EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

25 February 2022
EMA/CVMP/612534/2021
Committee for Veterinary Medicinal Products (CVMP)

Procedural advice – extended assessment time for initial marketing authorisation applications of 90 days

1. Introduction

For the majority of scientific evaluations of centralised marketing authorisation applications, the rapporteurs and their supporting assessment teams will have in-depth scientific knowledge and experience in the relevant scientific areas. However, in order to provide the highest level of relevant expertise, it is occasionally necessary to seek expertise from outside the allocated assessment teams, which can be a time consuming process, in particular if such a request occurs ad-hoc. In order to facilitate the assessment by the CVMP in such cases, Regulation (EU) 2019/6 has introduced a provision to exceptionally extend the standard timeframe for an initial assessment procedure by a maximum of 90 days in cases where particular expertise is required.

This document outlines the criteria for such "particular expertise", as well as the procedural steps to take into account when deciding on the use of such additional time.

2. Legal basis

Article 44(2) of Regulation (EU) 2019/6 establishes for centralised procedures that:
"*The Agency shall issue the opinion referred to in paragraph 1 within 210 days of receipt of a valid application. Exceptionally, where a particular expertise is required, the time limit may be extended by a maximum of 90 days*."

3. Criteria for "particular expertise"

"Particular expertise" will concern expertise that does not already exist within the Committee for a marketing authorisation application, and where the CVMP considers that there is a need for additional expertise. The expertise sought should help the CVMP to conclude on questions raised during the assessment and/or to come to final conclusions on a marketing authorisation application. The extended time frame should only be applied exceptionally, in cases where particular expertise is needed, i.e. not in order to extend the standard timeframe for an assessment procedure.

Particular expertise should only address specific points, i.e. clear questions need to be raised by the CVMP in a particular evaluation procedure.

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Scientific expertise might be sought from an already established group within the EMA (e.g. CxMP working party, scientific advisory group (SAG)), or by consulting an ad-hoc-expert group (AHEG) specifically set up for the procedure (as outlined in the "veterinary SAG policy", EMA/347137/2010). Examples of situations where particular expertise might be needed from existing regulatory bodies could include the need to liaise with a regulatory authority with a specific responsibility (e.g. other EU agencies such as EFSA, ECHA).

4. Steps and timing

A request to extend the standard timeframe can be made by the rapporteurs, CVMP members, or the Agency, and should be addressed at a CVMP meeting for consideration. Any extension of the timeframe should be duly justified and should be agreed by the CVMP.

The applicant should be notified as soon as possible by the Agency in case of an extension to the standard time limit for the assessment. The extended time frame should also be addressed in the CVMP assessment report, which will be published in line with the usual procedural steps.

In order to align the additional 90 days with the standard CVMP assessment timelines and meeting dates, the additional 90 days are split into 3 blocks of 30 days. Depending on the nature of the particular request, an extension to the usual timeframe of (up to) 30, 60 or 90 days could be used. Whilst the legislation does not restrict use of the extended timeframe to a single block within one step of the marketing authorisation application, for organisational reasons it is recommended to make use of this extension only once during one procedure.

The following options could be considered:

4.1. Decision by day 0:

If the CVMP prior to the submission of the application already anticipates that e.g. consultation with an expert group would be necessary, an extension to the standard timetable for the procedure could already be agreed by the CVMP prior to submission of the dossier. This could be done for the first phase of the assessment, resulting in the adoption of the CVMP List of Questions at day 150, 180 or 210 (instead of 120), or for a later stage in the procedure (e.g. during the second phase).

4.2. Decision by Day 120 or 180:

If the CVMP considers during the assessment that particular expertise would be needed on particular points of the application, the Committee may at Day 120 or Day 180 discuss if the usual timeline should be extended for

a) the *current assessment phase* for the purpose of further drafting of questions/outstanding issues to the applicant ("retrospective extension").
In such cases, the adoption by the CVMP of a list of questions/outstanding issues to the applicant would be postponed to a later CVMP meeting, e.g. by 30/60/90 days to Day 150/180/210 or Day 210/240/270, respectively.

b) the *following assessment phase* ("prospective extension") to facilitate the assessment by the Committee of responses to questions/outstanding issues during the next phase. In such cases, the following phase could be extended by up to the maximum number of 90 days, depending on the nature of the topic to be addressed and the availability of experts.

4.3. Decision by Day 210:

Following an oral explanation and/or the assessment of the responses to a List of Outstanding Issues, the Committee may consider that additional expertise is needed to conclude on an application. The Committee may in such cases decide at Day 210 that the *current assessment phase* may be extended. In such cases, the current phase could be extended by up to the maximum number of 90 days, depending on the nature of the topic to be addressed and the availability of experts. A clock extension at this stage should only be considered very exceptionally though, as the need for specific expertise would be expected to be identified earlier in the assessment process.

4.4. Decision at other CVMP plenary meetings:

Any extension to the normal timeframe should be agreed by the Committee at a CVMP meeting, ideally where discussions on the product application are routinely scheduled (i.e. prior to submission, D120, D180, or D210). However, if during the assessment, the rapporteurs consider that further expertise is urgently needed, exceptionally, a request for additional time could also be considered by the CVMP at another plenary meeting, or via written procedure.

Any such request should be clearly substantiated, involve the CVMP chair's agreement, and be undertaken in close liaison with the Agency. Particular care should be taken if such a request is made for the third phase of assessment and/or in case of a request that would require more substantial preparation, e.g. an AHEG meeting.

The applicant should be immediately informed about any changes in the timetable.

5. Further considerations

Depending on the actual CVMP meeting dates, intervals between CVMP meetings might be more or less than 30 days. When calculating 30, 60 or 90 day "extensions", consideration must be given to the actual CVMP meeting dates, and recommended submission dates for an applicant might therefore deviate from published dates.

Applicants are advised to work closely with the Agency and follow advice in regard to the date of submission. The recommended submission date for the application (or responses to questions, respectively) should take note of this extended timeline.

6. References

Summary of procedures for consultation by CVMP of Scientific Advisory Groups (SAGs) and ad-hoc expert groups functioning as SAGs in relation to applications for authorisation of veterinary medicinal products (EMA/347137/2010).

Examples for timetable:

	Extend phase 1 by (days)	**Phase 1 (days)**	Extend phase 2 by (days)	**Phase 2 (days)**	Extend phase 3 by (days)	**Phase 3 (days)**	**Examples**
Standard procedure	-	**120** **Total: 120**	-	**60** **Total: 180**	-	**30** **Total: 210**	-
Phase I: Decision by **day 0** (prospectively) or at **day 120** (retrospectively)	+ 30, 60 or 90	120 **Total: 150, 180 or 210**	-	60 **Total: 210, 240 or 270**	-	30 **Total: 240, 270 or 300**	At pre-submission (e.g. eligibility request), or at D 120 (when concluding on a LoQ) CVMP considers: - the involvement of a CxMP WP necessary - involvement of a SAG / AHEG necessary - other reasons
Phase II: Decision by **day 0** or at **day 120** (prospectively), or at **day 180** (retrospectively)	-	120 Total: 120	+ 30, 60 or 90	60 **Total: 210, 240 or 270**	-	30 **Total: 240, 270 or 300**	At pre-submission (e.g. eligibility request) or at D 120, CVMP considers involvement of a SAG / AHEG necessary for the second phase to evaluate the application. At D 180, CVMP considers involvement of a SAG / AHEG needed to conclude on a LoOI.
Phase III: Decision at **day 180** (prospectively) or at **day 210** (retrospectively)	-	120 Total: 120	-	60 Total: 180	+ 30, 60 or 90	30 **Total: 240, 270 or 300**	At D 180 or D 210, CVMP considers involvement of a SAG / AHEG necessary for the third phase to reach conclusions on an application.