Webinar Q&A -19 May 2022
Pharmacovigilance updates and the signal management process

Question 1
The PSMF slide first paragraph states that the PSMF summary is not needed in dossier for existing products, but next paragraphs states that a VNRA C.6 should be submitted for existing products. Do MAHs now have to submit a variation for the PSMF summary for all existing products or only include this summary in new registration applications? If a variation needs to be submitted, can this be a single submission comprised of all registered products? Is there a deadline for the submission of such?

Answer
While the Summary of the PSMF is not included on the UPD and does not need to be introduced for existing products by submission of a variation, the PSMF reference number and location are required fields of product information on the UPD. The only way to upload this information to the UPD is by a VNRA and it has been agreed by CMDv and the NCAs that for all existing products introduction of this information only will be required by submission of a C.6 VNRA.

Any updates to the information in the PSMF Summary are handled by submission of the relevant C category VNRA.

Current advice from the EMA is that MAHs should wait until July 2022 before submitting C.1, C.5 and C.6 variations as the UPD should have improved functionality after this date, including automatic update of the UPD following approval of these variations.

Current UPD functionality only allows for the inclusion of one product per VNRA submission so separate submissions will be needed; however, it is expected that future updates to the UPD should address this issue.

Question 2
In reviewing reports in DWH I have third country reports (reported by another MAH) prior to 28 Jan 22 which we never received. How should we deal with these cases in signal review given that we cannot carry out individual case review as the narrative is not visible - only VEDDRA codes.

Answer
The UPD will have functionality to capture 3rd country product names and link them to the relevant EEA name(s) in the future.
In this instance, until the above mentioned functionality has been developed in the UPD, the MAH should provide the EMA with the relevant EEA product, corresponding to the product mentioned in the report, to enable them to recode the data and this would enable access to the case narrative. Please contact the EMA at the email address vetchange.programme@ema.europa.eu

Question 3
For large numbers of signals it is a large job to submit every signal separately. Is the form required for all? Could a complete summary be submitted?

Answer
Currently, each signal must be submitted separately, however the EMA are working on updates to IRIS to improve this process. A signal assessment template is required for each confirmed signal; however, according to EMA advice, for refuted signals a summary paragraph containing information on the total number of cumulative cases in the pharmacovigilance database, a brief summary of these cases and the conclusion of the assessment detailing the reason for refuting the signal is considered sufficient.

Question 4
EVVET seems to have large number of uncoded products in AEs, which are assigned to us but may not be our product. Will these products be coded so then no longer assigned to us?

Answer
The EMA are best placed to answer any questions relating to coding and recoding of products as this is a technical issue relating to an EMA IT system. Please contact the EMA at the email address vetchange.programme@ema.europa.eu

Question 5
Does the HPRA has any plans to organise for training on signal management?

Answer
At present the HPRA does not plan to organise any specific signal management training as this has already been provided by the EMA with recordings available on their website and YouTube channel. https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/pharmacovigilance/eudravigilance-veterinary

Question 6
Are non-cap dates going to all be for the second half of 2022?

Answer
It is the understanding of the HPRA that the latest advice from the EMA is that due dates for non-CAPs will be available soon but the EMA are waiting for further updates to the UPD before publishing these dates.
However, MAHs should not wait for due dates to perform signal detection, this is a continuous process and can be carried out at any stage throughout the year. Signals can be submitted in the absence of due dates. Due dates only relate to the date by which the Annual Statement should be submitted.

Question 7
If a case is reported from third country (USA) for a product. The active of this product in third country is identical to the active in the EU, however different trade name. How should MAH submit this to the EVVET as trade name does not exist for third country reports? Please advise.

Answer

The report should be submitted with the original trade name in the third country. The UPD will have functionality to capture third country product names and link them to the relevant EEA name(s) in the future.

Question 8
If AE report is submitted to EVVet within 30 days, is that how a MAH submits to the UPD or are they required to submit to the UPD by separate means also?

Answer
As per the VGVP module 'Collection and recording of suspected adverse events for veterinary medicinal products', suspected adverse event reports are recorded in the Union pharmacovigilance database (EVVET3) which is interconnected with the Union Product Database (UPD) so the MAH is only required to submit the report to EVVET3.

As a point of note, the Union Pharmacovigilance Database is comprised of three parts - EVVET3, the Data Warehouse and IRIS. The Union Product Database (UPD) serves as a single source of information on all authorised veterinary medicines and their availability in European Union (EU) and European Economic Area (EEA) Member States.

Question 9
As MAH we are receiving so many SAE reports wrongly coded, included the API in the registered or brand name field, how can we handle this? We are not sure if this API belong to us or to other MAH.

Answer
The EMA are best placed to answer any questions relating to coding and recoding of products as this is a technical issue relating to an EMA IT system. Please contact the email address: vetchange.programme@ema.europa.eu

Question 10
Is there any update on when we might be able to view initials and postcodes on reports on EVVet which would help identify duplicates?

Answer
The Primary reporter information is classified as L3 on the EVVET access policy, so only the sender organisation will have access to this information, regardless of product ownership.

It is the understanding of the HPRA that this information is used in the algorithm designed to detect duplicates and that is why MAH's have been asked to include this information.

Question 11
We find it very difficult to identify what has changed in follow up reports/replaced reports on EVVet if this is not clearly indicated by the reporter in the narrative - is there anyway of easily identifying what has changed in a report without importing it onto our PV system e.g. 5 submissions - our original submission, NCA submission and 3 other submissions from MAHs of other products within the report. We expect that each of these submissions after our initial one is simply the NCA and other MAHs just fulfilling their obligations to report to the EVVet

database as no clear updates are identifiable when looking at the most recently submitted report.

Answer
It is very important that all MAHs select the 'Follow-up' option on EVET3 when submitting a follow-up report. This is the clearest way to indicate that the report is a follow-up. Similarly, it is important that all new information is clearly identified in the case narrative.

Question 12
We are performing daily checks of EVVet to identify any of our products (i.e. those which have a clear brand name belonging to us), however after the EMA finish recoding, are we expected to go back to the start of the year and perform another search to identify any 'new' reports which were initially added with an active (not an identifiable brand name) and if so, we assume that any reports found will not be classed as 'late' submissions since they were not identifiable on initial search before the recoding? Also will there be an option to export reports from EVVet onto an excel sheet for review rather than opening each case on the system - this would be a much easier way of identifying our products.

Answer
The EMA are best placed to answer any questions relating to recoding of products as this is a technical issue relating to an EMA IT system. Please contact the email address: vetchange.programme@ema.europa.eu

Question 13
Does Annual Statement Report (for refuted signal) include percentage incidence calculated based on sales data?

Answer
The Annual Statement is a document in which MAHs should confirm the benefit-risk balance of the product, confirm that the signal management procedure is in place and continuously applied and that all assessed signals have been submitted. MAHs do not need to submit an annual statement signal review or a benefit-risk assessment report and no signals should be attached to the annual statements. Signals must be submitted separately.

The issue of incidence calculations based on sales data and how this information should be used is still under discussion. More information will be provided by the EMA in due course.
Currently MAH's can provide sales data and incidence calculations within their analysis of signals if they wish.

Question 14
If a VMP is administered as treatment after the occurrence of a SAE, it has to be included in the SAE report as a suspect VMP?

Answer
Only VMPs which are considered to be involved in the adverse event should be reported as suspect products, any products administered as treatment after the adverse event should be included in the case narrative.

Question 15
Access to evweb and capabilities for improved searching. When are improvements expected?

Answer
The EVVet system is managed by the EMA. We recommend that MAHs keep a close eye on the EMA website for any updates. https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/pharmacovigilance/eudravigilance-veterinary

Question 16
Duplicate cases in EVVET - process for avoiding/handling

Answer
EVVet has been designed to automatically detect duplicate cases. Currently, however, this functionality is unavailable. It should be completed by the end of June. As an interim measure, the EMA have advised that MAHs should search the system prior to submitting a report to check if a similar report has already been submitted.
To aid EVVet in detecting duplicates, MAHs are asked to include the initials and the first 2 digits of the reporter's postcode when submitting a report. We advise MAHs to keep a close watch on the EMA website for updates. https://www.ema.europa.eu/en/veterinary-regulatory/post-authorisation/pharmacovigilance/eudravigilance-veterinary

Question 17
Are there any transition periods applied in regards to an update of the PhV System / availability of the PSMF?

Answer
In accordance with Article 77.2 of the Regulation, from 28 January 2022, MAHs must have in place a PSMF that describes in detail the pharmacovigilance system for their product(s). No transition period applies.