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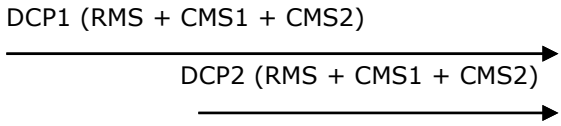
CMDh/271/2012, Rev.~~1~~2

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 reached by the CMDh:

1. Submission of multiple applications



Member states **accept** submission of multiple applications **during ongoing DCP** provided that the following conditions are met:

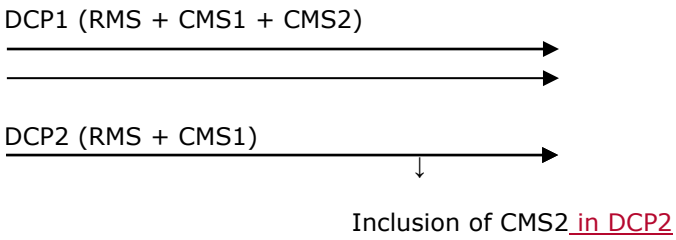
- Acceptance is received before submission of both the RMS and the CMS. A written confirmation of the CMS in the new multiple applications should be sent separately to the RMS in advance of the submission of the dossier.
- Submission of multiple applications **only to the same CMS as those already included 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 in case of on-going multiple/ duplicate applications with the same 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 new 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 of the application 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 with the same CMS

Inclusion of CMS2 in DCP1

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

- A justification is provided that the addition of the new CMS is to prevent or solve shortages
- A confirmation is provided that the product will be marketed in the new CMS
- Acceptance is received before submission of both the RMS and the new CMS: The applicant should contact the RMS and the new CMS prior to submission of the application in the new CMS. Prior to acceptance the applicant should send the RMS Day 70 Preliminary Assessment Report and the CMS Day 100 comments to the new CMS upon request. A written confirmation of the new CMS should be sent separately to the RMS in advance of the submission of the dossier.
- Submission of the same dossier: 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 in the new CMS. The RMS will actively inform the new 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, that withdrawal of the application 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~~In situations where there are no ~~on-going multiple/duplicate application~~

shortage problems Member states ~~present~~ view is~~,~~ that the addition of new CMS is **not found acceptable**, 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 on-going 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.