EU COMMUNITY 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 Community 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.

April 2016

CONTENTS

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] Human, 2 Veterinary, 3 Orphan medicinal product	1
[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:

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