CMDv/GUI/002
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 (VMP), 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 in the concerned MS, 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, the EMA will monitor the placing on the market of centrally authorised products and the National Competent Authorities will monitor the placing on the market of all nationally authorised products, including those authorised via MRP/DCP.

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 marketing authorisation will remain valid if at least one presentation or strength of the MA is placed on the market in the respective Member State.

3.3 To which products apply the Sunset clause?

The Sunset clause applies to all licensed veterinary medicinal products (VMPs).

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 is up to the MAH to justify why an exemption (before the three years elapses) should apply based on public /animal health grounds and the exceptional circumstances. Each justification should be notified to the National Competent Authority and will be considered on a case-by-case basis.

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 start date should be either the date from which:
(a) 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.
(b) a previously marketed product is no longer marketed. In cases where the medicinal product is not marketed temporarily and then put back on the market, the three year period restarts at zero the next time the product is not marketed.

Due to national requirements in the member states divergent rules may apply.

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?

In order not to disrupt the supply to CMSs of a product that is not marketed in the RMS, the MAH should consider changing the RMS before the Sunset Clause is applied, since the maintenance of the MA is reliant upon procedural responsibilities of the RMS. In that case, the CMDv guidance document “Best practice guide for changing the reference member state” (CMDv/BPG/021) should be followed.

3.9 How will duplicates be treated?

Duplicates are considered stand-alone products. Therefore, the provisions of Article 28(4, 5 and 6) should be applied individually to each MA granted by a National Competent Authority.

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 (i.e. the RMS and CMS).

3.11 Re-Registration after Sunset Clause has been triggered

A specific procedure does not exist concerning re-registration of a veterinary medicinal product after Sunset Clause was triggered. If the product is authorised elsewhere within the EEA then a MRP needs to be followed for the re-registration of that product in the MS(s) where it was previously authorised. If the product is no longer authorised within the EEA then a national, followed by MRP or a DCP application can be submitted depending on the marketing plans of the applicant.

4 References

i) Directive 2001/82/EC as amended, articles 27(a) and 28
ii) Regulation 2004/726/EC as amended, article 39(4) to (6)
iii) Notice to Applicants: Volume 6A, Procedures for marketing authorisation, Chapter 1 Marketing Authorisation, section 2.4.2
iv) Best practice guide for changing the Reference Member State CMDv/BPG/021