NOTICE TO MA AND REGISTRATION HOLDERS - SUNSET CLAUSE

Procedure relating to application of the sunset clause for MAs and registrations and applications for exemption

1. Principle of the sunset clause

In accordance with the provisions of Articles R.5121-36-2 and R.5121-102 of the French Public Health Code, marketing authorisations (MAs) and registrations granted by the French National Agency for the Safety of Medicines and Health Products (ANSM) cease to be valid in the event that:

- The medicinal product is not placed on the national market within three years of the authorisation or registration being granted;
or
- The medicinal product previously placed on the national market is no longer actually present on the market for three consecutive years.

The sunset clause principle applies for a given MA, i.e. for a strength and a pharmaceutical form (in other words, by NL or CIS). The fact that this authorisation may be part of a global MA as defined in Article R.5121-41-1 of the Code is irrelevant in this case.

When an MA or registration concerns several presentations of the same medicinal product (i.e., several CIP codes), the sunset clause principle does not apply as long as one of these presentations is marketed.

Similarly, when, in application of Article L.5121-14 of the Code, registrations mentioned in Article L.5121-13 cover a series of homeopathic medicines obtained from the same homeopathic stock(s), the sunset clause principle does not apply as long as at least one of these medicines is marketed.

The sunset clause applies *ipso jure* upon the occurrence of the event thus provided for by the regulations. It does not require a decision to be issued by the ANSM. However, in the interests of good administration and in order to avoid any ambiguity as to whether or not a marketing authorisation or registration exists, holders are asked to systematically notify the ANSM of any marketing authorisations or registrations concerned by a sunset clause (see notification procedures described in point 4). Following examination, the ANSM formally acknowledges these notifications for each MA or registration.

2. Time to application of the sunset clause

In accordance with Articles R.5121-36-2 and R.5121-102 of the Code, the three-year period after which the MA or registration ceases to be valid is counted starting from:

- Either 7 May 2008 (the date of publication of decrees No. 2008-435 and No. 2008-436 of 6 May 2008) for MAs and registrations granted up until this date, with the exception, however, of MAs for herbal medicines having been the subject of MA or registration applications submitted in accordance with the conditions scheduled in Article L.5121-14-1 of the Code, for which the three-year period only starts from the date of notification of the decision by the Director General of the Agency following the validation procedure;

- Or the date of issue for MAs and registrations granted after 7 May 2008.

As a reminder, the date of cessation of marketing is understood as the date on which the last batch of the medicinal product is no longer available to distribution or dispensing structures (wholesalers, pharmacies, etc.); it does not correspond to the expiry date of the last batch placed on the market. Holders must take all necessary steps, in particular with stock holders, to stop supplying the public with a medicinal product for which the marketing authorisation or registration has ceased to be valid before the last batch placed on the market expires.

3. Exemptions to application of the sunset clause

3.1. Principle

Article 24 of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, transposed in above-mentioned Articles R.5121-36-2 and R.5121-102, schedules the possibility for Member states to grant exemptions to the sunset clause principle on public health grounds and in exceptional circumstances.

3.2. Exemption criteria

According to the terms of Articles R.5121-36-2 and R.5121-102 of the Code, exemptions from the sunset clause may be granted for any of the following reasons:

1. public health grounds,
2. the medicinal product could not be legally placed on the market during the period considered,
3. the medicinal product is exclusively intended for export to a State not party to the Agreement on the European Economic Area (third country),
4. the medicinal product is marketed in at least one other State party to the Agreement on the European Economic Area, in which it has obtained an authorisation or registration under a mutual recognition or decentralised procedure for which France is designated as the reference Member State and at least one different strength or pharmaceutical form of this medicinal product is marketed in France.

- For situations falling within the scope of criteria 1 and 2, a justification with supporting documents, if applicable, must be specified in the form.
  Situations such as an application for inclusion in the list of reimbursable medicinal products, an application to set a price, an application for variation of the marketing authorisation liable to affect the marketing of the medicinal product concerned, which are currently being examined, may be considered as falling within the scope of criterion 2. However, contractual barriers to marketing do not fall under criterion 2.
- For situations falling with the scope of criteria 3 and 4, the supporting document to be provided is a notification by the holder engaging its responsibility with respect to the veracity and validity of the information provided to the ANSM.

3.3. Period of validity of exemptions

Exemptions are granted for a period not exceeding 5 years from the date originally scheduled for the cessation of validity of the marketing authorisation or registration.
A sunset clause exemption does not relieve the holder of its obligations relative to renewal of the MA or registration, stipulated in Articles R. 5121-45 and R. 5121-99 of the Code. In other words, in the absence of a regular application for renewal, required in accordance with the above provisions, a marketing authorisation or registration expires even if a sunset clause exemption has been granted. Similarly, if the renewal has been refused by the ANSM, the MA or registration expires even if it has previously been the subject of a sunset clause exemption.

Furthermore, the ANSM must be informed of any change that calls into question the exemption (removal of the legal obstacle to marketing, marketing, cessation of export, etc.) so that it may be revised.

At the latest 6 months before expiry of the period of validity of the exemption, the MA or registration holder may apply for a new exemption if any of the criteria set out in 3.2 are still met.

4. Notification and procedure relative to application of the sunset clause and applications for exemption

4.1 Procedures for sunset clause notification and application for exemption

Sunset clause notifications for marketing authorisations or registrations for medicinal products which are not marketed or applications for exemption must **imperatively** be sent to the ANSM by the holder concerned **at the latest 6 months before the expiry date of the marketing authorisation or registration.**

Any application for an exemption submitted after the actual sunset date of the marketing authorisation/registration is not admissible.

Sunset clause notifications or applications for exemption are submitted using a dedicated form, duly completed for each medicinal product (NL) concerned:
http://ansm.sante.fr/Activites/Autorisations-de-Mise-sur-le-Marche-AMM/Caducite-des-AMM-et-des-enregistrements/(offset)/2

This form is sent **by post to the Division for Quality, Data Flows and Repositories, with the following envelope codes:**
- **920 for non-generic medicines,**
- **950 for generic medicines**.

It should be noted that an application for variation of a marketing authorisation or registration liable to be concerned by the sunset clause principle does not constitute an implicit application for exemption. This must be requested separately, following the arrangements and procedure detailed in this notice to MA holders.

The ANSM acknowledges notification of the sunset clause for the marketing authorisation or registration and, if applicable, grants an exemption by returning the abovementioned individual form, completed, dated and signed, within a period of 6 months following receipt of the complete notification. During this interval, additional information may be requested by the ANSM if required.

4.2 Sunset clause concerning MAs for which France is the reference Member State

In the event that a marketing authorisation, obtained under a decentralised or mutual recognition procedure for which France is designated as the reference Member State (RMS), is concerned by the sunset clause principle, even if the conditions of reason 4 for an exemption are not met, it is the responsibility of the MA holder to take the necessary steps to change the RMS before the legal sunset date is reached*.

Any questions relating to the sunset clause principle for an MA/registration and exemptions from this principle may be submitted to the Legal and Regulatory Affairs Division / Regulatory Affairs by email to dajr@ansm.sante.fr.

* *Cf. CMDh procedural advice on changing the reference member state (Doc. Ref.: CMDh/039/2002)*