

**CMDh POSITION PAPER ON  
SUNSET CLAUSE AND ITS APPLICATION TO MARKETING  
AUTHORISATIONS GRANTED IN MORE THAN ONE MEMBER STATE**

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## **Legal background**

### *Sunset clause*

Article 24 (4,5 and 6) of Directive 2001/83/EC as amended relates to the so called sunset clause and states in 24(4): 'Any authorisation which within three years of its granting is not followed by the actual placing on the market of the authorised product in the authorising Member State shall cease to be valid.' More information on the sunset clause is to be found in Notice to Applicants Volume 2A, Chapter 1 (2.4.2 – Cessation of the marketing authorisation if the medicinal product is not marketed) - [http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a\\_chap1\\_2005-11\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-2/a/vol2a_chap1_2005-11_en.pdf).

### *Global marketing authorisation*

Article 6 (1) second subparagraph of the same directive says 'When a medicinal product has been granted an initial marketing authorisation in accordance with the first subparagraph, any additional strengths, pharmaceutical forms, administration routes, presentations, as well as any variations and extensions shall also be granted an authorisation in accordance with the first subparagraph or be included in the initial marketing authorisation. All these marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the application of Article 10(1).'

### *Duplicate*

A definition of a duplicate (multiple application, copy) is lacking in pharmaceutical legislation. The former MRFG (now CMDh) agreed that a duplicate application is defined by reference to the first application or marketing authorisation as follows:

- same dossier (copy of modules 1, 2, 3, 4 and 5);
- same legal basis according to Directive 2001/83/EC, as amended;
- different tradename;
- same or different marketing holder.

The above mentioned definition concerns an *application* for a duplicate. If a duplicate marketing authorisation (MA) is varied in a way that it deviates from the 'original' MA it automatically will be outside the definition of a duplicate.

## Problem statement

Will the sunset clause be applicable for duplicate(s) separate from the 'original MA' or should the concept of global marketing authorisation be applied meaning that as long as the 'originator' is marketed the sunset clause will not be applied for the duplicate(s)?

What happens if the 'original MA' or the duplicate(s) change owner (= transfer of MA)?

What happens with MAs authorised through DCP or a single/repeat use MRP and subsequently not marketed in the RMS or CMS?

## CMDh interpretation

1. The provisions of Article 24(4), (5) and (6) should be applied individually to each separate MA granted by a National Competent Authority even where those authorisations are duplicates, see definition above. Therefore it is not enough if the 'original MA' is marketed if the duplicate has not been marketed for three consecutive years. The MA of the duplicate should then cease to be valid. The same principle apply if only the duplicate is marketed and not the 'original'.
2. The change of ownerships to a MA does not change the application of the sunset clause. This means that if a duplicate (or an 'original MA') change MAH e.g. after two years, the new MAH must put the product on the market within a year in order to avoid the application of the sunset clause.
3. Where a product is not marketed for a consecutive period of 3 years in the Reference Member State (of a Mutual Recognition or Decentralised Procedure) then it is up to that Reference Member State Competent Authority to justify, on public health grounds, why that authorisation may be exempted from the application of the provisions of Articles 24 (4) and (5) on a case by case basis. MAH's should be made aware that such justification and decision can be changed at any subsequent time by the Competent Authority. The assurance of continuity of supply of medicines to patients is an important and valuable feature of European medicines legislation. In particular, attention is drawn to Articles 23a and 81 of the Directive. The invalidation of an authorisation in the Reference Member State (where the product is not marketed) may disrupt the continuity of supply in Concerned Member States or in third countries (where it is marketed) since the maintenance of the MA is reliant upon procedural responsibilities of the RMS<sup>1</sup>. To that extent, it may constitute a justified public health ground for maintaining the validity of the authorisation.
4. Notwithstanding the above point, CMDh recognises the possibility of transferring a RMSship in accordance with its procedure 'CMDh Procedural advice on changing the Reference Member State'-  
[http://www.hma.eu/fileadmin/dateien/Human\\_Medicines/CMD\\_h\\_/procedural\\_guidance/01\\_General\\_Info/CMDh-039-2002\\_Rev3-Clean\\_March09.pdf](http://www.hma.eu/fileadmin/dateien/Human_Medicines/CMD_h_/procedural_guidance/01_General_Info/CMDh-039-2002_Rev3-Clean_March09.pdf).
5. The determination of the start of the three year period from the granting of the marketing authorisation should be the date when the medicinal product can be marketed by the MAH, taking into account e.g. the market exclusivity and other protection rules which have to be respected. The individual MS will therefore need to take account of the specific situation for its own market.

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<sup>1</sup> See also CMDh Best Practice Guide for the Reference Member State in the Mutual Recognition and Decentralised Procedure

6. It should be noted that the application of the sunset clause is a national decision to be made by each concerned member state.

**Advice to MAH's**

If a product is not marketed in the RMS, MAH's are recommended to liaise with the RMS well in advance of the 3 years of non-marketing, in order to discuss whether a transfer of the RMS-ship will become necessary.