HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Notification of Marketing Status of Human Medicines

1 SCOPE

This guide relates to post-authorisation notifications of the marketing status of medicinal products and the operation of the 'sunset clause'. The requirements detailed in this guide apply to all products, including homeopathic products with a certificate of registration and herbal products with a certificate of traditional-use, but they do not apply to parallel import or centralised products.

For the withdrawal of an authorisation or a certificate, please see the 'Guide to the Withdrawal of Authorisations or Certificates for Human Medicines'.

2 INTRODUCTION

The Medicinal Products (Control of Placing on the Market) Regulations, 2007, require the authorisation or certificate holder to notify the Health Products Regulatory Authority (HPRA) of the date that the product was actually marketed and to notify the HPRA no less than two months in advance of a cessation in marketing, either temporary or permanent, unless there are exceptional circumstances.

For the purposes of the annual maintenance fee invoice, companies should notify the HPRA of products that have never been marketed.

Where a product ceases to be marketed permanently and there is no therapeutic alternative, notification must be given to the HSE 12 months in advance of the intended date of cessation of marketing.

Cessation of marketing, either temporary or permanent, is a separate activity from the total recall of all batches from the market, which is handled through the Compliance department of the HPRA.

Under the Regulations, the authorisation or certificate ceases to be valid if the product is either not marketed at all for a period of three consecutive years or is marketed but marketing ceases for a period of three consecutive years. This provision is termed the 'sunset clause'. The HPRA may grant exemptions from the three-year rule, if justified on public health grounds (see section 5 below).

These obligations are linked to the obligation in the Regulations requiring the PA holder or distributor, within the limits of their responsibilities, to ensure appropriate and continued supply of medicinal products to pharmacies and other persons authorised to supply the products.

3 MARKETING STATUS

A medicinal product is deemed to have been placed on the market when it is placed in the distribution chain, i.e. it leaves the control of the authorisation or certificate holder. For each authorisation or certificate, the holder should notify the HPRA of the date when the product is actually placed on the market. The HPRA expects companies to notify this date no later than two months after marketing commences.

A medicinal product ceases to be marketed when the authorisation or certificate holder stops releasing it to the distribution chain. Where the marketing of a product ceases permanently, the holder must notify the HPRA at least two months in advance, other than in exceptional circumstances. If the two-month advance notification cannot be given, the authorisation or certificate holder must notify the HPRA as soon as possible and provide a justification as to why the time limit could not be met. This justification will be taken into account by the HPRA in judging whether or not there were exceptional circumstances in the particular situation.

The temporary cessation of marketing a medicinal product may result in a shortage on the Irish market. Where this is the case, the authorisation or certificate holder should notify the HPRA Shortages Unit by completing the 'Notification of Medicinal Product Shortage from Marketing Authorisation Holders' form (available on the medicinal product shortages page of the HPRA website www.hpra.ie), and returning it electronically to shortages@hpra.ie and to the Health Service Executive Corporate Pharmaceutical Unit at CPU@hse.ie.

4 NON-MARKETING FOR REASONS OF QUALITY, SAFETY OR EFFICACY

When the marketing of a medicinal product ceases for reasons of quality, safety or efficacy, the quality defect or efficacy/safety issue must be reported to the Human Products Authorisation and Registration and/or Compliance departments of the HPRA as soon as possible. The formal notification of marketing status includes information on the reasons for the cessation of marketing for statistical purposes only and it must **not** be used to notify the HPRA of the quality, safety or efficacy issue.

In these circumstances, the sale or supply of batches which may be already on the market at wholesale or retail level will be addressed during discussions between the HPRA and the authorisation or certificate holder and in the context of the quality, safety or efficacy issue identified. All communications for healthcare professionals should be submitted to the HPRA for review and approval, as well as the proposed timescale for communication.

5 SUNSET CLAUSE

The sunset clause applies to products which are not marketed for a period of three consecutive years, whether originally marketed or not.

For new authorisations or certificates granted from 23 July 2007, the three-year period starts from the date of authorisation. This applies to all products where the application was made before 23 July 2007 and the authorisation granted after that date. It also applies to all products for which the application was made after 23 July 2007, except for the specific case of generics of

reference products where the application for the reference product was made after 23 July 2007. For these generic products, the three-year period begins when the market exclusivity period for the reference product expires. This will be 10 years from the date of authorisation of the reference product, or 11 years if an extension is granted for an indication for which significant clinical or non-clinical studies were provided.

For product authorisations issued prior to 23 July 2007, the three-year marketing period starts on 23 July 2007.

For the purposes of this Regulation, the authorisation or certificate will remain valid if at least one pack size of one presentation (i.e. strength, pharmaceutical form or other (line) extension) is marketed. There is no minimum period of marketing required.

In exceptional circumstances and for public health reasons the HPRA may grant an exemption from the sunset clause. The Regulations do not specify the situations in which an exemption may be granted. It is up to the authorisation or certificate holder to justify why the sunset clause should not apply and each case will be judged on an individual basis. Examples of situations where it would be appropriate to grant exemptions include:

- critical medicinal products produced only when needed, such as vaccines;
- medicinal products used in emergency situations in response to a public health crisis;
- medicinal products under litigation; and
- medicinal products where the authorisation or the use of the product is suspended.

6 NOTIFICATIONS TO THE HPRA

Notifications of marketing status and requests for exemption from the sunset clause should be made using the form 'Notification of Marketing Status of Human Medicines'. Different forms and strengths of a product may be combined on one form if the marketing status is the same for each, otherwise separate forms for each form and strength should be submitted.

Notifications of marketing status should be submitted electronically to medstatus@hpra.ie. Notifications of shortages should be submitted electronically to shortages@hpra.ie.

HPRA
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