HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Article 5(6) Regulation 2019/6 Manufacturing Requirements

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Webinar May 14th 2021

General Requirements

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- Classified as Veterinary Medicinal Products
- Medicines which qualify for supply to Irish market must be registered with the HPRA
- Medicines manufactured for export must comply with requirements in the intended market.
- Manufacturer's / Importer's Authorisation (MIA) issued by the HPRA:
  - Required for manufacture (in Ireland) or importation (from outside the EEA)
  - MIA uploaded to EU database (publicly accessible)
- Qualified Person required (Article 97 of Regulation 2019/6)
- Compliance with Good Manufacturing Practice (GMP) required

Importation of Veterinary Medicines

- MIA required for the following :
  - Site where batch certification by the QP takes place
  - Site of physical importation of the batch (if different to the above)

- Qualified Person (QP) must ensure that:
  - The imported batch has been manufactured in accordance with :
    - GMP
    - Terms of the Registration

Applying for an MIA

Documents available on the HPRA website

- Application Form for manufacturer's / importer's authorisation
- Guide to New Applications and Variations to Manufacturers Authorisations
- Guide to Fees for Veterinary Products
  - Application Fee for MIA
  - No MIA renewal
  - Variation Fees for MIA (2 categories – administrative and technical)
  - Annual maintenance fee

Inspections

- GMP inspections of manufacturers & importers by the HPRA
- Initial and ongoing inspections according to HPRA risk based inspection programme
- Inspection fees apply (see Guide to Fees)
- Inspect for compliance with EU GMP - Part I (see EudraLex Vol 4)
- Arising from Regulation 2019/6 there will be a future Implementing Act on GMP (coming into force in 2025)
- GMP certificates issued on EudraGMDP database if the inspection outcome is acceptable.

Wholesalers of Veterinary Medicinal Products

- Regulated by Dept. of Agriculture Food and the Marine (DAFM)
- Inspection and authorisation by DAFM
- Wholesale Distribution Authorisation uploaded to EU database (publicly accessible)
- Commission Implementing Regulation on GDP for Veterinary Medicinal Products.
  - Public consultation period 12th May – 9th June 2021
  - Planned Adoption Q4 2021
  - Coming into force 20 days after publication in the Official Journal of the EU

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Thank you

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