

SOP on Decentralised Procedure

Proposals for improvement

**Meeting with interested parties
November 2009**

Agence française
de sécurité sanitaire
des produits de santé



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SOP on DCP

New revision



- **CMD(h) decided to revise the SOP on DCP on a regular basis taking into account the experience gained**
- **Last version (revision 1) of the SOP adopted in November 2007**



Revision started in September 2009 with the aim to adopt a new version at the beginning of 2010

SOP on DCP

Proposed Changes



- Linguistic changes
- Recommendation to follow the Rules for allocating timeslot in RMSs
- Recommendation to use common request form for RMS + cover letter for the submission of the dossier
- Validation phase
- Proposal to simplify the end of Step I
- Clock-off period: proposal for improvement
- Suggestions to facilitate early discussions during Step II
- Particular situation in case of RMS negative opinion at the end of procedure

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Pre-procedural step / Main changes



- **The applicant is advised:**
 - to follow the rules adopted by the Member State chosen as the RMS for allocating a timeslot
 - and to use the common request form as adopted by the CMD(h) in order to ask a Member State to be the RMS in the DCP
- **It is recommended to use** the cover letter for the submission of the MAA as published on the CMD(h) website

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Pre-procedural step / Main changes



Validation phase

- To delete detailed information on the validation phase as currently described and to introduce a reference to the *“Procedural advice : Automatic validation of MR/Repeat-Use/DC Procedures”*
- To include that in case of different views on the validity of the legal basis, the RMS can propose to have a discussion in the CMD(h).
- To mention that the validation of the dossier does not preclude subsequent refusal, on grounds of non-compliance with the legislation or absence of satisfactory supporting data which become apparent on further consideration of the dossier

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Assessment Step I / Main changes



- **Proposal to simplify the end of Step I:**
 - Only 2 possibilities:
 - the procedure can be positively finalised at Day 105
 - or in the absence of consensus, the procedure will be stopped at Day 105.



Deletion of the possibility to have a short clock-stop and to finalise the procedure at Day 120



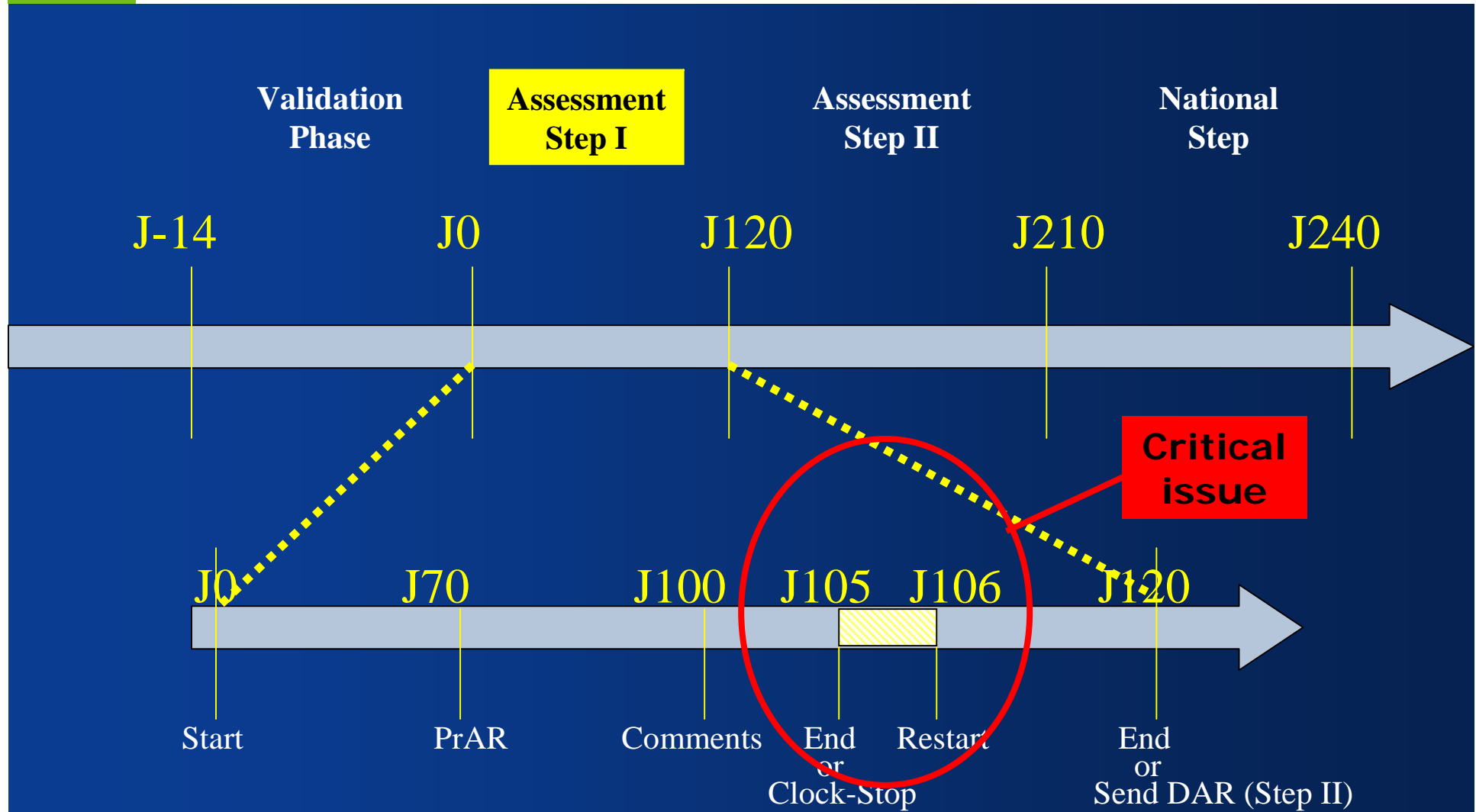
Practically very difficult



However, after the re-start of the procedure at Day 106, possibility to close the procedure at any time-point during Step II

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Clock-off period



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Clock-off period



Ongoing discussions in the CMD(h) in order to propose the best solution acceptable for applicants and Member states

2 objectives:



- 1- To improve the visibility of the procedure**
- 2- To harmonise the management of documents and time schedule between RMSs during the clock-off period**

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Clock-off period



- There is a need to improve this step by adopting new rules in order to avoid long delay in restarting the procedure.
- **For the applicant:** maximum time allowed to submit the response document. If it is not expected to receive the response document in due time, the applicant will be requested to withdraw the application.
- **For the RMS:** maximum time to provide a feedback about the draft response. This feedback will include a proposal of the date for the restart of the procedure, excepted in specific situations where the restart of the procedure will depend on the resolution of other issues.

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Assessment Step II / Main changes



- At the start of Step II (Day 120), the normal timetable should be followed i.e. comments from CMSs expected at Day 145.
- However, in specific situations, **a shorter timetable could be proposed**, especially when there are a few objections easily manageable. **But this short timetable has to be accepted by all CMSs. If not, the normal timetable will be maintained.**

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Assessment step II / Main changes



Suggestions to facilitate early discussions during the procedure in case of major issues:

- Possibility to organise a **hearing** as mentioned in the article 12 of the Rules of procedure of the CMD(h)
- Possibility to organise a BOS using **Vitero or telephone conference** in order to facilitate the participation from the Member States
- It is reminded that **during any time of the procedure, the RMS/CMSs could also use the meeting of the CMD(h)** as an opportunity to discuss major issues that are raised during the procedure and seek assistance in solving the issues

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End of procedure / Main changes



- Following the opinion received from EU Commission:

At the end of the procedure, if the RMS concludes that the product is not approvable:

the RMS includes information in the FAR on the remaining outstanding issues and closes the procedure.



No referral to CMD(h) will follow even if other CMSs are not in agreement with the RMS