HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Guide to
Withdrawal of Authorisations or Certificates for Veterinary Medicines

1 SCOPE

This guide applies to the withdrawal by the holder of an authorisation for a veterinary 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 veterinary medicines'.

2 INTRODUCTION

Withdrawal of an authorisation may occur during the period of validity of the authorisation or on renewal when the holder may decide not to renew it. In each case, the HPRA must be notified of the 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 (Veterinary Sciences 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 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When an authorisation is withdrawn for reasons of quality, safety or efficacy, no further batches of the product may be released onto the market after the date of withdrawal.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 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.

A When the authorisation is withdrawn for commercial reasons, no further batches of the product may be released onto the market after the date of withdrawal of the authorisation. 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 VPA holder retains full responsibility for all batches still on the market after the withdrawal of the VPA.

4 NOTIFICATIONS TO THE HPRA

Notification of the withdrawal of an authorisation should be made using the form 'Notification of withdrawal of authorisations or certificates for veterinary medicines', which is available on the 'Publications and Forms' section of www.hpra.ie. The HPRA will acknowledge the withdrawal from the intended date of withdrawal indicated on the form.

All notifications of withdrawal should be made to:
Veterinary Sciences Department
Health Products Regulatory Authority
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2