HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Withdrawal of Authorisations or Certificates for Human Medicines

1 SCOPE

This guide applies to the withdrawal by the holder of an authorisation for a medicinal product, a certificate of registration for a homeopathic medicinal product or a certificate of traditional-use registration for a herbal medicinal product. For the withdrawal of a product from the market, please see the 'Guide to Notification of Marketing Status of Human Medicines'.

2 INTRODUCTION

Withdrawal of an authorisation or certificate may occur during the period of validity of the authorisation or certificate or on renewal when the holder may decide not to renew it. In each case, the Health Products Regulatory Authority (HPRA) must be notified of the withdrawal.

Withdrawal of a marketing authorisation where there is no therapeutic alternative must be notified to the HSE 12 months in advance of the intended date of withdrawal.

The holder should indicate the reason for withdrawal, which may be commercial or may relate to concerns regarding the quality (including GMP status), safety or efficacy of the product. Where a quality defect or safety/efficacy issue arises, these must be reported as soon as they arise to the relevant departments of the HPRA (Human Products Authorisation and Registration and/or Compliance). The formal notification of withdrawal includes information on the reasons for the withdrawal for statistical purposes only and it must **not** be used to notify the HPRA of the quality, safety or efficacy issue.

Withdrawal of an authorisation or certificate is a separate activity to total recall of all batches from the market, which is handled through the Compliance department of the HPRA.

3 WITHDRAWAL AND THE MARKETING OF BATCHES

When an authorisation or certificate is withdrawn for reasons of quality, safety or efficacy, no further batches of the product may be released onto the market after the date of withdrawal. 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. In these circumstances, all communication for healthcare professionals should be submitted to the HPRA for review and approval, as well as the proposed timescale for communication.

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When the PA is withdrawn for commercial reasons, no further batches of the product may be released onto the market after the date of withdrawal of the authorisation or certificate. The product may not be promoted in any way. Batches already released and at wholesale or retail level may be sold until the end of their shelf lives. The PA holder retains full responsibility for all batches still on the market after the withdrawal of the PA.

4 NOTIFICATIONS TO THE HPRA

Notification of the withdrawal of an authorisation or certificate should be made using the form 'Notification of Withdrawal of Authorisations or Certificates for Human Medicines', which is available in the 'Publications' section of the HPRA website. The HPRA will acknowledge the withdrawal from the intended date of withdrawal indicated on the form.

All notifications of withdrawal should be submitted by email to submissions@hpra.ie or by post to the address below:

Receipts and Validation
Human Products Authorisation and Registration Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2
D02 XP77
Ireland

HPRA
16 April 2021

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