United Kingdom Public Assessment Reports (UKPARs)

Large Animal Diprevon Solution for Injection

This product was authorised via an application route known as Informed Consent.

This means that, instead of providing new data, the applicant referred to data which the VMD has assessed previously in connection with another product. Applicants may do this when a product contains the same amount of the same active ingredient, and has the same pharmaceutical form (i.e. tablet, injection, etc) as a product already authorised, provided the authorisation holder gives consent in writing. In some cases, the second product is identical to the first in all respects except for its name. In this case it is described in the UK as a “copycat”.

There is generally no scientific discussion for an informed consent application as no data will normally have been submitted. If the first product was authorised after the end of October 2005, the scientific discussion prepared for it can be accessed via its entry in the product list and this will be applicable to the new product. If, however, the first product was authorised before the end of October 2005, there will be no scientific discussion as there was no requirement for one at that time.

Summaries of Product Characteristics for both the copycat and parent products are available on the VMD website.

POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

(www.gov.uk/check-animal-medicine-licensed)

The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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