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Transitioning existing MAs to meet the requirements of Regulation 2019/6

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HPRA webinar – Update on the implementation of Regulation 2019/6 in Ireland

19th May 2022

Presentation outline

- SPC/labelling format (QRD template)
- CVMP Q&A on describing adverse events
- Classification of VMPs (Article 34)
- Requirements for antimicrobials (Article 107)

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SPC/labelling format (QRD template)

What are the timelines for QRD v.9 updates for existing MAs?

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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".*

European Commission

Statement of DG SANTE on Article 152(2) of Regulation 2019/6 on veterinary medicinal products

UPDATE: On 2 March 2022, the Commission adopted the legislative proposal for a legal act, referred to in the statement above

What is the process for updating to QRD v.9?

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CMDv
Coordination Group for Mutual Recognition and Decentralised Procedures for Veterinary Medicinal Products

Amsterdam, 18 March 2022
EMA/CMDv/181154/2021, Rev.1

Transitional arrangements for the entry into application of Regulation (EU) 2019/6 for veterinary medicinal products registered under national, mutual recognition and decentralised procedures
Update March 2022

The variation code G.I.18 and a timetable of 60 days are foreseen. The timing of submission should ensure that the variation is finalised and implemented on the printed labelling and package leaflet before 27 January 2027.

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CVMP Q&A on describing adverse events

QRD v.9 SPC – Section 3.6 Adverse events

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3.6 Adverse events

[Adverse events should be coded using VeDDRA standard terms (preferably VeDDRA low level terms (LLTs)) and ranked in "frequency categories" with the most frequently occurring clinical signs listed first. In each frequency category, clinical signs should be grouped in accordance with VeDDRA system organ classes (SOC). NB. Where there may not be an appropriate VeDDRA LLT, a request for a new LLT can be made to the VeDDRA subgroup]

{Target species:}*[the relevant single or multiple target species to be specified]*
[Adverse events should be presented in a tabular form for each target species. Adverse events related to several target species may be merged into a single table if they are strictly the same or when there are a few adverse events which have a different frequency, which can be annotated in a footnote immediately below the table. Tabular rows should be deleted if there are no adverse events in that frequency category. Tables can be omitted from the package leaflet, however the information contained, and structure should be maintained].

Very common (>1 animal / 10 animals treated):	{adverse event/VeDDRA LLT (relevant additional information*, adverse event/VeDDRA LLT (relevant additional information*) etc.}
Common (1 to 10 animals / 100 animals treated):	{adverse event/VeDDRA LLT (relevant additional information*), adverse event/VeDDRA LLT (relevant additional information*) etc.}
Uncommon (1 to 10~~100~~ animals / 1,000~~10,000~~ animals treated):	{adverse event/VeDDRA LLT (relevant additional information*), adverse event/VeDDRA LLT (relevant additional information*) etc.}
Rare (1 to 10 animals / 10,000 animals treated):	{adverse event/VeDDRA LLT (relevant additional information*), adverse event/VeDDRA LLT (relevant additional information*) etc.}
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	{adverse event/VeDDRA LLT (relevant additional information*), adverse event/VeDDRA LLT (relevant additional information*) etc.}

*[*Additional information should preferably be detailed in a footnote immediately under the table and should comprise information necessary for supporting adverse event management (i.e. administration of an antidote, removing of a collar, washing of an application site…). Where relevant, information on the expected severity, duration and outcome of the clinical signs that may result following administration of the veterinary medicinal product can be described (e.g. lameness, 1-3 weeks following booster vaccination, vomiting and/or diarrhoea, generally lasting 2 days, etc).*
Where relevant, information on different frequencies of adverse events reported depending on indication and dosing can be specified (e.g. vomiting is reportedly rare when given at 10mg/kg dose). If a footnote is

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25 March 2022
EMA/CVMP/150343/2016-Rev.1
Committee for Veterinary Medicinal Products (CVMP)

Questions and answers on describing adverse events in the product information (summary of product characteristics (SPC) and package leaflet (PL)).

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Classification of VMPs (Article 34)

QRD v.9 SPC - Section 10 Classification of VMPs

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10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

[Prescription status, as referred to in Article 34 of Regulation (EU) 2019/6, from the options below, for each Member State in which it is authorised. Any national sub-categories may be included in the separate boxed area at the end of the package leaflet.]

[NB Special conditions for use according to Article 106(4) e.g. 'For administration only by a veterinarian' to be included in SPC section 3.11 above.]

<Veterinary medicinal product subject to prescription.>
<Veterinary medicinal product not subject to prescription.>
<Veterinary medicinal product subject to prescription except for some pack sizes.>

Detailed information on this veterinary medicinal product is available in the Union Product Database.

Article 34 – Classification of VMPs

- CVMP guidance is under development.
- Article 33(1)(b) of Regulation (EU) 2019/6 specifies that the outcome of a competent authority's assessment on an initial marketing authorisation application **shall include the classification of a VMP** in accordance with Article 34.
- Objective of the guidance under development is to provide clear assessment principles for the various provisions of Article 34 and enable a consistent decision-making process, both for **initial marketing authorisation applications** and **variations to change the legal status** of a VMP.
- Implications for existing marketing authorisations?????

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25 March 2022
EMA/CVMP/65618/2022
Committee for Veterinary Medicinal Products (CVMP)

Concept paper on the elaboration of guidance for the application of Article 34 of Regulation (EU) 2019/6

Agreed by CVMP Drafting Group on Article 34 of Regulation (EU) 2019/6	March 2022
Adopted by CVMP for release for consultation	16 March 2022
Start of public consultation	25 March 2022
End of consultation (deadline for comments)	30 April 2022

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Requirements for antimicrobials (Article 107)

Article 107(3) - Requirements for antimicrobials

3. Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

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28 January 2022
EMA/CVMP/AWP/387275/2020
Committee for Veterinary Medicinal Product (CVMP)

Reflection paper on prophylactic use of antimicrobials in animals in the context of Article 107(3) of Regulation (EU) 2019/6

Draft

Draft agreed by AWP and EWP	24 November 2021
Adopted by CVMP for release for consultation	19 January 2022
Start of public consultation	28 January 2022
End of consultation (deadline for comments)	29 April 2022

Article 107(3) - Requirements for antimicrobials

- Review indications for existing AM products and determine the approach to ensuring that they are aligned with the Reflection Paper
- No formal transitional period to comply with Article 107(3), i.e. understood to fall outside the foreseen 5-year transitional period for revision of product information.
- Low number of impacted centralised products (<10), but substantial numbers of products authorised at a national level.
- For centrally authorised products,
  - EMA intending to proactively contact affected MAHs to outline the proposed approach.
  - MAHs will be asked to take regulatory action on this before end of 2022, i.e. within a variation application.
  - Intended liaison with CMDv for a consistent approach.
- For products authorised nationally, further discussion required.

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Thank you

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