

FLOW CHART OF THE DECENTRALISED PROCEDURE

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1. Introduction

In July 2005, The Heads of Medicines Agencies (HMA) agreed that common principles should apply to both human and veterinary medicinal products for the flow chart of the Decentralised Procedure (DCP). This revision of the flow chart has been made taking into account the experience gained during the first 3 years after implementation of the decentralised procedure.

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 Groups (Human and Veterinary) to assist in reaching consensus before Day 210 of the procedure, and ahead of the CMD referral procedure foreseen in the legislation to resolve disagreements.
- Detailed procedural guidance to complement the flow chart has been developed and published by CMDh and CMDv.

3. Conclusion

This new DCP flow chart has resulted in a simplified, attractive choice of procedure. It reflects a common strategy with human and veterinary procedures.

Flow Chart of the Decentralised Procedure – May 2010

Pre-procedural Step	
Before Day -14	Applicant discussions with RMS RMS allocates procedure number. Creation in CTS.
Day -14	Submission of the dossier to the RMS and CMSs Validation of the application
Assessment step I	
Day 0	RMS starts the procedure
Day 70	RMS forwards the Preliminary Assessment Report (PrAR) (including comments on SmPC, PL and labelling) on the dossier to the CMSs and the applicant
Until Day 100	CMSs send their comments to the RMS, CMSs and applicant
Until Day 105	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.
Clock-off period	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.
Day 106	RMS restarts the procedure following the receipt of a valid response or expiry of the agreed clock-stop period if a response has not been received.
Assessment step II	
Day 120 (Day 0)	RMS sends the DAR, draft SmPC, draft labelling and draft PL to CMSs and the applicant
Day 145 (Day 25)	CMSs send comments to RMS, CMSs and the applicant
Day 150 (Day 30)	RMS may close procedure if consensus reached Proceed to national 30 days step for granting MA
Until 180 (Day 60)	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
Day 195 (at the latest)	A Break-Out Session (BOS) may be held at the European Medicines Agency with the involved MSs to reach consensus on the major outstanding issues
Between Day 195 and Day 210	RMS consults with the CMSs and the applicant to discuss the remaining comments raised.
Day 210 (Day 90)	Closure of the procedure including CMSs approval of assessment report, SmPC, labelling and PL, or referral to Co-ordination group. Proceed to national 30 days step for granting MA.
Day 210 (at the latest)	If consensus on a positive RMS AR was not reached at day 210, points of disagreement will be referred to the Co-ordination group for resolution
Day 270 (at the latest)	Final position adopted by Co-ordination Group with referral to CHMP/CVMP for arbitration in case of unsolved disagreement
National step	
5 days after close of procedure	Applicant sends high quality national translations of SmPC, labelling and PL to CMSs and RMS
30 days after close of the procedure	Granting of national marketing authorisation in RMS and CMSs if outcome is positive and there is no referral to the Co-ordination group. (National Agencies will adopt the decision and will issue the marketing authorisation subject to submission of acceptable translations).
30 days after close of CMD referral procedure	Granting of national marketing authorisation in RMS and CMSs if positive conclusion by the Co-ordination group and no referral to the CHMP/CVMP. (National Agencies will adopt the decision and will issue the marketing authorisation subject to submission of acceptable translations).