HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Veterinary Info Day Q&A
Session 2 – Changes to Marketing Authorisation Procedures

Question: Would it be possible to submit the sales once a year divided by months and species, or should be submitted monthly? On the other hand, which will be the deadline for the submission of the data?

Answer: Marketing Authorisation Holders (MAHs) must provide the annual volume of sales according to Article 58(12) of Regulation (EU) 2019/6. In the minimum viable product (MVP) implementation of the Union Product Database (UPD), MAHs will have flexibility to decide the frequency (quarterly, monthly, yearly) for the data submission, with granularity fixed at monthly level.
Please use this link to an EMA presentation + Q&A of the UPD webinar for industry, Project ZX 00017 004: Union Product Database: data models (europa.eu).

Question: When will MAHs be able to register to the UPD? Will it be before Feb 2022?

Answer: Yes, we expect MAHs can register before February 2022. A training session in the second half of November 2021 on registering with UPD was indicated by the EMA. Specific timelines for registration can be queried with EMA via the following email address: vetchange.programme@ema.europa.eu

Question: Will the HPRA provide guidance to MAHs on what needs to be checked in UPD?

Answer: The HPRA will keep stakeholders up to date on new developments via the website and HPRA newsletter. We will also provide links to EMA guidance on UPD when available. Depending on the content of the EMA guidance, we may develop our on specific guidance in the future.
The Vet EU Implementation guides are very useful documents to gain an understanding of the data that will be in UPD and for determining stakeholder data responsibilities. They can be found at https://www.ema.europa.eu/en/veterinary-regulatory/overview/veterinary-medicines-regulation/union-product-database

Question: As there is no opportunity for dialog after VNRA submission, does that mean that validation period does not exist?

Answer: Yes, there is no validation period for VNRA's.

Question: In case of grouped variations, where highest ranking variation is IB, should this be submitted as VNRA or VRA?

Answer: VNRA's cannot be included in grouped variation application, they must be submitted individually to the UPD. Grouped variations requiring assessment will be processed according to the longest timetable applicable to any of the variations included in the group.

Question: For VNRA, will the MAH receive approval/rejection notification by email or will the MAH need to login on the UPD to check the status of the variation?

Answer: On Day 30 the RMS will inform the MAH and the CMS of the outcome of the variation recording the approval in the UPD. The decision notification can be accessed by the MAH and the CMS in the UPD in the notification section.

Question: Will the MAH be able to download a specific approval document from the UPD for VNRAs or will the approval just 'sit' within the UPD?

Answer: No, there is no specific 'approval document' in UPD. However, from your browser you should be able to save the details from the submission and save in your local drive.

Question: In relation to UPD and VNRA: In terms of reduction of administrative burden for the MAH with the option of submitting 'super-grouped' Type IA variations, will this option be unavailable when the UPD is in use?

Answer: Unfortunately, the option of submitting grouped VNRA's, will not be available when the UPD is first operational. It is acknowledged that this does create administrative burden for MAH's and NCA's alike and this functionality will be high priority for future enhancement of the UPD and is expected to be delivered within a few months of UPD being operational.

Question: For variation requiring assessment (VRA) can you confirm if the timeline passes the 30 days can we implement the change or must we wait for official approval?

Answer: An MAH may implement a variation requiring assessment only after a competent authority has amended the decision granting the marketing authorisation in accordance with that variation, has set a time limit for the implementation and has notified the MAH. The RMS will set up a common earliest possible implementation date for the implementation of the variations. For variations that affect the SPC/LAB/PL the common implementation date will be 60 days after the end of the procedure, provided that complete high quality translations have been submitted within 7 days after approval as outlined in the timetable. For variations that do not affect the SPC/LAB/PL the common implementation date will be 30 days after the end of the procedure.

Question: Is there a grace period to implement changes in the product information for VNRA?

Answer: Any grace periods for the implementation of changes to the product information arising from variations will be in line with national policies. In Ireland, details are provided in the 'Guide to Implementation of Packaging Changes to Authorised Veterinary Medicinal Products' which is available on the HPRA website.

Question: Is the 6 month gap between National Procedure and MRP is also relevant for Repeat-Use MRP (following a DCP)?

Answer: Article 52 of Regulation 2019/6 which describes the procedure for mutual recognition of national marketing authorisations is specific in regard to the six month time gap between the decision granting the national marketing authorisation and the submission of the application for mutual recognition of that national marketing authorisation. However, Article 53 of Regulation 2019/6 which describes the procedure for the subsequent recognition of marketing authorisations by additional Member States concerned (formerly known as repeat use procedure) is silent in relation to any time gap. The best practice guide for SRP advises that any ongoing procedure should be completed before the start of the SRP but that the SRP can start before all marketing authorisations are issued in the "old" CMS.

Question: Will CMS provide a format to the MAH for compiling all LOQs and responses?

Answer: Yes, CMDv are currently working on templates (for use by all MSs and applicants) to assist applicants in compiling these LoQs to ensure that the process is as lean and efficient as possible.

Question: MRP to be used if product authorised within 6 months from initial authorisation. What procedure to use if over 6 months?

Answer: The mutual recognition recognition procedure is used to recognise a national MA for a VMP in other MSs. With reference to the 6 months, Regulation 2019/6 now requires that a minimum of six months has elapsed between the decision granting the national MA and submission of an application for a MRP. It should be noted that the decentralised procedure is used to obtain a marketing authorisation in more than one member state (MS) for a product not already authorised in any MS within the EU.