Borderline veterinary medicinal products

Currently, it can be difficult to distinguish between some veterinary medicines, feed additives, biocidal products and other products that may be used in/on animals or in the animal's food or environment. The definition of a veterinary medicinal product is very broad (Article 4.1 of Regulation (EC) No 2019/6) and includes any product that is presented for the purpose of treating or preventing disease in animals. In accordance with Article 3 of Regulation (EC) No 2019/6, where a product also falls within the scope of Regulation (EC) No 1831/2003 (feed additive), or Regulation (EU) No 528/2012 (biocidal products), the primacy of the veterinary medicinal products legislation 'shall prevail'.

In general terms, products that are administered orally to animals for long periods of time for nutritional purposes and do not make medicinal claims are not regarded as veterinary medicinal products. Similarly products which are applied to the animal's environment (rather than to the animal directly) and intended to control germs in that environment are generally regulated as biocides. However, sometimes it can be difficult to distinguish whether a product is medicinal or not. In accordance with the provisions in national legislation (Regulation 3.3 (a)(i) of S.I. No. 786 of 2007) the HPRA is the competent authority for determining what is / is not an animal remedy. The HPRA has a guide to inform applicants how this system operates.

With the application of the New Veterinary Regulation (NVR)(Regulation (EU) No 2019/6), the regulatory framework governing these products will change. From 28 January 2022, new national legislation is expected to be introduced by the Department of Agriculture, Food and the Marine to regulate the supply of borderline products in Ireland.

In accordance with the NVR, which itself applies from 28 January 2022, an EU coordination committee of Member States has been mandated to provide recommendations on whether a specific veterinary product or class of products is to be considered a veterinary medicinal product within the meaning of the regulation. The net effect of this provision is that the decision to exempt a specific product (i.e. to decide that they do not require a marketing authorisation under the NVR) may no longer be taken by a Member State exclusively, and the status of any exempted product can be changed at the behest of the European Union.

In order to ensure that the market is regulated in compliance with the EU requirements, the HPRA is advocating with the Department of Agriculture, Food and Food (DAFM) for a new national registration system for borderline products, in compliance with the requirements of the NVR. In practical terms, the aim of such legislation would be to establish a new regulatory framework for classification of borderline products and their subsequent compliance on the market. In order to be regarded as a non-medicinal product, an applicant would be required to:

a. Ensure that the substances contained in the product are neither pharmacologically active at the dosages used, nor of toxicological concern for the target animal, the user, consumers or the environment.
b. Ensure that the labelling of the products concerned do not make medicinal claims.
c. Ensure that the presentation and labelling of the product would not mislead the average purchaser that they are veterinary medicinal products.

The HPRA has been designated competent authority for deciding whether or not a product falls within the definition of a veterinary medicinal product or not currently. The HPRA expects that we will continue to have this role in the future, but awaits confirmation of this status in new national legislation. The HPRA believes that any new national regulatory framework for such products must ensure that there is a track and trace system for individual products to ensure ongoing compliance

with the registration, and which would allow the decision in respect of the product to be revisited if/when the EU decides necessary.

The HPRA also believes that the labelling and basis of any exempted products are available for public scrutiny (e.g. by requiring their publication on the HPRA website). The HPRA believes that such transparency would also facilitate compliance monitoring on the ground by DAFM personnel.

Once the new national legislation has been developed and published by DAFM, the HPRA will update the position on this site. The new national legislation is expected to be available before the end of 2021.

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