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COMMITTEE FOR MEDICINAL PRODUCTS FOR VETERINARY USE (CVMP)

GUIDELINE ON THE PROCEDURE FOR ACCELERATED ASSESSMENT PURSUANT TO ARTICLE 39 (8) OF REGULATION (EC) No 726/2004

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1. LEGAL BASIS AND PURPOSE

Recital 33 of Regulation (EC) No 726/2004[1] states that "in order to meet, in particular the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies, accelerated assessment procedures should be set up, reserved for medicinal products of major therapeutic interest, and procedures for obtaining temporary authorisations subject to certain annually reviewable conditions".

Article 39 (8) of Regulation (EC) No 726/2004, states that 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 from the viewpoint of therapeutic innovation, the applicant may request an accelerated assessment procedure. The request shall be duly substantiated.

If the Committee for Medicinal Products for Veterinary Use (CVMP) accepts the request, the time-limit (of 210 days to give an opinion) laid down in Article 31(3), first subparagraph, shall be reduced to 150 days.

This document aims to provide guidance on the submission of a request for accelerated assessment, and the timetable of an accelerated assessment procedure. This document will be updated to include more detailed explanation and examples.

2. SCOPE AND GENERAL PRINCIPLES

The accelerated assessment procedure is applicable to marketing authorisation applications for veterinary medicinal products falling within the scope of articles 3(1) and 3(2) of Regulation (EC) No 726/2004.

Applicants requesting an accelerated assessment procedure should justify that the veterinary medicinal product is expected to be of major animal health interest particularly from the point of view of therapeutic innovation. Based on the request, the justifications presented, and the recommendations of the rapporteurs, the CVMP will formulate a decision on the request for accelerated assessment. At the time of the request, the CVMP assessment of the request is based on the justification presented in favour of a claim of major animal health interest and not on assessment of the marketing authorisation application. The CVMP will review the justifications and claims, and formulate a view on whether the request can be granted. After 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 31 (3) of Regulation (EC) No 726/2004. The duration of the assessment outside a formal request for accelerated assessment is part of the normal functioning of the CVMP and is outside the scope of this guideline.

There is no single definition of what constitutes major animal health interest. This should be justified by the applicant on a case by case basis. The justification should present the arguments to support the claim that the veterinary medicinal product introduces new methods of therapy or improves on existing methods, thereby addressing to a significant extent the greater unmet needs for maintaining and improving the animal health of the Community.

Typical examples of greater unmet needs are serious, or life-threatening conditions when available methods are absent or by and large insufficient in terms of lack of available products or lack of efficacy as well as serious epizootic animal diseases and animal health threats recognised either by OIE or by the Community.

[1] OJ L 136, 30/4/2004 p. 1 - 33.

The emphasis of the accelerated assessment procedure is on products that bring therapeutic innovation, i.e., products that introduce new methods (treatment, prevention, medical diagnosis), or improve on existing methods.

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 greater unmet needs, should be provided to establish that the product is expected to be of major animal health interest (see section 4.2, Justification for a request for accelerated assessment).

A decision on accelerated assessment will be taken without prejudice to the CVMP opinion (positive or negative) on the granting of a marketing authorisation.

The scientific evaluation of a marketing authorisation application is governed by a timetable adopted by the CVMP. The EMEA in consultation with the rapporteurs prepare a timetable. This timetable is then proposed to the CVMP for adoption. In general, the CVMP will take into consideration the standard timetable agreed for the evaluation of a centralised application (see Notice to Applicants, vol. 6A, chapter. 4). If a request for an accelerated assessment procedure is granted, the CVMP will take into consideration the standard timetable agreed for the accelerated assessment procedure (see section 6). The submission or outcome of a request for accelerated assessment is without prejudice to the fact that the CVMP may adopt a shorter or otherwise different than the standard timetable, as appropriate. In case of the granting of a request for an accelerated assessment procedure, the EMEA shall ensure that the opinion of the CVMP is given within 150 days.

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, it is recommended that a notification with the intent to submit a request for accelerated assessment be provided to the EMEA. The notification should be provided well in advance of the submission of the application for marketing authorisation. The actual request for accelerated assessment is submitted in a second step, prior to the start of the scientific assessment. Following assessment of the request, the CVMP decides on whether the request on accelerated assessment should be granted.

3. EMEA ADVICE PRIOR TO SUBMISSION

3.1 Notification of intent to submit a request for accelerated assessment

The applicant should notify the intent to submit a request for an accelerated assessment procedure as part of the “letter of intent to submit a marketing authorisation application” to be sent to the EMEA in advance of the submission of the marketing authorisation application (see Notice to Applicants, volume 6, chapter 4. Procedure for submission of the marketing authorisation application).

3.2 Pre-submission guidance

When preparing the submission of a marketing authorisation application, applicants have the opportunity to meet the EMEA to discuss relevant procedural or regulatory issues on the proposed submission. Applicants should seek guidance from the EMEA on the scheduled dates of CVMP plenary meetings and start of the procedure, to ensure timely submission of the request for accelerated assessment.

In view of a potential request for accelerated assessment, it is strongly recommended that the applicant requests EMEA pre-submission advice as early as possible, to discuss the request for an accelerated assessment procedure and the timetable for the accelerated procedure. If necessary, as soon as rapporteurs have been assigned, the applicant may request a pre-submission meeting with EMEA and the rapporteurs, to present and discuss issues related to dossier presentation or the substantiating of the request for accelerated assessment.

4. QUALIFICATION OF A REQUEST FOR AN ACCELERATED ASSESSMENT PROCEDURE

4.1 Timing of the submission of a request for accelerated assessment

For a smooth and reliable running of procedures and optimal planning of the work, the CVMP sets up timelines ahead of submissions for marketing authorisation. An accelerated assessment request has to be agreed in advance of the start of marketing authorisation application evaluation as it introduces changes in the operation of the CVMP and procedure timelines.

Any request for accelerated assessment should be made as early as possible before the actual submission of the marketing authorisation application. The timing of the request should be at least 10 working days in advance of the CVMP plenary meeting preceding the intended start of the centralised procedure (see 3.2, Pre-submission guidance). In practice, submission of the request will generally occur at least between 10 to30 days before the intended start of the procedure. The request (including the justification) should be sent electronically to the EMEA.

Following receipt of a request for accelerated assessment, the EMEA shall produce a briefing note 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 acceptability or not of the request.

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.

4.2 Justification for a request for accelerated assessment

Applicants requesting an accelerated assessment procedure should duly substantiate the request and in particular, justify their expectation that the veterinary medicinal product is of major animal health interest particularly from the point of view of 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).

A justification including the major benefits expected should be submitted. 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.
- The extent to which the veterinary medicinal product is expected to have major impact on veterinary practice, its major added value, and/or how it addresses the greater unmet needs.
- A brief outline of the main available evidence (e.g., number of clinical trials, key results) on which the applicant bases its claim of major animal health interest.

5. SPECIAL CONSIDERATIONS FOR AN ACCELERATED ASSESSMENT

5.1 Duration of the analysis of the scientific data

Article 39(8) of Regulation (EC) No 726/2004 states that the applicant may request an accelerated assessment procedure 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. If the Committee for Medicinal Products for Veterinary Use accepts the request the time-limit shall be reduced to 150 days.

In specific cases of a serious disease epidemic the assessment time could be further reduced if the CVMP considers this to be appropriate.

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 normal timetable (except for the different timelines).

Where necessary, the CVMP will express the need for further information from the applicant (list of questions) to be provided in writing and/or at an oral explanation. The CVMP may agree to postpone the oral explanation to the next plenary meeting (1-month clock-stop) following the adoption of the list of questions.

5.2 Possible switch to normal time table

Following the granting of a request, the CVMP shall adhere to the accelerated timetable in accordance with Article 39(8) of Regulation (EC) No 726/2004 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 under the standard centralised procedure assessment timelines, following an appropriate timetable to be adopted by the CVMP, according to Article 31(3) of Regulation (EC) No 726/2004. 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 prepare for the oral explanation, or when late in the procedure the need for GMP or GCP inspection becomes apparent. Similarly, in case of a negative trend following the oral explanation, the CVMP may decide to continue the assessment under standard assessment timelines.

Having taken into consideration the standard timetable agreed by the CVMP for the evaluation of a centralised application, a timetable is prepared by the EMEA in consultation with rapporteurs. This timetable is then proposed to the CVMP for adoption. The new timetable is communicated to the applicant. Where appropriate, the CVMP will consult the applicant to explain the reasons for the change to the assessment timetable, and seek clarifications and comments about the proposed revised timetable.

The applicant may also submit a justified request for a change to a standard assessment procedure, 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 time table following Article 31(3) of Regulation (EC) No 726/2004. The new timetable is communicated to the applicant.

6. TIMETABLE

6.1 Pre-submission phase

Pre-submission meeting <u>strongly recommended</u>

- Day –120 Notification of intent to submit a request for accelerated assessment (as part of the notification of intent to submit a marketing authorisation application, 4-6 months prior to submission of MAA)

- Day –30 to –10 Submission of request for accelerated assessment.

  The timing of the request should be at least 10 working days in advance of the CVMP plenary meeting preceding the intended start of the centralised procedure. The exact timing depends on the dates of the CVMP meeting preceding the intended start of the procedure. Generally this will occur between 10-30 days before the intended start of the procedure.

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– Day –20 to 0 CVMP plenary meeting preceding the start of the procedure

- Circulation of EMEA/Rapporteurs' briefing note 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.

– Day 0 Validation

6.2 Accelerated assessment procedure

– Day 1 Start of the centralised procedure

– Day 60 Rapporteurs' assessment reports

- The rapporteurs will ensure that there is adequate and early interaction between the assessment teams to prepare for the upcoming discussions and next steps
- If the CVMP considers that the accelerated assessment procedure is no longer appropriate, then this will lead to a switch to a normal timetable and adoption of a CVMP list of questions at day 120 (see 5.1 and 5.2).

– Day 90 Opinion, or CVMP expresses the need for further information

- The CVMP may agree to a justified request for a 1-month clock-stop to allow for the applicant to prepare oral and/or written explanations.
- Possible change to standard timetable (see 5.2)

– Stop clock Submission of written responses

– Day 91 The applicant provides the information requested, restart of the clock

– Day 115 Rapporteurs' joint assessment report

- Rapporteurs' views on the need for oral or written explanations
- The applicant may request to provide an oral explanation to the CVMP

– Day 120 Opinion, or CVMP request for oral or written explanations

- The CVMP may agree to a request for a 1-month clock-stop to allow for the applicant to prepare oral or written explanations, if justified. Possible switch to normal time table (see 5.2)

– Day 121 Oral explanation (as appropriate), and Opinion, or start of finalisation of opinion

- Possible change to standard timetable (see 5.2)

– Day 150 Opinion