HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

# Complementary national legislation

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## Background

- The future of S.I. No 786 of 2007
- Certain provisions of Regulation are ‘may’ provisions
- Focus on changes where the HPRA is competent authority

# Future of SI No 786 of 2007

- HPRA is engaged in discussions with DAFM:
  - As part of DAFM's public consultation, launched in June 2020
  - In respect of particular provisions e.g.
    - Language, identification code, electronic leaflets, legal classification of medicines, collection of sales and use data for antimicrobials etc.
  - In respect of elaboration of delegated and implementing acts
  - In respect of the future UPD system and link to e-prescribing
- Discussions ongoing, new SI expected towards end of year

## HPRA activities expected to remain largely as is

- Borderline product classification
- Clinical trials on veterinary medicines
- Homeopathic registrations
- HPRA role in collection of sales data on antimicrobials for ESVAC

## New HPRA activities or activities expected to change significantly

- Process of registration of certain veterinary medicines for exotic pets under Article 5(6)
- No PSURs
- No Renewal applications
- VNRA
- System of authorisation of parallel imports

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# Thank you

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