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Committee for Veterinary Medicinal Products (CVMP)

Procedural advice on the accelerated assessment of marketing authorisation applications pursuant to Article 44 (3) of Regulation (EU) No 2019/6

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1. Introduction

For a veterinary medicinal product of major interest, particularly from the point of view of animal health and therapeutic innovation, an applicant may request an accelerated assessment for an initial marketing application procedure. The request shall be duly substantiated. If the Agency accepts the request, the usual time limit of 210 days shall be reduced to 150 days.

This document provides guidance on the timelines and procedural steps for such a request, as well as considerations on the justification of the applicant that the veterinary medicinal product is of major interest. It only applies to marketing authorisation applications and does not cover any post-authorisation procedure. The document replaces the 'Guideline on the procedure for accelerated assessment pursuant to Article 39(8) of Regulation (EC) No 726/2004' (EMEA/CVMP/32995/2006).

2. General considerations

The accelerated assessment procedure is applicable to marketing authorisation applications for veterinary medicinal products falling within the scope of Article 44(3) of Regulation (EU) 2019/6.

For a smooth and reliable running of procedures and optimal planning of the work, the Committee for Veterinary Medicinal Products (CVMP) sets up timelines ahead of submissions for marketing authorisation. An accelerated assessment request has to be agreed by the CVMP before submission of a marketing authorisation application as it introduces changes in the operation of the CVMP and procedure timelines. As such, any request for accelerated assessment should be made as early as possible.

Applicants requesting an accelerated assessment procedure must justify that the veterinary medicinal product is expected to be of major interest, particularly from the point of view of animal health and therapeutic innovation. Based on the request, the justification presented, and the recommendations by the rapporteurs, the CVMP will formulate a decision on whether the request can be granted or not. In case of the granting of a request for an accelerated assessment procedure, and assuming there is no subsequent decision to revert to a standard timetable (see below) the Agency shall ensure that the opinion of the CVMP is given within 150 days.

At the time of the request, the CVMP will only assess the justification presented to support a claim of 'major interest', and not undertake any assessment of the marketing authorisation application. A decision on accelerated assessment will be taken without prejudice to the (future) CVMP opinion (positive or negative) on the granting of a marketing authorisation.

Once a request has been granted, at any time during the marketing authorisation application evaluation, if the CVMP considers that it is no longer appropriate to conduct an accelerated assessment (following discussion with the Applicant when necessary), the CVMP may decide to continue the assessment under standard centralised procedure timelines according to Article 44(2) of Regulation (EU) 2019/6.

To facilitate the process of evaluation of a request for accelerated assessment and the necessary planning in the pre-submission phase of the marketing authorisation, applicants are strongly advised to seek early dialogue with the Agency

3. Scope

The scope of this document is to provide applicants with guidance on the accelerated assessment request and the practical arrangements necessary to implement the legal provisions on the accelerated

assessment procedure. It forms the basis for requesting an accelerated assessment and should be followed unless otherwise justified.

This document only applies to marketing authorisations applications and does not cover any post-authorisation procedures.

4. Legal basis

This document has been developed in accordance with Article 44(3) of Regulation (EU) 2019/6: '*When an application is submitted for a marketing authorisation in respect of veterinary medicinal products of major interest, particularly from the point of view of animal health and therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated. If the Agency accepts the request, the time limit of 210 days shall be reduced to 150 days'.*

5. Steps and timing of submission of a request for accelerated review

5.1. Notification of intent to submit a request for accelerated assessment

As a first step, the applicant should notify the Agency about their intent to submit a request for an accelerated assessment. Such notification should be submitted approximately 4 months prior to the submission of a marketing authorisation application, i.e. together with the "request for eligibility for the centralised procedure". The intention should be noted in the "Additional information on the request" section of the pre-submission request form (EMA website - Veterinary pre-authorisation guidance, see link). A draft justification for accelerated assessment should already be provided in this section.

5.2. Pre-submission dialogue with the European Medicines Agency (EMA)

Following the notification of an intended request for accelerated assessment, applicants should enter proactively into an early dialogue with the Agency in order to discuss relevant procedural and/or regulatory issues on the proposed submission, in particular details of the potential accelerated assessment procedure. Such pre-submission advice should be sought as early as possible, to discuss the request for an accelerated assessment procedure and the timetable for the procedure, using the published template for such pre-submission meeting requests (EMA website - Veterinary pre-authorisation guidance, see link). Depending on the topics to be addressed, the pre-submission meeting might be a joint meeting with rapporteurs and the EMA product team attending.

When requesting such pre-submission meeting, applicants should include a draft of their justification for their request for accelerated assessment, an overview of the manufacturers of the active substance and finished product (to allow early identification of any Good Manufacturing Practices (GMP) inspections – see link) and an overview of the status of supporting documentation. In case the applicant might foresee that relevant supplemental data will only become available during the evaluation, details should be provided about timelines and how these supplemental data are considered of relevance for the marketing authorisation application. The rapporteurs might then advise on the submission strategy for the marketing authorisation application. It should be noted that applications should be mature in terms of the data submitted at the start of the evaluation, and that the planned submission timing is to be respected.

5.3. Request for an accelerated assessment procedure

The formal request for an accelerated assessment should be submitted approximately 3-2 months prior to the actual submission of the marketing authorisation application. The request should be submitted using the same pre-submission request form and choosing "Request for accelerated assessment", and include all the relevant documents, i.e. the justification for the request for accelerated assessment (see 5.1). It is recommended to copy the EMA procedure coordinator and allocated product mailbox in the correspondence, if already known.

Also, an early identification of a need for pre-authorisation Good Manufacturing Practices (GMP) inspections is advisable. The applicants should provide relevant information with the request for accelerated assessment to allow identifying such a need (see link).

5.3.1. Justification for a request for accelerated assessment

Applicants requesting an accelerated assessment procedure should duly substantiate the request and, in particular, justify why the veterinary medicinal product is of major interest, particularly from the point of view of animal health and therapeutic innovation. The risk of the epidemiological situation with regard to human and/or animal health must outweigh the benefit of a normal assessment timetable.

The key items to be described in the justification, and the appropriate level of detail, should be evaluated on a case by case basis. The request should be presented as a short but comprehensive document (ideal length 5-10 pages). The emphasis of the accelerated assessment procedure is on products that bring animal health and therapeutic innovation, i.e. products that introduce new methods (e.g. treatment, prevention, medical diagnosis), or improve on existing methods. It is noted that a new mechanism of action or a technical innovation *per se* may not necessarily represent a valid argument for justifying major interest.

The following list of key items would normally be addressed in a justification for a request for accelerated assessment:

- The **unmet needs** and the available methods of prevention, diagnosis or treatment.
  In general, a justification may be more convincing if based as much as possible on epidemiological data about the disease (e.g. life expectancy, clinical signs and duration, health-related quality of life). The claims could be substantiated from e.g. published literature or registries. If relevant, an unmet need could be described separately for different indications or subpopulations. In addition, a description of available treatment options/standard of care, including all relevant treatment modalities, e.g. medicinal products used in clinical practice (whether approved or not), devices, surgery, radiotherapy could be included. The effect of available treatments could also be described together with a description of how the unmet need is not fulfilled by the available treatments. Typical examples of greater unmet needs are serious or life-threatening conditions for which available methods are absent or insufficient in terms of lack of available products or lack of efficacy. Serious epizootic animal diseases and animal health threats recognised either by OIE or by the Union could also be considered unmet medical needs.
- A description of the **expected major impact** of the veterinary medicinal product in terms of veterinary practice, its major added value compared to existing methods, and/or how it addresses the unmet needs, should be provided to establish that the product is expected to be of major animal health interest. There is no single definition of what constitutes major animal health interest. This should be justified by the applicant and assessed by the CVMP on a case by case basis. Typically, the justification should present the arguments to support the claim that the veterinary medicinal product addresses to a significant extent the unmet needs for maintaining and

improving animal health of the Community, for example, by introducing new methods of therapy or improving existing ones.

- A brief outline of the main **available evidence** (e.g. number of clinical trials, sample size, design and key results) on which the applicant bases its claim of major animal health interest.

5.4. CVMP assessment of the request for accelerated assessment

Following receipt of a request for accelerated assessment, the Agency shall produce a briefing note for the CVMP, including the rapporteurs' recommendations as to the appropriateness of an accelerated assessment.

The CVMP will consider the request submitted by the applicant, the rapporteurs' recommendations, and the views of other CVMP members. If necessary, the CVMP may request clarifications from the applicant about the request. The CVMP will conclude on the request, either by consensus or majority, and the CVMP conclusions will be communicated to the applicant.

The reasons for accepting or rejecting the request will also be summarised in the CVMP assessment report of the marketing authorisation application. A decision on accelerated assessment will be taken without prejudice to the final CVMP opinion (positive or negative) on the granting of a marketing authorisation. Applicants are also reminded that evaluation under accelerated assessment is subject to the same evidence requirements for marketing authorisation as an evaluation under standard timetable.

6. Accelerated assessment of the marketing authorisation application

6.1. General considerations

The process of scientific assessment, distribution of the assessment reports to the CVMP and sharing of assessment reports and information about the procedure with the applicant, etc. will in principle be the same as for the standard timetable (except for the different timelines), i.e. generally allowing for three phases of assessment. However, as outlined by Article 44(3) of Regulation (EU) No 2019/6, the standard time limit of 210 days shall be reduced to 150 days, usually consisting of 90 + 30 + 30 days (see section 7.2).

The rapporteurs should ensure that there is adequate and early interaction between the assessment teams to prepare for the upcoming discussions and next steps.

Where necessary, the CVMP will express the need for further information from the applicant (list of questions/outstanding issues) to be provided in writing and/or at an oral explanation. The CVMP may agree to postpone an oral explanation to the next plenary meeting (allowing for a brief clock-stop) following the adoption of a list of outstanding issues.

The applicant should closely liaise with the Agency for the correct submission dates for the marketing authorisation application and any responses to questions, as these might differ from published guidance for the standard assessment timelines. Also, applicants are reminded of the importance in complying with their intended submission date of the application as any unexpected delay may considerably impact the rapporteurs' team organisation in handling the procedure under the accelerated timetable. Any changes to the submission time should be communicated promptly to the Agency. In order to allow for adequate evaluation periods, the Agency will usually not initiate any accelerated assessment evaluation with a starting date in December.

6.2. Possible switch to normal timetable

Following the granting of a request, the CVMP shall adhere to the accelerated timetable in accordance with Article 44(3) of Regulation (EU) 2019/6 for the assessment. However, at any time during the marketing authorisation application assessment, if the CVMP considers that it is no longer appropriate to conduct an accelerated assessment, the CVMP may decide to continue the assessment within the standard centralised procedure assessment timelines, according to Article 44(2) of Regulation (EU) 2019/6. Examples of such situations are when major objections have been identified that cannot be handled in an accelerated timetable, when a clock-stop longer than one month is requested by the applicant to provide responses to CVMP questions/outstanding issues, or when the need for GMP inspection becomes apparent. Similarly, in case of a negative trend following an oral explanation, the CVMP may decide to continue the assessment under standard assessment timelines.

If a switch to the standard timetable has been agreed by the CVMP for the remaining evaluation of the centralised application procedure, a timetable is prepared by the Agency in consultation with rapporteurs, and adopted by the CVMP. The new timetable is communicated to the applicant, and, where appropriate, the Agency will liaise with the applicant to explain the reasons for the change to the assessment timetable.

The applicant may also submit a justified request for a change to a standard assessment timetable, for example if additional time is needed for the applicant to provide any information requested by the CVMP. The CVMP shall consider such requests on a case by case basis and if appropriate adopt a revised timetable following Article 44(2) of Regulation (EU) 2019/6. The new timetable will be communicated to the applicant.

7. Timelines (examples)

7.1. Pre-submission phase

Time prior to submission of the marketing authorisation application	Action
4 months	**Notification of intent** to submit a request for accelerated assessment (together with the request for eligibility for the centralised procedure)* Confirmation of eligibility and appointment of rapporteurs will take place at the same CVMP plenary meeting.
4-3 months	**Pre-submission meeting** with the EMA (and rapporteurs, if applicable)
3-2 months	**Submission of request** for accelerated assessment to CVMP **
2-1 months	**Assessment of the request:** Circulation of EMA/Rapporteurs' briefing note to the CVMP with recommendations on the request for accelerated assessment. CVMP discussion, and conclusion on the request for accelerated assessment. Timetable to be adopted if appropriate. The conclusions are communicated to the applicant.

* The timing of the documents should be at least 21 working days in advance of the CVMP plenary meeting.
** The timing of the documents should be at least 11 working days in advance of the CVMP plenary meeting

7.2. Accelerated assessment procedure

Time	First assessment phase	Comments
Day 1	Start of the centralised procedure	
Day 60	(Co)Rapporteurs' assessment reports	
Day 70	CVMP members comments	
Day 90	Adoption of positive CVMP opinion or	
	Adoption of CVMP List of Questions	Clock stop: A short clock stop up to 1 month will be applied. Possible change to standard timetable (see 6.2) A clarification meeting may be arranged shortly after adoption of the list of questions, if applicable.

Time	Second assessment phase	Comments
Day 91	*Restart of the clock*	*The applicant provides the information requested (responses to questions)*
Day 100	Rapporteurs' joint assessment of responses to the LoQ	Rapporteurs' views on the need for oral or written explanations The applicant may request to provide an oral explanation to the CVMP
Day 107	CVMP members comments	
Day 120	Adoption of positive CVMP opinion or	
	Adoption of CVMP List of Outstanding Issues	Clock stop: A short clock stop up to 1 month may be applied, if appropriate. Possible switch to normal timetable (see 6.2)

Time	Third assessment phase	Comments
Day 121	Restart of the clock and/or oral explanation	The applicant provides the information requested (responses to outstanding issues)
Day 130	Rapporteurs' joint assessment of responses to the LoOI	
Day 137	CVMP members comments	
Day 150	Adoption of CVMP opinion	Possible switch to normal timetable (see 6.2)

References

Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

EMA website - Veterinary pre-authorisation guidance: https://www.ema.europa.eu/en/veterinary-regulatory/marketing-authorisation/veterinary-pre-authorisation-guidance

EMA website - Information required for early identification of a need for pre-authorisation GMP inspections: https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fwww.ema.europa.eu%2Fen%2Fdocuments%2Ftemplate-form%2Finformation-required-early-identification-need-pre-authorisation-gmp-inspections_en.doc&wdOrigin=BROWSELINK.