czech text required in the package leaflet</b>	<b>English translation</b>
For medicinal products subject to medical prescription	“Výdej léčivého přípravku vázán na lékařský předpis.”	Medicinal product subject to medical prescription.
For medicinal products not subject to medical prescription	“Výdej léčivého přípravku možný bez lékařského předpisu.”	Medicinal product not subject to medical prescription.

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 SUKL.

# 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.
<p>Section 2, Driving and using machines</p> <p><i>-Only for products which carry the red warning triangle</i></p>	<p>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.</p> <p><i>eller</i></p> <p>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.</p> <p><i>eller</i></p> <p>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.</p>	<p>The package contains a red warning triangle. This means that "X" can be sedating and can reduce the ability to drive and use machines.</p> <p><i>or</i></p> <p>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.</p> <p><i>or</i></p> <p>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.</p>
<p>Section 3, If you &lt;take&gt; &lt;use&gt; more X than you should</p>	<p>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).</p>	<p>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).</p>

### 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.

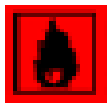
### Identification and Authenticity

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 / Explanation	Finnish text required in the package leaflet	Swedish text required in the package leaflet	English translation
Under heading number 1	(Lääkeainetta), jota (Kauppanimi) sisältää, voidaan joskus käyttää myös muiden kuin	(Aktiv substans) som finns i (produktnamn) kan också vara godkänd	(Active Substance) which is contained in (product) may

	<p>tässä pakkauselosteessa mainittujen sairauksien hoitoon. Kysy neuvoa lääkäriltä, apteekkihenkilökunnalta tai muulta terveydenhuollon ammattilaiselta tarvittaessa ja noudata aina heiltä saamiasi ohjeita.</p>	<p>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.</p>	<p>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.</p>
<p>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”</p>	<p>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 pakkauseloste opastukseksi. Keskustele lääkärin tai apteekkihenkilökunnan kanssa, jos olet epävarma.</p>	<p>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.</p>	<p>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.</p>
<p>Under the heading “If you take</p>	<p>Jos olet ottanut liian suuren lääkeannoksen tai vaikkapa lapsi on</p>	<p>Om du fått i dig för stor mängd läkemedel eller om</p>	<p>If you have taken more X than you should, or if</p>

<p>more X than you should”</p>	<p>ottanut lääkettä vahingossa, ota aina yhteyttä lääkäriin, sairaalaan tai Myrkytystietokeskukseen (puh. 0800 147 111 [Suomessa, 112 Ruotsissa]*) riskien arvioimiseksi ja lisäohjeiden saamiseksi.</p>	<p>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.</p>	<p>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.</p>
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\* square brackets if needed

# 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:

<b>French text required on the labelling</b>	<b>English translation</b>
“respecter les doses prescrites“	Respect the prescribed dose

- then following mentions:

<b>French text required on the labelling</b>	<b>English translation</b>
<ul style="list-style-type: none"><li>• «Liste I» or «Liste II»</li><li>• «Uniquement sur ordonnance»</li><li>• «Ne pas avaler» (if appropriate)</li></ul>	<ul style="list-style-type: none"><li>• List I or List II</li><li>• prescription only</li><li>• do not swallow (if appropriate)</li></ul>

## 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“	<b>narcotic</b>
	« prescription sur ordonnances sécurisées »	<b>prescription on a specific paper</b>
	“prescription limitée à x jours de traitement“	<b>prescription limited to 7x days of treatment</b>
If applicable:	“délivrance fractionnée par périodes de x jours“	<b>divided supply to the patient, for x days of treatment</b>

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”	<b>Medicinal product subject to hospital use only</b>
b) In case of medicinal product subject to hospital prescription only, the following must be stated:	“médicament soumis à prescription hospitalière“	<b>Medicinal product subject to hospital prescription only</b>
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“	<b>Medicinal product subject to initial hospital prescription only</b>
d) In case of medicinal product subject to specialist prescription only, the following must be stated:	“médicament à prescription réservée aux spécialistes en ... »	<b>Medicinal product subject to specialist prescription only</b>

The concerned specialists must be listed. 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”	<b>Medicinal product subject to special supervision throughout the treatment</b>
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 ».	<b>Medicinal product subject to professional use only, as referred to article R. 5121-80 of the French Public Health Code</b>
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”.	<b>Emergency situation use as referred to article R. 5121-96 of the French Public Health Code</b>
h) others restrictions or information may apply on a case by case basis		

### **Identification and Authenticity**

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

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

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

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”	<b>Human blood-derived medicinal product</b>

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
 <b>Soyez prudent</b> Ne pas conduire sans avoir lu la notice	<b>Be careful</b> <b>Don't drive before reading the leaflet</b>
 <b>Soyez très prudent</b> Ne pas conduire sans l'avis d'un professionnel de santé	<b>Be very careful</b> <b>Don't drive without an healthcare professional opinion</b>
 <b>Attention, danger : ne pas conduire</b> Pour la reprise de la conduite, demandez l'avis d'un médecin	<b>Warning, danger : do not drive</b> <b>Don't drive again without a doctor opinion</b>

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




	
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All pictograms and information on the risk level classification (1, 2 or 3) are available on the ANSM website: [www.ansm.sante.fr](http://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 *X*th month of pregnancy):

	French text required on the labelling	English translation
1	 <p>XXX + GROSSESSE = DANGER</p> <p>Ne pas utiliser chez [mentionner les personnes concernées], sauf en l'absence d'alternative thérapeutique</p>	<p>XXX + PREGNANCY = DANGER</p> <p>Do not use for [mention here the concerned population], unless there is no alternative treatment</p>
2	 <p>XXX + GROSSESSE = INTERDIT</p> <p>Ne pas utiliser chez [mentionner les personnes concernées]</p>	<p>XXX + PREGNANCY = PROHIBITED</p> <p>Do not use for [mention here the concerned population]</p>
3	 <p>XXXXX + GROSSESSE = DANGER</p> <p>Ne pas utiliser chez les filles, adolescentes, femmes en âge de procréer ou enceintes, sauf en cas d'échec des autres traitements</p>	<p>XXX + PREGNANCY = DANGER</p> <p>Do not use in female children, in female adolescents, in women of childbearing potential and pregnant women unless alternative treatments are ineffective</p>

# 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	ΒΣ, 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:

<b>Section / Explanation</b>	<b>Greek text required on the labelling</b>	<b>English translation</b>
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 pakning 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 lækningin 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 IMB.

### **Additional requirements for Package Leaflet**

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

# ITALY (IT)

## Additional Requirements for the Labelling

### Price

The price is required on the labelling.

### Reimbursement

The reimbursement conditions are required on the labelling.

Should a medicinal product be considered reimbursable by the National Health Service (SSN), the Company should insert within the blue box a peelable sticker containing the following information, in compliance with the Decree of Ministry of Health 2 August 2001:

- Bar code
- Name of the medicinal product (including strength, pharmaceutical form, units)
- National Identification Number
- Name of the Marketing Authorisation Holder

The following wording, printed in the area underneath the sticker, must appear once the latter has been removed: “Confezione dispensata dal SSN”

### Classification for supply

Section / Explanation	Italian text required on the labelling	English translation
For medicinal products not subject to medical prescription (OTC, SOP) one of the following is required:	Medicinale di automedicazione	Medicinal product for self-medication
	Medicinale non soggetto a prescrizione medica	Medicinal product not subject to medical prescription
For medicinal products subject to medical prescription the following is required (RR):	Da vendersi dietro presentazione di ricetta medica	Prescription-only medicinal product
For medicinal products subject to non renewable medical prescription the following is required(RNR):	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta	Medicinal product on prescription which may not be renewed
For medicinal products on restricted medical prescription, the specification of the restricted authorised prescriber [hospital department(s) or specialist(s)] has to be added to the general statement on prescription-	Da vendersi dietro presentazione di ricetta medica limitativa su prescrizione di centri ospedalieri o di specialisti <i>[indicare il tipo di struttura o di specialista autorizzato alla prescrizione]</i>	Prescription only medicinal product. Prescription restricted to hospitals or specialists [Specialist(s) to be specified]

only status (RRL)		
For medicinal products on restricted medical prescription, the specification of the restricted authorised prescriber [hospital department(s) or specialist(s)] has to be added to the general statement on restricted prescription-only status (RNRL):	Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta su prescrizione di centri ospedalieri o di specialisti [ <i>indicare il tipo di struttura o di specialista autorizzato alla prescrizione</i> ].	Product on prescription which may not be renewed. Prescription restricted to hospitals or specialists [ <i>Specialist(s) to be specified</i> ]
For medicinal products to be used only in hospitals, (OSP):	Uso riservato agli ospedali<alle cliniche e alle case di cura [where appropriate]>. Vietata la vendita al pubblico.”	Hospital use only, not to be sold to the public
For medicinal products to be used only by specialist(s), the following is required .	Uso riservato allo specialista. Vietata la vendita al pubblico [lo specialista deve essere specificato].	Medicinal product to be used by specialists only. Not be sold to the public. [ <i>Specialist(s) to be specified</i> ]
For psychotropic and narcotic medicinal products falling within the scope of the Italian law D.P.R. 9 Ottobre n. 309 as amended, the following is required (in compliance with the Decree of Ministry of Health 26 Marzo 1979).  For those psychotropic and narcotic medicinal products included in “Table of medicinal products, section A”, the statement must be marked with a red double line as described	<div style="border: 2px solid red; padding: 5px; margin-bottom: 10px;"> <p>Medicinale soggetto alla disciplina del D.P.R. 309/90 e s.m.i. Tabella medicinali sezione &lt;A&gt;&lt;B&gt;&lt;C&gt;&lt;D&gt;&lt;E&gt;</p> </div> <p>Da vendersi dietro presentazione di ricetta ministeriale a ricalco.</p>	<p>Medicinal product subject to the provisions of D.P.R. 309/90 and amendments, Table of medicinal products section&lt;A&gt;&lt;B&gt;&lt;C&gt;&lt;D&gt;&lt;E&gt;</p> <p>Medicinal product on special ministerial prescription.</p>
For psychotropic and narcotic medicinal products falling within the scope of the Italian law D.P.R. 9 Ottobre n. 309 as amended, included in	Medicinale soggetto alla disciplina del D.P.R. 309/90 e s.m.i.. Tabella medicinali sezione <A><D><E> <Allegato III bis>	Medicinal product subject to the provisions of D.P.R. 309/90 and amendments. Table of medicinal products section<A><D><E> <Annex III bis>

Annex III bis, the following is required		
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### Identification and Authenticity

National identification Number is required on any part of the labelling as well as on the peelable sticker.

### Particular information and statements

Section / Explanation	Italian text required on the labelling	English translation
Statement below the name of the medicinal product, in compliance with the requirements of the Italian Law 26 Luglio 2005 n 149, Art. 1 bis (for generic products only)	Medicinale Equivalente	“Equivalent medicinal product”
Statement, where appropriate, in compliance with the requirements of the Italian Law 219/2006, art. 73(1g)	Controindicato l’uso contemporaneo di bevande alcoliche	The concomitant use of alcohol is contra-indicated
Statement, where appropriate, in compliance with the requirements of the Italian Law 219/2006, art. 73(1g)	Può alterare la capacità di guidare veicoli e di usare macchinari	May influence the ability to drive and use machines
Medicinal products for intravenous use, containing $\geq 1$ mEq/ml potassium. In the outer package: in red characters in compliance with the requirements of the Determinazione 11 Novembre 2005 issued by the AIFA.	<b>K</b> Diluire prima della somministrazione: mortale se infuso non diluito	<b>K</b> To be diluted before administration: fatal if not diluted
Medicinal products for intravenous use, containing $\geq 1$ mEq/ml potassium. In the <b>immediate package</b> : in red characters in compliance with the requirements of the Determinazione 11	<b>K</b> Mortale se non diluito	<b>K</b> Fatal if not diluted

Novembre 2005 issued by the AIFA.		
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### Symbols and Pictograms

Doping pictogram: in compliance with the requirements of the Decree of Ministry of Health 19 Maggio 2005 (implementing the Italian Law 14 Dicembre 2000 n 376 as amended);



pictogram size: Ø17 mm

Smile pictogram: for medicinal products not subject to medical prescription and for self-medication in compliance with the requirements of the Decree of Ministry of Health 1 Febbraio 2002;



pictogram size: Ø17 mm

### Additional Requirements for the Package Leaflet

Section / Explanation	Italian text required on the Package Leaflet	English translation
Statement below the name of the medicinal product, in compliance with the requirements of the Italian Law 26 Luglio 2005 n° 149, Art. 1 bis (for generic products only)	Medicinale Equivalente	Equivalent medicinal product
<p>- Statement, where appropriate, according to the requirements of the Italian Law 14 Dicembre 2000 n° 376 as amended</p> <p>- Statement, where appropriate, according to the requirements of the Decree of Ministry of Health 19 Maggio 2005.</p>	<p>Per chi svolge attività sportiva: l'uso del farmaco senza necessità terapeutica costituisce doping e può determinare comunque positività ai test antidoping.</p> <p>- Attenzione per chi pratica attività sportiva: il principio attivo contenuto in questa preparazione è incluso nella lista delle sostanze vietate per doping [<i>Principi attivi appartenenti alla classe S5 – Sottoclasse: altri agenti mascheranti – Plasma expanders</i>]</p> <p>- Attenzione per chi svolge attività sportive: il prodotto medicinale</p>	<p>In case of any sport activity: the use of this medicinal product in the absence of a therapeutic need is doping and might cause a positive anti-doping result</p> <p>- Attention in case of any sport activity: the active substance of this preparation is included in the list of prohibited doping substances” [<i>active substances belonging to class S5– plasma expanders</i>]</p> <p>- Attention in case of any sport activity: medicinal</p>

	<p>contiene sostanze vietate per doping. È vietata un'assunzione diversa, per schema posologico e per via di somministrazione, da quelle riportate [<i>Specialità medicinali per uso topico, per uso dermatologico, oculistico, sinologico, odontostomatologico, auricolare contenenti principi attivi, appartenenti alle classi S5 – Diuretici e agenti mascheranti e S6 -stimolanti</i>]</p> <p>- Per chi svolge attività sportiva, l'uso di medicinali contenenti alcool etilico può determinare positività ai test antidoping in rapporto ai limiti di concentrazione alcolemica indicata da alcune federazioni sportive [<i>Specialità medicinali contenenti l'eccipiente alcool etilico</i>]</p>	<p>product contains doping substances. A different intake, dosage scheme or route of administration is forbidden [topically applied locally acting medicinal products belonging to class S5- S6]</p> <p>- In case of any sport activity, the use of medicinal product containing ethyl alcohol might cause a positive anti-doping result in relation to alcohol content limits as indicated by federations [<i>ethyl alcohol as excipient</i>]</p>
<p>Medicinal products for intravenous use containing <math>\geq 1</math> mEq/ml potassium. Statement in bold in compliance with the requirements of Determinazione 11 Novembre 2005 issued by AIFA.</p>	<p><b>Diluire prima della somministrazione: mortale se infuso non diluito.</b></p>	<p>To be diluted before infusion: fatal if not diluted</p>

# 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 should be printed on the pharmacy labelling.

### Reimbursement

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

### Legal Status

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.

## 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 bevat als werkza(a)m (e)	<b>Product contains as active ingredient (s)</b>

<p>product information because of patent law, the following sentence should be added in section 1 ‘What X is and what it is used for’</p>	<p>bestandde(e)l(en) &lt;na(a)m(en) van werkza(a)m(e) bestandde(e)l(en)&gt;, 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.</p>	<p><b>&lt;name of active ingredient(s)&gt;, approved for other disorders not mentioned in this package leaflet. Ask your doctor or pharmacist if you have further questions.</b></p>
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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

There are no reimbursement conditions to appear on the label.

### Legal Status

Section / Explanation	Norwegian text required on the labelling	English translation
There is no requirement for the legal status to appear on the label except for packages intended for dose dispensing	Kun til dosedispensering	For dose dispensing only

### Local Representative


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 EU text on the outer packaging) and if mentioned in the leaflet.

### Identification and Authenticity

The Nordic number is required on the outer labelling of all 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

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

Products which reduce the ability to drive or operate machines must have a warning triangle on the outer and inner packaging. The 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.



### Particular warning on the labelling for medicinal products containing glucosamine when extracted from shrimp or other shellfish

Norwegian text required on the labelling	Text in English
Skal ikke brukes av skalldyrallergikere	Not to be used if allergic to shellfish

### Additional Requirements for the Package Leaflet

In general: The below listed “Blue box” statements should for readability reasons be included in the package leaflet in connection with the corresponding headings. Thus the patients will read the adequate information where they would expect to find it.

#### Legal Status

If the medicinal product is fully or partially exempted from prescription, the indication and posology approved for OTC status should be clearly stated under the respective heading.

Section / Explanation	Norwegian text required in the package leaflet	English translation
Under the heading number 1 (May be waived for products intended for hospital use only, and administered by health care professionals)	Vær oppmerksom på at legen kan ha foreskrevet legemidlet til en annen bruk og/eller med en annen dosering enn angitt i pakningsvedlegget. Følg alltid legens forskrivning som er angitt på apoteketiketten.	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 labelling.
Under the heading “Driving and using machines” – A standard sentence for all products except mineral- and vitamin products and most topical products	Du må bare kjøre bil eller utføre risikofylt arbeid når det er trygt for deg. Legemidler kan påvirke din evne til å kjøre bil eller utføre risikofylt arbeid. Les informasjonen i	You should drive a vehicle or carry out dangerous work only when you can do it safely. Medicines may influence your capability to drive or carry out dangerous work. Read the information provided in the package



	pakningsvedlegget nøye. Er du i tvil må du snakke med lege eller apotek.	leaflet carefully. Ask your doctor or pharmacy for advice if you are unsure.
Under the heading "If you take more X than you should"	Kontakt lege, sykehus eller Giftinformasjonen (tlf. 22 59 13 00) hvis du har fått i deg for mye legemiddel eller hvis barn har fått i seg legemiddel ved et uhell. For andre spørsmål om legemidlet, kontakt lege eller apotek.	Contact your doctor, the hospital or Giftinformasjonen (tel. 22 59 13 00) if you have taken more X than you should or if children have been taking medicine by accident. For other questions about the medicine, contact your doctor or pharmacy.

### **Additional requirements regarding OTC**

In addition to these Blue Box texts there might be additional requirements concerning the OTC status. 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 EAN code (bar code) 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 (⊘) – 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-prescription 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	"Uso externo"	"External use"

area on the labelling:		
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 "Proibida 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 prescripție 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 prescripție medicală – **P6L**

For medicinal products supplied in pharmacy based on special medical prescription (narcotics and psychotropics):

Medicament eliberat pe bază de prescripție 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 prescripție 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 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 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 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 immuno-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 agents 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	H/Rp – Predpisovanje in izdaja zdravila je le na recept, zdravilo pa se uporablja samo v	H/Rp - Medicinal products prescribed and dispensed to medical prescription

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:	bolnišnicah. Izjemoma se lahko uporablja pri nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju.	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.

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

- △ 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 (narcotics) 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 izdaja 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	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.

required:		
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

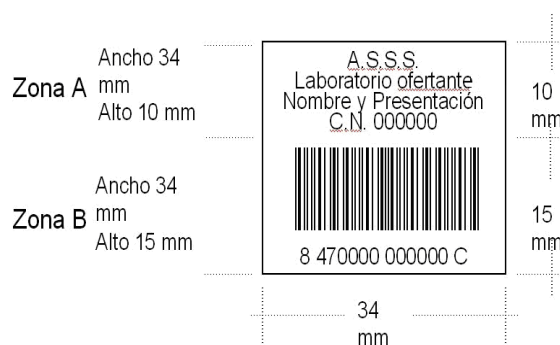
#### Price

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.

<b>Section / Explanation</b>	<b>Spanish text required on the labelling: acronyms</b>	<b>English translation</b>
Medicinal products subject to medical prescription	<b>MEDICAMENTO SUJETO A PRESCRIPCIÓN MEDICA</b> (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.

<b>Section / Explanation</b>	<b>Symbol in the labelling</b>
For medicinal products subject to medical prescription	○
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	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

	<p> 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.</p>	<p> 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.</p>
<p> Under the heading “If you take more X than you should”</p>	<p> 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.</p>	<p> 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.</p>

### **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 (UK)

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