

FLOW CHART OF THE DECENTRALISED PROCEDURE

Doc. Ref.: CMDh/080/2005/Rev10

~~July 2005~~ May 2010

1. Introduction

~~In July 2005, The Heads of Medicines Agencies (HMA) together with MRFG and VMRFG have agreed a flow chart for the Decentralised Procedure (DCP). Common~~ that common principles ~~will~~ should apply to both human and veterinary medicinal products.

~~2. Background~~

~~Early consideration for the flow chart of draft proposals for practical arrangements with the new~~ 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 resulted in many comments from stakeholders, including industry representatives. There has since been intensive work to develop an improved procedure suitable for national competent authorities and industry. A finalised outline procedure (flow chart) was agreed at the HMA meeting in July 2005.

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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 ~~SPCs~~ SmPCs
 - The quality of the file
 - The assessment report

~~It is possible to end the procedure at Day 105 any time point during the procedure if consensus is reached, at Day 120, at Day 150 and at Day 210 (followed in each case by 30 days for the national step — text translations/granting of marketing authorisation). Also at Day 270 if the Co-ordination Group (CMD) achieves agreement.~~

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Early ending of the procedure is likely for substances where a harmonised SPCSmPC 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 ~~60-Day-CMD~~CMD referral procedure foreseen in the legislation to resolve disagreements.
- ~~National~~Detailed procedural guidance to complement the flow chart has been developed and published by CMDh and European step concepts are replaced by Assessment Step I and Assessment Step II.CMDv.

~~4. Procedural Guidance~~

~~Detailed procedural guidance to complement the flow chart is under development by MRFG and VMRFG.~~

~~3. Conclusion~~

~~This will be released for consultation to interested groups when available. The guidance will stress the necessity for applicants to submit good quality translations at an early stage of the 30-Day national step that completes the procedure.~~

~~5. Conclusion~~

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

~~MRFG
JULY 2005~~

Flow Chart of the Decentralised Procedure – ~~July 2005 Revision Final~~ 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 (PAR), SPC-PrAR (including comments on SmPC, PL and labelling) on the dossier to the CMSs <u>and the applicant</u>
Until Day 100	CMSs send their comments to the RMS, <u>CMSs and applicant</u>
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 recommended period of 3 months, which could <u>can be extended if justified by a further 3 months.</u>
Day 106	Valid submission of the response of the applicant received. RMS restarts the procedure <u>following the receipt of a valid response or expiry of the agreed clock-stop period if a response has not been received.</u>
Day 106 – 120	RMS updates PAR to prepare Draft Assessment Report (DAR) draft SPC, draft labelling and draft PIL to CMSs.
Day 120	RMS may close procedure if consensus reached. Proceed to national 30 days step for granting MA.
Assessment step II	
Day 120 (Day 0)	If consensus not reached RMS sends the DAR, draft SPC SmPC, draft labelling and draft PH-PL to CMSs <u>and the applicant</u>
Day 145 (Day 25)	CMSs send final comments to RMS, <u>CMSs and the applicant</u>
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 and , prepare a short report for discussion at Coordination Group and forward it to the CMSs and the applicant
Until Day 205 (Day 85) Day 195 (at the latest)	Breakout Group of A Break-Out Session (BOS) may be held at the European Medicines Agency with the <u>involved Member States</u> reaches <u>MSs to reach consensus on the matter</u> <u>major outstanding issues</u>
Between Day 195 and Day 210 (Day 90)	Closure of the procedure including CMSs approval of assessment report, SPC, labelling and PIL, or referral to Co-ordination group. <u>Proceed to national 30 days step for granting MA.</u> RMS consults with the CMSs and the applicant to discuss the remaining comments raised.
Day 210 (at the latest) Day 90)	If consensus was not reached at day 210, points of disagreement will be referred to the Co-ordination group for resolution Closure of the procedure including CMSs approval of assessment report, SmPC, labelling and PL, or referral to Co-ordination group. <u>Proceed to national 30 days step for granting MA.</u>
Day 210 (at the latest)	<u>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</u>

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	
<u>Day 110/125/155/215/2755 days after close of procedure</u>	Applicant sends high quality national translations of <u>SPC</u> <u>SmPC</u> , labelling and <u>PL</u> <u>PL</u> to <u>CMSCMSs</u> and RMS
<u>Day 135/150/180/24030 days after close of the procedure</u>	Granting of national marketing authorisation in RMS and CMSs if <u>outcome is positive and there is</u> 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).
<u>Day 30030 days after close of CMD referral procedure</u>	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).