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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE (CHMP)

GUIDELINE ON THE PROCEDURE FOR ACCELERATED ASSESSMENT PURSUANT TO ARTICLE 14 (9) 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 14 (9) of Regulation (EC) No 726/2004, states that when an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health and in particular 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 Human Use (CHMP) accepts the request, the time limit (of 210 days to give an opinion) laid down in Article 6(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.

0. SCOPE AND GENERAL PRINCIPLES

The accelerated assessment procedure is applicable to marketing authorisation applications for medicinal products for human use falling within the scope of articles 3(1) and 3(2) of Regulation (EC) No 726/2004. This includes medicinal products for treatment, prevention or diagnosis.

Applicants requesting an accelerated assessment procedure should justify that the medicinal product is expected to be of major public 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 CHMP will formulate a decision on the request for accelerated assessment. At the time of the request, the CHMP assessment of the request is based on the justification presented in favour of a claim of major public health interest and not on assessment of the marketing authorisation application. The CHMP 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 CHMP considers that it is no longer appropriate to conduct an accelerated assessment the CHMP may decide to continue the assessment under standard centralised procedure timelines according to Article 6 (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 CHMP and is outside the scope of this guideline.

There is no single definition of what constitutes major public 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 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 health of the Community. (See section 4.2, Justification for a request for accelerated assessment).

A decision on accelerated assessment will be taken without prejudice to the CHMP 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 CHMP. The EMEA in consultation with the Rapporteurs prepares a timetable. This timetable is

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

then proposed to the CHMP for adoption. In general, the CHMP will take into consideration the standard timetable agreed for the evaluation of a centralised application (see Notice to Applicants, vol. 2A, chapter. 4). If a request for an accelerated assessment procedure is granted, the CHMP 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 CHMP 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 CHMP 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 CHMP decides on whether the request on accelerated assessment should be granted.

0. 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 4-6 months in advance of the submission of the marketing authorisation application (see Notice to Applicants, volume 2, chapter 4.3. 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 CHMP 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.

0. 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 CHMP 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 CHMP 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 CHMP 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 to 30 days before the intended start of the procedure. The request (including

the justification) should be sent electronically to the EMEA product team leader and all CHMP members.

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 CHMP will consider the request submitted by the applicant, the Rapporteurs' recommendations, and the views of other CHMP members. If necessary, the CHMP may request clarifications from the applicant about the request. The CHMP will conclude on the acceptability or not of the request.

The CHMP conclusions will be communicated to the applicant. The reasons for accepting or rejecting the request will also be summarised in the CHMP 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 medicinal product is of major public health interest particularly from the point of view of therapeutic innovation.

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 medicinal product is expected to have major impact on medical 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 public health interest.

0. SPECIAL CONSIDERATIONS FOR AN ACCELERATED ASSESSMENT

5.1 Duration of the analysis of the scientific data

The process of scientific assessment, distribution of the assessment reports to the CHMP and sharing of assessment reports and information about the procedure with the applicant, etc. will in principle be the same as for a standard timetable (except for the different timelines).

Where necessary, the CHMP 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 CHMP 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 change to "normal" timetable

Following the granting of a request, the CHMP shall adhere to the accelerated timetable in accordance with Article 14(9) of Regulation (EC) No 726/2004 for the assessment. However, at any time during the marketing authorisation application assessment, if the CHMP considers that it is no longer appropriate to conduct an accelerated assessment, the CHMP may decide to continue the assessment under the standard centralised procedure assessment timelines, following an appropriate timetable to be adopted by the CHMP, according to Article 6 (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 CHMP may decide to continue the assessment under "normal" assessment timelines.

Having taken into consideration the "normal" timetable agreed by the CHMP 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 CHMP for adoption. The new timetable is communicated to the applicant. Where appropriate, the CHMP 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 "normal" assessment procedure, for example if additional time is needed for the applicant to provide any information requested by the CHMP. The CHMP shall consider such requests on a case-by-case basis and if appropriate adopt a revised timetable following Article 6 (3) of Regulation (EC) No 726/2004. The new timetable is communicated to the applicant.

5.3 Scientific Advisory Groups

Following the acceptance of the accelerated assessment procedure, the need for consultation of the related Scientific Advisory Group (SAG) will be identified and a tentative meeting scheduled. The need for a meeting will be reconfirmed by the CHMP during the procedure (see section 6, Time table). The date of the tentative meeting and whether the need for a SAG meeting is confirmed will be communicated to the applicant.

0. STANDARD TIMETABLE FOR THE ACCELERATED ASSESSMENT PROCEDURE

6.1 Pre-submission phase

Pre-submission meeting strongly recommended (see 3.2)

– 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 CHMP plenary meeting preceding the intended start of the centralised procedure. The exact timing depends on the dates of the CHMP meeting preceding the intended start of the procedure. Generally this will occur between 10-30 days before the intended start of the procedure.

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

- Circulation of Rapporteurs' briefing note with recommendations on the request for accelerated assessment. Identification of the need for a SAG meeting.
- CHMP discussion, and conclusion on the request for accelerated assessment. The conclusions are communicated to the applicant.

6.2 Accelerated assessment procedure

– Day 1 Start of the centralised procedure

- Tentative SAG meeting scheduled after day 120 (see 5.3)

– Day 80 Rapporteurs' assessment reports, and start of the peer-review phase

- Rapporteurs highlight the need for questions for the SAG, and SAG meeting.

– Day 110 End of the peer-review phase

– Day 120 Opinion, or CHMP expresses the need for additional information

  - Adoption of list of questions to the applicant to be answered in writing and/or at an oral explanation
  - The CHMP may agree to a justified request for a 1-month clock-stop to allow for the applicant to prepare for the oral and/or written explanation.
  - Adoption of questions for the SAG and SAG meeting, if requested.
  - Possible change to “normal” centralised timetable (see 5.2)

– Stop clock Submission of written responses

– Day 121-150 Oral explanation, restart of the clock

  - Opinion or start of finalisation of opinion (see CPMP Guidance to Applicants on CPMP Oral Explanations in Relation to Centralised Applications, CPMP/2390/01 rev.1)
  - Possible change to “normal” centralised timetable (see 5.2)