Veterinary Info Day Q&A
Session 1 – Update on EU legislative framework for veterinary medicinal products

Question: Will the labelling of veterinary medicinal products have to be in Irish?

Answer: Regulation 2019/6 provides that the labelling shall be in an official language of the Member State. In the case of Ireland, both Irish and English languages are official languages.

Question: Will veterinary prescriptions also be in Irish?

Answer: The HPRA is not the competent authority for deciding the language requirement of a veterinary prescription. The question should be addressed to the Veterinary Medicines Section, Department of Agriculture, Food and the Marine (DAFM).

Question: For how long will veterinary prescriptions be valid?

Answer: The HPRA is not the competent authority for deciding the duration of validity of a veterinary prescription. Regulation 2019/6 specifies that a prescription for an antimicrobial medicinal product shall be valid for five days from the date of issue. For products containing other substances, the question should be addressed to the Veterinary Medicines Section, DAFM.

Question: What will happen antiparasitics that were labelled 'LM/ Licensed Merchant' supply after 28 January 2022?

Answer: The HPRA has taken care to provide marketing authorisation holders with adequate notice to allow them to plan for the change of labelling to ensure market compliance in January 2022 and to avoid large quantities of product in old livery being on the market at that time. The HPRA believes that only very small quantities of LM product should remain in retailers; however, the DAFM is the regulator with responsibility for the wholesale and retail chain and the not the HPRA and it will be for them to decide an appropriate course of action should large quantities of LM labelled product remain on the market as of 28 January 2022.

Question: If a generic product is approved after 2005 but before 2022, can it be submitted without an environmental risk assessment, or is it the originator that must be approved after 2022?

Answer: Article 18(7) of Regulation 2019/6 states that "*A competent authority or the Agency, as applicable, may require the applicant to provide safety data concerning the potential risks posed by the generic veterinary medicinal product to the environment where the marketing authorisation for the reference veterinary medicinal product was granted before 1 October 2005.*" This means that a generic product citing a reference product authorised after 1 October 2005 will not be required

to provide an environmental risk assessment. Note that the CVMP is in the process of drafting a reflection paper which aims to provide an approach to applying Article 18(7). A draft of that reflection paper has been published for public consultation and can be accessed here.

Question: Why is the Veterinary Practitioner Only (VPO) category being abolished?

Answer: The strictest form of control for supply of veterinary medicinal products allowed in Regulation 2019/6 is that the medicines shall be subject to veterinary prescription. This is the same for centralised veterinary medicinal products currently, so it is important that the national and centralised systems are consistent. This requirement does not preclude that the products shall only be administered by a veterinary practitioner; just that the VPO legal category shall cease to exist. In accordance with Article 34(1) Regulation 2019/6, most categories of veterinary medicinal products **shall** be classified as subject to veterinary prescription, including veterinary medicinal products containing narcotics or psychotropic substances, antibiotics, drugs for euthanasia etc. In accordance with Article 2(9) of Regulation 2019/6, narcotic and psychotropic substances may continue to be further restricted nationally e.g. under the Misuse of Drugs legislation, in addition to the requirements of the Regulation.