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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
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Comments should be provided using this template. The completed comments form should be sent to Vet-guidelines@ema.europa.eu

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1. Introduction

Article 33(1)(b) of Regulation (EU) 2019/6 specifies that in case of a favourable assessment, the outcome of a competent authority's assessment on an initial marketing authorisation application shall include the classification of a veterinary medicinal product in accordance with Article 34.

Article 34 of Regulation (EU) 2019/6 sets out criteria according to which veterinary medicinal products shall be subject to a veterinary prescription. The article is structured in three paragraphs:

- In paragraph 1, the eight categories (a-h) of veterinary medicinal products that shall be classified as subject to veterinary prescription by the competent authority or the Commission, as applicable, are listed.
- Paragraph 2 provides discretion to competent authorities to, notwithstanding paragraph 1, classify a veterinary medicinal product as subject to veterinary prescription if it is classified as a narcotic drug in accordance with national law or where special precautions are contained in the summary of product characteristics referred to in Article 35 of Regulation (EU) 2019/6.
- Finally, paragraph 3, by way of derogation from paragraph 1, lists the seven, cumulative conditions (also known as 'exemption criteria') (a-g) to be fulfilled for a veterinary medicinal product falling within the scope of paragraph 1 before it may be classified as not subject to veterinary prescription, noting the exception for veterinary medicinal products referred to in points (a), (c), (e) and (h) of paragraph 1 which may never be classified as not subject to veterinary prescription.

Consideration of whether a product is subject to veterinary prescription or not is an important component of product assessment that merits detailed consideration. Any application of Article 34 to veterinary medicinal products authorised in accordance with Directive 2001/82/EC or Regulation (EC) No 726/2004 may have the potential to result in the reclassification of their prescription status in some cases.

2. Problem statement

While some of the provisions in Article 34 for the classification of veterinary medicinal products are clear-cut ones, some others require further elaboration. The HMA Task Force on Coordination of the Implementation of the Veterinary Regulation (TFCIVR) discussed this article in their July 2021 meeting, and concluded that guidance was needed to ensure a harmonised EU approach to classification of veterinary medicinal products. This was subsequently discussed by the Vet Domain and CVMP and it was confirmed that the CVMP would develop guidance for the application of Article 34 of Regulation (EU) 2019/6. The development of this guidance is captured as an activity in the CVMP 2022 work plan[1].

The guidance should provide clear assessment principles for the various provisions of Article 34 and so enable a consistent decision-making process, both for initial marketing authorisation applications and variations to change the legal status of a veterinary medicinal product.

3. Discussion (on the problem statement)

Preliminary discussions have identified the following points where guidance on how to apply the provisions is needed, or where it is necessary to elaborate more detailed scientific criteria to ensure a clear and consistent implementation of Article 34:

[1] CVMP work plan 2022 (link)

1. Article 34(1)(d), which refers to "veterinary medicinal products intended for treatments of pathological processes which require a precise prior diagnosis or the use of which may have effects which impede or interfere with subsequent diagnostic or therapeutic measures".

2. Article 34(2) provides discretion to competent authorities to classify a veterinary medicinal product as subject to veterinary prescription "where special precautions are contained in the summary of product characteristics referred to in Article 35 of Regulation (EU) 2019/6". Guidance is needed on what type of "special precautions" contained in the summary of product characteristics are relevant to be taken into account in this respect.

3. Article 34(3)(a) refers to "pharmaceutical forms requiring no particular knowledge or skill in using the products". Although it is generally accepted that pharmaceutical forms requiring particular knowledge or skill include those administered by subcutaneous, intramuscular or intravenous routes, or those for which the use of a specialised administration device is needed, it would be beneficial to have further clarification on this.

4. Article 34(3)(b) refers to "direct or indirect risk (…) to the animal or animals treated or to other animals, to the person administering it or to the environment". A common understanding of what is meant by "direct or indirect risk" in the context of Article 34(3)(b) would be beneficial.

5. Article 34(3)(c) refers to "any warnings of potential serious adverse events deriving from its correct use". Guidance in defining a "potential serious adverse event" would help to ensure a clear and a consistent implementation of this provision, particularly since, in contrast to the previous veterinary legislation, there is no longer a legal definition of "serious adverse event".

6. Article 34(3)(d) refers to "frequent adverse event reporting". Agreement on what is meant by "frequent" would be beneficial since it does not directly correlate to the five frequency categories defined in the product information QRD template v.9. Furthermore, it is unclear if all adverse events, regardless of severity, are intended to be considered under this criterion.

7. Article 34(3)(e) refers to "veterinary medicinal products commonly used without prescription". It would be beneficial to have guidance on the types of product that should be considered as commonly used without prescription.

8. Article 34(3)(f) reads as follows: "there is no risk for public health as regards residues in food obtained from treated animals even where the veterinary medicinal product is used incorrectly". Agreement on what is meant by "no risk to public health" in this context is needed for consistent implementation of this provision.

9. Finally, Article 34(3)(g) makes reference to "risk (…) as regards the development of resistance". Cross-reference to other scientific guidance already available in this matter may be beneficial to ensure a consistent implementation.

4. Recommendation

The CVMP recommends drafting guidance taking into account the issues identified above with the aim to ensure a consistent implementation and a harmonised EU approach in implementing Article 34 both for initial marketing authorisation applications and variations to change the legal status of a veterinary medicinal product.

5. Proposed timetable

The availability of guidance on the application of Article 34 of Regulation (EU) 2019/6 is urgently needed as the Regulation became effective on 28 January 2022 and Article 34 needs to be applied for

applications received from this date. In the view of the CVMP, the guidance should become available as soon as possible, and preferably by the end of 2022.

The aim is to release the draft guidance for consultation following the July 2022 CVMP meeting and to finalise it in December 2022.

6. Resource requirements for preparation

The guidance will involve a CVMP Drafting Group, the EMA secretariat and the CVMP. The Drafting Group is composed of 9 members representing expertise from across the different scientific disciplines covered by the scope of Article 34 and includes one CMDv representative.

7. Impact assessment (anticipated)

The intended guidance will provide an opportunity for the CVMP to reflect on the appropriate criteria to apply for implementation of Article 34 and for stakeholders to feed into those reflections. This will contribute to the effective use of Article 34, taking into account the aims of the Regulation. It will facilitate the practical application of Article 34 for both regulatory authorities and industry.

8. Interested parties

Pharmaceutical industry, consultants, EU national competent authorities, veterinarians.

9. References

Regulation (EU) 2019/6 of the European Parliament and the Council on veterinary medicinal products and repealing Directive 2001/82/EC.