



HPRA webinar on registration requirements for veterinary medicines for pets that qualify for registration under Article 5(6) of Regulation 2019/6

Introduction

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Why are we here?

- Legislation is changing:
 - Regulation 2019/6, Article 5(6) allows Member States to grant exemptions from requirement for a marketing authorisation
 - Regulation applies from 28 January 2022; after that time no new product can be brought to the market without either a MA, or HPRA exemption
 - Under Article 152, existing MAs and registrations may continue to be made available until 29 January 2027. However, HPRA has never had a national registration system for such medicines under existing legislation
 - New national legislation will provide for a registration system from 2022



Regulation 2019/6, qualifying products

- Must be registered by the HPRA as meeting certain criteria specified in the NVR,
- Are subject to pharmacovigilance obligations,
- Must be manufactured according to GMP,
- Are subject to advertising controls,
- Are subject to controls by competent authorities, including inspections,
- Are subject to prohibition on supply and recall of batches.



Current position of these products nationally

- Relevant products containing antibiotics, or other active substances that are subject to veterinary prescription must have a marketing authorisation
- Relevant products that do not contain active substances that are subject to veterinary prescription have been exempted from Directive 2001/82/EC and national legislation
- Relevant product details must be entered into Union Product Database by 28 January 2024 (Regulation 2021/16)



Qualifying products 1

- Intended for:
 - Aquarium or pond animals, ornamental fish (including only fish kept in closed water systems),
 - cage birds (e.g birds kept in cages or aviaries),
 - homing pigeons,
 - terrarium animals (reptiles, amphibians and arthropods kept in tanks and cages – including animals free-living in domestic gardens),
 - small rodents (domestic mammals of the order rodentia),
 - ferrets and rabbits
- **Intended only for non-food producing animals**



Qualifying products 2

- Must **not** contain medicines that are subject to veterinary prescription (e.g. antibiotics, steroids, NSAIDs, sedatives, anaesthetics, etc.)
- Must **not** contain immunologicals
- Must contain known substances (i.e. **not** novel substances, stem cells etc.)
- Administered only by oral or topical routes [not for ocular use] (other routes of administration require either veterinary expertise to administer or are only used following a veterinary diagnosis).



Thank you
