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Health Products Regulatory Authority

The new Veterinary Medicines Regulation – SPC and Labelling

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Presentation outline

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- What changes are required to my SPC and Labelling texts?
- When do I have to implement these changes for existing VMPs?
- How will Regulation (EU) 2019/6 impact my joint labels with the UK?

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What changes are required to my SPC and Labelling texts?

Summary of Product Characteristics

Section 2 Qualitative and Quantitative Composition	New tabular format for excipients
Section 3.6 (previously 4.6) on adverse events	Drafted by PhVWP
Section 3.9 Administration route (s) and dosage	New standard sentences for correct administration of products (correct dosage calculations). Reference to the inclusion of drawings and pictures to aid administration.
Section 3.11 Special restrictions for use and Special conditions for use	To include any restrictions or conditions arising from Articles 106, 107, in particular 107(6), and 110 and from DAs and IAs related
Section 9 Date of last revision of SPC	New standard phrases required by the Regulation for VMPs authorised under limited markets or exceptional circumstances
Sections 5.5 and 10 Disposal and waste	Take-back schemes for disposal, instructions for handling Additional requirements of MS can also be included.
Section 11 Classification of VMPs	New section on high-level classification of the VMP i.e. prescription or non-prescription

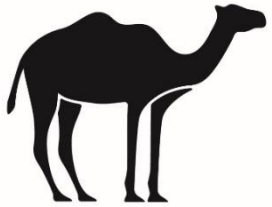
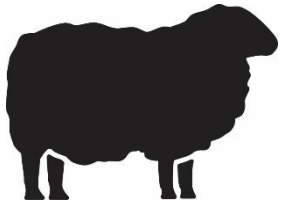
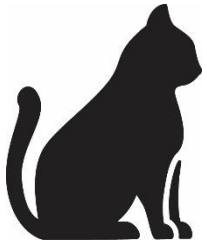
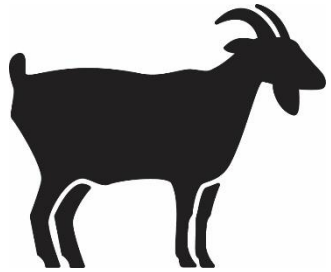
Labelling
Separate templates for immediate and outer labelling

Outer labelling (Article 11)	• Warnings to 'keep out of sight and reach of children' and 'for animal treatment only' but no other warnings • Indications for non-prescription medicines only • Name/company name/logo MAH only • Standardised terms for Expiry Date and Batch Number • New stand-alone heading for "Read the package leaflet before use"
Small immediate packaging (Article 12)	• There will be an **Implementing Act** (Article 17(3)) on size of packaging units for which this template can be used ○ Blisters and strips will need to be included within this Implementing Act

Labelling - Immediate labelling (Article 10)

Package Leaflet – Article 14

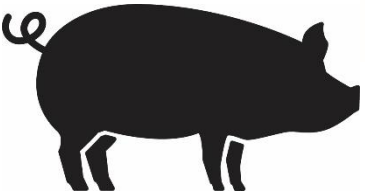
- Local representatives are listed primarily for the reporting of suspected adverse events
- Provisions of Article 14 (2) can appear at the bottom of the package leaflet (former ‘blue-box’)
- Package Leaflet may be made available on paper or electronically, or both

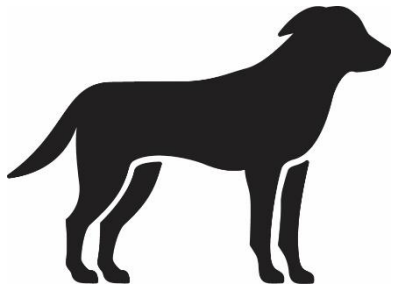
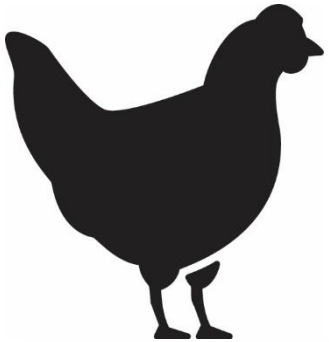
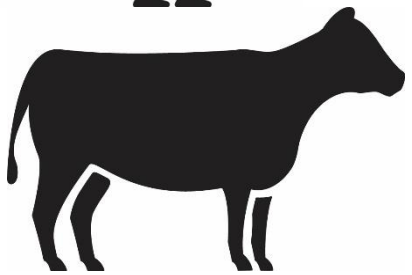
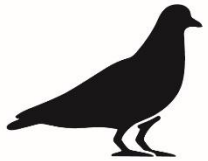





Implementing Act

Article 17 (2)

- *The information mentioned on the immediate and outer packaging shall appear in easily legible and clearly comprehensible characters, or in **abbreviations or pictograms** common throughout the Union – Adoption 2024.*



Article 13 – "Additional useful information"

"By way of derogation from Articles 10(1), 11(1) and 12(1), Member States may, within their territory, and ***on request of the applicant****, allow an applicant to include on the immediate packaging or outer packaging of a veterinary medicinal product additional useful information which is compatible with the summary of the product characteristics and which is not an advertisement for a veterinary medicinal product".*

Work to commence @ CMDv in June 2021

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When do I have to implement these changes for existing VMPs?

Management of Transition between 2001/82/EC and Regulation (EU) 2019/6

2022 2023 2024 2025 2026 2027

Article 152.2

*"Veterinary medicinal products placed on the market in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may continue to be made available until **29 January 2027**, even if they are not in compliance with this Regulation".*

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How will Regulation (EU) 2019/6 impact my joint labels with the UK?

Future of joint-labelling

- The HPRA will continue to support joint labelling with the UK subject to the UK and EU operating an equivalent regulatory framework and opinions align.

- Products that were joint-labelled prior to 28th January 2022 will remain joint-labelled once the product information is identical in both the UK and IE.

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Thank you

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