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Ad-hoc working group on 'market launch for centrally authorised products'

Reflection paper on the provisions of Article 14, paragraphs 4, 5 and 6 of Regulation (EC) No 726/2004
"Sunset clause"

1. Introduction

The rules on marketing authorisation (MA) laid down in Regulation (EC) No 726/2004 (the Regulation)[2] foresee that the validity of a MA shall be 5 years and may then be renewed for an unlimited period[3].

The validity period mentioned above is conditional to a "sunset clause". Authorization must be followed by an **actual placing** of the MP **on the Union market** within 3 years after authorization. If, following authorisation, the MP is not *actually* placed on the market the MA ceases to be valid[4]. The same applies when an authorised MP is no longer **actually present** on the market for **3 consecutive years**. The provision foresees an exemption to this rule for exceptional circumstances and public health grounds. Such exemptions are to be provided after due justification.

It is worth noting that Directive 2001/83/EC contains the same provision in an almost identical way. This new provision applies to all centrally authorised medicinal products from the date of application of Article 14 of the Regulation, i.e. 20 November 2005.[5]

[1] This document has not been adopted by the European Commission and, therefore, does not reflect an official position of the European Commission. It is meant to be a tool for discussion and the views expressed therein do not necessarily reflect those of the Commission and its services.
[2] Any citation to legislation made without mentioning the act refers to this Regulation.
[3] Unless reasons relating to pharmacovigilance justify another 5-year renewal
[4] Cessation of validity is automatic, no particular decision or administrative action is required for the validity to cease.
[5] https://www.ema.europa.eu/en/human-regulatory/post-authorisation/notifying-change-marketing-status#sunset-clause-monitoring-section

2. Legal context

The relevant section in Article 14 of the Regulation reads as follows:

'(4) Any authorization which is not followed by the actual placing of the medicinal product for human use on the Union market within three years after authorisation shall cease to be valid.

(5) When an authorised medicinal product previously placed on the market is no longer actually present on the market for three consecutive years, the authorisation shall cease to be valid.

(6) In exceptional circumstances and on public health grounds the Commission may grant exemptions from paragraphs 4 and 5. Such exemptions must be duly justified.'

The corresponding provision for nationally authorised products in Article 24 of Directive 2001/83/EC reads as follows:

'(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.'

3. The logic behind the provision

The "sunset clause" has been part of the Regulation since 2004. It was included in the first proposal made by the EC, where a period of 2 years was initially set in order to primarily avoid the administrative burden of maintaining MAs for MPs which are not actually marketed.[6] It was hence, primarily introduced as a counterbalancing element to the fact that within the same amendment, marketing authorisations became in principle valid for an unlimited period after an initial period of validity of five years. Prior to that amendment, marketing authorisations were renewed every 5 years.

During the co-legislative procedure, this principle was maintained by the European Parliament and the Council and eventually made its way to the final text. Recital nr. 35 of the Regulation provides a justification for the provision which was introduced to "*avoid the administrative burden of maintaining such authorisations".*

> *(35) […] Furthermore, any authorisation not used for three consecutive years, that is to say, one which has not led to the placing on the market of a medicinal product in the Community during that period, should be considered invalid, in order, in particular, to avoid the administrative burden of maintaining such authorisations. However, this rule should be subject to exemptions when these are justified on public health grounds.*[7]

The reference to administrative burden in the recital highlights the link between the unlimited validity of a marketing authorisation and the sunset clause. While this may be considered as the main reason (see the use of the term "in particular" in the recital), there might also be additional reasons, such as to encourage companies to place a product on the market in a timely manner after the authorisation or to avoid long interruptions of supply.

The EP in its first reading expanded the 2-year period initially proposed by the EC to 3 years explaining that a two-year period is not sufficient to allow for the various factors which may cause

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52001PC0404(01)&qid=1560170934011&from=EN

[7] A similar recital appears in Directive 2004/27/EC (rec. 17) which amends the text of Directive 2001/83/EC.

actual placing on the market to be deferred.[8] It also amended the EC proposed text to allow for the exemptions on the basis of public health grounds. The changes proposed by the EP in first reading provided a flexibility to the MAH both in terms of time allowed as well as exceptions to the application of the sunset clause. This position was also mirrored by the **Council** in its adopted position in first reading which added the exceptional circumstances exception.

The EC accepted these changes in its amended proposal[9] and reiterated the four basic objectives of the Regulation:

> *(1) to assure a high level of public health protection, notably by making safe, innovative products available to patients as quickly as possible, and by an increased supervision of the market through the strengthening of inspection procedures and of pharmacovigilance;*
>
> *(2) to complete the single market for pharmaceutical products (…);*
>
> *(3) to respond to the challenges of the future enlargement of the EU;*
>
> (4) to rationalise and simplify the system as well as to improve its overall coherence and visibility and the transparency of its procedures.

Part of the function of the sunset clause aims to enhance transparency of the MA system. This is prevalent in the obligation to inform the EMA of the actual marketing of a MP (Art 13(4) and 14b(1). For the purposes of the application of the so-called "sunset clause" (Art 14(4, 5 and 6), the European Medicines Agency has put in place a system to monitor the marketing status of centrally authorised medicinal products. When a three consecutive year period without marketing has elapsed, EMA notifies the Commission accordingly.

4. Modalities of application

The "sunset clause" has so far not been subject to an authoritative interpretation by the EU Courts, but many of the terms used in the wording of the provision, have been subject to Court rulings and Court interpretation, this includes notions such as "placing on the market" and " Union market", which are key to understand the scope of the provision.

Moreover, the Commission together with Member States provided some guidance regarding the modalities of the application in the 'Notice to Applicants'[10].

Placing on the market means the date of release into the distribution chain (i.e. the date when the MP comes out of the control of the MAH). According to Decision No 768/2008/EC placing on the market has been defined as the "first making available on the market" (by the manufacturer or the importer). Similarly, Regulation (EC) No 764/2008[11], which defines the rights and obligations for public authorities and enterprises that wish to market their products in another EU country, adopts the same interpretation of the 'union market.'

[8] For example, a product intended to treat a sporadic disease will not be sold until that disease breaks out. Furthermore, small and medium-sized businesses may need to find a partner for the purpose of marketing a new product.

[9] COM/2002/735/FINAL

[10] Chapter 1 (section 2.4.2), The rules governing medicinal products in the European Union, Notice to Applicants, Volume 2A.

[11] Regulation (EC) No 764/2008 lays down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State.

Making available on the market is defined in the same decision[12] as "any supply of a product for distribution, consumption, or use on the [...] market in the course of a commercial activity, whether in return for payment or free of charge". A good is "placed on the market" only once, but may be "made available" several times throughout the supply chain (first wholesaler, second wholesaler, retailer, etc.) before it reaches the final user (consumer or professional user) or is further processed into another product. The concept of placing on the market refers to each individual good, not to a type of good, and whether it was manufactured as an individual unit or in series. The making available of the product supposes an agreement for the transfer of ownership or possession concerning the product after the stage of manufacture. The transfer does not necessarily require the physical handover of the product.

For centrally authorised products, the product has to be placed on the **Union market**. According to the interpretation provided in the Notice to Applicants this means that the product is at least marketed in one Member State. This interpretation is in line with the concept behind the 'Union market' (or internal market or single market), which encompasses all Member States in the EU. According to Article 26(2) of the Treaty on the Functioning of the European Union, the internal market shall compromise an area without internal frontiers in which the free movement of goods […] is ensured in accordance with the provisions of the Treaties. It follows that from a legal perspective the Union market is served as soon as and as long as the product is placed on the market somewhere in the EU. The concept cannot be linked to a specific or minimum number of Member State's markets, as the Union market does not include borders.

In this regard, it is also useful to point to the differences in wording between the sunset clause in Regulation 726/2004 for centrally authorised products and the sunset clause for nationally authorised products in Directive 2001/83/EC. Only the latter refers to markets that are related to the territory of an individual Member State.

The term “no longer actually present on the market” should be understood in the same way as “ceases to be placed on the market”. Therefore, the sunset clause period in case of a complete marketing cessation of the product shall start from the last date of release into the distribution chain of the medicinal product.[13]

The start of the 3 year period should be the date when the medicinal product can be marketed by the MAH. For new products this is the date from which the marketing authorisation takes effect (i.e. as of the date when the MAH is notified of the Commission decision) for products authorised under abridged procedures, market protection rules need to be taken into account.

According to the Notice to Applicants the MA remains valid if **at least 1 presentation of the medicinal product is placed on the market** and if at least 1 pack-size of the existing pack-sizes for that presentation is marketed (i.e. is made available on the Union market). This interpretation corresponds to the established practice. A stricter interpretation however in regards pack-sizes and presentations would do little to increase accessibility to the medicine. The reason being that the core problem relates to the non-availability of the medicine *per-se* in each Member State and not to the number of its presentations.

In case a medicinal product is **withdrawn and placed back on the market** before the 3 consecutive years pass, the clock restarts. This process can be repeated. From a practical point of view however

[12] Article R1(1) of Annex I to Decision No 768/2008/EC of the European Parliament and of the Council.
[13] Cf. footnote nr. 3

such practices are rarely encountered, if ever, as companies do not have the commercial interest to market a medicinal product in the first instance.

The marketing authorisation holder has an **obligation to inform the EMA** of the date of actual marketing of the medicinal product in each Member State and the date of cessation of placing on the market (permanent or temporary). The MAH must mention the reasons of such actions.[14]

5. Conclusions

The "sunset clause" included in Art. 14 of the Regulation was primarily introduced to reduce administrative burden of maintaining marketing authorisations that were not used but also to increase transparency including encouraging companies to place a product on the market in a timely manner after the authorisation or to avoid long interruptions of supply.

The history of the provision and the modalities of application point towards a flexible approach towards marketing authorisation holders, who are in principle allowed to launch and cease marketing as they see fit as long as they respect the parameters set by the law.

The flexibility provided should be read in the light of the general objectives of the Regulation and cannot lead to situations which go against those objectives. In this case assuring a high level of health protection (which includes availability) and the transparency of the Regulation's procedures.

[14] Art. 13(4) and 14b of the Regulation.