



MINISTRY FOR AGRICULTURE,
FISHERIES AND ANIMAL RIGHTS

National Veterinary Laboratory
Animal Health and Welfare Department
Triq il-Bicċerija, Albertown, Marsa, MRS1123 - Malta

Circular Ref: VMS-AHWD Ref: 01/2020

17TH June 2020

To: All Veterinary Wholesale Dealers and all Registration/Authorisation Holders

Withdrawal of the veterinary medicinal product from the market

The Veterinary Medicines Section would like to remind all Authorisation/Registration Holders that an application form for the 'Withdrawal of a Veterinary Medicinal Product' must be used to inform the Veterinary Medicines Section of the intention of the Holder to withdraw the product/s from the Maltese market.

The on-line application forms can be found in the following URLs

https://servizz.gov.mt/mt/Pages/Ambjent_-Ener_ija_-Biedja-u-Sajd/_arsien-tal-Annimali/Servizzi-Veterinarji/WEB2451/default.aspx

https://servizz.gov.mt/en/Pages/Environment_-Energy_-Agriculture-and-Fisheries/Animal-Welfare/Veterinary-Services/WEB2451/default.aspx


Withdrawal of a product must not be confused with a product that is authorised but it is nevertheless not being marketed. In the latter case the relevant fees and post-licensing obligations (e.g. variations, pharmacovigilance obligation) should still continue to be honoured.

The 'Proposed Date of Withdrawal' marked on the application form must not precede the date on which the withdrawal application form is submitted.

If the product is not officially withdrawn by means of the 'Withdrawal of a Veterinary Medicinal Product' application form it will be considered as being still on the market and subject to the relevant fees.

The distributor must exhaust the stock of the veterinary medicine within 6 months from the 'Proposed Date of Withdrawal'

Registration/Authorisation/Marketing Authorisation Holders are still required to abide by their post-marketing and pharmacovigilance duties until all stocks available in veterinary pharmacies are exhausted.


Stephen Spiteri
Senior Principal Pharmacist
National Veterinary Laboratory
Animal Health and Welfare Department