EU UNION REGISTER OF MEDICINAL PRODUCTS
-
FREQUENTLY ASKED QUESTIONS

The purpose of these FAQ's is to provide an overview on issues that have been frequently raised by the public in the context of the EU Union Register of Medicinal products. The information in this document is however, for guidance only, not complete, is simplified and may not be updated.
Reference to the full legal texts can be found in the last question.

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CONTENTS

WHAT IS A MARKETING AUTHORISATION?

Whether for human or veterinary use a medicinal product must be the subject of a valid Marketing Authorisation (MA) before it can be placed on the market for sale and supply. The Marketing Authorisation Holder (MAH) has to market the product in compliance with the terms of the authorisation.

MAs issued only allow the product in question to be marketed by the MAH in that EU Member State, unless the product has been authorised via the centralised procedure in which case a single MA (a Community Authorisation) is granted by the European Commission and is considered valid in all EU Member States.

All applications for a MA are assessed based on supporting data provided for safety, quality and efficacy. A product only receives a MA if its benefits outweigh any risks.

Not all products for which MA applications are submitted are subsequently granted a Marketing Authorisation. Some applications are refused due to insufficient and/or inadequate data.

HOW LONG IS A MARKETING AUTHORISATION VALID?

A national Marketing Authorisation (MA) is initially valid for five years from the date of first authorisation. At the end of the five year period it will be subject to renewal, which is a mechanism for reviewing the product to ensure the benefit/risk balance remains favourable.

This review takes into consideration any further information obtained about the product from the experience gained of its use since it was first authorised, e.g. pharmacovigilance data. This is to ensure that the product's MA is still appropriate. Following this review the MA will be valid indefinitely, or the MAH will be asked to submit another renewal in a further five years' time.

HOW CAN A PRODUCT BE AUTHORISED?

There are four different routes to obtaining a Marketing Authorisation (MA) which result in the issue of three different types of MA ; a National only MA , a Mutually Recognised MA or a Community Authorisation. These routes determine the procedures, processes and timelines used in progressing an application for a new MA in accordance with EU legislation. Once granted, the authorisation will be classified as nationally authorised, mutually recognised or centrally authorised.

- A nationally authorised product is one that has been assessed and approved on a national basis only, i.e. there has been no interaction with other Member States. For information about nationally authorised products please visit the website of your national health authority (see: http://www.hma.eu/nationalcontacts.html).
- A mutually recognised product is one that has been assessed and approved at a European level involving at least two Member States, i.e. evaluated via the mutual recognition or decentralised procedure. For information about mutually recognised products please visit the MRI Product Index (Human) (see: http://mri.cts-mrp.eu/Human/) or the VMRI Product Index (Vet) (see: http://mri.cts-mrp.eu/veterinary/)
- A centrally authorised product is one that has been assessed and approved on a community level involving all EU Member States.

WHAT IS THE CENTRALISED PROCEDURE?

The centralised procedure is a European authorisation route resulting in a centrally authorised product with a single Marketing Authorisation.

If a product has been authorised using the centralised procedure it has been assessed on an EU wide basis and approved by the European Commission. The European Medicines Agency (EMA) organises the process of evaluation using scientific expertise from the Member States.

The centralised procedure is compulsory for some products and optional for others. Some products are not eligible for the centralised procedure.

WHAT IS THE MUTUAL RECOGNITION PROCEDURE?

The mutual recognition procedure (MRP) is a European authorisation route resulting in a mutually recognised product.

Mutual recognition must be used when a product is already authorised in at least one Member State on a national basis and the Marketing Authorisation Holder wishes to obtain a Marketing Authorisation (MA) for the same product in at least one other Member State.

The Member State that has already authorised the product is known as the Reference Member State (RMS). The RMS submits their evaluation of the product to other Member State/s, these are known as Concerned Member States (CMS). The CMS is asked to mutually recognise the MA of the RMS.

If the applicant is successful, the CMS will then issue a MA for that product permitting the marketing of that product in their country.

WHAT IS THE DECENTRALISED PROCEDURE?

The decentralised procedure (DCP) is a European authorisation route resulting in a mutually recognised product (MRP).

The difference between MRP and DCP is that a product must already be authorised in at least one Member State on a national basis in order for MRP to be used. DCP may be used if the product is not already authorised in any Member State, but does not want to use the centralised procedure, or the product is not eligible for the centralised procedure.

One of the proposed Member States will be asked by the applicant company to act as Reference Member State (RMS). The RMS does the initial evaluation of the product and issues a draft assessment report. The other Member States, known as the Concerned Member States (CMS), either agree with the RMS's evaluation or they ask further questions/raise objections.

If all the issues are resolved and the application is successful, each Member State will then issue a MA for that product permitting it to be marketed in their country.

WHAT IS A REFERRAL PROCEDURE?

A referral is a procedure used to resolve issues such as concerns over the safety or benefit-risk balance of a medicine or a class of medicines. The medicine, or the class of medicines, is 'referred' to the European Medicines Agency, so that it can make a recommendation for a harmonised position across the European Union (EU).

Referrals can be started by the European Commission, any Member State or by the company that markets the medicine.

For most referrals, the European Commission issues a decision to all Member States reflecting the measures they need to take to implement the Agency's recommendation.

WHAT PRODUCTS ARE AUTHORISED CENTRALLY BY THE EUROPEAN COMMISSION AND WHAT PRODUCTS BY THE NATIONAL AUTHORITIES OF THE MEMBER STATES?

1. High-technology medicinal products, particularly those resulting from one of the following biotechnological processes:
    - recombinant DNA technology,
    - controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells,
    - hybridoma and monoclonal antibody methods.
2. Medicinal products for veterinary use intended primarily for use as performance enhancers in order to promote the growth of treated animals or to increase yields from treated animals.
3. Medicinal products for human use containing a new active substance for which the therapeutic indication is the treatment of any of the following diseases:
    - acquired immune deficiency syndrome (AIDS),
    - cancer,
    - neurodegenerative disorder (like amyotrophic lateral sclerosis (ALS), Parkinson's disease, Alzheimer's disease, and Huntington's disease),
    - diabetes

    and with effect from 20 May 2008
    - auto-immune diseases and other immune dysfunctions,
    - viral diseases.
4. Medicinal products that are designated as orphan medicinal products

All other products will be authorised by the national authorities from the Member States.

HOW IS THE EU NUMBER COMPOSED?

EU/[1/2/3]/[YY]/[NNN]/[XXX]

EU	Indicates that it is a European centrally authorised or designated product	[1/2/3] 1 Human, 2 Veterinary, 3 Orphan medicinal product
[YY]	last two digits of the year (98 for 1998; 04 for 2004)	
[NNN]	chronological number of product authorised (NNNN from 1000 on)	
[XXX]	number attributed to each individual package presentation of this product	

HOW IS THE EMA (EMEA) PROCEDURE NUMBER COMPOSED?

FOR CENTRALLY AUTHORISED PRODUCTS

[EMEA/EMA]/[H/V]/[XXX]/[Variation type]/[YYY]/[W/WS]/[ZZZ]/[G]

[H/V]	H = Human medicinal products V = Veterinary medicinal product	
[XXX]	Chronological numbering of the products	
[Variation type]	[missing] or /0000	Authorisation
	I	Variation type I. A minor variation (existed 1995-2004).
	IA	Minor variation type A. Variations that may be implemented immediately by the marketing authorisation holder and must be notified within 12 months.
	IAin or IAIN	Minor variation type I immediate notification. These are variations that may be implemented immediately by the marketing authorisation holder and must be notified immediately.
	IB	Minor variation type B. Variations that are not type IA, IAin, II or X variations. They must be notified immediately and may be implemented by the marketing authorisation holder after 30 days if no objection is received.
	IG	Minor variation type I that was part of a grouping. II
	II	Variation type II. Major variation.
	N	Notification according to article 61(3) of Directive 2001/83 of a change to an aspect of the labelling or package leaflet text (Annex III) with no change to the summary of product characteristics (Annex I).
	SU	String update (vaccines).
	R	Renewal of the marketing authorisation after five years or annual renewal in case of a conditional marketing authorisation.
	X	Extension. As extensions to the marketing authorisation are considered changes to the active substance(s), to the strength, to the pharmaceutical form or to the route of administration.
	T	Transfer of marketing authorisation from one marketing authorisation holder to another.
	S	Annual reassessment of a product that is authorised under exceptional circumstances or authorised conditionally, where specific obligations, to be tested annually, are imposed.
	PSUR or PSU or PSUV	Variation after a Periodic safety update report (pharmacovigilance)
	PSUSA	Variation after Periodic safety update report with a single assessment for more than one product (pharmacovigilance)
[YYY]	Chronological number of the procedures for this product	
[W/WS]	Work-sharing: the same Type IB or Type II variations, or the same group of variations affecting more than one marketing authorisation from the same marketing authorisation holder, or group of companies having concluded agreements or exercising concerted practices concerning the placing on the market, in one application. When a group of variations only consists of type-IA or -IAIN variations affecting several marketing authorisations, this is considered as a 'group' of variations and not a 'work-sharing' procedure. However, it is possible to include a group of type-IA and -IAin variations with a type-IB or a type-II variation, which is submitted for a work-sharing procedure. In such cases, the review of the type-IA or -IAin variation is done as part of the work-sharing procedure.	

[ZZZ] Chronological number for work-sharing not limited to this product or chronological referral number

[G] Grouping of minor variations for one marketing authorisation holder. A grouping of variations can concern several variations for one or several medicinal products of one marketing authorisation holder in one application. If for example the postal code of the marketing authorisation holder changes he may in one application apply for the change to all his products.

Note that the EMA variation number EMEA/H/C/1206/II/34 may also be represented as EMEA/H/C/001206/II/034 with a varying number of leading zeros or as EMA/H/C/00001206/II/000034 in the documents.

FOR REFERRALS:

[EMEA/EMA]/[H/V]/ A[-Article] /[XXX]

[H/V] H = Human medicinal products
V = Veterinary medicinal product

A[-Article] A procedure triggered by Article NN in the Pharmaceutical legislation, referred to as A-NN or without the article simply indicated as A, that may be applicable to one or a group of products both centralised and national. Most common values for [Article] are:

For human products:

- 107 triggered when a Member State intends to vary, suspend or revoke the marketing authorisation for a medicine in its territory because of a safety issue [in application until 2012, now replaced by 107i]
- 107i triggered by a Member State or EC in case of a safety issue
- 13 triggered for a medicine that has been authorised by mutual recognition or via the decentralised procedure when there is disagreement between Member States on a variation
- 20 triggered for medicines that have been authorised via the centralised procedure in case of concerns affecting the quality, safety or efficacy of the product
- **29** triggered by a marketing-authorisation holder when applying for a new indication, new pharmaceutical form or new route of administration for use in children
- 29(4) triggered when there is a disagreement between Member States regarding a medicine being evaluated during a mutual-recognition or decentralised procedure, on the grounds of a potential serious risk to public health
- 29 triggered when harmonisation of national authorisations across the EU is needed
- 30 triggered when the interest of the Union is involved, following concerns relating to the quality, safety or efficacy
- 36 triggered when a Member State considered that action (variation, suspension or withdrawal) was needed on the grounds of the need to protect public health for a marketing authorisation that were granted via the mutual-recognition or decentralised procedure [discontinued as of 2012]
- 5(11) triggered for a medicine that had been authorised by mutual recognition or via the decentralised procedure when there was disagreement between Member States on a variation (type IB) [discontinued as of 2010]
- 6(12) triggered for a medicine that had been authorised by mutual recognition or via the decentralised procedure when there was disagreement between Member States on a variation (type II) [discontinued as of 2010]

6(13)	triggered by the marketing-authorisation holder for a medicine that had been authorised by mutual recognition or via the decentralised procedure when Member States could not accept the variation (type II) [discontinued as of 2010]
For veterinary products:	
13	triggered for a medicine that has been authorised by mutual recognition or via the decentralised procedure when there is disagreement between Member States on a variation
33	triggered when disagreement between Member States within the framework of the mutual- recognition or decentralised procedure
34	triggered when disagreement between Member States within the framework of the mutual- recognition or decentralised procedure
35	triggered when harmonisation of national authorisations across the EU is needed
36	in cases involving the interests of the Union or concerns relating to the protection of human or animal health or the environment
39	follow-up referral
40	follow-up referral
45	triggered for medicines that have been authorised via the centralised procedure in case of concerns affecting the quality, safety or efficacy of the product
78	triggered as a result of the evaluation of veterinary pharmacovigilance data, a Member State considers that a marketing authorisation should be suspended, withdrawn or varied to restrict the indications or availability, amend the posology, add a contraindication or add a new precautionary measure
[XXX]	chronological referral number

The EMEA procedure numbers for referrals may be represented in different ways in the documents over time the number EMEA/V/A-34/88 can also be found as EMEA/V/A/88/Art.34, EMEA/V/A/88 or even EMEA/V/R/88 or EMEA/V/R88. In these cases the numbers have, where possible, been standardised in the Union Register.

FOR ORPHAN DESIGNATIONS:

[EMEA/EMA]/OD/[XXX]/[YY]

[XXX]	Chronological number restarting at 001 every year
[YY]	last two digits of the year (98 for 1998; 04 for 2004)

WHY ARE THERE EU NUMBERS MISSING IN THE CHRONOLOGICAL SERIES?

Sometimes a marketing authorisation holder decides to withdraw an application for a new authorisation in a late stage of the authorisation process, long after the EU number has been designated. EU numbers are never re-used.

WHY DOES THE EU NUMBERING OF PRODUCTS NOT FOLLOW THE CHRONOLOGICAL ORDER OF AUTHORISATION?

The EU number is attributed in the course of the evaluation process by the Agency because the Annexes that are needed for a full evaluation by the Agency, Commission and Member States contain these EU numbers. If the decision making process is held up for any reason in a later stage (scientific concerns, objection by Member States, legal issues etc.) the final authorisation may sometimes be delayed for many months.

WHY IS THE PRODUCT I CAN BUY IN MY LOCAL PHARMACY NOT LISTED IN THE UNION REGISTER?

The Union Register only contains the centrally, for all EU Member States, by the European Commission since 1995 authorised products and not the nationally authorised products in every Member State of the EU.

WHY CAN'T I BUY THE PRODUCT LISTED IN THE UNION REGISTER IN MY LOCAL PHARMACY?

The Union Register only contains the centrally, for all EU Member States, by the European Commission since 1995 authorised products. The marketing authorisation holder has the right to sell the product in any Member State, not the obligation. Also the actual marketing of the product depends on many factors as: the price and reimbursement (often to be negotiated with the national health systems), availability and price of competitive products, local habits of patients and healthcare professionals etc.

WHY THE DATA ON THE PROCEDURES IN THE UNION REGISTER ARE NOT AVAILABLE THE DAY THE DECISION IS TAKEN?

Commission Decisions only enter into force once they have been notified to whom the Decision is addressed. The Commission waits until the proof of notification is received before the Decision will be published. Publication will generally be done the first working day after proof of notification is received.

WHAT IS MEANT WITH MINOR - AND MAJOR VARIATIONS?

A variation is considered to be minor if there is a minor or no impact on the quality, safety or efficacy of a medicinal product (for example change in the address of the marketing authorisation holder).

A variation is considered to be major if there is a significant impact on the quality, safety or efficacy of a medicinal product (for example change in indication of the medicinal product or the addition of a new one).

CAN I BE ALERTED TO CHANGES IN THE EU UNION REGISTER FOR A SPECIFIC PRODUCT OR GROUP OF PRODUCTS?

News feeds (also called RSS feeds) are available for the Union Register of Medicinal Products for both individual products as for different product groups. This opens the possibility to be alerted to changes in the Union Register as soon as they are published.

How these news feeds are handled on your computer depends on the internet browser you use, all browsers do have integrated news feed capabilities; you can also use a dedicated news feed application independent from your internet browser.

For subscription to a news feed for a **specific medicinal product**, human, veterinary or orphan, go to the specific page for that product and press the RSS feed button behind the name of the product. You will be directed to the news feed page for that product where you may subscribe. These feeds give all changes about the concerned product, whether new documents are available or not. These feeds are divided into two categories, the updates with new documents (Commission Decisions or Annexes) and updates without new documents.

Note that RSS feeds are only available for active or suspended products, not for withdrawn products:

- **News feed for all new published documents, human, veterinary or orphan.**
  This feed is divided into three categories: Human products (including referrals), Orphan designations and Veterinary products (including referrals).
- **News feed for Human medicinal products.**
  This feed only alerts to changes in the status of human medicinal products (new products, withdrawals, refusals, suspensions).
- **News feed for Veterinary medicinal products.**
  This feed only alerts to changes in the status of veterinary medicinal products (new products, withdrawals, refusals, suspensions).
- **News feed for Orphan medicinal products.**
  All new documents concerning orphan designations, removals and transfers.
- **News feed for Referral procedures concerning human and veterinary medicinal products.**
  This feed is divided into two categories: Human products and Veterinary products. Note that referral procedures concerning products authorised through the centralised procedure are placed under the concerned centralised products.

To access the general news feed pages see:
http://ec.europa.eu/health/documents/community-register/html/index_rss_en.htm

WHAT IS INN?

INN means International Non-proprietary Name, a name used to facilitate the identification of pharmaceutical substances. In general the INN is much shorter and simpler than the chemical or systematic name.

For example the INN 'desloratadine' has the systematic name '8-chloro-6,11-dihydro-11-(4-piperdinylidene)-5H-benzo[5,6]cyclohepta[1,2- b]pyridine'.

Each INN is a unique name that is globally recognised, is public property and is established in collaboration the WHO (World Health Organisation). A non-proprietary name is also known as a generic name.

WHAT IS EPAR?

European Public Assessment Report: a set of documents describing the evaluation of a medicine authorised via the centralised procedure, including the product information, published by the European Medicines Agency.

WHAT IS ATC?

ATC means Anatomical Therapeutic Chemical Classification System and is used for the classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties. It is controlled by the World Health Organization Collaborating Centre for Drug Statistics Methodology (WHOCC).

WHAT LANGUAGES ARE MEANT WITH THE CODES IN THE LANGUAGE SELECTORS?

BUL	Bulgarian (български)
CES	Czech (čeština)
DAN	Danish (dansk)
DEU	German (Deutsch)
ELL	Greek (ελληνικά)
ENG	English (English)
SPA	Spanish (Español)
EST	Estonian (eesti keel)
FIN	Finnish (suomi)
FRA	French (français)
HRV	Croatian (hrvatski)
HUN	Hungarian (Magyar)
ITA	Italian (italiano)
LIT	Lithuanian (lietuvių kalba)
LAV	Latvian (latviešu valoda)
MLT	Maltese (Malti)
NLD	Dutch (Nederlands)
POL	Polish (polski)
POR	Portuguese (Português)
RON	Romanian (română)
SLK	Slovak (slovenčina)
SLV	Slovenian (slovenščina)
SWE	Swedish (svenska)

WHY ISN'T THERE A COMMISSION DECISION FOR ALL VARIATIONS?

A minor or major change may take place in the technical dossier of the product without this being reflected in the Annexes to the Commission Decision. If e.g. a major change is made to the manufacturing process of the active substance then there is a significant impact on the quality, safety or efficacy of a medicinal product, but because no information about the manufacturing process is contained in the annexes, there is no need to change the original Commission Decision.

Minor variations where a change in Annexes is needed may sometimes be implemented immediately by the marketing authorisation holder but are only updated in a later Commission Decision.

WHAT DO CONTAIN THE ANNEXES TO A DECISION?

Integer parts of the Decisions are the Annexes that contain:

FOR CENTRALLY AUTHORISED PRODUCTS:

Annex I	Summary of product characteristics as the name, composition, pharmaceutical form, indication, clinical particulars and marketing authorisation holder.
Annex II	Data on the manufacturer of the active substance, the conditions and restrictions regarding supply and use and conditions and the requirements of the marketing authorisation.
Annex III	Labelling (what is marked on the different packaging's of the product) and full text of the package leaflet.
Annex IV[optional]	Specific obligations imposed if a product has a conditional or exceptional marketing authorisation.

FOR REFERRALS:

Annexes can be, but are not limited to:

- List of the names, pharmaceutical forms, strengths, routes of administration and marketing authorisation holders of the concerned products in the Member States
- Scientific conclusions and grounds for variation to the terms of the marketing authorisations
- Amendments to the product information and package leaflets of the medicinal products
- Conditions of the marketing authorisation
- Summary of the scientific evaluation of the follow-up conditions for the safe and effective use
- Revised conditions for the safe and effective use of the medicinal product

FOR ORPHAN DESIGNATIONS:

Orphan designation Decisions do generally not contain annexes.

WHY ARE PACKAGE PRESENTATIONS AND FULL EU NUMBERS NOT SHOWN IN THE UNION REGISTER?

Since the entry into force of the Variations Regulation 1234/2008 the marketing authorisation holder may in well- defined cases add or withdraw package presentations on informing the Agency (EMA) without informing the Commission and thus not being reflected in a Commission Decision until the next update. This would mean that the information in the Union Register could be incomplete or out-dated for up to one year.

This information is now available on the Agency's website as soon as the Agency has been informed by the marketing authorisation holder. To find the presentations go to the Agency's website and proceed as follows: Find medicine > Product page > Product information > EPAR - All authorised presentations

WHAT STATUS CAN A MEDICINAL PRODUCT HAVE?

Active	A marketing authorisation has been issued by the European Commission that is still valid. This does not necessarily mean that the product is (already) on the market. The marketing authorisation holder has the right to put the product on the market in any Member State, not the obligation.
Withdrawn	The marketing authorisation has been withdrawn by the European Commission on the basis of new scientific evidence (e.g. risk to public health) or on demand of the marketing authorisation holder itself for commercial reasons.
Expired (sunset clause)	If a medicinal product is not placed on the EU market within three years after its authorisation or when a product previously placed on the market is no longer actually present on the EU market for three consecutive years the sunset-clause leads automatically to the cessation of the validity without the need of a Commission Decision (exceptions may be granted by the Commission)
Refused	A marketing authorisation has been requested but has been refused by the European Commission and has for that reason never been active
Suspended	A marketing authorisation has been issued by the European Commission that is still valid, but has been suspended. Reasons for suspension can be problems in the production phase of the product, newly discovered serious side-effects etc. After suspension will in general follow a (partial) lift of suspension or (partial) withdrawal of the product.
Not renewed	A first marketing authorisation is normally valid for 5 years. After five years a renewal must be requested by the marketing authorisation holder. If this renewal is not requested the validity of the authorisation will cease automatically.

CAN I MAKE A LINK TO THE LATEST ANNEXES FOR A CENTRALISED PRODUCT?

Yes. A special link in the Union Register gives the possibility to use one entry point per medicinal product and retrieve the latest annexes (SPC, MAH data, COND, Packaging and PL) of a European centrally authorised medicinal product as published in the Union Register, human or veterinary, in any EU official language. This option was requested by some Member States, so they do not have to update their databases every time a new series of Annexes is issued by the EC.

Additional information:

- The files are called “h_direct_anx.htm” for human and “v_direct_anx.htm” for veterinary medicines.
- For no longer valid authorisations the file name must be preceded by the letter “x” (“xh_direct_anx.htm” for human and “xv_direct_anx.htm” for veterinary medicines).
- The domain is always http://ec.europa.eu/health/documents/community-register/html/
- The hash data - characters added to a URL after a hash sign (#) - that can be added are:
    - the EU sequential authorisation number (mandatory) - Directly after the # sign in any number format “1”, “123”, ”0005” or “006”,
    - the language (optional) - In two letter ISO format preceded by an underscore (“_fr” for French, “_de” for German, etc.), when omitted English is used.

Examples:

- The last valid annex for the human product Ziagen (EU/1/09/112) can be retrieved in English with the URL:
  http://ec.europa.eu/health/documents/community-register/html/h_direct_anx.htm#112
- The French version by using:
  http://ec.europa.eu/health/documents/community-register/html/h_direct_anx.htm#112_fr
- For the veterinary product Convenia (EU/2/06/059) the URL for the latest annex in Dutch could be:
  http://ec.europa.eu/health/documents/community-register/html/v_direct_anx.htm#00059_nl

If a wrong number is used or the link is used without a # sign the files redirect to the Union Register index page. If a language is chosen for which the annex does not exist, but it exists in other languages, you will be proposed to choose one of the existing languages (the interface language will be the language requested).

Two letter ISO codes and EU languages:

bg	Bulgarian	fi	Finnish	nl	Dutch
cs	Czech	fr	French	pl	Polish
da	Danish	hr	Croatian	pt	Portuguees
de	German	hu	Hungarian	ro	Romanian
el	Greek	it	Italian	sk	Slovak
en	English	lt	Lithuanian	sl	Slovenian
es	Spanish	lv	Latvian	sv	Swedish
et	Estonian	mt	Maltees		

WHY IS IRISH (GAELIC) MISSING IN THE UNION REGISTER?

Up to 31 December 2006, Irish was not included in the working languages of the EU institutions. Pursuant to an Agreement made in 1971 between Ireland and the Community, Irish was considered an official Community language, it being understood, however, that only primary legislation was drawn up in that language.

On 1 January 2007, Irish became a full EU official language, with a temporary derogation for a renewable period of five years (see Council Regulation (EC) No 920/2005 of 13 June 2005 (OJ L 156, 18.6.2005, p. 3)) stating that 'the institutions of the European Union shall not be bound by the obligation to draft all acts in Irish and to publish them in that language in the Official Journal of the European Union', except for regulations adopted jointly by the European Parliament and the Council. This derogation has been extended for a period of five years (until 31 December 2016) by Council Regulation (EU) No 1257/2010 (OJ L 343, 29.12.2010, p. 5).

WHAT ARE PRODUCTS REGISTERED UNDER ARTICLE 126A OF DIR 2001/83/EC?

In order to increase availability of medicinal products, in particular on smaller markets, Article 126a of Directive 2001/83/EC provides that, in the absence of a marketing authorisation or of a pending application for authorisation for a medicinal product, which has already been authorised in another Member State, a Member State may for justified public health reasons authorise the placing on the market of that medicinal product. In such cases, the competent authority of the Member State has to inform the marketing authorisation holder in the Member State in which the medicinal product concerned is authorised, of the proposal to authorise the placing on the market under this Article.

The Commission shall amend the register of medicinal products accordingly and make this register available on their website.

WHERE CAN I FIND MORE INFORMATION ON HOW THE AUTHORISATIONS AND THE FOLLOW- UP PROCESSES WORK?

The legal provisions can be found in the EudraLex collection (The rules governing medicinal products in the EU) (http://ec.europa.eu/health/documents/eudralex/index_en.htm)

The major developments, background information and information on future developments can be found at the following places:

- **Human medicines**
  https://ec.europa.eu/health/human-use_en
- **Veterinary medicines**
  https://ec.europa.eu/food/animals/health/veterinary-medicines-and-medicated-feed_en

Detailed information on every concerned medicinal product and the work of the scientific committees can be found at the European Medicines Agency (http://www.ema.europa.eu), responsible for the scientific evaluations on which the Commission Decisions are based.

Special attention is drawn to the **EudraBook Compendium of EU pharmaceutical law** (ISBN: 978-92-79-44434-0) published in 2015 on the occasion of 50 years of European pharmaceutical legislation. This E-Book is intended to support readers by putting together the most recent versions of the key legal instruments on medicinal products for human use. It provides a useful overview for stakeholders, especially the pharmaceutical industry, regulatory authorities, legal practitioners, but also interested citizens, patients and healthcare professionals.

This E-book id available for free at the EU Bookshop