CMDh position paper concerning Applicants request of submission of multiple applications during ongoing Decentralised Procedures or inclusion of new CMS or additional strength(s) in an already ongoing Decentralised Procedure (DCP)

Member states have been approached by applicants requesting submission of multiple applications during ongoing DCP or inclusion of new CMS or additional strength(s) in already started DCP procedures.

This position paper provides the position of Member states as given in a questionnaire circulated by the CMDh in May-June 2012. Furthermore the paper will also highlight concerns as expressed by the Member states in their response to the questionnaire.

The Member states have among other things raised the following general concerns:

- Agreement both from RMS and CMS in advance of the submission of new multiple applications.
- How will the validation phase be managed in case of submission of new multiple applications.
- The restart date (step II) for all procedures: ongoing and new multiple applications.
- Possible impact on the workload and planning of allocation of resources due e.g.
  - new data/study (ies) may often need to be submitted which require additional assessment.
  - planned re-start of a procedure may need to be postponed due to the requested inclusion as validations is still on-going.
  - negative impact on the final national phase if any remaining minor validation issues haven’t been solved due to the late inclusion in the procedure.

Concerns have also been raised about the reviewing time of the dossier and thereby the opportunity to raise comments/potential serious risk to public health (PSRPH), if included late.

After sharing the view of the Member states, the following position has been reached by the CMDh:

1. Submission of multiple applications

   DCP1 (RMS + CMS1 + CMS2) ----> DCP2 (RMS + CMS1 + CMS2)
Member states accept submission of multiple applications during ongoing DCP provided that the following conditions are met:

- Acceptance is received before submission of both the RMS and the CMS. A written confirmation of the CMS in the new multiple applications should be sent separately to the RMS in advance of the submission of the dossier.
- Submission of multiple applications only to the same CMS as those already included in the ongoing DCP.
- Submission of the same dossier (as defined in CMDh guidance “Recommendations on Multiple/Duplicate Applications in MRP & DCP”): the RMS and new CMS are allowed a validation period according to the automatic validation period. All validation questions already raised should be taken into account for the submission of the multiple/duplicate application. The RMS will actively inform the CMS about the timetable to be applied.
- Multiple applications have to be submitted before Day 106 of the ongoing DCP, preferably during the clock-off period.
- The RMS may need to reschedule the re-start if the RMS is informed too close to Day 106 about the wish to submit multiple applications.

After the submission and validation of the multiple applications, the RMS will restart the clock for all procedures (ongoing DCP and multiple applications) at the same time: same timetable for Step II of the DCPs.

2. Inclusion of new CMS

Member states accept inclusion of new CMS during and only during the clock-stop provided that the following conditions are met:

- Acceptance is received before submission of both the RMS and the new CMS. A written confirmation of the CMS in the new multiple applications should be sent separately to the RMS in advance of the submission of the dossier.
- The requested new CMS are already CMS in an on-going multiple/duplicate application.
- Submission of the same dossier (as defined in CMDh guidance “Recommendations on Multiple/Duplicate Applications in MRP & DCP”): The new CMS is allowed a validation period according to the automatic validation period. All validation questions already raised should be taken into account for the submission of the multiple/duplicate application. The RMS will actively inform the CMS about the timetable to be applied.
• The RMS might need to postpone re-start due to changed resource allocation or may need time to reschedule the re-start of procedure(s) due the inclusion of new CMS which are entitled to have a validation period.

The applicant should also be aware about the risk, although it might be seen as minimal as the new CMS already are included in a multiple/duplicate application, that withdrawal in the new CMS due to PSRPH after day 120 is to be dealt with by the CMDh according to article 29(1) of directive 2001/83/EC as amended.

3. Inclusion of new CMS in case of no on-going multiple/duplicate application

Member states present view is, that as new CMS added during the clock-stop, Member state will have limited possibility and not at least time to review the dossier and raise comments, which is not found acceptable. The workload for the RMS may also be increased.

Member states position is therefore that inclusion of new CMS in case of no ongoing multiple/duplicate application is not possible.

4. Inclusion of additional strength(s) in an already on-going DCP during the clock-stop

As addition of new strength(s) can require a significant amount of additional quality data and also may require submission of new bioequivalence study(-ies) both RMS and the CMS express the need of appropriate assessment time of such new data. For the RMS it also might increase the workload significantly.

Member states position is therefore that it is not possible to include additional strength(s) in an ongoing DCP.

Some National Competent Authorities (NCA), e.g. CY and IS, in order to increase the availability of medicinal products on their market, may though have a broader acceptance level on agreeing to be included as CMS than stated above in this paper. The CMDh recommends applicants directly to contact these NCA for further guidance.