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Committee for Medicinal Products for Veterinary Use (CVMP)

Questions and answers on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)

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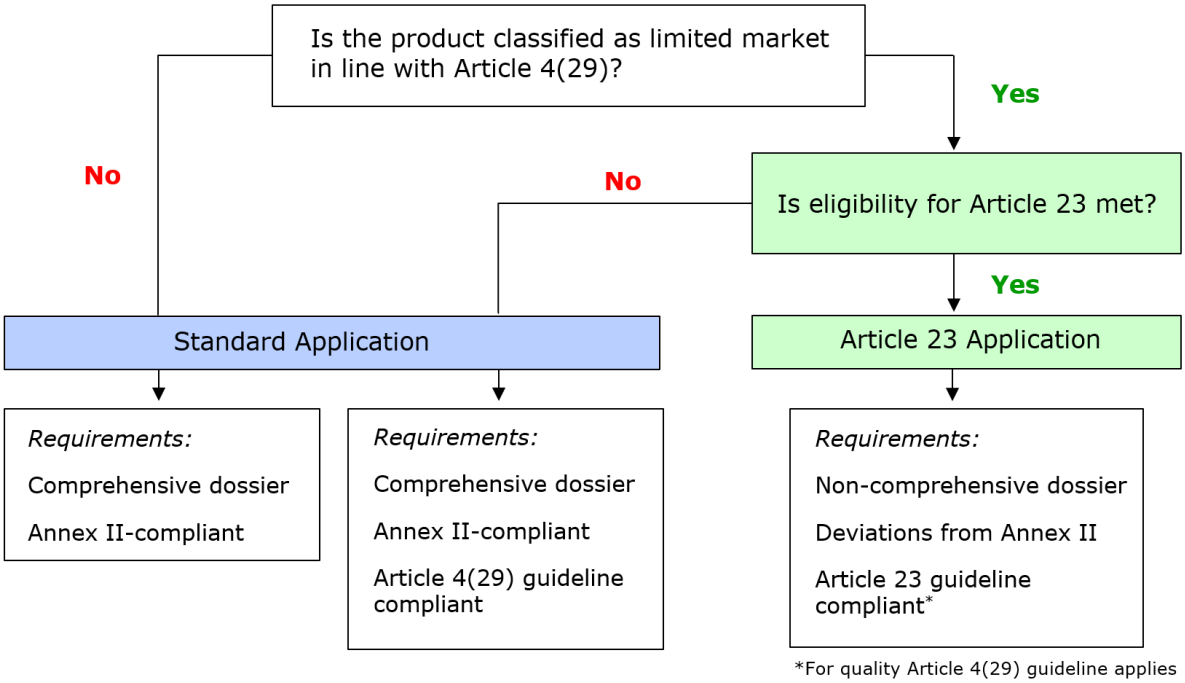
Background and scope

'Limited market' is defined by Art. 4(29) of the Regulation. Article 23 of Regulation (EU) 2019/6 provides for a specific type of marketing authorisations for certain veterinary medicinal products intended for limited markets. Under this provision, a marketing authorisation can be granted in the absence of comprehensive safety and efficacy data provided that the benefits in availability of the veterinary medicinal product outweighs the risks inherent in the lack of comprehensive data. The validity of these marketing authorisations is limited in time but may be extended based on a re-examination procedure.

This Q&A document is aimed at providing guidance to assessors and applicants on relevant key criteria for classifying a product as intended for a limited market (in accordance with Article 4(29)) and confirming that the product is eligible for a marketing authorisation for a limited market (in accordance with Article 23). The document addresses aspects not covered by the European Commission Notice: Guidance to Applicants - Veterinary Medicinal Products (Corrigendum, C/2024/90009) in order to facilitate intended marketing authorisation applications for limited markets. The Reflection paper on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (EMA/CVMP/235292/2020) is replaced by this document.

1. How is a product classified as limited market and considered eligible to Article 23, and which data requirements apply?



*For quality Article 4(29) guideline applies

There are two questions that have to be addressed when considering eligibility for authorisation of products intended for a limited market. The first of these questions is "is the proposed product for a limited market as defined in Article 4(29) of the Regulation?".

If the answer to the first question is ***no***, the product will by default require a standard application based on comprehensive technical documentation in accordance with Article 8(1) and in compliance with Annex II.

If the answer to the first question is ***yes*** and the product is classified as limited market, the second question to be addressed in order to be considered eligible for authorisation in accordance with Article 23 is "does the proposed product satisfy the condition detailed in Article 23(1)(a)?".

Where the answer to the second question is ***yes*** and eligibility for consideration in accordance with Article 23 is accepted, a non-comprehensive dossier with deviations from Annex II in parts 3 and 4 (absence of some pivotal data) may be accepted. Guidelines detailing the gaps in pivotal data relative to Annex II that may be accepted for a product deemed eligible to Article 23 have been developed (see point A below).

If the answer to the second question is ***no*** and a product that is classified as a 'limited market' is not eligible for consideration under Article 23 then, by default, a standard application with a comprehensive dossier compliant with Annex II will be required. There is, however, the possibility of flexibilities in data requirements as detailed in CVMP guidance (see point B below).

A) CVMP guidelines on data requirements for limited market products eligible to Article 23:

- Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/345237/2020)
- Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/52665/2020)
- Guideline on data requirements for applications for immunological veterinary medicinal products intended for limited markets submitted under Article 23 of the Regulation (EU) 2019/6 - (EMA/CVMP/59531/2020)

B) CVMP guidelines on data requirements for limited market products <u>not</u> eligible to Article 23:

- Guideline on quality data requirements for applications for veterinary medicinal products other than biologicals intended for limited markets – (EMA/CVMP/QWP/47285/2022)
- Guideline on quality data requirements for applications for biological veterinary medicinal products intended for limited markets – (EMA/CVMP/IWP/228730/2022)
- Guideline on safety and efficacy data requirements for applications for immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 – (EMA/CVMP/IWP/224724/2022)
- Guideline on safety and residue data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 – (EMA/CVMP/SWP/32027/2022)
- Guideline on efficacy and target animal safety data requirements for applications for non-immunological veterinary medicinal products intended for limited markets but not eligible for authorisation under Article 23 of Regulation (EU) 2019/6 – (EMA/CVMP/EWP/231668/2022)

Further information on the limited markets scheme can be found in the European Commission Notice: Guidance to Applicants - Veterinary Medicinal Products (Corrigendum, C/2024/90009)

2. How are limited market status and eligibility to Article 23 decided?

The procedure set up by the Agency consists of a two-step process which allows for a separate determination of the limited market status (Article 4(29)) and of eligibility for an Article 23 marketing authorisation application (compliance with Article 23(1)(a) and (b)).

Limited market status, if of relevance and eligibility for authorisation in accordance with Article 23 is recommended to be requested in advance of dossier submission. It should provide guidance to the applicants on:

- whether a product intended for cattle, sheep for meat production, pigs, chickens, dogs or cats could be considered for classification as limited market according to Article 4(29)(a).
- whether a product classified as limited market according to Article 4(29) could be considered eligible for Article 23.

For products intended for animal species other than cattle, sheep for meat production, pigs, chickens, dogs and cats, requests for classification under Article 4(29)(b) of Regulation (EU) 2019/6 are not needed as these products are limited markets according to the Article and estimation of the market size (Question 3, below) is therefore not relevant.

Please, note that:

- a request for limited markets classification and confirmation of eligibility for Article 23 is not mandatory but recommended.
- the recommendation on eligibility reflects the status quo at the time when the recommendation is issued. In the context of the authorisation procedure, the competent authority will confirm whether the conditions for a submission under Article 23 are met. This means, if the circumstances at the time of the classification change any time before the MA is granted (e.g. authorisation of alternative veterinary medicinal products for the same species and indication for use through a comprehensive dossier) the product may no longer be considered eligible for authorisation according to Article 23.
- It is the responsibility of the applicant to monitor the situation and justify the eligibility for Article 23 at the time of MA application and during the procedure.

For product-specific questions on data requirements, the applicant is strongly encouraged to request formal scientific advice.

3. How is the size of the limited market estimated?

The estimated potential size of the market is the total number of animals that could potentially be administered the product annually (animals suffering or at risk of exposure to the disease/condition). This value should be expressed as a percentage of the EU (EEA) target species population.

$$\text{Estimated potential size of the market \%} = \frac{\text{total annual number of animals potentially treated}}{\text{EU (EEA) target species population}} \text{ X } 100$$

This value will be influenced by factors such as:

- The expected target population (sub-category of target species, e.g. type of production, age).
- The prevalence[1] of the disease/condition in the EU relevant to the indication for use sought. Diseases/conditions with low prevalence, occurring infrequently or sporadically and in only a small number of animals will be considered for classification as a limited market. Estimates of disease/condition prevalence should be supported by up-to-date data in the published literature, where available, and from appropriate and reliable sources.
- The precise wording of the indication for use. The proposed indication should reflect current scientific knowledge and veterinary practice for the treatment of the respective disease/condition. It follows, that indications that are artificially restricted with a view to fit under the criteria in Article 23 are not acceptable. For example, if the disease/condition to be treated is limited to a specific stage, severity or underlying pathophysiological mechanism this may be reflected in the indication. However, when considering such 'restricted' indications, the likelihood that the product may, in practice, be used for a broader indication should be taken into account as this may lead to the conclusion that the indication has been artificially restricted (see Guidance to Applicants).
- The geographical area in which the disease/condition is present. Diseases/conditions that occur in limited geographical areas or regions that are distinguished by physical, chemical or biological factors that limit the distribution of a disease or condition will be considered for classification as limited market.

A product will be considered for classification as limited market when the potential market size is estimated to be less than 0.5% of the EU target species population or, in the case of immunological products used for prevention of disease only (e.g. veterinary vaccines), is estimated to be less than 5.0% of the EU target species population. The market size threshold for these vaccines is greater than that for other products recognising that the intended target population for a vaccine used for prevention of disease is typically expected to be greater than that for a product intended to treat disease.

Further refinement of the potential market size will not be accepted, unless robust scientific data can be presented to justify the applicant's position.

4. What is a seriously debilitating or life-threatening disease?

When considering the seriousness of a disease in the context of veterinary medicines, there is a need for a veterinary specific definition which encompasses all relevant elements (impact on target population, possible impact on non-target populations (zoonosis) and impact on animal production).

[1] 'Prevalence' is defined as: the total number of animals in a given population affected by a disease or health condition at a specific period of time, usually expressed as a percentage of the population.

Seriously debilitating or life-threatening disease/condition:

- a disease or condition that is associated with morbidity that has substantial impact on day-to-day functioning or is associated with mortality in the target animal; or
- a disease or condition in animals that is zoonotic and that presents a risk of a serious or life-threatening disease or condition to human beings, whether or not it also presents a risk of harm to the target animal receiving the product; or
- a disease or condition that has the potential to cause significant impact on animal production, even if the effect of the disease or condition on an individual-animal basis is minor.

Procedural/regulatory guidance

5. How can applicants request limited markets classification and eligibility for Article 23?

Before submitting an application for a limited market marketing authorisation, it is advisable to request that the CVMP checks whether a product meets the above eligibility criteria.

The CVMP will:

- classify the product as intended for a limited market (in accordance with Art. 4(29)) or not – known as a limited market classification;
- verify that the product is eligible for a marketing authorisation for a limited market (in accordance with Art. 23) or not.

It should be noted that the CVMP recommendation on eligibility reflects the status quo at the time when the recommendation is issued. Before submission of a marketing authorisation application, the applicant should verify that the proposed indication for use matches the one provided at the time of classification of the product as intended for a limited market according to Article 4(29) and/or eligible for authorisation according to Article 23, and that the condition of Article 23 1(a) is still met.

The validity of the legal basis will be assessed and confirmed by the CVMP/NCA (national competent authority; for national/DCP/MRP MA applications) at the time of the final opinion and considering the final approved indication(s) for use.

Applicants should submit their request via Eudralink to vetlimitedmarkets@ema.europa.eu using the form published on the EMA webpage request-cvmp-classification-veterinary-medicinal-product-intended-limited-market-according-article-429-eligibility-authorisation-according-article-23-applications-limited-markets_en.docx.

Applicants should submit their request at least 30 calendar days prior to the CVMP meeting when they wish their request to be considered. For more information on CVMP meeting dates, see EMA webpage - CVMP Meetings.

EMA can advise applicants on the kind of information to provide in the request in writing or as part of a pre-submission advice meeting focused on limited markets eligibility only. To request this pre-submission advice meeting, applicants should write to vetlimitedmarkets@ema.europa.eu.

EMA publishes a summary table of the CVMP's classifications and confirmations of eligibility on its website.