Veterinary Info Day Q&A
Session 3 – Pharmacovigilance changes, compliance and monitoring

Question: Is there guidance on how to allocate a reference number to a PSMF?

Answer: The actual format of the PSMF reference number is still under discussion so once that has been finalised the EMA will be in a position to provide further guidance on allocation of the reference number. This should be covered in one of the EMA training sessions which are due to begin in November, however there are no finalised dates yet. The EMA will announce details of the training sessions in due course so it is advisable to sign up for these sessions once the dates are announced.

Question: The role of the QPPV may involve extensive tasks, can any tasks be delegated?

Answer: The QPPV may delegate specific tasks to appropriately qualified and trained individuals provided that the QPPV maintains system oversight and overview of the safety profiles of all veterinary medicinal products. Such delegation should be documented in the PSMF. It is the responsibility of the QPPV to ensure that all personnel involved in pharmacovigilance activities receive appropriate training.

Question: Will a template be available setting out the structure for the annual Signal Management report like the template that is currently available for PSURs? If so, when will it be available?

Answer: It is the HPRA's understanding that a template is currently being developed by the EMA. As the VGVP (guideline on veterinary good pharmacovigilance practices) modules have not been finalised we are unsure when it will be published. To note, while the template won't specifically be included in the signal management module it is being developed in tandem.

Question: Do all entities need to be considered for a risk-based audit scheduling, and is there a minimum/set frequency for audits of partners to be conducted that can be recommended?

Answer: All parts of your PV system should be considered for audit, including third-parties/partners. There is no set frequency per VGVP, however, risk-based methodology may be applied to determine which parts of the PV system will be selected for audit, and the frequency. The process for risk-based planning shall be described and the rationale documented in the pharmacovigilance system master file.

Question: Can you comment on the use and compliance risks of external pharmacovigilance service providers for pharmacovigilance system set up and maintenance?

Answer: MAHs may use third parties, including for the set-up and ongoing conduct of pharmacovigilance systems. It is important for MAHs to understand that they will have the overall responsibility to ensure the PV system is compliant. Depending on the type and level of activities outsourced, the MAH should ensure they have sufficient measures in place to determine that the service provider is able to perform activities to an appropriate standard, and compliance is monitored. Activities the MAH may consider include pre-qualification checks, routine meetings between the MAH and vendor, metrics relating to key tasks, frequent risk-based audits by appropriately qualified and intendent auditors and having a system in place to implement CAPAs where deviations are identified. It is also important that a sufficiently detailed contract is in place with the vendor outlining roles and responsibilities, duty of all parties to comply with PV requirements, the right for the MAH (and their agents) to audit such vendors, orderly return of PV data and transition of activities following cessation of services. Note that the aforementioned examples are not exhaustive, and will be dependent on the type and level of activities outsourced.