



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Work instructions

Title: Marketing status and sunset clause monitoring for centrally authorised veterinary medicinal products		
Applies to: Veterinary Medicines Division		
Status: PUBLIC		Document no.: WIN/V/4125
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1. Changes since last revision

New WIN following revision of IQM structure and simplification of procedure.

2. Records

All records generated by this procedure are stored electronically only in DREAM under *Cabinets/01. Evaluation of Medicines/V - C/4. General correspondence to MAHs/Verification of marketing status (sunset clause)*.

3. Instructions

3.1. Purpose

This WIN intends to describe:

- The handling of the marketing status reporting provided by marketing authorisation holders (MAHs) and the monitoring of the sunset clause period by the Agency, based on marketing data for centrally authorised veterinary medicinal products.
- The handling of subsequent information received on cessation, which may be related to a public or animal health concern, and the granting of an exemption to the application of the sunset clause by the European Commission.
- The procedure for managing the end of the 3-year period without marketing and notifying this situation to the European Commission.



3.2. Responsibilities

It is the responsibility of the Head of Veterinary Medicines Department (delegated to the Head of Service for Veterinary Regulatory and Organisational Support) to ensure that this procedure is adhered to within their own department/service. It is the responsibility of the Head of Veterinary Regulatory and Organisational Support to monitor the overall sunset periods. The responsibility for the execution of a particular step of this procedure is identified in the right-hand column in the instructions below.

3.3. Related documents

- Post-authorisation questions and answers on the sunset clause provision (http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/q_and_a/q_and_a_detail_000106.jsp&mid=WC0b01ac058029bdd9)
- WIN/V/4126 on the Handling of withdrawals of marketing authorisations for veterinary medicinal products (*tbc*)
- Checklist for sunset clause monitoring (EMA/188882/2017)
- Template email to MAHs (EMA/217699/2017)
- Reporting form for marketing status (EMA/217698/2017)

3.4. Abbreviations

CVMP	Committee for Medicinal Products for Veterinary Use
DREAM	Document Records Electronic Archive Management
EC	European Commission
EEA	European Economic Area
HSer	Head of Service (here: HSer VROS)
MA	Marketing authorisation
MAH	Marketing authorisation holder
MS	Member State
PC	Procedure Coordinator (here: PC assigned to sunset clause monitoring)
SIAMED	Product information and application tracking system (at the Agency)
VROS	Veterinary Regulatory and Organisational Support

3.5. Instructions

Step	Action	Responsibility
1.0	Routine tasks for all products	
1.1	<i>1st quarter of each year:</i> Send email request to all current MAHs to provide marketing status update within 2 weeks. Attach blank template for marketing status report.	PC

Step	Action	Responsibility
1.2	Track receipt of responses. Send reminders and ensure receipt of response only for those products that benefit from fee incentives (e. g. epizootic vaccines) and those whose sunset timer is set as “on” in SIAMED.	PC
1.3	Archive responses, update SIAMED as necessary. Prepare outcome report and send to HSer for information.	PC
2.0	Quarterly check	
2.1	<i>At the beginning of each quarter:</i> Check the vet.applications inbox for any ad-hoc notifications from MAHs in relation to the marketing status of their products, if not previously processed. Update SIAMED, if applicable.	PC
2.2	Check sunset timer of all authorised products in SIAMED to identify any products with sunset timer set as “on”, where the 3-year period expires within the next 5 months.	PC
3.0	Products close to expiry	
3.1	<i>Approx. 3 months before expiry:</i> Check if cessation procedures would result in serious concerns regarding public/animal health or the environment.	PC
3.2	<i>If there are serious cessation concerns:</i> Check if other procedures have been followed (e. g. product defect, PhV reporting, etc.). Consider need for follow-up actions (e. g. involvement of Rapporteur, CVMP public statement, etc.). Update marketing status in SIAMED, if applicable.	PC
3.3	<i>If outcome of considerations is likely cessation of authorisation:</i> Discuss withdrawal process with MAH.	PC
3.4	<i>In case of no concerns related to cessation:</i> Notify MAH of imminent sunset period expiry, requesting clarification on the marketing status.	PC
3.5	<i>Approx. 2 months before expiry:</i> Ensure response from MAH has been received. If product is on the market: set sunset timer to “off”.	PC
3.6	<i>If product is not on the market:</i> Prepare correspondence/notification to EC and initiate legal review, approx. 1 month before expiry.	PC
3.7	<i>One working day after expiry:</i> Send notification letter to EC, copy MAH and CVMP.	PC
3.8	<i>Upon receipt of notification on validity of MA from EC:</i> Update SIAMED and proceed to withdrawal process. [End of procedure]	PC