HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Veterinary parallel trade applications

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What is parallel trade?

- Parallel trade is the importation from an EU Member State (MS) or a country within the European Economic Area (EEA) of a veterinary medicinal product (VMP) which shares a 'common origin' with a VMP already authorised in another MS.
- Source MS = MS in which the VMP is sourced
- Destination MS = MS into which the VMP is imported

What is parallel trade?

- Parallel trade authorisations for nationally, decentralised, mutually recognised or subsequent recognition VMPs are managed by the destination MS. In IE, these procedures are managed by the HPRA.
- Parallel trade of centrally authorised products (CAPs) is managed by the EMA.

Changes to parallel trade applications

- Now enshrined in legislation under Article 102 of Regulation 2019/6
- Called **parallel trade**, rather than 'parallel import'
- For products to be parallel traded from more than one source country, **each source country** requires a **separate application** and will result in issue of a separate authorisation.
- The major change to the procedure is the requirement for **common origin** to be demonstrated
- In order for a wholesale distributor to parallel trade a veterinary medicinal product, a common origin must be shared between the VMP intended to be traded from the source Member State and the VMP already authorised in the destination Member State.

What is Common Origin? Article 102(1)

- The veterinary medicinal products are considered as sharing a common origin if they **fulfil all the following conditions:**

(a) they have the same qualitative and quantitative composition in terms of active substances and excipients;

(b) they have the same pharmaceutical form;

(c) they have the same clinical information and, if applicable, withdrawal period; *[note Article 35(1)(c)]* and

(d) they have been manufactured by the same manufacturer or by a manufacturer working under licence according to the same formulation.

Demonstrating common origin is the responsibility of the wholesaler distributor applying for the parallel trade authorisation

Parallel trade application

- There are a number of documents to be supplied in addition to the application form. These include:

✓ Evidence of shared common origin

✓ Declaration re pharmacovigilance issues

✓ Notifications to source and destination product MAHs and source MS competent authority

✓ Proposed SPC/PL/labels in English and mock-ups, including scans/photographs

✓ Relevant GMDP authorisations

Parallel trade guidance

- CMDv will shortly publish a Best Practice Guide for Parallel Trade on their website at https://www.hma.eu/veterinary-medicines/cmdv/implementation-of-the-vmp-regulation.html
- The HPRA veterinary parallel trade can be found at http://www.hpra.ie/homepage/veterinary/regulatory-information/medicines-authorisation/parallel-trade

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