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Veterinary Medicines Division

QRD veterinary v.9.1 – Implementation plan

The following implementation plan is proposed after the release of an updated product information template QRD version 9.1 for veterinary medicinal products (VMPs):

VMPs with product information in QRD v.8.2

Marketing authorisation holders (MAHs) should use the new v.9.1 when they submit the VRA G.I.18 (v.9.0 can be used for G.I.18s for a transitional period of 3 months once v.9.1 is published).

If the products are affected by Regulation (EU) 2024/1159[1] and the MAH intends to integrate the additional statements in section 3.9 and 5.1 of the SPC and the corresponding section of the package leaflet during the VRA G.I.18, this can only be accepted if no new or additional data is required for assessment. Should the change involve the submission of new/additional quality-related data, MAHs should submit a dedicated VRA (can be grouped with the VRA G.I.18).

Initial marketing authorisation applications currently under assessment which started with QRD v.9.0

The applicant can switch to v.9.1 during the procedure if the revised product information using the new version of the template can be submitted with the responses to the D120 LoQ or with the responses to the D180 LoOI.

VMPs with product information already aligned with v.9.0 through a VRA G.I.18

There is no deadline for MAHs to align the product information of these VMPs with QRD v.9.1.

When they are aligned, this can be done with any VRA that affects the product information, if no new or additional data is required for an assessment. If the change implies the submission of new/additional quality-related data, a dedicated VRA should be used.

[1] Commission Delegated Regulation (EU) 2024/1159 of 7 February 2024 supplementing Regulation (EU) 2019/6 of the European Parliament and of the Council by laying down rules on appropriate measures to ensure the effective and safe use of veterinary medicinal products authorised and prescribed for oral administration via routes other than medicated feed and administered by the animal keeper to food-producing animals - link

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NB. For products whose product information is under v.9.0 and which are affected by Regulation (EU) 2024/1159, Regulation (EU) 2024/875[2], or Regulation (EU) 2024/878[3], the transitional deadlines laid down in the respective legal acts apply:

- 9 May 2029 for the Delegated Regulation for oral administration,
- 11 April 2029 for the Implementing Regulation on abbreviations and pictograms,
- 11 April 2031 for the Implementing Regulation on the small immediate packaging.

Changes can be implemented through the dedicated VNRA categories and in line with the guidance and standard sentences included in QRD v.9.1.

[2] Commission Implementing Regulation (EU) 2024/875 of 21 March 2024 adopting a list of abbreviations and pictograms common throughout the Union to be used on the packaging of veterinary medicinal products for the purposes of Article 10(2) and Article 11(3) of Regulation (EU) 2019/6 of the European Parliament and of the Council - link
[3] Commission Implementing Regulation (EU) 2024/878 of 21 March 2024 adopting uniform rules on the size of small immediate packaging units of veterinary medicinal products as referred to in Article 12 of Regulation (EU) 2019/6 of the European Parliament and of the Council - link