Flow chart of the Decentralised Procedure

1. Introduction

This flow chart of the Decentralised Procedure (DCP) is applicable for human medicinal products.

2. Flow Chart

Key aspects of the agreed flow chart include:

- A streamlined procedure with the possibility for shortened approval times in straightforward cases.
  The DCP is a single procedure that could end at different stages taking into account:
  - Harmonisation of originator SmPCs;
  - The quality of the file;
  - The assessment report;

It is possible to end the procedure at any time point during the procedure if consensus is reached.

Early ending of the procedure is likely for substances where a harmonised SmPC is already available.

- There will be early involvement by the Co-ordination Group to assist in reaching consensus before Day 210 of the procedure, and ahead of the CMDh referral procedure foreseen in the legislation to resolve disagreements.

- Detailed procedural guidance to complement the flow chart has been developed and published by the CMDh.

3. Conclusion

This DCP flow chart has resulted in a simplified, attractive choice of procedure.
## Table 1. Flow Chart of the Decentralised Procedure

<table>
<thead>
<tr>
<th>Pre-procedural Step</th>
<th>Description</th>
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<tbody>
<tr>
<td>Before Day -14</td>
<td>Applicant discussions with RMS. RMS allocates procedure number. Creation in CTS.</td>
</tr>
<tr>
<td>Day -14</td>
<td>Submission of the dossier to the RMS and CMSs. Validation of the application using RMS / CMS validation checklist for human medicinal products in DCP. Positive validation by CMS should only be indicated in CTS, not via e-mail.</td>
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### Assessment step I

<table>
<thead>
<tr>
<th>Day 0</th>
<th>RMS starts the procedure. The CMSs are informed via CTS.</th>
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<tbody>
<tr>
<td>Day 70</td>
<td>RMS forwards the Preliminary Assessment Report (PrAR) (including comments on SmPC, PL and labelling) on the dossier to the CMSs and the applicant.</td>
</tr>
<tr>
<td>Until Day 100</td>
<td>CMSs send their comments to the RMS, CMSs and applicant. It may also be sufficient for the CMS to indicate in CTS only in case there are no additional comments.</td>
</tr>
<tr>
<td>Until Day 105</td>
<td>Consultation between RMS and CMSs and applicant. If consensus not reached RMS stops the clock to allow applicant to supplement the dossier and respond to the questions.</td>
</tr>
<tr>
<td>Clock-stop period</td>
<td>Applicant may send draft responses to the RMS and agrees the date with the RMS for submission of the final response. Applicant sends the final response document to the RMS and CMSs within a period of 3 months, which can be extended by a further 3 months.</td>
</tr>
<tr>
<td>Day 106</td>
<td>RMS restarts the procedure following the receipt of a final response or expiry of the agreed clock-stop period if a response has not been received. The CMSs are informed via e-mail and CTS will be updated accordingly.</td>
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### Assessment step II

<table>
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<tr>
<th>Day 120 (Day 0)</th>
<th>RMS sends the DAR, draft SmPC, draft labelling and draft PL to CMSs and the applicant. The quality assessor at the RMS completes a product surveillance risk assessment template, if applicable. This risk assessment is designed to provide information for post-marketing surveillance analysis by Official Medicines Control Laboratories.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 145 (Day 25)</td>
<td>CMSs send comments to RMS, CMSs and the applicant. It may also be sufficient for the CMS to indicate in CTS only in case there are no additional comments.</td>
</tr>
<tr>
<td>Day 150 (Day 30)</td>
<td>RMS may close procedure if consensus reached. Proceed to national 30 days step for granting MA.</td>
</tr>
<tr>
<td>Day 160</td>
<td>Applicant sends the response document to CMSs and RMS.</td>
</tr>
<tr>
<td>Until 180 (Day 60)</td>
<td>If consensus is not reached by day 150, RMS to communicate outstanding issues with applicant, receive any additional clarification, prepare a short report and forward it to the CMSs and the applicant.</td>
</tr>
<tr>
<td>Day 195 (at the latest)</td>
<td>A Break-Out Session (BOS) may be held at the European Medicines Agency (or via TC) with the involved MSs to reach consensus on the major outstanding issues.</td>
</tr>
<tr>
<td>Between Day 195 and Day 210</td>
<td>RMS consults with the CMSs and the applicant to discuss the remaining comments raised.</td>
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#### Day 210 (Day 90)

If consensus is reached:
- In case of positive position from RMS, Closure of the procedure including End of Procedure letter, final Day 210 overview AR, SmPC, labelling and PL, active substance and finished product specifications and proceed to national 30 days step for granting the MA.
- In case of negative position from the RMS, closure of the procedure negatively. The End of Procedure letter and final Day 210 overview AR is circulated.

If consensus is not reached:
- In case of negative position from CMS, CMS notify the RMS, the other CMSs, applicant and the secretariat of the CMDh. Referral to the CMDh.
- At the latest, within 7 days after Day 210)

If consensus on a positive RMS AR was not reached at day 210, the points of disagreement submitted by CMS will be referred by the RMS to the CMDh for resolution.
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<th>Day 270 (at the latest)</th>
<th>Final position adopted by CMDh with referral to CHMP for arbitration in case of unsolved disagreement.</th>
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<tr>
<td><strong>National step</strong></td>
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<tr>
<td>7 days after close of procedure</td>
<td>Applicant sends high quality national translations of SmPC, labelling and PL to CMSs and RMS.</td>
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<tr>
<td>30 days after close of the procedure</td>
<td>Granting of national marketing authorisation in RMS and CMSs if outcome is positive and there is no referral to the CMDh. (National Agencies will adopt the decision and will issue the marketing authorisation subject to submission of acceptable translations).</td>
</tr>
<tr>
<td>30 days after close of CMD referral procedure</td>
<td>Granting of national marketing authorisation in RMS and CMSs if positive conclusion by the CMDh and no referral to the CHMP (National Agencies will adopt the decision and will issue the marketing authorisation subject to submission of acceptable translations).</td>
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