United Kingdom Public Assessment Reports (UKPARs)

Cefenil 50mg/ml Powder and Solvent for Solution for Injection for Cattle and Pigs

This product has been authorised via the Decentralised procedure or via the Mutual Recognition Procedure (MRP). It is expected that a Public Assessment Report (PuAR) for this product will be available on the Heads of Medicines Agencies (HMA(v)) website by approximately 3 months from its date of authorisation.

HMA(v) represents the veterinary regulatory agencies of the EU.

There is a section in the HMA(v) website called 'VMRI': Veterinary Mutual Recognition Index. This contains a list of the veterinary medicinal products approved via the Decentralised Procedure or via the MRP.

To go to the PuAR for this veterinary product, click on the link to the HMA(v) website then click on VMRI. Whilst there are various ways to search for a product, clicking on 'ABC' and then finding the product alphabetically is probably the easiest.

In this list, the first column gives the Reference Member State, i.e. the Member State who first evaluated the product. If it says UK, the assessment report was written by the Veterinary Medicines Directorate. If it gives another Member State, the assessment report was written by the regulatory agency of that Member State.

As the EU legislation requiring a PAR came into force on 30 October 2005, it only applies to products authorised on or after 30 October 2005 (i.e. granted a Marketing Authorisation on or after 30 October 2005). As the Scientific Discussion (the largest part of the PuAR) has to be specially written for the PuAR, this document may not be available for products authorised before 30 October 2005.

Link to HMA(v) 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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