SIDLEY

Explaining the Detailed Description of Pharmacovigilance System and Qualified Person for Pharmacovigilance (QPPV) From January 1, 2021 for the Veterinary Pharmaceutical Industry

The Veterinary Medicines Directorate (VMD) has published new guidance titled "From January 1, 2021 Pharmacovigilance System and Qualified Person for Pharmacovigilance explainer."

The new guidance covers the following matters:

- **Location of the Qualified Person for Pharmacovigilance (QPPV):**
  - **Centrally authorised Marketing Authorisations (MAs):** The QPPV must be located in the EU for these products to be on the Northern Ireland (NI) market. From January 1, 2021, for existing centralised MAs, you will be offered a GB MA for these products.
  - **GB MAs:** The QPPV can be located anywhere.
  - **MAs issued following mutual recognition/decentralised procedures:** These will continue to be issued by the VMD in respect of NI. The QPPV can be located in the EU, NI or GB, due to interpretation of the requirements of the Northern Ireland Protocol.
  - **UK national MAs (existing) and NI MAs:** The QPPV can be located in the EU, NI or GB for authorisations issued by the UK in respect of NI due to interpretation of the requirements of the Northern Ireland Protocol. The QPPV for GB MAs can be located anywhere.
- **Pharmacovigilance inspections:** From the January 1, 2021, the VMD will carry out inspections of all marketing authorisation holders (MAHs) for products authorised in the UK; this includes those MAHs located outside the UK
  - The VMD will use a risk-based approach to scheduling inspections; risk basis considerations will include last EU inspection date, previous inspection findings, and surveillance intelligence.
  - Inspections will be conducted remotely where possible.
- **Detailed Description of Pharmacovigilance system:** The UK requirement for the Detailed Description of Pharmacovigilance System is under review; the VMD will provide more information as it becomes available.