HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Veterinary Regulation 2019/6
GMP & GDP Topics

Paul Sexton

GMP Policy Manager

Webinar March 31st 2021

GMP & GDP Topics

Outline of Significant Changes

- Registration requirements for manufacturers, importers and distributors of active substances
- GMP Guidance for active substances
- GDP Guidance for active substances
- GMP for Veterinary Medicinal Products
- Wholesaling of Veterinary Medicines (regulated by DAFM)

Registration Requirement (1)

- Registration of Irish manufacturers, importers and distributors of active substances with the HPRA and information will be uploaded to the EU database (publicly accessible)

- Anticipate similar registration process to that already in place in relation to active substances for use in human medicines.

- Annual Update to Registration details required or Immediate update if quality or safety impacted.

- Obligation to only source from registered manufacturers importers and distributors operating, when these activities are taking place within the EEA.

Registration Requirement (2)

- Manufacturers of veterinary medicines in Ireland which import active substances will have to register with the HPRA.

- Distribution includes activities such as:
  - Procurement (purchase) of active substance within the EEA
  - Holding (storage) of active substances
  - Supply (selling) of active substances within the EEA
  - Export (sale or physical supply) of active substances outside the EEA

GMP Guidance for Active Substances

- Part II of the EU GMP Guide includes manufacture of active substances for use in veterinary medicines within its scope.
- Future Implementing Act on GMP for active substances.
- HPRA will conduct inspections of manufacturers against the Implementing Act on GMP for active substances.
- Plan to conduct initial and ongoing inspections of manufacturers of active substances in Ireland in accordance with the HPRA risk based inspection programme.

GDP Guidance for Active Substances (1)

- Implementing Act on GDP for active substances used as starting materials in veterinary medicinal products will come into force in January 2022.
- Similar principles to the existing GDP guidelines for active substances for medicinal products for human use.
- HPRA will conduct inspections of importers and distributors against the Implementing Act on GDP for active substances.
- Plan to conduct initial and ongoing inspections of importers and distributors in accordance with the HPRA risk based inspection programme.

GDP Guidance for Active Substances (2)

- Further Reading – (EMA website)

Advice on implementing measures under Article 95(8) of Regulation (EU) 2019/6 on veterinary medicinal products - Good distribution practices (GDP) for active substances used as starting materials in veterinary medicinal products

https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/advice-implementing-measures-under-article-958-regulation-eu-2019/6-veterinary-medicinal-products-good-distribution-practices-gdp-active-substances-used-starting_en.pdf

GMP for Veterinary Medicinal Products (1)

- Map supply chain for active substances

- Manufacturers of veterinary medicines must use active substances which have been manufactured in accordance with GMP (existing requirement) and distributed in accordance with GDP (future requirement under the Regulation).

- Manufacturers of veterinary medicines will be obliged to perform risk based audits of manufacturers, importers and distributors in the supply chain for active substances.

GMP for Veterinary Medicinal Products (2)

- Currently same general GMP Guidance for Human and Veterinary Medicines (Part I of the GMP Guide)

- Revisions proposed to specific Annexes addressing veterinary topics
  - Annex 4 Manufacture of Veterinary Medicinal Products other than Immunological Veterinary Medicinal Products
  - Annex 5 Manufacture of Immunological Veterinary Medicinal Products
  - Revision of Annexes 4 & 5 will be joint initiative between EMA and PIC/S

GMP for Veterinary Medicinal Products (3)

- New GMP Guidance planned
  - Autogenous Vaccines (based on CMDv Paper)

    https://www.hma.eu/fileadmin/dateien/Veterinary_medicines/CMDv_Website/Procedural_guidance/Miscellaneous/Recommendations_manufacture_control_use_inact_autogenous_vaccines.pdf

    Autogenous vaccines - IABS Meeting | Autogenous Vaccines: Quality of Production and Movement in a Common Market - Munich – Germany 14-16 Sept 2021
  - Novel Therapies for veterinary use

- Regulation requires implementation of new GMP Guidelines in 2025 for legal reasons. Continued alignment of the general GMP requirements for Human and Veterinary medicines is foreseen.

Wholesalers of Veterinary Medicinal Products

- Regulated by DAFM (as currently)
- Inspection and authorisation by DAFM
- Wholesale Distribution Authorisation & GDP Certificate uploaded to EU database (publicly accessible)
- Implementing Act on GDP for Veterinary Medicinal Products to come into force in January 2022.
- Largely based on existing GDP guidelines for human medicines

HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

www.hpra.ie

Thank you

Follow **@TheHPRA**

newvetreg@hpra.ie