

CHAPTER 7 GENERAL INFORMATION

Revision

July 2007

1. FORMAT FOR APPLICATIONS IN THE E.U.

Marketing Authorisation Applications, which should be submitted in either a national or Community procedure (i.e. to competent authorities of the Member States and the European Medicines Agency), consist of administrative information and the necessary documentation to demonstrate the quality, safety and efficacy of the product.

All applications have to be made entirely in accordance with the EU-CTD presentation outlined in the 2001 edition of NTA, Vol. 2B or its subsequent updates

The **Common Technical Document** is organized into 5 modules. The content of **Module 1** is defined by the European Commission in consultation with the competent authorities of the Member States, the European Medicines Agency and interested parties. Concerning the structure of Modules 2, 3, 4, and 5 they are intended to be common for all regions.

Module 2 contains high level summaries (the Quality Overall Summary, the Nonclinical Overview / Summaries, and the Clinical Overview / Summaries).

Chemical, Pharmaceutical and Biological documentation is provided by **Module 3**.

The documentation on the Toxicological and Pharmacological Tests performed on drug/active substance and a drug/medicinal product is provided in the Nonclinical Written Summaries (from Module 2) and by the Nonclinical Study Reports (**Module 4**).

The documentation on the Clinical Trials performed on the drug/medicinal product is provided in the Clinical Written Summaries (from Module 2) and in the Clinical Study Reports (**Module 5**).

Further information on the presentation and format of a dossier is given in '*The Rules Governing Medicinal Products in the European Union, Vol. 2B and Vol. 2C*'

Table of Content

	Page
1. FORMAT FOR APPLICATION IN THE EU	1
2. LANGUAGES TO BE USED FOR DOSSIER, RESPONSES, VARIATIONS AND RENEWALS	3
2.1 National, Mutual Recognition and Decentralised applications	3
2.2 Centralised procedure applications	6
3. NUMBER OF COPIES OF THE DOSSIER, RESPONSES, VARIATIONS AND RENEWALS	
3.1 National, Mutual Recognition and Decentralised Procedures	7
3.2 National, Mutual Recognition and Decentralised Procedures: “additional data” requested	12
3.3 National, Mutual Recognition and Decentralised Procedures: number of copies requested for renewal	15
3.4 Applications in the Centralised Procedure	18
4. DOSSIER CHECK-IN PROCEDURE	20
5. MOCK-UPS, SPECIMENS AND SAMPLES	22
6. NATIONAL PROCEDURE AFTER A COMMISSION DECISION ON A REFERRAL	27
7. LIST OF OFFICIAL JOURNALS	37
8. ADDRESSES FOR DELIVERY OF THE DOSSIER AND SUBSEQUENT CORRESPONDENCE	42
9. ADDRESSES FOR RECEIPT OF FEES AND TERMS FOR PAYMENT	54
10. ‘BLUE-BOX’ REQUIREMENTS	77

2. LANGUAGES TO BE USED FOR DOSSIER, RESPONSES, VARIATIONS AND RENEWALS

2.1 National, Mutual Recognition and Decentralised applications

CTD	AT	BE	DE (PEI)	DE	DK	EL	FI	FR	IE	IT	LU	NL	PT	SE	ES	UK	EFTA	
																	NO	IS
Module 1.1	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN		FI/SE/EN	FR/EN	EN			NL/EN	PT/EN/	SE/EN	ES/EN	EN	NO/EN	IS/EN
Module 1.2	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT	SE/EN	ES	EN	NO/EN	IS/EN
Module 1.3.115	DE/EN	FR/NL & EN ₁	DE/EN	DE/EN	DK/EN ²	EL	FI	FR&EN	EN	IT	FR/DE/LU	NL/EN	PT/EN	SE/EN ³	ES	EN	NO/EN ¹¹	IS/EN
Module 1.3.2 – 1.3.415	DE/EN	FR/NL ₁	DE/EN	DE/EN	DK/EN ¹	EL	FI & SE	FR/EN	EN	IT	FR/DE/EN	NL	PT/EN	SE/EN	ES	EN	NO/EN ¹¹	IS/EN ⁴
Module 1.4	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN/	SE/EN	ES/EN	EN	NO/EN	EN
Module 1.5	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN		FI/SE/EN	FR/EN	EN			NL/EN	PT/EN/	SE/EN	ES/EN	EN	NO/EN	EN
Module 1 - Annex	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN		FI/SE/EN	FR/EN	EN			NL/EN	PT/EN/	SE/EN	ES/EN	EN	NO/EN	EN
Module 2	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN		FI/SE/EN	FR/EN	EN			NL/EN	PT/EN/ ₅	SE/EN ⁶	ES/EN	EN	NO/EN	EN
Module 3	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Module 4	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Module 5	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Written responses	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Variations																		
Application form	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT	SE/EN	ES	EN	NO/EN	IS/EN
Type I documentation	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Type II documentation	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	IS/EN
Written responses	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	EN
Renewal	DE/EN	FR/NL/EN	DE/EN	DE/EN	DK/EN	EL/EN	FI/SE/EN	FR/EN	EN	IT/EN	FR/DE/EN	NL/EN	PT/EN	SE/EN	ES/EN	EN	NO/EN	IS/EN

2.1 National, Mutual Recognition and Decentralised applications (cont')

CTD	BG	CY	CZ	EE	HU	LV	LT	MT	PL	RO	SK	SI
Module 1.1	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT ⁷	PL/EN	RO/EN	SK/CZ/EN	SI&EN ¹⁷
Module 1.2	BG /EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN ¹⁸	RO/EN	SK/EN ¹⁴	SI&EN ¹⁵
Module 1.3.1	BG/EN ²⁰	EL	CZ	EE	HU/EN	LV/EN	LT & EN	EN/ MT	PL&EN	RO/EN ¹²	SK/EN	SI&EN ¹⁶
Module 1.3.2 – 1.3.4	BG /EN ²⁰	EL	CZ	EE	HU/EN	LV	LT & EN	EN/ MT	PL&EN	RO/EN ¹³	SK/EN	SI&EN ¹⁶
Module 1.4	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 1.5	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 1 - Annex	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 2	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 3	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 4	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN \	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Module 5	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Written responses	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Variations										RO/EN		
Application form	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN ¹⁹	RO/EN	SK/EN	SI&EN ²²
Type I documentation	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Type II documentation	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Written responses	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN
Renewal	BG/EN	EL/EN	CZ/EN/SK	EE/EN	HU/EN	LV/EN	LT/EN	EN/ MT	PL/EN	RO/EN	SK/CZ/EN	SI/EN ¹⁷

¹ The MAH is obliged to choose, at the time of submission, either Dutch or French. After a MA is granted, the MAH must translate SPC, leaflet and labels into the other national languages (Dutch or French and German). The responsibility for the correct translation rests with the MAH.

² EN for MRP/DCP and DA for national procedures. An electronic version (QRD Template) is also required.

³ For national applications SPC, PL and labelling in SE. For MRP/DCP applications SPC, PL and labelling in EN. An electronic version (EMEA template) is also required

⁴ An exemption from Icelandic translation of PIL and labels may be given if the product is not intended to be delivered directly to the patient hospitals

5 Introduction, Quality Overall Summary, Non Clinical Overview and Clinical Overview PT/EN/FR, recommended Portuguese translation; Overall CTD table of contents, Non Clinical and Clinical Summaries
EN/FR/PT

6 An electronic copy, preferably in word format, is also requested

7 English or Maltese

8 Verified translation of SPC (English version, approved by RMS) from English into Slovene language, signed by sworn interpreter for the English/Slovene language, which is appointed by Competent
Institution (e.g. Ministry of Justice for Slovene interpreters) should also be submitted

9 Application form, SPC, PIL, labelling: SI; other documentation: SI/EN

10 AT: For pure national applications only DE for SPC/PL/ label is accepted.

11 MRP/DCP: EN until end of procedure and NO for final MA. National: NO. An additional electronic version is required

12 RO for Module 1.3.2 and Module 1.3.3 and EN for Module 1.3.4

13 An electronic copy, preferably in word format is also required

14 Special cover letter for the application filled in the Slovak language must be submitted (cover letters are published at: <http://www.sukl.sk/regziad.doc>, <http://www.sukl.sk/zmeziad.doc>,
<http://www.sukl.sk/preziad.doc>)

15 For MRP/DCP: An electronic version is also required. For NP: SI version only.

16 For MRP/DCP: English version only. An electronic version is also required. When the international phase is finalised, the MAH should submit SPC, leaflet and labelling in SI for granting MA.
For NP: SPC, leaflet and labelling must be submitted in SI.

17 For MRP/DCP: cover letter and application form should be submitted in EN and SI. Other documents should be submitted in EN or SI. When the procedure is finalised, the MAH should submit SPC, leaflet
and labelling in SI. For NP: cover letter and application form, SPC, leaflet and labelling should be submitted in SI. Other documents should be submitted in EN or SI.

18 The national application form has to be in polish (available on the website http://www.urpl.gov.pl/lecznicze/narodowa/wnioski/za%2012_wniosek_Procedura_Narodowa.pdf)

19 The national application form has to be in polish (available on the website <http://www.urpl.gov.pl/wnioskizm.asp>)

20 For pure national applications English and/or BG for SPC/PL/ label is accepted. For MRP/DCP: English version only.
An electronic version is also required. When the international phase is finalised, the MAH should submit SPC, leaflet and labelling in BG for granting MA.

2.2 Centralised procedure applications

Dossier CTD	EMEA
Module 1.1	EN
Module 1.2	EN
Module 1.3.1	EN
Module 1.3.2. – 1.3.4	EN
Module 1.3.5	N.A.
Module 1.4	EN
Module 1.5	EN
Module 1 – Annex	EN
Module 2	EN
Module 3	EN
Module 4	EN
Module 5	EN
Written responses	EN
Variations	
Application form	EN
Type IA/IB Documentation	EN All ¹ for SPC/PL/LAB
Type II Documentation	EN All ¹ for SPC/PL/LAB
Written responses	EN All ¹ for SPC/PL/LAB
Renewal	EN All ¹ for SPC/PL/LAB

1. Not always required at submission - See also EMEA “Post-Authorisation Guidance” document on the EMEA Website.
One copy in all official EU languages and Norwegian and Icelandic for the SPC, Labelling and Package Leaflet.

3. NUMBER OF COPIES OF THE DOSSIER, RESPONSES, VARIATIONS AND RENEWALS

3.1 National, Mutual Recognition and Decentralised Procedures

CTD (Modules)	AT ⁶	BE	BG	CY	CZ	DE (PEI) ₁	DE _{1,2}	DK ₃	EE	EL	FI	FR	HU	IE	IT	LT	LV	LU	MT ₄	NL	PL	PT	RO	SE	SK	SI	ES	UK ₅	EFTA IS NO	
Full dossier	1	1 ⁷	1 ⁸⁰	1 ⁴	1 ⁸	3	2	1 ⁶⁹	1 ⁹	1	1 ¹⁰	3	1 ¹¹	2 ¹²	1 ¹³	1 ¹⁴	1 ¹⁵	1 ¹⁶	1 ¹⁷	1 ¹⁸	1 ¹⁹	4 ^{20, 21}	1 ⁷²	1 ⁷⁷	1 ^{75, 76}	1 ²²	1 ²³	1	1 ²⁶	1 ²⁷
Module 1.1	1	4	1	-	1 ²⁸	5	5	2	-	-	1	-	-	1	-	1	-	-	-	-	1	1 ²⁹	-	-	-	1	-	-	-	-
Module 1.2	1	4	2	-	2 ³¹	3	5	2	-	2	1	2 ⁰	4 ²⁹	1	1 ³⁴	-	1	-	-	-	4 ³⁵	1 ²⁹	2	-	3	1 ³⁷	1	1	-	-
Module 1.3.1, 1.3.2, 1.3.3	1	-	3 ⁸¹	-	2 ³¹	3	5	2	0 ³⁸	2	1	2 ⁰	1 ^{29, 53}	1	1 ³⁴	1 ⁴⁰	1	-	-	-	4 ⁴¹	1 ^{29, 42}	2	7 ⁸	2	1 ⁴³	-	1 ⁴⁴	-	-
Module 1.3.4	1	4	2	-	1 ²⁸	1	3	2	0 ³⁸	-	1	2 ⁰	2 ⁹	1	-	-	-	-	-	-	1	1 ²⁹	1	-	-	-	-	1	-	-
Module 1.3.5	1	4	2	-	1 ²⁸	1	-	2	-	-	1	2 ⁰	-	1	-	-	-	-	-	-	1	1 ²⁹	3	-	-	-	-	1	-	-
Module 1.4	1	4 ₃	2	-	1 ²⁸	3	3	2	-	2	1	2 ⁰	-	1	1 ³⁴	-	-	-	-	-	1	1 ²⁹	-	3	-	1	-	1	-	-
Module 1.5	1	4	2	-	1 ²⁸	1	3	2	-	-	1	2 ⁰	-	1	-	-	1	-	-	-	1	1 ²⁹	-	-	-	-	-	1	-	-
Module 1 – Annex	1	4	2	-	1 ²⁸	1	3	2	-	-	1	2 ⁰	-	1	-	-	-	-	-	-	1	1 ²⁹	-	-	-	-	-	1	-	-
Module 2	1	4	1	-	1 ²⁸	4	3	2	-	-	1	2 ⁰	-	1	-	-	1	-	-	-	3	-	1	1 ⁴⁵	-	1 ⁴⁶	-	1	-	-
Module 3	-	-	1	-	-	3	-	-	-	-	-	1	-	-	1 ³⁴	-	-	-	-	-	-	-	3	-	-	1	1	-	-	-
Module 3 for Biological /Biotech.	-	-	1	-	-	3	3	-	-	-	-	2	-	-	1 ³⁴	-	-	-	-	-	-	-	-	-	-	1	-	-	-	-
Module 4	-	-	1	-	1 ⁴⁷	1	-	-	-	-	-	0 ⁴⁸	-	-	1 ³⁴	-	-	-	-	-	-	-	1	-	-	-	-	-	-	-

	AT	BE	BG	CY	CZ	DE (PEI)	DE	DK	EE	EL	FI	FR	HU	IE	IT	LT	LV	LU	MT	NL	PL	PT	RO	SE	SK	SI	ES	UK	EFTA IS NO	
Module 5	-	-	1	-	1 ⁴⁷	2	-	-	-	-	-	0 ⁴⁸	-	-	1 ³⁴			-	-	-	-		-	-	-	-	-	-	-	-
Written responses	1	1 ⁵⁰	1	1	1	3	5 ⁵¹	2 ⁵⁴	1	2	1 ⁵⁰	4	5 ²	2 ⁵⁴	1 ⁵⁰ 1 ³⁴	1	2	1 ⁵⁵	1 ³⁰	1 ⁵⁶	-	1 ³⁶	2 ⁷³	1 ⁷⁹	-	1 ⁵⁸	2	1	1 ⁵⁹ 1 ⁵⁰	
Variations								-																						
Application form	1		2	2	2	2	3	1	1	2	1	3 ⁶⁰	₅₃	2	1 ⁵⁰ 1 ³⁴	1	2	1 ⁵⁵	1 ⁶¹	1 ¹⁸	2	1 ⁶³	2	1	2	2	1	1	1	1
Type I documentation	1		1	1	1	2	3	1 ⁷⁰	1	1	1	3 ⁶²	₅₃	1	1 ⁵⁰ 1 ³⁴	1	2	-	1 ³⁰	1	2 ₁₉	1 ⁶³	1 ⁷⁴	1	1	2	1	1 ⁶⁵	1	1
Type II documentation	1	1	1	1	1	2	3	1 ⁷⁰	1	1	1	3 ⁶²	₅₃	1	1 ⁵⁰ 1 ³⁴	1	2	-	1 ³⁰	1	2 ₁₉	1 ⁶³	1 ⁷⁴	1	1	2	1 ⁶⁶	1	1 ⁵⁹ 1 ⁷¹	1
Supplementary info	1		1	1		2	3	1	1	1	1	4	₅₃	1	1 ⁵⁰ 1 ³⁴	1	2	-	1 ³⁰	1	1	1 ⁶⁴	-	1	1	2	2	1	1	1
Additional SPC/ Leaflet	-		2	1	2	2	3	-	0 ³⁸	-	1	-	₅₃	-	-	1 ⁴⁰		-	1 ⁶¹	-	1	-	-	1	-	-	-	-	-	-
Additional Labels	-	-	3	1	-	2	3	-	0 ³⁸	-	1	-	₅₃	-	-	1 ⁴⁰		-	1 ⁶¹	-	1	-	-	1	-	-	-	-	-	-
Additional statement on Qualitative & quantitative composition		-	-	-	-	2	3	1	-	-	-	-	₅₃	-	-	-		-	-	-	1	-	-	-	-	-	-	-	-	-
Written responses	1	1	1	1	1 ⁶⁸	3	5 ⁵¹	1	1		1 ⁵⁰	3	2 ⁵²	2 ⁵⁴	1 ⁵⁰ 1 ³⁴	1	2		1 ³⁰	1 ⁵⁶	2 ⁷³	1 ³²	1 ⁶⁴	1 ⁷⁹	1	1		1	1 ⁵⁰	

¹ Obligation to use electronic data media for the submission of documents (all information available on the web-site of the Federal Institute for Drugs and Medical Devices

(http://www.bfarm.de/de_ver/arzneimittel/zulassungen/index.html)

² In case of electronic submission (preferable in eCTD-format) one paper and two electronic copies (CD-ROM/DVD)

³ Subsequent correspondence during national and mutual recognition/DPC procedures submitted electronically are to be send to GOD-afdelingspostkasse@dkma.dk

⁴ Whenever possible CD-ROM version of all sections of Modules 4 and 5 would be preferable

5 One copy only required either in paper or electronic (pdf) form. Full information on electronic submission standards, application forms and templates can be found
6 on www.mhra.gov.uk

7 AT: See Section 8 and subsequent correspondence

8 For Belgium, send an original cover letter on paper together with the CDrom as recommended in the Belgian e-guideline:

9 http://www.afigp.fgov.be/New/NL/Nuttige%20informatie/eSubmission/eSubmission%20Guidelines_v1-1.pdf

10 Modules 4 and 5 may be submitted in electronic form only if a commitment is made that upon SUKL's request a paper copy of specified parts
11 of Modules 4 and/or 5 will be submitted within 48 hours and, if necessary, full paper version of Modules 4 and/or 5 within 1 week. If a letter of authorisation is
12 attached in Annex 6.4, the signatures must be officially authenticated (by a notary or administrative official).

13 Modules 4 and 5 should be provided on CD-ROM version only. Paper copy should be available on request

14 Paper copies of full dossier + 2 copies on CD-ROMs at least of module 1 and 2. Electronic versions preferable in editable format

15 National Procedures and MRP/DCP where HU acts as CMS: Whenever possible all modules only on CD-ROM (two copies; in editable format) would be preferable.
16 MRP/DCP where HU acts as RMS: All modules only on CD-ROM (two copies; in editable format) should be provided, with the additional modules described below
17 on paper. In case of Immunologicals: three copies are required (whenever possible only on CD-ROMs (in editable format)).

18 One full copy + (in total) two further copies of Modules 1-2 for MR applications where Ireland is a CMS only. One copy of the total dossier can be electronic with a
19 signed declaration i.e. one full copy + (in total) one further copy of Modules 1-2 for MR applications where Ireland is a CMS only. Refer to <http://www.imb.ie> for
20 dossier requirements.

21 Modules 4 and 5 to be held available by the applicant for supply on request. Italy requests CD-ROM version of the full dossier

22 National Procedure: a paper copy of all modules + all modules on CD-ROM. Mutual Recognition Procedure where LT acts as CMS: a paper copy of 1&2 modules +
23 all modules on CD-ROM

24 Additional copy of all modules on CD – ROM

25 Only Parts 1.2, 1.3.1/2/3/5 (Applic/SPC/Package Leaflet of the originating Member State) other documents available on request.

26 National Procedures and in cases where Malta is RMS: One electronic copy (CD-ROM / DVD) and 1 paper copy of all Modules

27 In cases where Malta is CMS: One electronic copy (CD-ROM / DVD) of all Modules and a paper copy of modules 1 and 2.

28 If a dossier is completely filed in electronic form (Module 1-5), then only one additional paper copy is needed only for the cover letter and the application form. (see
29 also <http://www.cbg-meb.nl/uk/reghoudr/index.htm>)

30 1 paper copy of full dossier + 1 copy on CD-ROM, with declaration that the information is identical to paper copy – (if not possible – second paper version)

31 1 paper copy of Mod. 1 and 4 CD_ROM of Mod.1 – 5 in editable format

Portugal Renewal applications: 3 CD ROM. Structure of the information contained in the CD roms available at :

http://www.infarmed.pt/pt/medicamentos/uso_humano/org_cd_rom/medicamentos.exe

Module 1 should be in paper version, Modules 2, 3, 4 and 5 preferably in electronic version with written declaration that the applicant will submit paper version
within 30 days upon request. Additionally requested copies should be submitted to Ptujaska 21, SI-1000 Ljubljana and should be preferably in electronic version with
written declaration that the applicant will submit paper version within 7 days upon request, except part 3.2.P.5 should be in paper.

Biological/Biotechnological products: 2 full dossiers

Only Modules 1 and 2 as hard copies (paper). All modules (1-5) on CDs

If eCTD is available, this is encouraged to be submitted a paper version must always be filed in addition

Paper submission may be replaced by electronic form

Paper format and ONE copy of electronic version (editable CD-ROM).

National Procedures and in cases where Malta is RMS: One electronic copy (CD-ROM / DVD) and 1 paper copy

In cases where Malta is CMS: One electronic copy (CD-ROM / DVD)

One copy shall be submitted in electronic version. In addition SPC, PIL and labelling in the Czech language shall be submitted in electronic version in Word (6.0 or
higher version). In the MRP mock-up in the Czech language can be submitted at the latest 5 days after day 90 together with Czech translations of agreed SPC, PIL
and labelling.

32 -----
 34 Italy requests this copy in electronic format (for information see:<http://www.sanita.it/farmaci>)
 35 1 original signed + 3 paper copies
 36 By e-mail + 4 CD-ROM copies
 37 Application form in SI an EN should also be submitted in electronic version (preferably in Word) to the following E-mail address: mrp.arszmp@gov.si
 38 SPC, PIL and mock-ups in Estonian language should be submitted electronically
 40 Proposed SPC, PIL and labelling in Lithuanian language should be submitted in electronic version for NP
 41 In polish language- SPC, PIL and Labelling- 1 copy
 42 Portugal: At the end of the procedure, the approved SPC, PIL and package should be submitted electronically in a word format. Please check the following
 43 information: http://www.infarmed.pt/pt/noticias_eventos/noticias/2005/nt_30_08_2005.pdf
 44 For MRP/DCP: English version of SPC, PIL and labelling should also be sent in electronic version (preferably in Word) to the following E-mail address:
 45 mrp.arszmp@gov.si. For granting MA in the MRP/DCP mock-up in SI should be submitted within 5 days at the latest after the procedure is finalised together with
 46 the SI translations of agreed SPC, PIL and labelling in electronic version (mrp.arszmp@gov.si) and 1 paper version (additional copies on request)
 47 Using the SPC templates for each section found on www.mhra.gov.uk
 48 An electronic copy, preferably in word format, and one extra paper copy of 2.5 and 2.7 is required.
 49 Quality Overall Summary only
 50 Paper submission may be replaced by electronic form, the additional copy not requested in case of CMS
 51 Modules 4 and 5 to be held available by the applicant for supply on request
 52 -----
 53 The Written response should be bound in separate volumes so that the pharmaceutical assessor can review the response to Modules 1, 2, 3, the pre-clinical assessor
 54 the response to Modules 1, 2, 4 and the clinical assessor the response to Modules 1,2,5;
 55 Preferably in electronic format to the E-mail address mrp@bfarm.de or for submissions exceeding 1.9 MB via Eudralink to the E-mail-address mrp@bfarm.de. In
 56 this case only one paper copy has to be send to the BfArM.
 57 For European procedures: only electronically, by email (mrp-dcp-new-cms@ogyi.hu). For national procedudres: 2 copies of CD-ROMs.
 58 See our homepage: www.ogyi.hu At the end of the procedure, the approved SPC, PIL and Labelling should be submitted electronically and with track changes for
 59 variations.
 60 Two copies of responses if responses to Modules 1 – 5 are combined. Otherwise, two copies of responses to Modules 1+2 and one copy each of responses to
 61 Modules 3, 4 and 5.
 62 IA, IB only (CTD 1.2, 1.3.1/2/3/5)
 63 Preferably in electronic format via Eudralink to the E-mail address case@cbg-meb.nl. In case of electronic submission, the submission of paper copies is not
 required.
 Portugal: Responses to Modules 3, 4 and 5 in separate CD roms
 Concerning quality part only
 Preferable as CD-ROM (WORD)
 One additional copy is requested for pharmaceutical variations. Additional copies may be available upon request
 One electronic copy and one paper copy
 One additional copy is requested for pharmaceutical variations. Additional copies may be available upon request
 MRP/DCP variations: 1 paper copy application form and cover letter + 1 full electronic copy (CD-ROM). National Type I variations non consequential to type II are
 only accepted by electronic submission. Please check the following information:
http://www.infarmed.pt/pt/medicamentos/uso_humano/submissao_alteracoes/index.html
 For all variations: at the end of the procedure, the approved SPC and PIL should be submitted electronically. Please check the following information:
http://www.infarmed.pt/noticias_eventos/noticias/2005/nt_30_08_2005.pdf

64 In electronic format only (CD-ROM or via e-mail).
65 1 copy of a Type 1A application or a Type 1B application
66 2 copies of clinical Security (FV) for Type II variations. An electronic version of the proposed SPC, leaflet and packaging with changes must be submitted
simultaneously when there are changes related.
67 -----
68 Applicant's responses within MRP should be sent via Eudralink to the e-mail address mrp@sukl.cz, however hard copy of the response document is still needed
69 An additional electronic version of the dossier (e.g CD-Rom/DVD as Adobe Acrobat PDF format, structure and names of files as CTD) is strongly recommended.
Harmonised product information after the EU procedure must be submitted as Word files. If eCTD is filed, a paper version must be filed too with additional copies
as mentioned in the table
70 An electronic version of the proposed SPC with track changes must be submitted simultaneously to GOD-afdelingspostkasse@dkma.dk
71 SPC and PIL, in Icelandic in word format, with track changes for variations
72 1 paper copy of full dossier + 1 copy on CD-ROM + 1 paper copy for Module 1, only for MRP/DC procedures. The written response should be bound in separate
volumes so that the pharmaceutical assessors can review the response CTD 1,2,3, the pre-clinical and clinical assessor the response to CTD 1,2,3,4,5 (x 2) and
CTDI. 1 extra copy on CD-ROM.
73 The written responses should be bound in separate volumes so that the pharmaceutical assessor can review the response to Modules 1, 2, 3, the pre-clinical assessor
the response to Modules 1, 2, 4 and the clinical assessor the response to Modules 1, 2, 5. Application form for National and Mutual Recognition Procedure
Variation: 1 original signed + one copy
74 An electronic version of SPC and PIL in RO in word format, with track changes for variations. Type I and Type II documentation for National Variation: 2 paper
copy and for Mutual Recognition application: 1 paper copy of full dossier + 1 copy on CD-ROM
75 In general Modules 3, 4 and 5 may be submitted in electronic form if a commitment is made that upon SUKL's request a full paper version of Modules 3, 4 and/or 5
will be submitted within 48 hours.
76 In case of submitting registration dossier for several strengths of the medicinal products with the same active substance, where a part of the documentation for all
these strengths is identical, applicant should submit "identical" Modules (except Module 1.2) only once as a paper copy and the rest of the identical documentation
has to be submitted electronically (on a CD).
77 If one or more module is common for multiple strengths or for duplicate applications, one copy of those modules is sufficient if a clear reference is given in the
cover letter. An electronic copy of the full dossier, preferably in eCTD format, is highly appreciated.
78 "An electronic version (EMEA template) is also required"
79 An electronic copy, preferably in word format, is highly appreciated.
80 1 paper copy of Module 1, 2, 3 + 1 copy on CD. Modules 4 and 5 may be submitted in electronic form only if a commitment is made that upon BDA's request if
necessary, full paper version of Modules 4 and/or 5 within one week. If a letter of authorisation is attached in Annex 6.4, the signatures must be officially
authenticated (by a notary or administrative official), and legalised translation in BG.
81 In addition SPC, PIL and labelling in the Bulgarian language shall be submitted in electronic version in Word (6.0 or higher version). In the MRP mock-up in the
Bulgarian language can be submitted at the latest 5 days after day 90 together with Bulgarian translations of agreed SPC, PIL and labelling.

3.2 National, Mutual Recognition and Decentralised Procedures: “additional data” requested

Additional data requested	AT	BE	BG	CY	CZ	D K	DE	E E	E L	ES	FI	F R	H U	IE	IT	LV	L T	LU	MT	NL	PL	PT	R O	SE	S K	SI	U K	IS	N O
Statement for the MA transfer to local subsidiary	-	-	X	-	-	-	-	-	X	-	X	X	X	-	-	-	X	-	-	-	-	-	-	-	X	-	-	-	-
A <i>certified</i> copy of the marketing authorisation granted by the RMS	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-
An <i>original or certified</i> copy of the contract between MAH and responsible of batch release / manufacturer / importer/legal representative	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-
Application form signed by the MAH of the medicinal product in the RMS	-	-	-	-	-	-	X	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	X	-	-	-
The person responsible for placing the product on the market in France (so called “exploitant” in French) should be specified, knowing that this “exploitant” should be a pharmaceutical	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

(original)																														
Declaration from MAH of submitting samples on request of the President of the Agency (original)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	
Annex 6.4 Letter of authorisation for communication on behalf of the applicant/MAH (signatures must be officially authenticated by a notary or administrative official)	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Confirmation of the identical dossier with an original signature	-	-	-	-	X*	-	-	-	-	-	-	X*	-	-	X*	-	-	-	-	-	-	X*	-	-	-	-	-	-	-	
Declaration of patent/data exclusivity	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Special national requirements regarding the ASMF (incl. special application form) Information given on the national competent authorities website	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	
Cover letter, similar to a standard one, in	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	X	-	-	-	-		

Trade mark of the product to be submitted with the new application	-	-	-	-	-	-	-	-	X	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
--	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---

* If not mentioned in the signed cover letter

3.3 National and Mutual Recognition and Decentralised Procedures: number of copies requested for renewal

Further information on the presentation and content of renewal application is given in 'The Rules Governing Medicinal Products in the European Union, volume 2C'. See also table 3.2 of this chapter for requested additional data.

Renewal	AT	BE	BG	CY	CZ	DE (PE D)	DE ₂₂	DK	EE	EL	FI	FR	HU	IE	IT	LV	LT	LU	MT	NL	PL	PT	RO	SE	SK	SI	ES	UK	EFTA IS / NO	
European renewal application form	2	1 ¹	2	2	2	4	4	1	1	2	2	4	2 ¹⁷	2 ²¹	1	2	1	1	1 ¹²	1 ³⁵	4 ³⁴	National: 3 ^{1,2} MR: 1 ^{1,2,3}	2	4	1	2 ¹⁴	2	1	1	1
PSUR, incorporating compiled data on 5 years (4.5 years for the first renewal)	1	1	1	1	1 ⁵	4	4	1	1 ⁹	1	1 ²³	4	1 ¹¹	1	1 ⁴	1	1	1	1 ³⁶	1	2	National: 3 ² MR: 1 ^{2,3}	1 ²⁶	1	1	2	1	1	1	1
Clinical expert report/statement that addresses the current risk/benefit of the product	1	1	2	1	1	4	4	1	1	1	1	4	1 ¹¹	1	1 ⁴	1	1	1	1 ¹²	1	2	National: 3 ² MR: 1 ^{2,3}	1 ²⁷	1	1	1	1	1	1	1
Current mutually recognised SPC	1	1	3	1	1	4	4	1 ²⁵	1	1	2 ²⁰	4	1 ¹¹	2	1 ⁴	2	1	1	1 ¹²	1	4 ³³	MR: 1 ^{2,3}	1 ²⁸	1	1	1	2	1	1	1
Proposed SPC	2	2	3	1	2 ⁶	4	4	1	1 ⁹	1	2 ²⁰	4	1 ¹⁰	2	1 ⁴	2	1 ³¹	1	2 ¹²	1	4	National: 3 ² MR: 1 ^{2,3}	1 ²⁹	1	1	2	2	1	1	1
Commitment to take account of new studies considered necessary by the expert through the variation procedure after the renewal	1	1	1	1	1	4	4	1	1	1	1	1	1 ¹¹	1	1	1	1	-	1 ³⁶	1	4	National: 3 ² MR: 1 ^{2,3}	1	1	1	1	2	1	1	1

¹ For Belgium, send an original cover letter on paper together with the CDrom as recommended in the Belgian e-guideline: http://www.afipg.fgov.be/New/NL/Nuttige%20informatie/eSubmission/eSubmission%20Guidelines_v1-1.pdf

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26. A copy in paper format and 1 copy in CD-Rom
 27. In paper format
 28. 2 copies in paper format and 1 copy in CD-Rom
 29. In addition to 2 paper copies, SPC, PIL and labelling in the Romanian language shall be submitted in electronic version in word (6.0 or higher version)
 30. The fee will be invoiced by the National Medicines Agency
 31. Proposed SPC, PIL and labelling in Lithuanian language should be submitted in electronic version.
 32. Proof of payment should be submitted together with the application
 33. In addition current mutually recognized PL
 34. Labelling original signed +3 paper copies
 35. If a dossier is completely filed in electronic form, then only one additional paper copy is needed for the cover letter and the application form. (see also <http://www.cbgmeb.nl/uk/reghoudr/index.htm>)

3.4 Applications in the Centralised Procedure:

New Applications	
Full dossier ¹ :	1 copy for the EMEA, 2 copies for the Rapporteur ² , 2 copies for the Co-Rapporteur ²
Full or partial copy of the dossier	As requested by the CHMP members ³ (see "EMEA Pre-Submission Guidance for users of the Centralised Procedure" on the EMEA Website)
Additional copies of Module 1 and 2	1 copy for the EMEA+ 1 electronic copy (WORD)
Written responses to questions from CHMP	1 copy for the EMEA+ 1 electronic copy of the complete responses (incl. revised SPC, LAB, PL in WORD) ⁹ 2 copies for the Rapporteur ² , 2 copies for the Co-Rapporteur ² , 1 copy for each of the other members of the CHMP ⁴
Type IA/IB Variation Application	
Application form and supportive documentation	1 copy for the EMEA+1 electronic copy (incl. revised SPC, LAB, PIL in WORD, if applicable) 1 copy for the Rapporteur
Type II Variations Applications	
Cover letter & Application form	1 copy for the EMEA, 1 copy for the (Co-) Rapporteur, 1 copy for each CHMP member ⁶
Supportive documentation as appropriate: Module 1 - 2	1 copy for the EMEA + 1 electronic copy (WORD), 1 copy for the (Co-) Rapporteur ⁷ , 1 copy for each CHMP member ⁶
Module 3 - 5	1 copy for the EMEA, 1 copy for the (Co-) Rapporteur ⁷
Full Variation Application on CD-ROM	1 copy for EMEA, (Co-)Rapporteur and all CHMP members
Written responses to Request for Supplementary Information from CHMP	1 copy for the EMEA+ 1 electronic copy of the complete responses (incl. revised SPC, LAB, PIL in WORD) ⁹ 1 copy for the (Co-) Rapporteur ⁷ 1 copy for each of the other members of the CHMP ⁴
Extension Applications	
All Modules	1 copy for the EMEA 2 copies for the Rapporteur
Module 1-2	1 additional copy for the EMEA + 1 electronic copy (WORD) 1 copy for each CHMP member ⁶

All modules on CD-ROM	1 copy for EMEA, (Co-)Rapporteur and all CHMP members
Written responses to questions from CHMP	1 copy for the EMEA+ 1 electronic copy of the complete responses (incl. revised SPC, LAB, PL in WORD) ⁹ 2 copies for the Rapporteur ² 1 copy for each of the other members of the CHMP ⁴
Urgent Safety Restrictions¹⁰	
Cover letter	1 copy for the EMEA, 1 copy for the (Co-) Rapporteur, 1 copy for each CHMP member
Supportive documentation:	1 copy for the EMEA + 1 electronic copy (WORD/PDF), 1 copy for the (Co-) Rapporteur
Renewal Applications	
Cover letter & Application form	1 copy for the EMEA, 1 copy for the (Co-) Rapporteur ⁷ , 1 copy for each CHMP member ⁸
Supportive documentation: Module 1 - 2	1 copy for the EMEA + 1 electronic copy (WORD), 1 copy for the (Co-) Rapporteur ⁷ , 1 copy for each CHMP member ^{5, 6}
Module 5	1 copy for the EMEA, 1 copy for the (Co-) Rapporteur ⁷
Full Renewal Application on CD-ROM	1 copy for EMEA, (Co-)Rapporteur and all CHMP members ⁵
Written responses to Request for Supplementary Information from CHMP	1 copy for the EMEA+ 1 electronic copy of the complete responses (incl. revised SPC, LAB, PL in WORD) 1 copy for the (Co-) Rapporteur, 1 copy for each of the other members of the CHMP ⁴

Note: 'CHMP member' includes Iceland & Norway and co-opted members, but does not refer to the Alternates

- Whenever a full dossier is to be provided, the complete ASMF (Active Substance Master File) should be included. The full paper copy of the application may be replaced by a full electronic copy. In that case, 2 additional paper copies of Modules 1+2 should be provided to the EMEA. For more details, please consult the "EMEA Pre-submission Guidance for users of the Centralised Procedure" on the EMEA website.
- Maximum figures. If in individual situations (e.g. multiples applications) there is any divergence from the standard requirement the EMEA will inform the applicant accordingly
- The EMEA will always inform applicants of the exact number of copies required by the CHMP members, after validation of the application and adoption of the timetable for the evaluation
- For IS and LUX: only responses related to Module 1 and/or 2. For MT, CZ, AT, EE, SI and PT: electronically only.
- Not required for Lux (cover letter only)
- No paper copy for MT, CZ, SI (only to be provided as part of the full electronic application on CD-ROM). For EE, AT, CY and PT electronically only.
- Two paper copies for FR when (Co-)Rapporteur
- For EE, AT, CY and PT electronically only.

-
9. In case a full electronic copy of the responses is not available, at least the revised SPC, labelling and PL needs to be provided in WORD together with a second paper copy of the responses.
 10. For urgent safety restrictions supportive electronic documentation for each CHMP member.

4. DOSSIER CHECK-IN PROCEDURE

National application number:

Date of entry

Date of decision

Conclusion

file accepted **not accepted**

Yes

No

Language

Module 1

ToC - Module 1.1

Application forms / Module 1.2

[-----]

SPC / Module 1.3.1

[-----]

Leaflets & label / Module 1.3.2 – 1.3.4

Module 1.4

Module 1.5

Module 1 – *This part of the table would need to be updated to reflect the latest Module 1 structure.*

Module 2

Quality

[-----]

Pharmacology/Toxicology

[-----]

Clinical

[-----]

Proof that fees have been paid

All pages present and legible

Draft labelling national language/EN

[-----]

Draft package leaflet in national language(s)/EN

Draft SPC in national language(s)/EN

Manufacturers' authorisation of finished product

[-----]

Marketing authorisation(s)

[-----]

Sample(s)

Letter of access to the Drug Master File

Mock-ups

Readability Test

Information relating to Pharmacovigilance

Pharmacovigilance System

Risk Management Plan

Environmental risk assessment

Module 1 acceptable

Not acceptable for reasons.....

Module 2 acceptable

Not acceptable for reasons.....

Module 3

Chemical, Pharmaceutical and Biological documentation

[-----]

Drug Master File/CEP

[-----]

All volumes present

All pages present and legible

Module 3 acceptable

Not acceptable for reasons.....

Module 4

Pharmaco-Toxicological Documentation	<input type="radio"/>	<input type="radio"/>	[-----]
All volumes present	<input type="radio"/>	<input type="radio"/>	
All pages present and legible	<input type="radio"/>	<input type="radio"/>	
Module 4 acceptable	<input type="radio"/>	<input type="radio"/>	
Not acceptable for reasons.....			

/ Module 5

Clinical Documentation	<input type="radio"/>	<input type="radio"/>
All volumes present	<input type="radio"/>	<input type="radio"/>
All pages present and legible	<input type="radio"/>	<input type="radio"/>
/ Module 5 acceptable		
Not acceptable for reasons.....		

Application according to Article 10 of Directive 2001/83/EC

Yes No

Application according to Directive 2001/83/EC, as amended, Article 10
 Evidence that a reference medicinal product has been authorised within the Community in accordance with Community provision in force for not less than eight years

 Application according to Article 10c of Directive 2001/83/EC

Application according to Directive 2001/83/EC, as amended, Article 10c
 Letter of consent from the holder of the authorisation of the original proprietary medicinal product for reference to

Module 3

Module 4

Module 5

5. MOCK-UPS, SPECIMENS AND SAMPLES:

5.1 Mock-ups and specimens

In accordance with Directive 2001/83/EC, as amended, Article 8, a mock-up of the sales presentation of the medicinal product, together with the proposed package leaflet must be included with the application. In addition, Member States/EMA may require specimens of the sales presentation of the medicinal product to be submitted, in order to check compliance with the relevant articles in Title V of Directive 2001/83/EC, as amended.

A "Mock-up" is a copy of the flat artwork design in full colour (incl. Braille if applicable), presented so that, following cutting and folding where necessary, it provides a replica of both the outer and immediate packaging, so that the three dimensional presentation of the labelling text of the medicinal product is clear. It is generally referred to as a "paper copy" or "computer generated version".

A "Specimen" should be interpreted as referring to a sample of the actual printed outer and inner packaging materials and package leaflet (i.e. the sales presentation).

5.1.1 National, Mutual Recognition and Decentralised applications

Specimens or mock-ups of the sales presentation, together with a proposal for the package leaflet, should be translated into the national language(s) of the Member state concerned with the application.

5.1.2 Applications in the Centralised Procedure

The EMA is responsible for checking of mock-ups and specimens.

Requirements for the submission of mock-ups and specimens, and their subsequent review, are detailed in "The revised checking process of mock-ups and specimens of outer/immediate labelling and package leaflets in the Centralised Procedure" (<http://www.ema.europa.eu/pdfs/human/regaffair/30582106en.pdf>)

5.2 Samples

5.2.1 National, Decentralised and Mutual Recognition applications

For the purposes of implementing Article 10 of Directive 2001/83/EC, samples of the (non-) active substances and of the finished medicinal product must be supplied at the same time as the submission of the dossier as a matter of course to the competent authorities in Italy (see table below), Luxembourg, Spain, Sweden and Portugal in accordance with the requirements set out in this Table. In other cases, samples should be provided at the request of the competent authorities.

Number of samples	BE	BG	CY	CZ	DE	EE	EL	ES	H U	IE	IT	LV	LT	MT*	NL	PL	PT	RO	SE	SK	SI	IS	N O
Finished medicinal product	I	A, I	E	L	B, G	X ¹	H	C	M	B, E	H	A ¹	H		H	*	H	H	A I	X ²	N	H, K	H
All active substances	J	J	H			Y	H	D	D	B, E		B ¹	H		H	*	H	-	J	X ²	N		H
Non-pharmacopoeial active substances		E	-			-	H					E	H			*	H	-		X ²	N		-
Non-active substances		H	-			-	H					E	H			*	H	-		X ²	N		-

The appropriate number of samples should be provided

A in the form of final sales presentation of the medicinal product

A¹ 2 samples in the form of final sales presentation of the medicinal product

B in sufficient quantity to permit a full assay and the verification of the control methods used by the manufacturer.

B¹ to permit 3 full assays in sufficient quality and the verification of the control methods used by the manufacturer

C in the presentation authorized in the RMS and in sufficient quantity to permit 2 full assays and the verification of the control methods included in Module 3. For expensive medicinal products the applicant may send a reduced number with a reasoned justification

- D** For each active substance:
- 5 g with a corresponding analytical certificate which must include: name of manufacturer (or supplier if different), date of manufacture and analytical results:-
 - 0.5 g of reference standard
 - 0.05 g of each impurity present in the active substance
 - 0.05 g of each degradation product present in the finished medicinal product
 - In medicinal products where the active substance in the dosage unit is less than 1 mg. the amount required is 1 g
- E** Samples should be provided within 7 calendar days of any request by the authorities, they are not required to accompany the application.
- F** Reference materials, main impurities and main degradation products and non-active substances must be submitted on request.
- G** For all medicinal products the Paul-Ehrlich-Institut is competent for (sera, vaccines, allergens, blood products, gene therapy medicinal products, somatic and xenogenic cell therapy medicinal products and tissue engineering products) samples must be supplied at the same time as the submission of the dossier.
- H** Samples should be made available on request
- I** On request, samples should be provided within 7 calendar days in the presentation authorised in the RMS and in sufficient quantity to permit 2 full assays and the verification of the control methods included in **Module 3**. If a measuring device is included in the medicinal product, two samples should also be provided.
- J** Reference materials, main impurities and main degradation products should be provided on request within 7 calendar days and in sufficient quantity to permit 2 full assays and the verification of the control methods used by the manufacturer.
- K** Always provide final sales presentation samples of tablets and capsules
- L** One sample of a medicinal product from each type of immediate packaging should accompany the application, or should be submitted before issue of the decision. In justified cases the submission of the sample can be waived. The sample in final immediate packaging may be submitted without final labelling.
Before placing the medicinal product on the market one sample of the product in the form of final sales presentation is requested. In justified cases the submission of the sample can be waived.
Each packaging of a medicinal product placed on the market in the Czech Republic shall show on the label a European EAN code which serves for the purposes of electronic processing. The 13 digit EAN code has to be provided to the SUKL to be entered in the database. It can be submitted either together with the application for marketing authorisation or later, but before placing on the market.
- M** One sample of a medicinal product from each type of immediate packaging should accompany the application, or should be submitted before the 40. day of the procedure. In justified cases the submission of the sample can be modified (products with controlled substances). The sample in final immediate packaging may be submitted without final labelling.
Before placing the medicinal product on the market one sample of the product in the form of final sales presentation is requested.
- N** Samples should be submitted on request of the Competent Authority in quantity and time frame indicated in request (in principle materials should be in quantity sufficient to permit a full assay and the verification of control methods by the manufacturer).
- X¹** In the presentation authorised in RMS
- X²** Samples of medicinal product in the form of final sales presentation and reference substances of active substance, main degradation products and main impurities should be provided in quantity sufficient for three full analysis, not requested for MRP where SK is CMS
- Y** Reference materials, main impurities and main degradation products and non-active substances should be submitted on request and in sufficient quantity to permit full assay and the verification of the control methods used by the manufacturer
- MT*** Should be submitted upon the request of the Competent Authority in quantity and time as indicated in request (the quantity should be a sufficient amount to permit 2 full assays and the verification of the control methods used by the manufacturer)
- PL*** Should be submitted upon the request of Competent Authority in quantity and time indicated in request (usually the quantity should be sufficient amount to permit a full assay and the verification of control methods used by the manufacturer)

Requirements for samples in case of certain Type I variations

No	1084/ 2003 No	Sample	AT	BE	BG	CY	CZ	DE (PEI)	EE	EL	FR	HU	IT	IE	LV	LT	MT	NL	PL	RO	SK	SI	EFTA NO IS
5	34	Dosage unit (e.g. tablet)	A	B	C*	B	C*	A	A	A	C	D	A	B	1	X	A	A	X	A	A	A	A
10a	43	Measuring device	A	B	C*	B	C*	A	A	A	C	D	A	B	1	X	A	A	X	A	A	A	A
31	36	Container (old and new)	A	B	C*	B	C*	A	A	A	C	D	A	B	1	X	A	A	X	A	Y	A	A
32	39	Dosage unit (e.g. tablet)	A	B	C*	B	C*	A	A	A	C	D	A	B	1	X	A	A	X	A	Y	A	A
33	40	Dosage unit (e.g. tablet)	A	B	C*	B	C*	A	A	A	C	D	A	B	1	X	A	A	X	A	Y	-	A
	28	Container (old and new)			C*	-	C*		-			-			-	-	A				-	-	
	29	Container (old and new)			C*	-	C*		-			-			-	-	A				-	-	

A Samples should be made available on request

B Samples should be provided within 7 calendar days of any request by the authorities, they are not required to accompany the application.

C **FR 3** Samples should be provided with the application

C* Samples should accompany application

D 1 sample should be submitted with the application

X Samples should be submitted only upon the request of Competent Authority in quantity and time indicated in request

Y Samples of new container or new dosage unit should accompany the application

5.2.2 Applications in the Centralised Procedure

Samples for testing the proposed medicinal product are not required at time of submission of the application.

The CHMP may however request the testing of samples of the medicinal product and/or its ingredients during the assessment of the application in accordance with the provisions of Article 7 b of Regulation (EC) No 726/2004.

In this case the Rapporteur and/or Co-Rapporteur will specify a test protocol (type of samples, number of samples, number of batches, testing to be performed and methods and specifications to be used) and agree with the EMEA which laboratory e.g. Official Medicines Control Laboratory (OMCL) or other laboratories designated for this purpose by the CHMP will carry out the required testing.

The results of the tests are reported to the Rapporteur and Co-Rapporteur and the CHMP for consideration in finalising the CHMP Assessment Report.

6. NATIONAL PROCEDURE AFTER A COMMISSION DECISION ON A REFERRAL

Information on national procedures to be followed to adapt national marketing authorisations after a Commission Decision on a referral is provided below.

AUSTRIA

Following a Commission decision after an Art. 30 or Art. 31 referral, it is the obligation of the MAH to submit a national variation according to §24 of the Austrian Medical Act (Arzneimittelgesetz).

Within 10 days companies should send to the Austrian Federal Agency for Safety in Health Care (Bundesamt für Sicherheit im Gesundheitswesen)

- Cover letter
- Application form
- Amended SPC (highlighted and clean version)
- Amended PL and labelling (highlighted and clean version)

The Federal Agency for Safety in Health Care will amend the marketing authorisation and inform the Commission.

For products not included in a Commission decision, but concerned – in case of Article 30 – it is highly recommended that MAH also implement the Commission decision via a national variation procedure according to §24 of the Austria Medical Act.

BELGIUM

The Belgian authorities send a letter to the companies concerned to amend their marketing authorization accordingly. Within 10 days, companies should send to the Belgian authorities the following documentation:

- original marketing authorisation forms
- adapted Summary of Product Characteristics (highlighted and clean versions)
- adapted Package Information Leaflets and Labeling (highlighted and clean versions) (if applicable)

Consequently the Belgian authorities issue an updated marketing authorisation and inform the Commission thereof.

BULGARIA

The Bulgarian Drug Agency will request the MAH to amend the marketing authorisation via a national type II variation in accordance with the Commission Decision. The MAH should send to the BDA the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended Summary of Product Characteristics (highlighted and clean versions)

- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The Bulgarian Drug Agency will amend the marketing authorisation and inform the Commission and EMEA.

CZECH REPUBLIC

For the implementation of the Commission Decision concerning referral Art. 30 and 31 the State Institute for Drug Control starts the administrative procedure for medicinal products included in the Commission Decision asking for sending adapted summary of product characteristics, package information leaflet and labelling (if applicable) - no application for variation is needed.

For medicinal products not included in the Commission Decision the national implementation of the Decision should be done via variation application - Type IB No. 46 for referral Art 30 and Type II for referral Art 31.

DENMARK

The Danish Medicines Agency amends the marketing authorisation and issues a revised SPC (if relevant) according to the Commission Decision.
The Danish Medicines Agency will inform EMEA and the European Commission of the date of implementation of the decision.

For products not included in the Commission Decision, the national implementation of the decision should be made with a Type IB variation application for Art. 30 referrals (IB no. 46 within 90 days of CD) and with a Type II variation application for Art. 31 referrals.

ESTONIA

The state Agency of Medicines sends a letter or e-mail to the companies concerned to amend their marketing authorisations accordingly. Within 10 days the company should send to SAM the following documentation:

- Application for variation (if applicable)
- Amended (highlighted) version of Summary of Product Characteristics electronically.
- Amended (highlighted) version of Package Information Leaflet and labelling (electronically).

Consequently the State Agency of Medicines issues approval of variation and/or amended SPC, PIL and labelling and informs the Commission thereof.

FINLAND

The National Agency for Medicines will request the MAH to amend the marketing authorisation via a national type II variation in accordance with the Commission Decision. The MAH should send to the National Agency for Medicines the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended Summary of Product Characteristics (highlighted and clean versions)
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

The National Agency for Medicines will amend the marketing authorisation and inform the Commission and EMEA.

FRANCE

Afssaps sends a letter or e-mail to the MAHs to modify their marketing authorisation accordingly. Within 5 days, the MAHs should send to Afssaps an electronic version (Word version) of the following documentation:

- amended Summary of Product Characteristics (highlighted and clean versions)
- amended Package Information Leaflets and Labeling (highlighted and clean versions)

Consequently Afssaps issues an updated marketing authorisation and inform the Commission thereof.

GERMANY

To facilitate a national implementation of the commission decision (CD) concerning referral Art 30 and Art 31 it is the obligation of the MAH to follow the requirements of § 29 Arzneimittelgesetz (= AMG; German Drug Law) and to submit a national variation.

For products not included in the commission decision (in the case of Article 30) it is highly recommended to adopt the commission decision. Depending on the route of marketing authorisation (only national or MRP/DCP) this can either be done with a national variation according to § 29 AMG or with a Type IB No 46 notification (within 90 days after CD).

For referrals Art 29 no variation application is required for the national implementation

GREECE

National Organization of Medicines (EOF) adopts each Commission decision, issues the amended Summary of Product Characteristics within 30 days, and informs the Commission thereof.

All Marketing Authorisation Holders concerned are informed of the above-mentioned adoption of Commission decision in order to implement the amendments of the Summary of Product Characteristics and Package Information Leaflets / Labelling (if applicable) of their pharmaceutical products concerned, in a preassigned time frame.

HUNGARY

After receiving the Commission Decision the Applicant /Marketing Authorisation Holder should submit a variation type II to the National Institute of Pharmacy within 30 days after notification.

The following documentation should be submitted:

- Cover letter
- Proof of payment
- Application form (for type II variation)
- Amended Summary of Product Characteristics (highlighted, clean and electronic version)
- Amended Labelling and Package Leaflets (highlighted, clean and electronic version)

Consequently, National Institute of Pharmacy will approve the variation and will grant an approval decree in order to indicate that the SPC, Package Leaflet and Labelling have been updated.

For products not included in the Commission Decision but owning a national MA in Hungary it is highly recommended to adopt the Commission Decision. (Type IB No 46 notification).

IRELAND

After receiving the Commission decision an applicant or marketing authorisation holder should submit promptly (within 10 days) to the IMB a **national** Type II **variation** with the following:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended Summary of Product Characteristics with changes highlighted
- Amended Package Leaflets and Labelling (highlighted and clean versions, if applicable)

If a variation is not received within 10 days the Irish Medicines Board will contact the companies concerned requesting them to submit a **national** Type II variation to update their marketing authorisation in line with the commission decision.

On receipt, the variation is processed which results in an updated licence issued to the company.

For products not included in the Commission Decision, the national implementation of the decision should be made with a national Type IB variation application for Art. 30 referrals (IB no. 46 within 90 days of Commission Decision) and with a national Type II variation application for Art. 31 referrals.

ITALY

According to the Commission Decision concerning referral art 30 and art 31 and within 10 days from its publication, all the applicants/marketing authorisation holders concerned should submit a variation type II to the Italian Agency of Medicines.

Companies should send the following documentation:

- Cover letter
- Proof of payment of fees
- Application form (for type II variation)
- Amended Summary of Product Characteristics (highlighted ,clean and electronic version)
- Amended Labelling and Package Leaflets (highlighted, clean and electronic version, if applicable)

Consequently, Italian Agency of Medicines will approve the implementation and will grant an approval decree in order to indicate that the SPC, Package information leaflet and labelling have been updated.

LATVIA

The Latvian authority sends a letters to the companies concerned to amend their marketing authorisation accordingly. Within 10 days, companies should send to the Latvian authority the following documentation:

- application form for variation
- adapted Summary of Product Characteristics (highlighted and clean versions)
- adapted Package Information Leaflets and Labeling (highlighted and clean versions) (if applicable)

Consequently the Latvian authority issues an updated marketing authorisation and informs the Commission thereof

LITHUANIA

Marketing Authorisation Holders for products listed in a Commission Decision should submit a national Type II variation within 10 days of the Decision being published, otherwise SMCA requests via e-mail the companies to submit immediately a national Type II variation application. The application form should be accompanied by:

- the Summary of Product Characteristics attached to the Decision on the relevant referral;
- the revised Summary of Product Characteristics for the product(s) affected (change highlighted and clean versions) both paper and electronic version;
- revised patient information leaflet and product labelling, if appropriate (change highlighted and clean versions) both paper and electronic version.

The SMCA approves submitted variation and publishes updated Annexes within 5 days.

MALTA

Correspondence is sent to company informing them that they need to apply for a variation within 10 days from receipt of the letter. They are also required to submit 2 versions (a highlighted and a clean version) of the revised SmPC (in editable word format), package leaflet and labelling (if effected by the change) for approval with the variation application.

NETHERLANDS (THE)

The MEB send a letter to the companies concerned to amend their marketing authorisation accordingly. Within 10 days, companies should send to the MEB the following documentation:

- adapted Summary of Product Characteristics (highlighted and clean versions)
- - adapted Package Information Leaflets and Labeling (highlighted and clean versions) (if applicable))

Consequently the Dutch authorities issue an updated marketing authorisation and inform the Commission thereof.

POLAND

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products request the MAH to amend the marketing authorisation via a national type II variation in accordance with the Commission Decision.

Within 7 days the MAH should submit to Polish Agency the following documentation:

- Application form for variation
- Marketing authorisation
- Amended version Summary of Product Characteristics
- Amended version of Package Information Leaflet and labeling (if applicable)

- Approved version Summary of Product Characteristics
- Approved version of Package Information Leaflet and labeling (if applicable)
- Power of attorney
- Proof of payment of fees

The Minister of Health will amend the marketing authorization.

PORTUGAL

Infarmed issues a Deliberation on the implementation of each Commission Decision and all the Marketing Authorisation holders/applicants included in the Commission Decision are notified thereof in writing in order to send the amended SPC, PIL and labeling, if appropriate, and the conditions of the marketing authorisation required in annex 4, within 10 working days.

Infarmed notifies the Marketing Authorisation holders/applicants that the implementation is complete and informs the Commission thereof.

For article 29 referrals, no variation application is required for the national implementation.

Subsequently to an article 30 referral, the Marketing Authorisation holders of essentially similar products, are requested to submit a type IB n.º46 variation application, within 90 days of the publication of the Commission Decision, in order to harmonise the SPC, PIL and labelling, if appropriate. Later than this deadline the variations are type II.

Following an article 31 referral, the Marketing Authorisation holders of products containing the same active substance(s) but not included in the Commission Decision, are requested to submit a type II variation application in order to harmonise the SPC, PIL and labelling, if appropriate.

ROMANIA

Following a Commission decision being published after an Art. 30 or Art. 31 referral, it is the obligation of the MAH to submit a national variation type II.

Within 10 days companies should send to the National Medicines Agency the following:

- Cover letter
- Application form
- Proof of payment of fees
- Amended SPC (highlighted and clean version)
- Amended PL and labelling (highlighted and clean version)

The National Medicines Agency will amend the marketing authorisation and inform the Commission.

For products not included in a Commission decision, but concerned – in case of Article 30 or Article 31 referrals – it is highly recommended that MAH of the products containing the same active substance(s) but not incorporated in the Article 30 or Article 31 referrals also implement the Commission decision via a national type IB 46 variation procedure (within 90 days of the decision).

SLOVAK REPUBLIC

After receiving the Commission decision, MAH should submit promptly a national type II variation in accordance with the Commission Decision. The MAH should send to the National Agency for Medicines the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Amended SPC, PIL and Labelling where applicable

The National Agency for Medicines will amend the marketing authorisation and inform the Commission and EMEA.

SLOVENIA

After receiving the Commission decision an applicant or marketing authorisation holder should submit promptly (within 10 days) via a national type II to the Agency for Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP) the following documentation:

- Cover letter
- Application forms
- Proof of payment of fees
- Adapted Summary of Product Characteristics (highlighted and clean versions)
- Adapted Package Information Leaflets and Labelling (highlighted and clean versions) (if applicable)

Consequently the JAZMP issues an updated marketing authorisation and inform the Commission thereof.

For products not included in the Commission decision, the national implementation of the decision is highly recommended and should be done with a Type IB n 46 variation application for Art. 30 referrals, and with a Type II variation application for Art. 31 referrals.

For Art. 29 referrals, no variation application is required for the national implementation.

SPAIN

After receiving the Commission Decision, the Spanish Agency for Medicines will request MAH to amend the marketing authorisation within 10 days via a national type IB category 46.

The MAH should submit to the AEMPS the following documentation:

- Cover letter
- Application Form
- Proof of payment of fees
- Amended SPC with changes highlighted and clean version
- Amended PIL and labelling (highlighted and clean version), when applicable.

The national implementation of the Commission Decision for article 30 and 31 referral should be made through a type IB46.

For products containing the same active substance(s), associated names, but not included in the Art. 30 or 31 referral (or follow up referral if considered), the MAH should submit a type IB46 variation application within 90 days.

The applicable fee is fixed as 335.17 €

Consequently, the Spanish Health Authorities will issue an approval letter for the variation indicating that the marketing authorisation has been updated and inform the Commission thereof.

SWEDEN

To facilitate a national implementation of the commission decision concerning referral Art 30 and Art 31 the MPA requests via fax the companies to immediately submit a national Type II variation application. For product not included in the Commission decision the national implementation of the decision should be done with a Type IB variation application for referral Art 30 (IB 46 with 90 days after CD) and with a Type II variation application for referral Art 31.

For referrals Art 29 no variation application is required for the national implementation.

Article	Products included in the decision	Products not included in the decision
29	No variation notification is required.	-
30	National Type II variation (request via fax to MAH)	IB46 notification (within 90 days of the decision)
31	National Type II variation (request	Type II variation

	via fax to MAH)	
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UNITED KINGDOM

Marketing Authorisation holders for products listed in a Commission Decision should submit a national Type IB category 46 variation within 10 days of the Decision being published, unless otherwise instructed in a letter from the MHRA. The application form should be accompanied by

- the Summary of Product Characteristics attached to the Decision on the relevant referral
- the revised Summary of Product Characteristics for the product(s) affected (change highlighted and clean versions)
- revised patient information leaflet and product labelling, if appropriate (change highlighted and clean versions of mock-ups).

The UK authority will issue an approval letter for the variation indicating that the marketing authorisation has been updated.

EFTA STATES

ICELAND

Following Commission Decision on an Article 30 or 31 Referral IMCA will request the MAH of products containing the same active substance(s) but not included in the referrals, by letter or e-mail to amend the marketing authorisation via a national type II variation or variation IB/46, as relevant.

The MAH shall send the following documentaion to IMCA

- Cover letter.
- Application form.
- Amended Summary of Product Characteristics (with track changes) both paper an electronic version.
- Amended Package leaflet and labelling (with track changes) both paper an electronic version (if applicable).

Consequently IMCA sends an invoice to the MAH and updates the MA accordingly.

NORWAY

As part of the arbitration procedure a national translation of the text of the SPC is assessed in our agency when the CHMP opinion is finalised, thus following the PIPIT procedure.

When a Commission Decision (CD) following an Article 30 or 31 referral is received it is adopted by the Norwegian Medicines Agency (NoMA). NoMA receive via Eudralink the corrected Norwegian translation of the SPC, PL and label as appropriate, from the MAH via EMEA, as part of the PIPIT procedure. NoMA does not consider the result of a referral procedure to be a variation.

MAH of products containing the same active substance(s) but not incorporated in the Article 30 or Article 31 referrals, are encouraged to submit variation applications in order to harmonise the SPC, PL and label as appropriate. The variations are considered as type I B notifications provided that they are submitted within 90 days of the publication of the CD. Later than this deadline the variations are type II.

7. LIST OF OFFICIAL JOURNALS

In accordance with Article 125 of Directive 2001/83/EC, all decisions to grant marketing authorisation must be published. The name and address of the Official Journal in each Member State is given below.

Austria

Mitteilungen der Sanitätverwaltung
Medieninhaber und Herausgeber:
Bundesministerium für Gesundheit und Frauen
Sektion III/Gesundheitswesen
Radetzkystr. 2
A-1031 Wien

Belgium

Belgisch Staatsblad / Moniteur Belge
Leuvensestraat 40-42 / Rue de Louvain 40-42,
B-1000 BRUSSELS
www.just.fgov.be

Bulgaria

Decisions will be published on the web-page
www.bda.bg

Contact

Bulgarian Drug Agency
26 Yanko Sakazov blvd
Sofia1504, Bulgaria

Cyprus

Επίσημη Εφημερίδα της Δημοκρατίας
(Cyprus Government Gazette)
Michalaki Karaoli str.
1445 Nicosia
Tel: +35722405829, +35722405838-9
Fax: +35722303175
E-mail: www.cygazette.com

Czech Republic

Věstník Státního ústavu pro kontrolu léčiv
(Official Journal of the State Institute for Drug Control)
Šrobárova 48
100 41 Praha 10
<http://www.sukl.cz/cs05vestnik/cs05vestnik.htm>

Denmark

Decisions and details of authorisation are published on the DMA website: www.dkma.dk

Estonia

Decisions will be published electronically on the web-page
www.sam.ee

Contact

State Agency of Medicines
Nooruse 1
50411 Tartu
ESTONIA
phone: +372 7 374 140
fax: +372 7 374 142
e-mail : sam@sam.ee

Finland

Virallinen Lehti, Officiella tidningen

Oy Edita Ab/Virallinen Lehti
P.O.Box 745
FIN-00043 EDITA

France

Journal Officiel de la République Française

rue Desaix
F-75727 PARIS

Hungary

Egészségügyi Közlöny

(EÜ. Min. H-1054 Budapest Arany János u. 6-8.
Tel.: +36 1/ 301 7958 Fax: +36 1 / 331 6712)

Germany

Bundesanzeiger

Bundesanzeiger Verlagsgesellschaft mbH
P.O. Box 10 05 34
D-50445 Köln
tel: (49) (221) 976 68-0
fax: (49) (221) 976 68-278

Greece

Ephimeris Kyverniseos Ellenikis Dimokratias

(Official Journal, Government Publications)
Kapodistriou 34
ATHENS

Ireland

Iris Oifigiúil,
Stationery Office
Bishop Street
DUBLIN 8

Italy	Gazzetta Ufficiale della Repubblica Italiana Istituto Poligrafico e Zecca dello Stato Piazza G. Verdi 10 I-00198 ROMA
Latvia	Latvijas Vēstnesis Official Journal of the Republic of Latvia Bruņinieku street 41 RIGA, LV – 1011, LATVIA
Lithuania	„Valstybės žinios“, Gedimino pr.53, LT-2002 Vilnius
Luxemburg	Mémorial Service Central de Législation Boulevard F. D. Roosevelt L-2450 LUXEMBURG
Malta	http://www.medicinesauthority.gov.mt
Netherlands (The)	Nederlandse Staatscourant Postbus 20014 NL-2500 EA DEN HAAG
Poland	Official Journal of Minister of Health Dziennik Urzędowy Ministra Zdrowia 15 Miodowa Str PL 00 – 952 Warsaw Poland http://www.mz.gov.pl/wwwmz/index?mr=m111111&ms=&ml=pl&mi=&mx=0&mt=&my=0&ma=06085
Portugal	Diário da República Casa da Moeda IN Rua D. Francisco Manuel de Melo, 5 P-1092 LISBOA Codex
Romania	Decisions are published on the NMA website : www.anm.ro

Slovakia

Decisions will be published electronically on the web-page
www.sukl.sk

Vestník ministerstva zdravotníctva SR
vydáva MZ SR vo vydavateľstve OBZOR s.r.o.
Špitálska 35
811 08 Bratislava
Slovak Republic
tel/fax: 00421 2 529 68 395
email: obzor@obzor.sk
www.obzor.sk

Slovenia

Uradni list Republike Slovenije,
Slovenska 9,
SI-1000 Ljubljana, Slovenia

Spain

Boletín Oficial del Estado
Trafalgar 27
E-28010 MADRID
tel/fax: 0034 902 365 303/00 34 91 5382121
email: libreria2boe.es

Sweden

Decisions are published on the **MPA website**: www.mpa.se

United Kingdom

Marketing Authorisation decisions and Public Assessment Reports are published on the MHRA website at:
<http://www.mhra.gov.uk>

European Union

Official Journal of the European Union

Office for Official Publications of the European Communities
2 rue Mercier
L-2985 LUXEMBURG

EFTA STATES

Iceland

Lögbirtingablaðið
Síðumúli 29
150 Reykjavík

Norway

Norsk Lysingsblad
Njøsavegen 2
NO-6863 Leikanger

Lysingsbladet@norge.no

8. ADDRESSES FOR DELIVERY OF THE DOSSIER AND SUBSEQUENT CORRESPONDENCE

AUSTRIA

Federal Agency for Safety in Health Care
(Bundesamt für Sicherheit im Gesundheitswesen)
Institut: LCM
Schnirchgasse 9
A-1030 Wien

New applications:

Preferable electronic submission: e-CTD: additional to the e-CTD submission only 2 papercopies of Module 1 are mandatory, further papercopies only on request.

In case of nonavailability of e-CTD: applications on CD-ROM are highly recommended.

Additional:

Module 1 and 2 2 papercopies for each application (strength, pharmaceutical form etc.)

Module 3, 4 and 5 paper on request

During national phase companies should send SPC, PL and Labelling for Austria within 5 days to mrp-spc@ages.at.

Variations:

Preferable electronic submission whenever possible (CD-ROM and Module 1 in paper).

During national phase MAH should send SPC, PL and Labelling to mrp-spc@ages.at within 5 days.

Renewals:

AT=CMS: Preferable electronic submission whenever possible (CD-ROM and Module 1 in paper)

AT=RMS and pure national: Preferable electronic submission whenever possible (CD-ROM and Module 1 in 2 paper copies)

During national phase MAH should send German SPC, PL and Labelling to mrp-spc@ages.at within 5 days.

Written responses:

Preferable electronic submission whenever possible (CD-ROM). In urgent cases send an e-mail to responses@ages.at

CD's always have to be labelled with the complete MRP-number, ATC-Code and name of the product.

BELGIUM

Federal Agency for Medicines and Healthcare Products
Eurostation building – block II – 8th floor
Victor Horta square, 40 – box 40
B-1060 Brussels

For all mutual recognition, decentralised and national applications, electronic submission is strongly recommended. All recommendations on electronic submission can be found on following website:

http://www.afigp.fgov.be/New/NL/Nuttige%20informatie/eSubmission/eSubmission%20Guidelines_v1-1.pdf

Note: The delivery should be announced by e-mail (by preference) or fax one week in advance of the submission of the application.

fax: 0032 (0) 2 524 81 05

e-mail: DG3_dispatching@health.fgov.be

BULGARIA

Bulgarian Drug Agency
26 Yanko Sakazov blvd.
Sofia 1504 Bulgaria
Tel: 00 359 2 944 38 36
Fax: 00 359 2 943 44 87

CYPRUS

The Registrar Drugs Council
Pharmaceutical Services
1475 Nicosia, Cyprus
Tel: +35722407159
Fax: +35722305255

CZECH REPUBLIC

Státní ústav pro kontrolu léčiv (State Institute for Drug Control)
Šrobárova 48
100 41 Praha 10
Czech Republic

Any documentation that is not sent by post should be delivered
(Monday - Friday, 8.00 – 15.00) to the above address.

In the case of particularly large deliveries (more than one pallet), it is advisable to contact the head of the Mail Room, Mrs. Eva Bártová (e-mail: eva.bartova@sukl.cz, tel: +420 272 185 720), well in advance to discuss the expected date and time of delivery.

Please, provide each binder with both a label, on which the content is clearly indicated (product name, part of the dossier, volume number), and a table of contents.

Please note that (in case of CMS) **Modules 4 and 5** may be submitted in **electronic form only** if a commitment is made that upon SUKL's request a paper copy of specified parts of Modules 4 and/or 5 will be submitted within 48 hours and, if necessary, full paper version of Modules 4 and/or 5 within 1 week.

DENMARK

Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København S
tel: (45) 44 88 95 95
fax: (45) 44 88 95 99
GOD-afdelingspostkasse@dkma.dk

ESTONIA

State Agency of Medicines
Nooruse 1
50411 Tartu
ESTONIA
phone: +372 7 374 140
fax: +372 7 374 142
e-mail : sam@sam.ee

FINLAND

The delivery of the dossiers
National Agency for Medicines
Marketing Authorisations
Nauvontie 4
P.O. Box 55
FIN – 00301 HELSINKI
tel: + 358 9 47 33 41
fax: + 358 9 47 33 42 60

FRANCE

Delivery of the dossier for all applications, variations, renewals, written responses data on centralised, mutual recognition and national procedures:
Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS)
Unité Recevabilité AMM/DEMEB

143-147 Boulevard Anatole France
F – 93285 SAINT-DENIS Cedex
tel: (33) (1) 55.87.33.11
fax: (33) (1) 55.87.33.12

Delivery schedule

9.00 – 4.30 pm – Monday to Friday

For bulky deliveries (more than 20 parcels), thank you to inform the “Unité Recevabilité AMM/DEMEB” by fax 10 days in advance 33 1 55 87 33 11

GERMANY

For sera, vaccines, allergens and blood products:

Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Str. 51-59
D – 63225 LANGEN
tel: (49) 61 03 77 0
fax: (49) 61 03 77 1234

For other human medicinal products:

Bundesinstitut für Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
D-53175 Bonn
tel : (49) (228) 207 - 30
fax : (49) (228) 207 - 5207

GREECE

**Dossier delivery, subsequent correspondence of
Administrative data, Variations and renewals:**

Registration Division, EOF
Mesogion Avenue 284
Holargos
GR – ATHENS 155 62
tel: (30) (210) 650 72 01
fax: (30) (210) 654 70 04 or 654 55 35

Subsequent correspondence Pharmaceutical Part (Module 3)

Laboratory Division, EOF (address see above)
tel: (30) (210) 650 72 21
fax: (30) (210) 654 95 94

**Subsequent correspondence Pharmacotoxicological and Clinical Part (Module 4 and
Module 5)**

Evaluation division, EOF (address see above)
tel: (30) (210) 650 72 09
fax: (30) (210) 654 72 02

HUNGARY

Országos Gyógyszerészeti Intézet (H-1051 Budapest, Zrínyi u. 3.

Tel. : (36)(1)88-69-300

Fax.: (36)(1)88-69-460

Email-addresses:

General email: ogyi@ogyi.hu

For new applications – national: elo@ogyi.hu

For new applications - European procedures HU as CMS: mrp-dcp-new-cms@ogyi.hu

For new applications - European procedures HU as RMS: mrp-dcp-new-rms@ogyi.hu

For renewal procedures European procedures HU as CMS: mrp-dcp-renew-cms@ogyi.hu

For variations - national: nat-var@ogyi.hu

For variations – European procedures: mrp-dcp-var-rms@ogyi.hu; mrp-dcp-var-cms@ogyi.hu

IRELAND

For submission of applications:

Receipt and Validation Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Terrace

DUBLIN 2

Ireland

tel: (353) (1) 676.49.71

fax: (353) (1) 676.78.36

For submission of Subsequent Correspondance relating to Pre-Licensing applications:

Pre-Licensing Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Terrace

DUBLIN 2

Ireland Tel : (353) (1) 676.49.71

Fax : (353) (1) 676.25.17

For submission of Subsequent Correspondance relating to Post-Licensing applications:

Post-Licensing Section

Irish Medicines Board

Kevin O'Malley House

Earlsfort Terrace

DUBLIN 2

Ireland Tel : (353) (1) 676.49.71

Fax : (353) (1) 676.84.90

ITALY

For all types of applications and written responses data:

Agenzia Italiana del Farmaco
Via della Sierra Nevada, 60
00144 ROMA

(Full dossier in electronic format (CD-ROM)
Paper copy for Module 1, 2 and 3 mandatory
Paper copy of Module 4 and 5 to be held available by the applicant for supply upon request.).

For sera, vaccines, allergens and blood products
(one further full copy of the dossier, for the marketing authorization and type II applications (Italy CMS)).

Instituto Superiore di Sanità
Viale Regina Elena, 299
I-00161 ROMA

LATVIA

State Agency of Medicines of the Republic of Latvia
Jersikas street 15,
RIGA, LV – 1003,
tel : +371 7078424
fax : +371 7078428

LITHUANIA

State Medicines Control Agency
Trakų str. 9/1
LT-01132, Vilnius
Lithuania
Tel. +370 5 263 92 64
Fax. +370 5 263 92 65
E-mail: vvkt@vvkt.lt
Website: <http://www.vvkt.lt>

LUXEMBURG

Villa Louvigny
Division de la Pharmacie et des Médicaments
Allee Marconi

L – 2120 LUXEMBURG
tel: (352) 478 55 90 or 478 55 93
fax: (352) 26 20 01 40 or 26 20 01 47

MALTA

Awtorita' Dwar il-Medicini
Medicines Authority
198, Rue D'Argens
Gzira GZR 1368
Malta
Tel: 00356-23439000
Fax: 00356-23439158
E-mail: prelicensing.mru@gov.mt

NETHERLANDS (THE)

College ter beoordeling van geneesmiddelen
Medicines Evaluation Board
Postbus 16229
Kalvermarkt 53
2500 BE Den Haag
tel: (31) (70) 356 74 00
fax: (31) (70) 356 75 15

For all types of applications and written responses data:

Submission of paper copies of the regulatory information is no longer a requirement in The

Netherlands if appropriate file formats are used and the electronic submission complies with the general and specific requirements provided in the Guidance for Industry on Providing Regulatory

Information in Electronic Format in the Netherlands (available by: <http://www.cbg-meb.nl/uk/docs/reghoudr/meb-ers-2.pdf>).

There are two exemptions to this rule: the signed cover letter and application form should be

submitted both electronic and in paper until a proper system is in place for electronic signatures.

More information available on the website: <http://www.cbg-meb.nl/uk/reghoudr/index.htm> .

POLAND

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
41 Żąbkowska str.
03-736 Warszawa

Tel: +48 22 492 11 00

Fax: +48 22 492 11 09

<http://www.mz.gov.pl/wwwmz/index?mr=m111111&ms=&ml=pl&mi=&mx=0&mt=&my=0&ma=06085>

PORTUGAL

Instituto Nacional da Farmácia e do Medicamento (INFARMED)

Parque de Saúde de Lisboa

Avenida do Brasil 53

1749-004 LISBOA

PORTUGAL

tel: (351) 217987100

fax: (351) 217987316

<http://www.infarmed.pt>

E-mail: infarmed@infarmed.pt

ROMANIA

National Medicines Agency

48, Av. Sanatescu Street

011478 – Bucharest

Romania

Tel.: 0040 21 316 10 79

Fax: 0040 21 316 34 97

SLOVAK REPUBLIC

State Institute for Drug Control

Kvetná 11

825 08 Bratislava 26

Slovak Republic

Tel.: + 421 2 5070 1111

Fax: + 421 2 555 7 11 05

email: registracia@sukl.sk

In general Modules 3, 4 and 5 may be submitted in electronic form if a commitment is made that upon SUKL's request a full paper version of Modules 3, 4 and/or 5 will be submitted within 48 hours.

In case of submitting registration dossier for several strengths of the medicinal products with the same active substance, where a part of the documentation for all these strengths is identical, applicant should submit "identical" Modules (except Module 1.2) only once as a paper copy and the rest of the identical documentation has to be submitted electronically (on a CD)

SLOVENIA

New applications:

1 copy to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Mali trg 6, SI-1000 Ljubljana, Slovenia

Tel: (+386) 1 478 62 40

Fax: (+386) 1 478 62 60

1 additional copy of Part IA, SPC, Quality Overall Summary, Module 3 to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ptujška 21, SI-1000 Ljubljana, Slovenia.

Tel: (+386) 1 300 37 00

Fax: (+386) 1 300 37 01

E-mail: elektronska.dok@zaf.si

Renewals:

1 copy to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Mali trg 6, SI-1000 Ljubljana, Slovenia

Tel: (+386) 1 478 62 40

Fax: (+386) 1 478 62 60

Variations:

1 copy to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Mali trg 6, SI-1000 Ljubljana, Slovenia.

Tel: (+386) 1 478 62 40

Fax: (+386) 1 478 62 60

1 additional copy for variations concerning Module 3 to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ptujška 21, SI-1000 Ljubljana, Slovenia.

Tel: (+386) 1 300 37 00

Fax: (+386) 1 300 37 01

E-mail: elektronska.dok@zaf.si

Written responses:

1 copy to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Mali trg 6, SI-1000 Ljubljana, Slovenia

Tel: (+386) 1 478 62 40

Fax: (+386) 1 478 62 60

Please note that Agency for Medicinal Products and Medical Devices of the Republic of Slovenia prefers to receive response documents in electronic format. These documents have to be sent to the following E-mail address: mrp.arszmp@gov.si. In case of electronic submission, the submission of paper copies is not required.

1 additional copy concerning Module 3 to: Agency for Medicinal Products and Medical Devices of the Republic of Slovenia, Ptujška 21, SI-1000 Ljubljana, Slovenia.

Tel: (+386) 1 300 37 00

Fax: (+386) 1 300 37 01

E-mail: elektronska.dok@zaf.si

SPAIN

Ministerio de Sanidad y Consumo

Agencia Española del Medicamento y Productos Sanitarios

Campezo 1.Parque Empresarial Las Mercedes. Edif 8

CP 28022. MADRID.

fax: (34) (91) 822 51 61

<http://www.agemed.es>

SWEDEN

Medical Products Agency

Registration Office

Dag Hammarskjölds väg 42

P.O. Box 26

SE – 751 03 UPPSALA

tel: (46) (18) 17 46 00

fax: (46) (18) 54 85 66

Responses that are submitted by e-mail should be addressed to the general e-mail address sok.central@mpa.se via normal e-mail or Eudralink. A hard copy is also requested.

Please indicate on both documents that they have also been sent by e-mail/as hard copy

UNITED KINGDOM

Subscribers to the MHRA External Portal may use it to make all types of applications and submissions in secure electronic form (including eCTD.) Alternative methods of submission are described below.

Applications and Submissions in Electronic Form on Disk.

All disks should be sent to the address below ensuring that the correct Area Code for the type of submission is used.

Information Processing Unit

[Area Code - Please see list ** below]

Medicines & Healthcare products Regulatory Agency

Market Towers

1 Nine Elms Lane

LONDON

SW8 5NQ

** Address to one of the following Area Codes depending on the type of submission on the disk (including responses to our requests for further information):

- Area 1 New National Market Authorisation Applications
- Area 2 MR and Decentralised Procedures Applications
- Area 3 Variation Applications
- Area 4 MA Renewals, PSURs
- Area 5 Parallel Import Licences, Homeopathic and Herbal Registrations, Notified Body (Drug-Device) Applications
- Area 6 Clinical Trial Applications
- Area 7 Active Substance (Drug) Master Files

Paper Applications and Submissions

The MHRA works in a fully electronic manner. Companies are strongly encouraged not to submit any applications or submissions on paper. However, where necessary, paper submissions should be sent to one of the following addresses depending on the type of submission:

Marketing Authorisation Applications (National and European procedures), Change of Ownership applications, Master File submissions, and all associated communications and responses (by regular postal service):

MHRA
PO Box Number 14
Mitcheldean
Gloucestershire GL17 0WX
UK

Variation applications and all associated communications and responses (by regular postal service):

MHRA
PO Box Number 15
Mitcheldean
Gloucestershire GL17 0WU
UK

Renewal applications, all associated communications and responses, and PSUR submissions (by regular postal service):

MHRA
PO Box Number 16
Mitcheldean
Gloucestershire GL17 0WU
UK

All paper-based submissions using a Courier Service or by personal delivery:

Xerox Ltd
Building 9 Floor 3 (MHRA contract)
Vantage Point Business Village
Mitcheldean
Gloucestershire GL17 0DD
UK

For any queries regarding the procedures for the submission of applications please contact the MHRA Regulatory Information Service by telephone (+44) (0)207 084 3400 or e-mail RIS.NA@mhra.gsi.gov.uk.

EMEA

European Medicines Agency (EMA)
Central Information Group (CIG)
7 Westferry Circus
Canary Wharf
UK – LONDON E14 4HB
tel: (44) (0207) 418 84 00
fax: (44) (0207) 418 84 16

(1) All dossiers are to be delivered to the following address:

EMEA Loading Dock
Ontario Way
Canary Wharf
UK - LONDON E14 4HB

(located at the rear of EMEA premises)
(9:00 – 17:30 hours Monday to Friday)

- (2) For health and safety reasons and in accordance with recognised safe lifting limits, an application dossier should be packed in boxes weighing **no more than 15kgs** each
- (3) All boxes should be numbered by an indication of the dossier part or module inside with the box containing the cover letter and diskettes/CD-Roms clearly identified
- (4) Very large dossiers of 10-15 boxes or more should be packed on pallets and delivered by truck with a tail lift unloading facility

**The information below should be sent to the EMEA by fax to
+44 20 7418 8660 before shipment of your dossier.**

Company name:
MAA/dossier name:
No of boxes:
Estimated date of arrival:

In the event of queries, please contact: +44 20 7523 7081 or
+44 20 7523 7193

EFTA STATES

ICELAND

Lyfjastofnun

The Icelandic Medicine Control Agency (IMCA)

P.O. Box 180

Eiðistorg 13 – 15

172 Seltjarnarnes

Iceland

tel : (354) 520 2100

fax : (354) 561 2170

email : lyfjastofnun@imca.is

NORWAY

Statens legemiddelverk

Sven Oftedals vei 8

NO-0950 OSLO

Tel.: 47 22 89 77 00

Fax numbers:

Mutual Recognition matters: 47 22 89 75 21

Central Procedure matters: 47 22 89 77 54

Other matters: 47 22 89 77 99

9. ADDRESSES FOR RECEIPT OF FEES AND TERMS FOR PAYMENT

AUSTRIA

Published national rules

Verordnung des Bundesamtes für Sicherheit im Gesundheitswesen über den Gebührentarif gemäß GESG

Available in Internet www.ages.at

Fees payable to:

Bank Austria-Creditanstalt
Konto Nummer: 50670 871 619
BLZ: 12000
IBAN; AT971200050670871619
BIC/SWIFT: BKAUATWW

Method of payment:

Only on postal account - please be aware that banks will charge you for transactions fees, cheques are not accepted.

The invoice number, the client number and the name of the product must be stated.

No fees should be paid in advance of the submission.

BELGIUM

Published national rules:

- Koninklijk besluit van 3 juli 1969 betreffende de registratie van geneesmiddelen
- Arrêté royal du 3 juillet 1969 relatif à l'enregistrement des médicaments
(text available only in Dutch and French)

Available on website: www.afigp.fgov.be and from address for advice on fees:

Federal Agency for Medicines and Healthcare Products
Eurostation building – block II – 8th floor
Dispatching Unit
Victor Horta square, 40 – box 40
B-1060 Brussels
Fax: 0032 (0) 2 524 81 05
e-mail : DG3_dispatching@health.fgov.be

Fees payable to:

Federal Agency for Medicines and Healthcare Products
Eurostation building – block II – 8th floor
Comptabilité / Boekhouding
Victor Horta square, 40 – box 40
B-1060 Brussels

Tel: 0032 (0) 2 524 80 47

Fax: 0032 (0) 2 524 80 01

On Postal Account number (PRK - CCP) 679 - 002 19 42 - 20

IBAN-CODE : BE28 6790 0219 4220

Swift code: PCHQBEBB

For Community procedure :

On Postal Account number (PRK - CCP) 679 - 000 15 14 - 59

IBAN-CODE : BE84 6790 0015 1459

Swift code: PCHQBEBB

Method of Payment

Only on the postal account, in EUROS (please be aware that banks will charge you for transactions fees).

Cheques are not accepted

The name of the applicant and the name of the product must be stated.

Proof of payment is required in part IA before an application can be accepted.

BULGARIA

Available in Internet www.bda.bg

Address for advice on fees:

Tel: 00 359 2 943 48 13

Email: mitova@bda.bg

Fees payable to:

Bank: Bulbank PLC, Branch Kaloyan

IBAN: BG77 BFTB 7630 3100 1128 90

BIC: BFTBBGSF

Method of payment:

Payment to be made with the application, in Bulgarian leva.

Proof of payment should accompany the application.

CYPRUS

Published national rules:

PI 873/2004 published in Cyprus Government Gazette 3940-31/12/2004

Available from:

Government Printing Office

Michalaki Karaoli

1445 Nicosia

Tel: +35722405829, +35722405838-9

Fax: +35722303175

Address for advice on fees:

Pharmaceutical Services
1475 Nicosia, Cyprus
Tel: +35722407159
Fax: +35722305255
http://www.capc.org.cy/MOH_forms.html

Fees payable to:

Central Bank of Cyprus (to the account of the Registrar Drugs Council)
Michael Karaolis str.
1441 Lefkosia
http://www.capc.org.cy/MOH_forms.html

Method and time of payment:

Payment to be made with the application, in Cyprus pounds.
Proof of payment should accompany the application.

The proof of payment should include the following information:

- Name, pharmaceutical form, strength of the product
- Mutual Recognition and Decentralised procedure reference number
- Name of the applicant/Marketing Authorisation Holder

http://www.capc.org.cy/MOH_forms.html

CZECH REPUBLIC

Published national rules:

Act No. 79/1997 Coll., on pharmaceuticals, as amended
Act No. 368/1992 Coll., on administrative fees, as amended
SUKL Guideline UST-29 (or its revised version)

Available from address for advice for fees:

Státní ústav pro kontrolu léčiv (State Institute for Drug Control)
Šrobárova 48
100 41 Praha 10
Czech Republic
sukl@sukl.cz
<http://www.sukl.cz/>

Fees payable to:

Administration fee in the amount stipulated by the Act on Administrative Fees shall be paid by means of revenue stamps (fee stamps) attached to the form which shall form part of any application (see SUKL website <http://www.sukl.cz/en10fees/en10fees.htm>). Applicants who are not able to obtain revenue stamps are advised to contact Dr. Markéta Hrbasová (e-mail: marketa.hrbasova@sukl.cz, Tel: +420 272 185 717)
Payment of costs incurred by expert activities in the amount stipulated by the SUKL Guideline shall be paid prior to submission of the application by bank transfer (see SUKL <http://www.sukl.cz/en10fees/en10fees.htm>). The application shall be accompanied also by one copy of the payment order confirmed by the bank.

DENMARK

Published national rules:

Indenrigs- og Sundhedsministeriets bekendtgørelse nr. 1416 af 13.12. 2006 om afgifter for lægemidler og lægemiddelvirksomheder

Available from address for advice on fees:

Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København S Danmark
Tel. +45 44 88 95 95

Fees payable to:

Lægemiddelstyrelsen
Axel Heides Gade 1
DK – 2300 København Danmark
Tel. +45 44 88 95 95

The fee will be invoiced by the Danish Medicines Agency

Method of payment:

Postal cheque service 9 18 4295

From other EC countries:

Jyske Bank
Vesterbrogade 9
DK-1780 København V, Danmark
reg. no. 8109
account no. 100835 or
reg. no. 5010
account no. 122275-5
S.W.I.F.T. address: JYBADKKK

ESTONIA

Published national rules:

Ravimiseadus (Medicinal Products Act)
www.sam.ee

STATE FEE payable to
Rahandusministeerium (Ministry of Finance)
Address: Suur-Ameerika 1, Tallinn 15006, ESTONIA

Account no: 221023778606
IBAN: EE932200221023778606
SWIFT code: HABA EE2X
Bank : HANSAPANK
Address: Liivalaia 8, Tallinn 15040, ESTONIA

The proof of payment should include at least the following data:

- the name of the product, pharmaceutical form and strength;
- the number and type of application;
- reference number (2900073517)

Reference number for application for marketing authorisation, renewal, variation application of human medicinal product and clinical trials applications: 2900073517

Method of payment:

The state fee has to be paid prior the submission of the application.

Proof of payment of the state fee should be enclosed to the application

ASSESSMENT FEE payable to:

Rahandusministeerium (Ministry of Finance)

1 Suur-Ameerika Str., 15006 Tallinn, Estonia

Beneficiary's bank: Hansapank, Liivalaia 8, 15040 Tallinn, Estonia

Account number: 221013921094

IBAN: EE492200221013921094

SWIFT/BIC code: HABAE2X

Through: Deutsche Bank, Frankfurt

SWIFT/BIC code: DEUTDEFF

reference number 2100010891

Reference number and invoice number must be stated

Method of payment

An invoice will be sent upon receipt of the application. **No payment of assessment fee should be made in advance.**

Please make sure that the whole amount of the will be credited to our account net of any charges from the issuing or receiving bank

FINLAND

Published national rules:

Decree of the Ministry of Social Affairs and Health concerning activities of the National Agency for Medicines subject to fees

Available in internet www.nam.fi and also from:

National Agency for Medicines

Department of General Affairs

Mannerheimintie 103b

P.O. Box 55

FIN – 00301 HELSINKI

tel: +3589 473341

fax: +3589 714 469

Fees payable to:

National Agency for Medicines
Marketing Authorisations

Method of Payment:

Account no. 800014 - 21 979 of Sampo Bank plc, preferably wire transfer (swift-code PSPBFIHH, IBAN number: FI1480001400021979).

The proof of payment of the fee should be included to the application. The proof should contain the information on the date of payment, the (proposed) name for the product with the strength and pharmaceutical form, the name of the applicant/marketing authorisation holder, method of procedure (national procedure/mutual recognition/decentralised procedure) and the type of applicant

FRANCE

Published national rules:

Décret n° 96-653 du 16 juillet 1996 portant application de l'article L-602 du Code de la Santé Publique.

Available from address for advice on fees:

Agence Française de Sécurité Sanitaire des produits de Santé
143-147 Boulevard Anatole France
Unité Recevabilité AMM/DEMEB
F – 93285 SAINT-DENIS Cedex
tel: (33) (1) 55.87.33 11
fax: (33) (1) 55.87.33 12

Method of payment:

By cheque

Cheques should be made payable to "Agent comptable de l'Affsaps"

Payment to be made with marketing authorisation application

GERMANY

For sera, vaccines, allergens and blood products

GERMANY

For sera, vaccines, allergens and blood products (Somatic cell therapy- and xenogeneic cell therapy medicinal products, gene therapy medicinal products and tissue engineering products)

Published national rules:

Kostenverordnung für Amtshandlungen des Paul-Ehrlich-Instituts nach dem Arzneimittelgesetz in der Fassung der Bekanntmachung vom 04. Oktober 2002 (BGBl. I, S. 4017), zuletzt geändert durch die Dritte Verordnung zur Änderung der Kostenverordnung für Amtshandlungen des Paul-Ehrlich-Instituts nach dem Arzneimittelgesetz vom 06. Dezember 2006 (BGBl. I, S. 2807).

Available from:

Bundesanzeiger Verlagsgesellschaft mbH

P.O. Box 10 05 34
D – 50445 Köln
tel: (49) (221) 976 68-0
fax: (49) (221) 976 288

Adress for advice on fees:
Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Str. 51-59
D – 63225 Langen
tel: (49) (6103) 77 0
fax: (49) (6103) 77 – 1234

Fees payable to:
Bundeskasse Trier
Deutsche Bundesbank Filiale Trier
Account No. 585 010 03
BLZ 585 000 00
IBAN: DE 44 5850 0000 0058 5010 03
BIC: MARKDEF 1585

Method of Payment
Payment on request according to a account of fees (Kostenbescheid). The
“Kostenbescheidnummer” and the “Kassenzeichen” must always be indicated.

Payments to be made by automated credit transfer, payments from foreign countries by
automated credit transfer or exceptionally by cheque. All banking charges are to be borne by
the debtor.

*For other human medicinal products than sera, vaccines, blood products, and
allergens.*

Available from:
Bundesanzeiger Verlagsgesellschaft mbH
P.O. Box 10 05 34
D-50445 Köln
tel: (49) (221) 976 68-0
fax: (49) (221) 976 68-278

Published national rules:

Kostenverordnung für die Zulassung von Arzneimitteln durch das Bundesinstitut für
Arzneimittel und Medizinprodukte und das Bundesamt für Verbraucherschutz und
Lebensmittelsicherheit vom 16. Dezember 2003 (published in Bundesgesetzblatt 2003 I
page 2510) as amended by Verordnung vom 21. Dezember 2004 (published in
Bundesgesetzblatt 2004 I page 3719)

Available from:

Bundesanzeiger Verlagsgesellschaft mbH
P.O. Bos 10 05 34
D – 50445 Köln
tel: (49) (221) 976 68-0
fax: (49) (221) 976 68-278

Address for advice on fees:

Bundesinstitut für Arzneimittel und Medizinprodukte
Kurt-Georg-Kiesinger-Allee 3
D – 53175 BONN
tel: (49) (228) 207-30 or ext. 4148
fax: (49) (228) 207-5207

Fees payable to:

Bundesinstitut für Arzneimittel und Medizinprodukte
D – 53175 BONN

Method of payment

Bundeskasse Trier
Deutsche Bundesbank Filiale Bonn
Postfach 42 20
D-54232 Trier
Account no. 585 010 03
BLZ 585 000 00
IBAN: DE 44 5850 0000 0058 5010 03
BIC: MARKDEF 1585

Method of payment

Payment on request according to account of fees (Kostenbescheid).
The “Kostenbescheidnummer” and the “Kassenzeichen” must always be indicated.

Payments to be made by automated credit transfer, payments from foreign countries by automated credit transfer or exceptionally by cheque. All banking charges are to be borne by the debtor.

GREECE

Published national rules:

Ministerial Decree Y6a/11094/97 published in the Official Gazette 235/B/11-3-98

Available from address for advice on fees:

NATIONAL ORGANIZATION FOR MEDICINES
284 Messogion Avenue
HOLARGOS
GR – 15562 ATHENS

Fees payable to:

Bank of Greece (to the account of the National Organization for Medicines / **Account number: 263038**)
Foreign Exchange Department
Section C
21 Panepistimiou Avenue
GR – 10250 ATHENS
IBAN: GR5301000240000000000263038
SWIFT CODE: BNBNGRAA

Payment to be made on application. Proof of payment is necessary

Address for advice on fees

Registration Division,
EOF
284 Messogion Avenue
Holargos
GR – 15562 Athens
tel: (30) (210) 650 72 01
fax: (30) (210) 654 70 04, 654 55 35

HUNGARY

Published national rules:

Az egészségügyi miniszter 32/2005. (VIII. 11.) EüM rendelete az emberi felhasználásra kerülő gyógyszerekkel kapcsolatos egyes engedélyezési eljárások során fizetendő igazgatási szolgáltatási díjakról
(text available in Hungarian and English)

Available from:

NIP website: www.ogyi.hu

Address for advice on fees:

Application Screening Department
National Institute of Pharmacy
Address:
H-1051 Budapest,
Zrínyi utca 3.
HUNGARY
Tel. : (36)(1)88-69-308
Fax.: (36)(1)88-69-460
elo@ogyi.hu

Fees payable to:

Név/Name: Országos Gyógyszerészeti Intézet / National Institute of Pharmacy - Hungary
Cím/Address: H-1051 Budapest; Zrínyi utca 3.; HUNGARY
Bank neve/Name of Bank: Magyar Államkincstár / Hungarian State Treasury
Bankszámlaszám/Account number: 10032000-01492695-00000000
Adószám/Tax number: 15310037-2-41
Közösségi adószám/VAT number: HU 15310037
IBAN szám/IBAN number: HU25 1003 2000 0149 2695 0000 0000
SWIFT kód/SWIFT code: MA NE HU HB

Method of payment:

Payment to be made with the application in any convertible currency, and the proof of payment should accompany the application.

Exceptions when an invoice will be sent by the National Institute of Pharmacy:

- Renewal fee
- Maintenance fee

The proof of payment should include information on the product and the procedure (for details see NIP website www.ogyi.hu)

IRELAND

Published national rules:

Irish Medicines Board (Fees) (Amendment) Regulations, 2000
SI No 233/2000

Available from:

Government Publications Sale Office,
Molesworth Street,
Dublin 2
Tel: (353) (1) 661 3111

Address for advice on fees

Irish Medicines Board
Earlsfort Centre
Earlsfort Terrace
IRL – Dublin 2
Tel: (353) (1) 676 4971
Fax for fee advice: (353) (1) 661 4764

Fees payable to:

Irish Medicines Board
Account no: 33712185; sort code: 93-10-12
IBAN:IE 54AIBK 93101233712185
Allied Irish Bank,
1-3 Baggot St. Lr., DUBLIN 2

Method and time of payment:

Payment to be made with the application, in Euros.
All cheques and drafts should be drawn on an Irish bank.

When making a payment by EFT/credit transfer, all associated charges including beneficiaries must be settled. The bank advice should detail the PA number and product name, and invoice number where applicable. Proof of payment (EFT/direct debit) should accompany the application

ITALY

Published national rules:

Registration fees

Decreto 24 maggio 2004 del Ministero della Salute

Available for advice on fees:

Dr. Giovanna Romeo
Agenzia Italiana del Farmaco
Via della Sierra Nevada, 60
I - 00144 ROMA
Tel: 00390659784204
Fax: 00390659784055

Method and time of payment

Licence Processing Fees

To be paid when submitting marketing authorisation and variation applications in Euro,

If the payment is made in Italy

Through:

- Postal Account No: 94151008
In the name of "Ministero della Salute – Direzione Generale dei Farmaci e dei Dispositivi Medici".
Behind the form of the a.m. current account, under the notice "Spazio per la causale del versamento", the motive of payment should be specified with the product name and the procedure number.
- Postal account No. 94151008 by swift (free of bank charges):
BIC code: BPPIITRRXXX
IBAN code: IT 84 W 07601 03200 000094151008

In the name of "Ministero della Salute – Direzione Generale dei Farmaci e dei Dispositivi Medici".
The motive of payment should be specified with the product name and the procedure number.

If the payment is made from abroad

For countries belonging to the European Monetary Union (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxemburg, the Netherlands, Portugal, Spain).

Through:

For countries belonging to the European Monetary Union (Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, the Netherlands, Portugal, Spain).

The TARGET system

BIC code: BITA IT RR XXX

IBAN code: IT 87 N010 0003 2040 0000 0000 350

The motive of payment should be specified with the product name and the procedure number, furthermore, the following wording should be added: "tariffe AIC Capitolo 2230 articolo 12".

For all other countries:

The payment must be made through the Ufficio Italiano Cambi through the following banks:

1 Beneficiary	UFFICIO ITALIANO DEI CAMBI
Bank of the beneficiary	DEUTSCHE BANK A.G. FRANKFURT/MAIN
SWIFT code	DEUTDEFF
IBAN	DE03 5007 0010 0935 6403 00
2 Beneficiary	UFFICIO ITALIANO DEI CAMBI
Bank of the beneficiary	SOCIETE' EUROPEENNE DE BANQUE S.A. - LUXEMBURG
SWIFT code	SEBKULL
IBAN	LU44 0872 4236 7000 0000
3 Beneficiary	UFFICIO ITALIANO DEI CAMBI
Bank of the beneficiary	MONTEPASCHI BANQUE S.A.-PARIS
SWIFT code	MONTFRPP
IBAN	FR76 3047 8000 1608 1159 8000 141

The motive of payment should be specified with the product name and the procedure number, furthermore, the following wording should be added: "tariffe AIC Capitolo 2230 articolo 12"

LATVIA

Published national rules :

Regulation of the Ministry of Health of the Republic of Latvia concerning registration fees No. 179 (10.07.2003) ; homepage
<http://www.zva.gov.lv>

Fees payable to :

State Agency of Medicines of Republic of Latvia
(VAT) LV90001836181
Jersikas street 15,
LV – 1003, RIGA
LATVIA
tel. +371 7078405

Method of payment :

The TREASURY OF THE REPUBLIC OF LATVIA
account number – LV63TREL2290650340000
Code – BIC TREL LV22

LITHUANIA

Published national fees:

<http://www.vvkt.lt>

The fees indicated do not include any payment for bank transactions

Fees payable to:

VILNIUS COUNTY STATE TAX INSPECTORATE
Sermuksniu 4, LT- 01509 Vilnius
Lithuania

Method of payment:

Applicants or MAH's outside Lithuania should make their payments to:

<i>Correspondent Bank</i>	DEUTSCHE BANK AG, Frankfurt SWIFT: DEUTDEFF BLZ 500 700 10
<i>Beneficiary's Bank Beneficiary's Bank address</i>	AB bankas "Hansabankas" Savanoriu 19, Vilnius SWIFT: HABALT22
<i>Beneficiary's Acc. No</i>	LT23 7300 0100 0245 8204
<i>Beneficiary Beneficiary's address</i>	Vilnius County State Tax Inspectorate Sermuksniu 4, LT-01509 Vilnius
<i>Reference No.*</i>	5710

Applicants or MAH's within Lithuania should make their payments to:

Vilniaus apskrities valstybinė mokesčių inspekcija (kodas 188728821)	
AB bankas „Hansabankas“	
Banko kodas	73000
Sąskaitos Nr.	LT23 7300 0100 0245 8204
Įmokos kodas*	5710

Proof of payment should be provided with the application form submitting to **State Medicines Control Agency** of Lithuania.

Cheques are not accepted.

LUXEMBOURG

Published national rules

Règlement grand-ducal du 24.12.93 fixant les droits dus pour la mise sur le marché des médicaments

How available

Sent on request

Address for Advice on Fees

Villa Louvigny
Division de la Pharmacie et des Médicaments
Allee Marconi
L – 2120 LUXEMBURG
tel: (352) 478 55 94
fax: (352) 26 20 01 40 or 26 20 01 47

Fees payable to:

Administration de l'Enregistrement et des Domaines
Plateau du St. Esprit
L – 2010 LUXEMBURG

Method and Time of Payment

Proof of payment must accompany the dossier.
Payment must be made through Postal Account No. 77 33 70. Cheques are not accepted. Contact person: Mr. Carlo Scholl, Inspector.
tel: (352) 478 55 94

MALTA

Published national rules:

<http://www.doi.gov.mt>

Payment to be affected upon submission of the application form.

Payment of the relevant fee is to be made at: (when executing the payment the amount should be remitted in full, net of all bank charges)

Bank Details: HSBC Malta plc.
Gzira Branch
Malta

Account Name: MEDICINES AUTHORITY

Account Number: 039-011176-002

IBAN: MT78MMEB44392000000039011176002

Swift Code: MMEBMTMT

NETHERLANDS (THE)

Published national rules are available on the website: <http://www.cbg-meb.nl/uk/reghoudr/index.htm>

Advice can also be requested at the following address:

College ter Beoordeling van Geneesmiddelen

Medicines Evaluation Board

Kalvermarkt 53

Postbus 16229

2500 BE Den Haag

Tel: +31 (0)70 356 74 00

Fax: +31 (0)70 356 75 15

Fees payable to:

College ter beoordeling van geneesmiddelen

Den Haag

Method of payment:

No payment in advance. A bill is sent after receipt of the dossier/application."

POLAND

Available from: Published national rules:

Rozporządzenie Ministra Zdrowia z dnia 4 sierpnia 2004 r. w sprawie sposobu ustalania i uiszczania opłat związanych z dopuszczeniem do obrotu produktu leczniczego (Dziennik Ustaw Nr 04.180.1870 z dnia 18 sierpnia 2004)

Address for advice on fees:

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

41 Żąbkowska str.

03-736 Warszawa

Tel: +48 22 492 11 00

Fax: +48 22 492 11 09

<http://www.urpl.gov.pl>

PORTUGAL

Published national rules:

Portaria No. 377/2005 de 4 de Abril

Diario da Republica, I - serie B, N°65

Available from the address for advice on fees:

INFARMED – Direcção de Medicamentos e Produtos de Saúde

Parque de Saúde de Lisboa

Avenida do Brasil 53

1749-004 LISBOA

PORTUGAL

tel: (351) 217987100

fax: (351) 217987316

e-mail: centro.informacao@infarmed.pt

<http://www.infarmed.pt/portal/page/portal/INFARMED/TAXAS> (includes Q&A, the Procedure to be followed and the Form to be filled in)

Fees payable to:

Instituto Nacional do Farmácia e do Medicamento (INFARMED)

Parque de Saúde de Lisboa

Avenida do Brasil 53

1749-004 LISBOA

PORTUGAL

tel: (351) 217987100

fax: (351) 217987316

Method of payment

Money order or bank deposit on account based on Direcção-Geral do Tesouro.

Information for the bank transfer:

- NIB 078101120000000624751
- IBAN PT50078101120000000624751
- SWIFT CODE TESPPTP1

(i) Fees should be paid before deposit of the dossier,

(ii) Confirmation of deposit should preferably be included in the application or be sent to:

INFARMED

Parque de Saúde de Lisboa

Avenida do Brasil, nº53 - Pavilhão 21 A

1749-004 LISBOA

PORTUGAL

tel: (351) 217987100

fax: (351) 217987316

ROMANIA

Address for advice on fees

National Medicines Agency

48, Av. Sanatescu Street

011478 – Bucharest

Romania

Tel.: 0040 21 316 10 79

Fax: 0040 21 316 34 97

Fees payable to:

Cash:

National Medicines Agency

48, Av. Sanatescu Street

011478 – Bucharest

Romania

Tel.: 0040 21 316 10 79
Fax: 0040 21 316 34 97
Room no: 11

Bank transfer:

For payments in LEI:

Trezoreria Sector 1, Str. Dimitrie Gerota Nr. 13, Sector 1, Bucuresti, Romania
IBAN: RO29TREZ7015025XXX000326

For payments in EUROS:

Banca Comerciala Romana – Agentia Doamnei, Str. Doamnei Nr. 14-16, Sector 3,
Bucuresti, Romania
IBAN: RO06RNCB0080005629990005
SWIFT: RNCBROBU

Methods of payment

The applicant fills-in the payment form, as indicated on the NMA web-site. The NMA issues an invoice. The invoice is picked up by the applicant from the NMA headquarters or sent to the billing address indicated by the applicant; the invoice must contain clear details of the product and procedures involved, the type of fee, the amount of the fee, the bank account to which the fee is payable. Payment shall be made in advance of the procedure. When executing the payment, the amount shall be remitted in full, net of all bank charges.

More information on fees is available on the NMA website: www.anm.ro.

SLOVAK REPUBLIC

Published national rules available from:

State Institute for Drug Control
Department of registration
Kvetná 11
825 08 Bratislava 26
Slovak Republic
Tel.: + 421 2 5070 1111
Fax: + 421 2 555 7 11 05
email: registracia@sukl.sk

Address for advice on fees

State Institute for Drug Control
Department of registration
Kvetná 11
825 08 Bratislava 26
Slovak Republic
Tel.: + 421 2 5070 1111
Fax: + 421 2 555 7 11 05
email: registracia@sukl.sk
http://www.sukl.sk/payment_reg.doc

Fees payable to

The bank account (payment from foreign countries):

- **IBAN: SK348180000007000133673**
- **SWIFT (BIC): SUBASKBX**

The bank account (domestic payment):
7000133673/8180

constant symbol: 0558

variable symbol: application number (SIDC reference number)

The bank account in **NBS - 6015-327-062/0720** Národná banka Slovenska, Bratislava which has been valid till 31.12.2004, it **has been canceled from 01.01.2005.**

Method of payment

Contact with the SIDC to obtain a variable number for the payment is requested.

Payment only to the bank account.

Payment to be made in advance of procedure.

Proof of payment should accompany the application

SLOVENIA

Published national rules:

- Rules on fees (Official Gazette of the Republic of Slovenia, no. 3/2007, available on website: <http://www.jazmp.si>)
- Act on Administrative fees (Official Gazette of the Republic of Slovenia, no. 138/2006)

Fees payable to:

Bank name: Banka Slovenije

Branch address: Slovenska 35

Town/City: Ljubljana

Post code: 1505

Account number: 01100-6000020296

Ref. No: 00 760002-400 (Application fees for medicinal products for human use; if the payment is made in Slovenia)

Ref. No: 00 760002-402 (Annual fees for medicinal products for human use; if the payment is made in Slovenia)

Ref. No: 00 760102-400 (Application fees for medicinal products for human use; if the payment is made from abroad)

Ref. No: 00 760102-402 (Annual fees for medicinal products for human use; if the payment is made from abroad)

IBAN: SI56011006000020296

SWIFT code: BSLJSI2X

Administrative fees payable to:

Administrative fees should be paid by means of revenue stamps (fee stamps) attached to the cover letter

Administrative fees can also be paid to:

Bank name: Banka Slovenije

Branch address: Slovenska 35

Town/City: Ljubljana
Post code: 1505
Account number: 01100-1000315637
Ref. No.: 11 27650-7111002
IBAN: SI56011001000315637
SWIFT code: BSLJSI2X

Method of payment:

Fees have to be paid prior to submission of the application, in Euros.
The purpose should be also stated (application for MRP/DCP xxx) and the claimant (Agency for Medicinal Products and Medical Devices of the Republic of Slovenia = JAZMP).

SPAIN

Published national rules:

Ley 29/2006 de Garantias B.O.E. (27.07.06).

Available from the address for advice on fees:

Ministerio de Sanidad y Consumo
Agencia Española del Medicamento y Productos Sanitarios
Campezo 1.Parque Empresarial Las Mercedes. Edif 8
CP 28022. MADRID.
fax: (34) (91) 822 51 61
<http://www.agemed.es>

Fees payable to:

TESORO PUBLICO. Agencia Española del medicamento

Method and time of payment

The persons and entities not resident in Spain who should apply to the SAMHP, the execution of their competent activities or services regarding medicinal products, should pay the corresponding fees. This can be done by bank transfer to the Agency's collections bank account. The SAMHP doesn't admit checks neither entrance in cash.

The bank account is opened in the name of the SAMHP in BBVA, number:

0182 2370 46 020397751 6

(International bank account code and number: IBAN ES27 0182 2370 4602 0397 7516).

Swift / BIC: BBVAESMMXXX

The money deposit in the SAMHP's Account by this procedure must be exactly the same, no matter the currency is, to the established rates in peseta/Euro hereby enclosed, depending on the group of the requested activity.

IMPORTANT: Art. 113.4 Law 29/2006, of 26 of July: Once paid the fees, the interested will present the application in the SAMHP before three months from their payment.

Each application should be accompanied by the original payment voucher.

SWEDEN

Published national rules:

State Control of Medicinal Products (Fees) Ordinance (1993:595)
Ordinance on change in the ordinance (1993:595) on fees for the governmental control of medicinal products (SFS 1997:961 and 1998:1813) Medical Products Agency's provision and guidelines (LVFS 1995:12)

Available from:

Fritzes
SE – 106 47 STOCKHOLM
tel: +46 8 690 90 90

Method of payment:

An invoice will be sent upon receipt of the application. No payment should be made in advance.

See also the MPA website: www.mpa.se

UNITED KINGDOM

Published national rules

The Medicines (Products for Human Use – Fees) Regulations 1995 (as amended).

How available

from: Her Majesty's Stationery Office (HMSO)
P.O. Box 276
LONDON SW8 2DR
UK

Reference SI 1995 No 1116

Address for advice on fees

Fees Policy Unit
Room 16-159
Medicines and Healthcare products Regulatory Agency
Market Towers
1 Nine Elms Lane
LONDON SW8 5NQ
UK

And website www.mhra.gov.uk

Fees payable to:

Cashier
Room 21-137

Medicines and Healthcare products Regulatory Agency
 Market Towers
 1 Nine Elms Lane
 LONDON SW8 5NQ
 UK
 tel: (44) (0207) 084 2507 fax: (44) (0207) 084 2528

Methods of payment

Cheques should be made payable to "Medicines and Healthcare products Regulatory Agency"

Banks Details for Payment by Bank Transfer:

Please send remittances for the attention of the Cashier **OR** fax to 020 7084 2528 **OR** e-mail to cashiers@mhra.gsi.gov.uk

BACS Payments (UK Accounts)

Bank Name	Bank of England
Bank Address	Government Counter Threadneedle Street London, EC2R 8AH UK
Sort Code	10 14 99
Account no	06781000
Reference	Invoice Number and/or Account Number (please ensure this is quoted on transfer)

Sterling CHAPS Payments from a UK Account

Bank Name	Natwest Bank
Bank Address	6 Coldharbour Lane Hayes Middlesex, UB3 3EL UK
Sort Code	16 53 60
Account No	6781
Reference	MHRA (Invoice Number or Account Number) (please ensure this is quoted on transfer)

For EURO currency payments from a Member State

Account name	Office of HM Paymaster General - Euro Receipts
Account number	5500108304793
Sort Code	60 10 43
Swift Code	NWBKGB2L
Reference	6781 MHRA (please ensure this is quoted on transfer)
IBAN	GB43NWBK60720608304793 OPG Euro Receipts Account

Branch Address	Natwest Bank 6 Coldharbour Lane Hayes Middlesex UB3 3EL UK
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For all other Overseas transfers (Non UK Account)

Account name	Office of HM Paymaster General - Cash a/c
Account number	25021001
Sort Code	10 00 00
Swift Code	BKENGB33
Reference	6781 MHRA (please ensure this is quoted on transfer)
IBAN	GB57BKEN10000025021001
Bank Address	Bank of England Government Counter Threadneedle Street London, EC2R 8AH UK

Except for companies able to use the MHRA Variations Deposit Scheme, proof of payment is required before applications can be processed. All remittances should quote the product licence reference and/or invoice number and this should be written on the back of the cheque.

EMEA

European Medicines Agency
7 Westferry Circus
Canary Wharf
GB – LONDON E14 4HB
tel: (44) (0207) 418 8400
fax: (44) (0207) 418 8416

Method of payment:

The EMEA will issue an invoice on the date of the notification of the administrative validation to the Applicant and fees will be payable within 45 days of the date of the said notification. The invoice will be sent to the billing address indicated by the Applicant and will contain clear details of the product and procedures involved, the type of fee, the amount of the fee, the bank account to where the fee should be paid and the due date for payment. Where more than one procedure is processed in a given month a summary invoice or statement will be issued at the end of each month for payment within 30 days of the end of the month.

To facilitate this operation Applicants/Marketing authorisation Holders who are demanding a Purchase Order Number on the EMEA invoice are requested to indicate this Number clearly on the cover letter of a given application. The EMEA will no longer accept separate notifications of Purchase Order numbers, not associated with the dossier. Applicants/Marketing authorisation Holders must state the following sentence on the Cover letter of each application:

Please quote Purchase Order Number on the invoice.

If the Applicants/Marketing authorisation Holders do not require a Purchase Order Number on the EMEA invoice, this should also be clearly stated in the cover letter.

More information on the Application fees in the Centralised Procedure is available on the EMEA Website <http://www.emea.europa.eu/htms/general/admin/fees/feesfaq.htm>

EFTA STATES

ICELAND

Published national rules:

Reglugerð um skráningu-, árgjöld og önnur leyfisgjöld.

Available from:

Heilbrigðis- og tryggingamálaráðuneytið
Laugavegi 116
105 Reykjavík
Iceland.

Address for advice on fees:

Lyfjastofnun
The Icelandic Medicine Control Agency (IMCA)
P.O. Box 180
Eiðistorgi 13-15
170 Seltjarnarnes Iceland
tel. (354)- 5202100
fax number: (354)-5612170
email: lyfjastofnun@imca.is

Fees payable to:

The Central Bank of Iceland
Bank account no.: 0001-26-025017,
Ríkisfóhirðir, kt. 540269-6459
Swift address is: *sislisre*

In receipt of an application an invoice is sent to applicant
Deposit into bankaccount. Cheques not accepted. All remittances should quote invoice number, the name and address of the applicant and the name of the product. Proof of payment is required before applications can be processed.

NORWAY

Published national rules:

”Forskrift om legemidler”

Available from:

Statens legemiddelverk

Sven Oftedals vei 8
NO-0950 OSLO

Fees payable to:

In receipt of an application an invoice identified by KID number is sent to the applicant.

Statens legemiddelverk
Sven Oftedals vei 8
NO-0950 OSLO
Tel: 47 22 89 77 00
Den Norske Bank
P.O.Box 1171, Sentrum
NO-0107 Oslo
Bank account no.: 7694 05 00903
SWIFT: DNBANOKK
IBAN nr NO71 7694 05 00903

10. '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 Mutual Recognition or Decentralised Procedure only. Blue-Box requirements for products authorised via the Centralised Procedure are detailed in the "Guideline on Packaging Information of medicinal products for human use authorised by the Community" as published in Volume 2C.

AUSTRIA

Additional labelling requirements

Price

The price is not required and not wanted on the label.

Reimbursement

The reimbursement conditions are not required and not wanted on the label.

Legal status

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

- „rezept- und apothekenpflichtig“ = available only on prescription and only in pharmacies
- „apothekenpflichtig“ = available only in pharmacies;
- If the supply is not restricted to pharmacies, this has to be declared appropriately.
 - Radiopharmaceuticals: „Rezeptpflichtig. Abgabe nur an Inhaber einer Bewilligung für den Umgang mit radioaktiven Stoffen gemäß Strahlenschutzgesetz“ = available only on prescription for authorised personnel.
 - Vaccines and blood derivatives: „Charge staatlich freigegeben“ = Batch released by OMCL

Identification and authenticity


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

Symbols or pictograms

A pictogram for medicines which cause tiredness:



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

“Der Gruene Punkt”  or other recycling symbols are accepted on the label, but not required.

Radiopharmaceuticals  if applicable

Additional requirements for Package Leaflet:

A pictogram for medicines which cause tiredness:



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

MA-No.: “Z.Nr.”

For Blood derivatives or vaccines: in order to allow traceability from patient back to biological starting material (e.g. blood donation), the Austrian legislation requires attachment of a self-adhesive label – stating the name, expiry date and batch number – to each primary package of blood derivatives or vaccines for human use.

“Each application should be documented in patient history or vaccination document using the self-adhesive label attached.”

“Jede Verabreichung soll mittels beigefügter Selbstklebeetikette in der Krankengeschichte oder Impfpass dokumentiert werden.“

BELGIUM

Additional labelling requirements

Price

The following statements are required for the price on the label:

- the price for ordinary reimbursement*,
- the price to be paid by those in certain social circumstances*.

**If the reimbursement is subject to a specific authorisation, the price should be mentioned between brackets.*

The price is required only on products which are not restricted to hospital use.

Reimbursement

The reimbursement conditions are required on the label and can be classified in five categories which are indicated using the following letter designation: “A”, “B”, “C”, “Cx” or “Cs”, which must appear in red on a white background with a black border.

- If those medicinal products are reimbursed only when used in hospitals, the above-mentioned letter designations must be followed by the letter “h”.
- If their reimbursement is subject to a specific authorisation the above-mentioned letter designations must be followed by the letter “f”.

Legal status

The major narcotic or psychotropic drugs, subject to special medical prescription, require the following labels:

- a number/code assigned by the Minister of Public Health
- a double red line which must be as large as the largest characters on the label. These double red lines must be parallel, 1-3 cms apart and with an angle of 45° starting from the left lower corner to the right upper corner of the label.

Identification and authenticity

For all medicinal products a national code (possibly presented as a bar code) is accepted on the label, but not required.

For reimbursed medicinal products (except containers with oxygen gas) a unique numerical bar code, printed in black with a white background, must appear on the label. An irremovable sticker may be used as well. *The unique numerical bar code is required only on products, which are not restricted to hospital use.*

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

For medicinal products intended for external application, 'external application' should be printed in black letters on a red-orange background in the three national languages: French, Dutch and German (usage externe - uitwendig gebruik - äusserliche anwendung). All packaging containing those medicinal products for external application should be delivered with a warning symbol in relief, recognisable by touch.

Additional requirements for Package Leaflet

- In section 3. **HOW TO <TAKE> <USE> X**

If you <take> <use> more X than you should :

If you have taken/used too much X, contact your doctor, pharmacist or the poisoncentre (tel. 070/245 245)

- In section 6. **FURTHER INFORMATION**

Supply classification of the medicinal product : <...>

Mention the registration number of the medicinal product

BULGARIA

Additional labelling requirements

Price

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

Reimbursement

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

Legal Status

For products available without medical prescription, the expression “без лекарско предписание”

For products available with medical prescription, the expression “по лекарско предписание”

For products on restricted medical prescription the restriction will be expressed as follows:

- hospital use “за болнична употреба”
- for psychotropic medicinal products two parallel blue band on the outer pack are required
- for narcotic medicinal products the symbol two parallel red band on the outer pack are required

Identification and authenticity

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

- In the case of sera the kind of creature from which the serum has been obtained has to be specified.
- Regarding viral vaccines the host system used for viral reproduction has to be specified

Specific types of medicinal products:

- 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
- Homeopathic medicinal products

The expression “Хомеопатичен лекарствен продукт” must appear

- Traditional Herbal Medicinal Products

Information that it is a traditional herbal medicinal product

Information on symbol in relief/Braille. The use of Braille is mandatory with exception of vaccines and for hospital use only.

Recycling symbols are required on the outer pack.

CZECH REPUBLIC

Additional labelling requirements

Price

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

Reimbursement

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

Legal Status

There is no requirement for the legal status to appear on the label. However, if the legal status is stated on the label, than the following text has to be used:

- For medicinal products subject to medical prescription - “Výdej léčivého přípravku vázán na lékařský předpis.”
- For medicinal products not subject to medical prescription – “Výdej léčivého přípravku možný bez lékařského předpisu.”

Identification and authenticity

Each packaging of a medicinal product placed on the market in the Czech Republic shall show on the label a European EAN code which serves for the purposes of electronic processing.

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

On the outer packaging the following text has to be included - „Nepoužitelné léčivo vraťte do lékárny.“

Additional requirements for Package Leaflet

Legal Status

There is no requirement for the legal status to appear in the package leaflet. However, if the legal status is stated in the package leaflet, than the following text has to be used:

- For medicinal products subject to medical prescription - “Výdej léčivého přípravku vázán na lékařský předpis.”
- For medicinal products not subject to medical prescription – “Výdej léčivého přípravku možný bez lékařského předpisu.”

The Package Leaflet blue box may also contain particular statements that are required under national legislation or as specified by the SUKL.

DENMARK

Additional labelling requirements

Price

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

Reimbursement

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

Legal status

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

Identification and authenticity

The Nordic number is required on the outer label of all medicinal products, except radiopharmaceuticals, certain vitamins and mineral products, homeopathic, herbal and traditional herbal medicinal products. It may be written as “Vnr XX XX XX”.

A bar code is accepted on the label but not required.

Symbols or pictograms

Products which may reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are 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 “Bekendtgørelse nr. 1210 af 7. December 2005 om mærkning m.m. af lægemidler, section 29(3-5) and section 31(2-6).

Additional requirement for Package Leaflets

Section / explanation	English text	Danish text
Before you take/use “X”	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.	Lægen kan have foreskrevet anden anvendelse eller dosering end angivet i denne information. Følg altid lægens anvisning og oplysningerne på doseringsetiketten.
Driving and using machines <i>-Only for products which carry the red warning triangle</i>	The package contains a red warning triangle. This means that “X” can be sedating and can reduce the ability to drive and use machines. <i>or</i> 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. <i>or</i> The package contains a red warning	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. <i>eller</i> 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.

	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.	<i>eller</i> Pakningen er forsynet med en rød advarselstrekanter. 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.
If you take more ”X” than you should	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).	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).
Possible side effects <i>After the sentence “If any of the side effects.....”</i>	Side effects can thereby be reported to the Danish Medicines Agency and the knowledge about side effects can be improved. Patients or their relatives can also report side effects directly to the Danish Medicines Agency. You can find guidance on The Danish Medicines Agency’s website (see Pharmacovigilance) http://www.laegemiddelstyrelsen.dk/	Bivirkningerne kan dermed blive indberettet til Lægemiddelstyrelsen, og viden om bivirkninger kan blive bedre. Patienter eller pårørende kan også indberette bivirkninger direkte til Lægemiddelstyrelsen. De/du finder skema og vejledning under Bivirkninger på Lægemiddelstyrelsens netsted http://www.laegemiddelstyrelsen.dk/

ESTONIA

There are no additional requirements.

FINLAND

Additional labelling requirements

Price

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

Reimbursement

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

Legal status

There is no requirement for the legal status to appear on the label.

Identification and authenticity

The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”.

A bar code is accepted on the label but not required.

Symbols or pictograms

- Products containing inflammable material must bear the international warning symbol:
- Products which may reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and the width of the frame is usually 2 mm:

FRANCE

Price

The price is required only on products which are not restricted to hospital use and are reimbursable by the French national health and pensions organization. The information on price must appear in the form of a sticker.

Reimbursement

The reimbursement conditions are required on the label. They must appear on the same sticker as the price. The sticker is coloured:

- white if the reimbursement rate is 65%
- blue if the reimbursement rate is 35%
- orange if the reimbursement rate is 15 %
- white with a cross through it “X” if the reimbursement rate is 100%
- white and surrounded by a green coloured line for the so called ‘drug of exception’ (very expensive medicinal products prescribed in specific indications)

Moreover, on the sticker, it should be mentioned:

“vignette” or “vign.” ; but “vignette” or “vign.” if the sticker is on the smallest or the single pack size of a medicinal product.

- the bar code corresponding in particular to the administrative identification number (« code CIP » see below), the price and the reimbursement conditions of the medicinal product.

Legal status

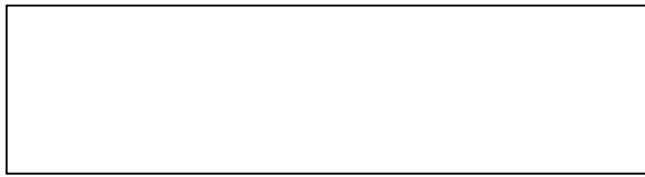
The legal status is required to be expressed on the label for prescription-only products.

The following details must appear in the blue box:

- an empty frame with:
 - A red border for list I products,
 - A green border for list II products,
- below this frame, written in dark characters on a red rectangular background:
 - “respecter les doses prescrites“,
- then following mentions:
 - «Liste I / Liste II»

- «Uniquement sur ordonnance»
- «Ne pas avaler» (if appropriate)

Below : recommended format:



List I products: red border
List II products: green border

There is no minimum size for the red border.

Respecter les doses prescrites (Red background / Dark characters)

Liste I / Liste II

Uniquement sur ordonnance

Ne pas avaler (if appropriate)

The following restrictions may apply and are required on the label:

1 - for medicinal product subject to special medical prescription:

- “stupéfiant“
- “prescription limitée à 7, 14, or 28 jours“

If applicable: “délivrance fractionnée par périodes de (7 or 14) jours“

2 - In addition, for medicinal products subject to restricted prescription:

a) In case of medicinal product for hospital use only, the following must be stated:

“médicament réservé à l’usage hospitalier”

b) In case of medicinal product subject to hospital prescription only, the following must be stated:

“médicament soumis à prescription hospitalière“

c) In case of medicinal product subject to initial hospital prescription the following must be stated:

“médicament soumis à prescription initiale hospitalière“

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

d) In case of medicinal product subject to specialist prescription only, the following must be stated:

“médicament à prescription réservée aux spécialistes en ... »

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”

f) In case of medicinal product restricted to professional use the following must be stated :

“medicament reserve à l’usage professionnel selon l’article R.5121-80 du code de la santé publique ».

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”.

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

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

Identification and authenticity

- It is required that the following sentence is mentioned: “Médicament autorisé n° + code CIP“

- A bar code is accepted but not required.

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

- mention of the following statement : “Médicament dérivé du sang humain”

-follow-up called “traceability“ from the manufacturing to the administration which is mandatory in France. Consequently, 3 detachable labels should be put on the outer packaging with the following mentions:

- the name of the medicinal product
- the marketing holder or the local representative
- the batch number
- the corresponding bar code

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

Products which may reduce the ability to drive or operate machines must have a pictogram (warning triangle).

Three categories of pictogram have been identified in relation with the effect on the ability to drive. Its size is adapted to fit the label.

Pictograms and information on the risk level classification (1,2 or 3) are available on the Afssaps’ website: www.afssaps.sante.fr



GERMANY

Additional labelling requirements

Price

The marketing authorisation holder is not required to put the price on the label.

Reimbursement

The “Pharmazentralnummer” (a 7 digit number,) has to be indicated in figures and as bar code (code 39). The bar code must appear on the label.

The reimbursement conditions are required on the label:

- “N1” for the small pack size
- “N2” for the medium pack size
- “N3” for the large pack size
- “Klinikpackung” for the hospital pack size
- “Unverkäufliches Muster” in the case of a sample pack size

The reimbursement conditions N1, N2, N3 are not relevant for products sold directly to hospital units.

Legal status

The legal status is required on the label:


“Apothekenpflichtig” = in the case of medicinal products that are not subject to medical prescription but are only available in pharmacies.

“Verschreibungspflichtig” = in the case of medicinal products that are subject to medical prescription only.

Identification and authenticity

- In the case of active substances manufactured by genetechnological means, the active substance and the designation of the genetechnologically modified microorganism or cell line.
- In the case of sera the kind of creature from which the serum has been obtained has to be specified.
- Regarding viral vaccines the host system used for viral reproduction has to be specified.

Symbols or pictograms

- the official pictogram in case of radiopharmaceuticals.
- “Der Grüne Punkt” , or other recycling symbols.
- address of the website of the MAH is possible

GREECE

Additional labelling requirements

Price

The price is required on the label.

Reimbursement

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

If any of the sub-categories appear in the decision they are to be stated on the label. Other, more specific requirements are outlined hereunder.

Legal Status

Specific national provisions (defined by EOF or by the Ministry of Health and Welfare in compliance with SPC requirements and concerning either medicinal products subject to special medical prescription or medicinal products subject to restricted prescription) must appear on the label.

- For instance, medicinal products subject to special medical prescription (narcotics) must have a letter/code assigned by the Ministry of Health and Welfare with special colour (red or green) according to the assigned classification.

For medicinal products classified as narcotics according to Greek Law 1729/87 as modified, the following text must appear on the label:

a. Products belonging to List B must mention in red letters “B, to be dispensed with special prescription for narcotics”:

« B, χορηγείται με ειδική συνταγή Ναρκωτικών »

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

« BΣ, χορηγείται με συνταγή του Ν.1729/87»

c. Products belonging to list Γ must mention in red letters “Γ, to be dispensed with special prescription for narcotics”:

« Γ, χορηγείται με ειδική συνταγή Ναρκωτικών»

d. Products belonging to the exceptions of list Γ must mention in green letters “ΓΣ, to be dispensed with prescription of Law 1729/87”:

« ΓΣ, χορηγείται με συνταγή του Ν.1729/87»

e. Products belonging to list Δ must mention in green letters

“Δ, to be dispensed with prescription of Law 1729/87”:

« Δ, χορηγείται με συνταγή του Ν. 1729/87»

- Other instances relate to medicinal products restricted to hospital use. These products must state “only for hospital use” on the label:

«μόνο για νοσοκομειακή χρήση »

- They might be other restrictions/ provisions to medicinal products according to current National Decisions

Identification and authenticity

All medicinal products must be identified by a safety coded sticker on the outer package. This sticker is issued by EOF (National Organisation for Medicines) free of charge to companies. It is produced by a special aquarelled paper; the national emblem and the name of EOF are visible only by U.V. The sticker is 27mm x 24mm and the following are typed by EOF: name of the company, production year and sticker number. The company is obliged to type the following: product name, pharmaceutical form and strength, code number (assigned by EOF and unique to the product) and the retail price.

Greek safety and authenticity requirements related to radiopharmaceuticals : the safety coded stickers which are described in the Greek requirements for the blue box (Guideline on Packaging Information for Community Authorized Products) are not implemented in radiopharmaceuticals.

HUNGARY

Label information for products authorised by the mutual recognition procedure or decentralised procedure.

Legal Status

Blue box	<i>Applicable to</i>
Orvosi rendelvény nélkül is kiadható gyógyszer (VN).	Medicinal product not subject to medical prescription.
Orvosi rendelvényhez kötött gyógyszer (V).	Medicinal product subject to medical prescription.
Orvosi rendelvényhez kötött gyógyszer (J).	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 (Sz).	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 (I).	Medicinal product subject to restricted medical prescription, reserved for treatments which can only be followed in a hospital environment.
Orvosi rendelvényhez kötött gyógyszer (V/J/Sz,KP)	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, H).	Medicinal product subject to special medical prescription written in two copies, likely, if incorrectly used, to present a substantial risk of

	medicinal abuse, to lead to addiction or be misused for illegal purposes.
Orvosi rendelvényhez kötött gyógyszer (V/J/Sz, Ú).	Medicinal product subject to special medical prescription written in two copies, containing a substance the activity and/or adverse reactions of which, by reason of its novelty, require further investigation.

Identification and authenticity

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

Local representative

The local representative is accepted but not required on the label.

Price

The price is not required and not wanted on the label.

Reimbursement

The reimbursement conditions are not required and not wanted on the label.

Blue box requirements for the Package leaflet for MRP/DCP products**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 leaflet.

IRELAND***Additional labelling requirements*****Price**

The price is not required on the label.

Reimbursement

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

Legal status

The non-prescription status of certain medicinal products, containing certain active substances, must be stated. These active substances include: acyclovir, diclofenac diethylammonium, famotidine, hydrocortisone, hydrocortisone acetate, ibuprofen, ketoprofen, naproxen, nicotine, nicotine resinate, oxethazine and piroxicam, when contained in medicinal products specifically authorised for sale without a prescription.

(Other medicinal products containing any of these active substances remain subject to prescription control.)

The designation “POM” (for prescription-only medicines) is in common use and would be in the boxed area.

Identification and authenticity

The Irish marketing authorisation number is required on the label. Bar codes are accepted on the label, but are not required. The name of the local representative may be added if they appear on the leaflet (local representatives should be included in the leaflet where applicable).

Additional Requirements

The Patient Information Leaflet and/or Labelling may also contain particular statements that are required under Irish national legislation or as specified by the IMB.

ITALY

Additional labelling requirements

Price

The price is required on the label.

Reimbursement

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

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

The following wording, printed in the area underneath the sticker, must appear once the latter has

been removed: “Confezione dispensata dal SSN”

Legal status

The requirements in respect of the legal status are the following:

A) For medicinal products not subject to medical prescription one of the following is required:

- 1 “Medicinale di automedicazione” (medicinal products for self-medication)
- 2 “Medicinale non soggetto a prescrizione medica” (medicinal product not subject to medical prescription)

B) For medicinal products subject to medical prescription the following is required:

- 1 “Da vendersi dietro presentazione di ricetta medica” (prescription-only medicinal product)

C) For medicinal products subject to non renewable medical prescription the following is required:

1 “Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta”

D) For medicinal products on restricted medical prescription, the specification of the restricted authorised prescriber [hospital department(s) or specialist(s)] has to be added to the cases B1 and C1:

1 “Da vendersi dietro presentazione di ricetta medica rilasciata dallo specialista (o dal centro specializzato)” [Specialist(s) to be specified]

2 “Da vendersi dietro presentazione di ricetta medica utilizzabile una sola volta rilasciata dallo specialista (o dal centro specializzato)” [Specialist(s) to be specified]

E) For medicinal products to be used only in hospitals, the following is required:

1 “Uso riservato agli ospedali.<alle cliniche e alle case di cura [where appropriate]>Vietata la vendita al pubblico.” (Hospital use only, not to be sold to the public)(OSP 1)

2 “Uso riservato agli ospedali.<alle cliniche e alle case di cura [where appropriate]> <o in ambito extraospedaliero [where appropriate] >” (in compliance with the requirements of Determinazione 25 Luglio 2005 issued by Agenzia Italiana del Farmaco) “Vietata la vendita al pubblico” (Hospital use only, not to be sold to the public)(OSP 2)

3 “Utilizzabile esclusivamente in ambito ospedaliero da specialisti identificati [where appropriate]” (in compliance with the requirements of Determinazione 25 Luglio 2005 issued by Agenzia Italiana del Farmaco) “Vietata la vendita al pubblico” (Hospital use only, not to be sold to the public)(OSP L)

F) For medicinal products to be used only by specialist(s), the following is required:

1 “Uso riservato allo specialista. Vietata la vendita al pubblico. [Specialist(s) to be specified]”

G) For psychotropic and narcotic medicinal products falling within the scope of a specific Italian law (D.P.R. 9 Ottobre n. 309 as amended) the following is required (in compliance with the Decree of Ministry of Health 26 Marzo 1979):

1 “Soggetto alla disciplina del DPR 309/90 Tabella II <A><C><D><E>”

For psychotropic and narcotic medicinal products belonging to Table II, section A referred to in D.P.R. 9 Ottobre n. 309 as amended, the statement must be marked with a red double line as described below (in compliance with the Decree of Ministry of Health 26 Marzo 1979):

Soggetto alla disciplina del DPR 309/90 Tabella II A

Identification and authenticity

National Identification Number must appear on any part of the label as well as on the peelable sticker.

Particular information and statements

Statement: “Medicinale Equivalente” 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)

Statement: “Controindicato l’uso contemporaneo di bevande alcoliche”, where appropriate, in compliance with the requirements of the Italian Law 30 Marzo 2001 n 125, Art.7;

Statement: “Può alterare la capacità di guidare veicoli e di usare macchinari”, where appropriate, in compliance with the requirements of the Italian Law 30 Marzo 2001 n 125, Art.7

Medicinal products for intravenous use, containing ≥ 1 mEq/ml potassium.

In the outer package: in red characters, the chemical symbol “K” followed by the statement “Diluire prima della somministrazione: mortale se infuso non diluito.”

In the immediate package: in red characters “the chemical symbol “K” followed by the statement: “Mortale se non diluito.” in compliance with the requirements of the Determinazione 11 Novembre 2005 issued by Agenzia Italiana del Farmaco.

Pictograms

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



pictogram size: Ø17 mm

Smile pictogram: for non prescription medicinal products in compliance with the requirements of the Decree of Ministry of Health 1 Febbraio 2002;



pictogram size: Ø17 mm

National Requirements for Package Leaflets

Statement: “Medicinale Equivalente” 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).

Statement: “Per chi svolge attività sportiva: l’uso del farmaco senza necessità terapeutica costituisce doping e può determinare comunque positività ai test antidoping”, where appropriate, according to the requirements of the Italian Law 14 dicembre 2000 n° 376 and following amendments.

Medicinal products for intravenous use, containing ≥ 1 mEq/ml potassium.

The statement in bold: “Diluire prima della somministrazione: mortale se infuso non diluito.” in compliance with the requirements of the Decree of Italian Medicines Agency 11 Novembre 2005.

LATVIA

There are no additional specific requirements.

Price

The price is not required on the label.

Reimbursement

The reimbursement conditions are not required on the label.

Legal status

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

Identification and authenticity

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

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

Any symbols and pictograms can be used (but is not obligatory) on the label, if there are no elements of advertising.

For example:

Products which may reduce the ability to drive or operate machines can have a warning triangle. (A red triangle on a white background.)

Products containing inflammable material can have the international warning symbol.

Product containing the active substances manufactured by genetical-technological means or the active substance and the designation of the genetical technologically modified microorganism or cell lines can have special phrases:

“Ģī produkta sastāvā ir ģeņētiski modificētie organismi (ĢMO)”

“Ģī produkta sastāvā var būt ģeņētiski modificētie organismi (ĢMO)”..

LITHUANIA

No specific requirements except information of classification.

MALTA

There are no additional specific blue box requirements.

NETHERLANDS (THE)

Additional labelling requirements

Price

The price is not required on the label for medicinal products supplied without prescription.

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

Reimbursement

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

Legal status

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

(1) If supply is restricted to pharmacy, this has to be expressed in the blue box areas as "UA", "U.A." or "Uitsluitend apotheek".

(2) 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." or "Uitsluitend apotheek en drogist".

(3) 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." or "Algemene verkoop".

Identification and authenticity

Information for the identification and authenticity are not required on the label. Bar codes are accepted on the label, but are not required.

Additional requirements for Package Leaflet

For non-prescription medicines, the section "Duration of treatment" must include a passage warning the consumer that the product must not be used for longer than 14 days without consulting a doctor. A period other than 14 days may be given if this is justified by the data in the SPC.

If not all indications can be mentioned in the product information because of patent law, the following sentence should be added in the chapter 1 'What X is and what it is used for'

Product bevat als werkzaam bestanddeel <naam van werkzaam bestanddeel>, dat ook is goedgekeurd voor andere aandoeningen die niet in deze bijsluiter staan vermeld. Vraag uw arts of apotheker als u nog nadere vragen heeft.

At the chapter 'Marketing Authorisation Holder and Manufacturer' the national marketing authorisation number in the Netherlands (RVG-number) should be added.

POLAND

Additional labelling requirements

Price

The price is not required and not wanted on the label.

Reimbursement

The reimbursement conditions are not required and not wanted on the label.

Legal status

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

- Lek wydaje się na specjalnie oznakowaną receptę (Rp.w). = available only on special prescription (eg. narcotica)
- Lek dostępny wyłącznie w lecznictwie zamkniętym (Lz) = only for hospital use

Identification and authenticity

Specific for Poland EAN code is required on the label.

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

The symbols and pictograms, which are recommended but are not required on the label:

- the road sign, symbol of prohibition to entry (Θ) – the pharmaceutical product which strongly influence the psychophysical coordination and have the information that prohibits to drive and operate the mechanical equipment for 24 hours after taking;
- the road sign, symbol of warning (Δ) – the pharmaceutical product when prescribed dosage or road of administration indicates that the product may impair the psychophysical coordination and necessity of special caution while driving or operating the mechanical equipment should be indicated to the patient;
- radioactivity pictogram – the pharmaceutical product which contains radionuclids.

PORTUGAL

Additional labelling requirements

Price

The price is required on the label for “medicamentos sujeitos a receita médica”, except on medical products restricted to hospital use.

Legal status

If applicable, the specific legal status must appear on the label. The legal status “medicamento sujeito a receita médica” can be divided in sub-categories that must appear on the label. These sub-categories are:

- “*medicamento de receita médica renovável*”

- “*medicamento de receita médica especial*”
- “*medicamento de receita médica restrita, de utilização reservada a certos meios especializados*”

Identification and authenticity

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

Symbols and pictograms

- Products for external use should state "Uso externo" in a red boxed area on the label.
- MG symbol for generic medicinal products

Other relevant information to appear on the label:

- The name of the local representative may be added if they appear 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 when applicable
- Different print colours and/or types should be used for the different pharmaceutical forms/strengths of the same medicinal product

Specific types of medicinal products:

- 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

- Homeopathic medicinal products

The expression “Medicamento Homeopático” on blue background must appear

- Traditional Herbal Medicinal Products
 - Information that it is a traditional herbal medicinal product

ROMANIA

Additional labelling requirements

Price

There is no requirement for the price to appear on the label. Nevertheless, according to national legislation, the price will be placed locally in the boxed area by the pharmacist.

Reimbursement

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

Legal status

The legal status is required to be expressed on the label for prescription-only products. The following mentions must appear in the boxed area:

For medicinal products supplied in pharmacy based on medical prescription valid for 6 months which can be retained by the patients:

- Se eliberează pe bază de prescripție medicală – **P-6L**

For medicinal products supplied in pharmacy based on medical prescription which is retained by the pharmacy:

- Se eliberează pe bază de prescripție medicală – **P-RF**

For medicinal products supplied in pharmacy based on special medical prescription with raised seal (narcotics):

- Se eliberează pe bază de prescripție medicală specială – **P-TS**

For medicinal products subject to restricted prescription:

- Se eliberează pe bază de prescripție medicală restrictivă – **S**

Identification and authenticity

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

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

Medicinal products contraindicated to vehicle drivers must have a distinctive sign - an equilateral triangle with the top up, of white color, with red sides and with the length of 10 mm and the thickness of 1,5 mm, having in the center an exclamation mark of black color, triangle framed in a square of white color with the side of 15 mm:



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



SLOVAK REPUBLIC

Additional Labelling requirements

Price

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

Reimbursement

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

Legal Status

Under section 7. INÉ ŠPECIÁLNE <UPOZORNENIE> <UPOZORNENIA>, AK JE TO POTREBNÉ please specify:

in the case of homeopathic medicinal product „HOMEOPATICKÝ LIEK“

in the case of homeopathic medicinal product registered under simplified procedure, please specify „LIEK NIE JE KLINICKY SKÚŠANÝ“.

in the case of traditional herbal medicinal product, please specify „Tradičný rastlinný liek určený na indikácie overené výhradne dlhodobým používaním“.

Under section 10. ŠPECIÁLNE UPOZORNENIA NA LIKVIDÁCIU NEPOUŽITÝCH LIEKOV ALEBO ODPADOV Z NICH VZNIKNUÝCH, AK JE TO VHODNÉ please specify „NEPOUŽITÝ LIEK VRÁŤTE DO LEKÁRNE“.

Under section 14. ZATRIEDENIE LIEKU PODĽA SPÔSOBU VÝDAJA

In the case that the medicinal product is only subject to medical prescription is required:

<Výdaj lieku viazaný na lekársky predpis.>

For product not subject to medical prescription is required:

<Výdaj lieku, ktorý nie je viazaný na lekársky predpis.>

Identification and authenticity

The EAN code is required.

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

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

For the small immediate packaging

Under section 6. INÉ please specify:
 in the case of homeopathic medicinal product „**HOMEOPATICKÝ LIEK**“,
 In the case of radiopharmaceuticals an international symbol for radioactivity and the amount of radioactivity should be stated.

Additional Package Leaflet requirements

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 traditional herbal medicinal product, package leaflet shall include a statement: „tradičný rastlinný liek je určený na indikácie založené výhradne na jeho dlhodobom používaní“.

In the case of imuno-biologic medicinal product, package leaflet shall include an information about presence of chemical substances classified as carcinogenic or mutagenic agents and of substances with toxic effect on nervous system, especially mercury (present as a thiomersal), aluminum (present in its compounds) and formaldehyde (and its compounds) and statement about their quantitative content within a single dose of dosage form.

Information about presence and quantitative content of substances used for inactivation of agents and their approved weight limits on human shall be also included.

Package leaflet shall include information about genetically modified substances.

SLOVENIA

Blue Box Requirements (MRP and DCP)

Additional Labelling requirements

Price

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

Reimbursement

The reimbursement conditions are not recommended on the label.

Legal status

The following requirements concerning the legal status for supply to the patient are to be stated in the boxed area:

- For medicinal product subject to medical prescription only, the following information is required: "Zdravilo se izdaja le na recept."
- For medicinal products, reserved for treatments, which can only be followed in a hospital environment, the following information is required: "H - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah."
- For medicinal products, reserved for treatments, which can only be followed in institutions/health care centers with adequate facilities, the following information is required": ZZ - Zdravilo se izdaja le na recept, uporablja pa se samo v javnih

zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost”.

- For medicinal products, reserved for treatment of conditions which must be diagnosed in a hospital environment, although administration and follow-up may be carried out elsewhere, the following information is required: “H/Rp - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah. Izjemoma se lahko uporablja pri nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju”.
- For medicinal products intended for outpatients, but which may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision through the treatment, the following information is required: Rp/Spec. – “Zdravilo se izdaja le na recept, uporablja pa se po navodilu in pod posebnim nadzorom zdravnika specialista ali od njega pooblaščenega zdravnika”.
- For medicinal products not subject to medical prescription and supplied in pharmacies only, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah."
- For medicinal products not subject to medical prescription and supplied either in pharmacies or non-pharmacy outlets, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah in specializiranih prodajalnah."

If there is insufficient space on the label, only abbreviations can be used (i.e. H, ZZ, H/Rp or Rp/Spec.)

Identification and authenticity

- The Slovenian EAN code on the label is required.
- In case of medicinal products derived from blood or plasma, there are some additional specific requirements: country of origin of blood/plasma must be stated
- In the case of active substances manufactured by genetechnological means, the active substance and the designation of the genetically modified microorganisms or cell lines.

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

△ Medicinal products which may reduce the ability to drive or operate machines must have a warning triangle (an empty triangle in the colour of the text)

▲ Medicinal products which significantly reduce the ability to drive or operate machines must have a warning triangle (a full triangle, red colour)

§ Narcotics must be marked with (§) in the colour of the text

! Limited quantity that may be dispensed at one time; the sign (!) in the colour of the text

Additional Requirements for Package Leaflet:

Legal status

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

- For medicinal product subject to medical prescription only, the following information is required: "Zdravilo se izdaja le na recept."
- For medicinal products, reserved for treatments, which can only be followed in a hospital environment, the following information is required: "H - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah."
- For medicinal products, reserved for treatments, which can only be followed in institutions/health care centers with adequate facilities, the following information is required": ZZ - Zdravilo se izdaja le na recept, uporablja pa se samo v javnih zdravstvenih zavodih ter pri pravnih in fizičnih osebah, ki opravljajo zdravstveno dejavnost".
- For medicinal products, reserved for treatment of conditions which must be diagnosed in a hospital environment, although administration and follow-up may be carried out elsewhere, the following information is required: "H/Rp - Zdravilo se izdaja le na recept, uporablja pa se samo v bolnišnicah. Izjemoma se lahko uporablja pri nadaljevanju zdravljenja na domu ob odpustu iz bolnišnice in nadaljnjem zdravljenju".
- For medicinal products intended for outpatients, but which may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision through the treatment, the following information is required: Rp/Spec. – "Zdravilo se izdaja le na recept, uporablja pa se po navodilu in pod posebnim nadzorom zdravnika specialista ali od njega pooblaščenega zdravnika".
- For medicinal products not subject to medical prescription and supplied in pharmacies only, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah."

For medicinal products not subject to medical prescription and supplied either in pharmacies or non-pharmacy outlets, the following information is required: "Zdravilo se izdaja brez recepta v lekarnah in specializiranih prodajalnah."

SPAIN

Additional labelling requirements

Information on symbol in relief/Braille . The use of Braille is mandatory.

Instructions and conditions for the implementation are available in the AEMPS web page.

It is mandatory an official translation of the ONCE (Organización Nacional de ciegos)

Price

The expression of the price is not mandatory

Reimbursement

The reimbursement conditions are shown on the perforated detachable section which shall include:

. Abbreviation "A.S.S.S." if the product is reimbursable and the symbol "●" on the left side of "A.S.S.S." if the patient is of the 10% of the price

The symbol “▲” on the right side of “A.S.S.S.” if the medicinal product is also one of the so called “hospital diagnostic”

.The national product number

.The bar code

This perforated detachable section should have a black line around 1 mm in Part A of the perforate detachable for medical products which are subject to a special control as regards reimbursement.

Legal status

The legal status is shown as follows:

. for products available without medical prescription, the expression “sin receta” or the abbreviation EFP, if the product can be advertised is required

. for prescription only products, the symbol : “O”

. for products on restricted medical prescription the restriction will be expressed as follows:

- hospital use “USO HOSPITALARIO” (H) both words and abbreviation
- Diagnosis performed in hospital: “DIAGNOSTICO HOSPITALARIO” (DH) both words and abbreviation
- Specialist supervision “ESPECIAL CONTROL MEDICO” with the abbreviation “ECM” which should be placed on the right side of “ASSS” (on the perforated detachable section)
- For psychotropic medicinal products the “D” and “O*” are required
- For narcotic medicinal products the symbol “●” is required

* symbole divided in back and white

Identification and authenticity

A bar code is required. The national product number is also required (6 digits.7th digit)

Symbols or pictograms

. The symbol “❄” for products which must be stored between 2-8 ° C

. The symbol “⏸” for products which have a shelf life less than 5 years

Hospital pack : “Envase clínico prohibida su venta al detalle”

It is possible to use any symbol belonged to any Integrated System of Residues treatment authorised in the country. The symbol is:



SWEDEN

Additional labelling requirements

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

There is no requirement for the legal status to appear on the label.

Identification and authenticity

The Nordic number is required on the label of all medicinal products, except radiopharmaceuticals and herbal remedies. It is written as “Vnr XX XX XX”.

A bar code is accepted on the label but not required.

(See guidelines for the centralised procedure)

Additional requirement for Package Leaflet

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

Under heading number 1.

” (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.”

” (Aktiv substans) som finns i (produktnamn) kan också vara godkänd för att behandla andra sjukdomar som inte nämns i denna produktinformation. Fråga läkare, apotek eller annan hälsovårdspersonal om du har ytterligare frågor och följ alltid deras instruktion.”

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”.

“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.”

“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”.

Under the heading ”If you take more X than you should”

“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.”

”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”.

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.

UNITED KINGDOM

Medicinal product labelling in the UK must include an indication of the legal supply 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 patient information leaflet for certain medicines placed on the UK market. The requirements are set out in Schedule 5 to the Medicines (Marketing Authorisations etc.) Regulations 1994 number 3144 [SI 1994/3144].

The additional requirements affect medicines which contain any of the following substances:

- Aspirin
- Aloxiprin
- Paracetamol
- Ephedrine
- Hexachlorophane
- Sedating antihistamines
- Certain medicines which are intended for external use

Applicants whose products contain such substances should refer to the regulations above for detailed requirements.

Additional information: 'keep the container in the outer carton'

EFTA STATES

ICELAND

Package leaflet (PL)

Under the heading number 1

”Verið getur að læknirinn hafi ávísað lyfinu við öðrum sjúkdómi eða í öðrum skömmtum en tiltekið er í þessum fylgiseðli. Ávallt skal fylgja fyrirmælum læknis og leiðbeiningum á merkimiða frá lyfjabúð.”

English translation: “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”.

Under the heading ”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).”

English translation: “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.”

Under the heading “Driving and using machines”

Lyf geta haft áhrif á hæfileikann til að aka bíl eða framkvæma áhættusöm verk vegna verkana sinna eða aukaverkana. Lesið vandlega upplýsingarnar í fylgiseðlinum. Hafið samband við lækni eða lyfjafræðing ef þörf er á frekari upplýsingum.

English translation:

Medicines may influence your capability to drive or carry out dangerous work. Read the information provided in the package leaflet carefully. Ask your doctor or pharmacy for advice if you are unsure. “

Label

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

There is no requirement for the legal status to appear on the label except for packages intended for dose dispensing.

- Þessi pakkning er eingöngu ætluð til skömmtunar.
- English translation: For dose dispensing only

Identification and authenticity

The Nordic number required (exception: radiopharmaceuticals)
Written as “Vnr XX XX XX”.
Bar code is accepted

Symbol and pictogram

Products containing inflammable material must bear the international warning symbol

Eldfimt + tákn



- English translation: Inflammable + symbol

Products which reduce the ability to drive or operate machines must have a warning triangle. The tip of the triangle points upwards. It is a red triangle on a white background. Its size is adapted to fit the label; its sides are usually 10 mm long and



the width of the frame is usually 2 mm.

NORWAY**Package leaflet (PL)**

In general: The below listed “Blue box” statements should for readability reasons be included in the 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.

Under the heading number 1

”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.”

English translation: “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”.

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 arbeide når det er trygt for deg. Legemidler kan påvirke din evne til å kjøre bil eller utføre risikofylt arbeide. Les informasjonen i pakningsvedlegget nøye. Er du i tvil må du snakke med lege eller apotek ”

English translation: “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 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.”

English translation: “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.

Label

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

There is no requirement for the legal status to appear on the label except for packages intended for dose dispensing.

- Kun til dosedispensering
- English translation: For dose dispensing only

Local representative

The local representative may be indicated in the “blue box” on the label 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 required (exception: radiopharmaceuticals)

Written as “Vnr XX XX XX”.

Bar code is accepted

Symbol and pictogram

Products containing inflammable material must bear the international warning symbol

- Brannfarlig + symbol 

English translation: Inflammable + symbol