Co-ordination Group for Mutual Recognition and Decentralised Procedures – Veterinary

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GUIDANCE

for

Administration of the Sunset Clause

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1. Introduction

This Guidance document addresses questions that a Marketing Authorisation Holder (MAH) may have on how the Competent authority of a Member State (MS) will monitor the marketing of any veterinary medicinal product, which has been authorised via a Mutual recognition (MRP) or Decentralised (DCP) procedure. For products that have not been marketed within three years of issuing the marketing authorisation or where a product previously placed on the market is no longer actually present on the market for three consecutive years, the marketing authorisation will become invalid.

The monitoring of the so-called Sunset clause provision will be based on the data related to marketing of the products as reported by the MAH.

It should be noted that the application of the Sunset clause is a national decision to be made by each MS.

2. Aim and Scope

The Sunset clause is applicable to all products and whereas the EMA will monitor the placing on the market of centrally authorised products, the National Competent Authorities will monitor the placing on the market of all nationally authorised products, i e all products not centrally approved, in the Member States, including those authorised before the new legislation came into force.

3. Application of the Sunset Clause

3.1 Legal base

Article 27a of Directive 2001/82/EC as amended introduces the obligation for all Marketing Authorisation holders, after the granting of a Marketing Authorisation (MA):

- to inform the competent authority of the dates of actual marketing of the veterinary medicinal product in the Member State, taking into account the various presentations authorised
- to notify the competent authority if the product ceases to be placed on the market, either temporarily or permanently. Such notification shall, otherwise than in exceptional circumstances, be made no less than 2 months before interruption in the placing on the market of the product.

In Article 28 (4, 5 and 6) it is spelt out that a MA shall cease to be valid if the authorised product has not been placed on the market within three years of its granting or, if the placing on the market has been interrupted for a period exceeding three years. This text is referred to as the Sunset clause. The Competent authority may grant exemptions on public and/or animal health grounds and in exceptional circumstances if duly justified.

3.2 What is required to retain a MA?

The notion of a global marketing authorisation (Article 5.1 of Directive 2001/82/EC as amended) applies, which means that the marketing authorisation will remain valid if at least one presentation of the MA is placed on the market in the respective Member State.

3.3 Does the Sunset clause apply to existing products?

Yes, the Sunset clause applies to all products.
As the new legislation was implemented on different dates in the MSs, the first deregistration based on the Sunset clause cannot occur until three years have passed from the implementation of the new legislation in the respective MS. See Annex.

3.4 Will exemptions be possible?

It is the respective National Competent authority that will decide when exemptions from the application of the Sunset clause can be granted. Exemptions can be granted at any time of the MA life cycle depending on the type of exemption.
It will up to the MAH to justify why an exemption should apply based on public /animal health grounds and in exceptional circumstances. Each justification should be notified to the National Competent authority and will be considered on a case-by-case basis.
A copy of such a request should also be addressed to the RMS.

3.5 Definitions

3.5.1 The term ‘actual placing on the market’ is defined as when the veterinary medicinal product is “released into the distribution chain”, i e out of the direct control of the MAH

3.5.2 The “cessation of placing on the market” shall be defined by analogy as the “cessation of release into the distribution chain” with the consequence that the product is no longer available for supply. It means that the date of cessation shall be the date of the last release into the distribution chain.

3.6 When will the three year period start?

The starting date should be the date from which the product can be placed on the market by the MAH. This is normally the date the authorisation is granted but market exclusivity and other protection rules have to be respected and therefore, the starting date may in certain cases be later than the date of authorisation.

3.7 What happens when an MA is transferred to another MAH?

A change of MAH has no effect on the Sunset clause. If a product which has not been placed on the market two years after authorisation is transferred to another MAH, it will have to be placed on the market within one year after the transfer.

3.8 What happens with MAs authorised through MRP or DCP and not marketed in the RMS?

The invalidation of an authorisation in the RMS (where the product is not marketed) may disrupt the continuity of supply in CMSs since the maintenance of the MA is reliant upon procedural responsibilities of the RMS. In that respect, the CMDv guidance document "Position paper on changing of RMS"(CMDv/POS/002) should be followed.

3.9 How will duplicates be treated?

The provisions of Article 28(4, 5 and 6) should be applied individually to each separate MA granted by a National Competent Authority also when those authorisations are duplicates.

3.10 How will the Sunset Clause be applied?

As it is the responsibility of the respective Competent Authority to apply the Sunset clause, information about placing a product on the market will have to be submitted to all MSs involved in an MRP or DCP where the product is authorised.

4 References

Directive 2001/82/EC as amended, articles 27a and 28
NtA: Volume 6A,Chapter I point 2.4.2
CVMP/EMEA document : Sunset Clause-Question and Answer document (EMEA/CVMP/120559/2006)
CMD(h) document : CMDh agreement on Sunset Clause and its application to marketing authorization granted in more than one MS/December 2006.

ANNEX Implementation of Directive 2004/28/EC in the MSs

MS	Implementation date Directive 2004/28/EC
AT	02-01-2006
BE	02-2006
BG	
CY	17-2-2006
CZ	31.12.2007
DE Pharmaceuticals DE Immunologicals	07-09-2005 31-10-2006
DK	17-12-2006
EE	01-03-2005
EL	16-06-2006
ES	12-08-2008
FI	07-11-2005
FR	01-05-2008
HU	13-07-2006
IE	17-11-2005

MS	Implementation
IS	Waiting for EEA agreement
IT	26/05/2006
LI	Waiting for EEA agreement
LT	01-11-2006
LU	
LV	11-08-2006
MT	
NL	13-01-2006
NO	Waiting for EEA agreement
PL	01-05-2007
PT	29-09-08
RO	Implementation in process
SE	01-06-2006
SI	8-4-2006
SK	01-06-2006
UK	30-10-2005