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UK to update parallel import guidance in summer

POLICY & REGULATION

BY DR TAMSIN DAWSON

The UK aims to update guidance regarding marketing authorisations for parallel imports (MAPIs) of veterinary products.

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At the recent Veterinary Medicines Directorate (VMD) Biologicals Information Day, the organisation's Rory Cooney said revised guidance should be published later this summer. The amendments will clarify requirements for biologicals and lessons learned from recent applications.

A MAPI is required when a veterinary medicinal product is authorised in the UK and an identical (for food-producing species) or therapeutically the same (non-food producing species) product is authorised in another EU member state, and bought from wholesalers in that member state and imported into the UK for distribution. For biologicals, the interpretation of 'identical' means the 'parent' UK product would have to be mutually recognised.

The data and documents required in support of an applicant are listed on the MAPI application form. The applicant must list all member states from which the MAPI product is to be imported from – further member states can be added at a later date by variation.

Eligibility for MAPI relies on the product being authorised in accordance with directive 2001/82/EC, as amended in the member states it is to be imported from.

The applicant must be established within the community and hold a UK Wholesale Dealer's Authorisation and a Manufacturer's Authorisation (or have contracts with companies that hold such authorisations). Refused applications are given the opportunity to appeal.

Pharmacovigilance – Detailed Description of the Pharmacovigilance System (DDPS), summary of product characteristics and packaging – and batch release requirements for the MAPI product are the same as for any veterinary medicinal product.

There is currently one veterinary MAPI authorised in the UK. However, the MAPI scheme is used widely in the human medicine field.

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