Decentralised Procedure Process Timetable

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Experts in Decentralized Procedures (DCP) in EMA

More than 80 successfully submitted DCP

Pre-submission

- Applicant discussions with RMS.
- RMS allocates procedure number.
- Submission of the dossier to RMS and CMSs.
- Creation of the procedure in CTS database.
- Pre-procedural steps.
- Valid submission of the application received.
- RMS starts the procedure.

Start of the procedure

Assessment step I

- **Day 70:** RMS forwards the Preliminary Assessment Report (PAR), SPC , PL and labelling to CMSs and applicant.
- **Day 100:** CMSs send their comments to RMS.
- Consultation between RMS and CMSs and applicant.
- If consensus is not reached, RMS stops the clock to allow applicant to supplement the dossier and respond to the questions.

Clock Stop

Day 105 LoQ

Clock stop Max. 6 months

Preparation of Responses

- Publishing activities connected with Response Document (Day 106).
- Draft response submission to the RMS, if agreed by the RMS
- Applicant agrees on submission date of final response document with RMS.

Restart of the clock

Submission of responses

Assessment step II

Day 120:

- RMS sends the Draft Assessment Report (DAR), draft SmPC, draft labelling and draft PL to CMSs and applicant.

Day 0 — 105 — 106 — 120 — 145 — 210 — Day 270 — 30 days after closure of the procedure

National marketing authorisation

National Step

7 days after procedure is closed:

- In case the procedure ends with a decision that the product is approvable, applicant sends national translations of SmPC, labelling and PL (and mock-ups, if required) to CMSs and RMS.

30 days after submission of translations:

- Granting of national marketing authorisations in RMS and CMSs.

Closure of Procedure

Day 210: RMS closes the procedure if consensus is reached that the product is approvable.
If consensus is not reached, points of disagreement are referred to the CMDh for resolution.
Day 270: Final position adopted by CMDh with referral to CHMP for arbitration in case of unsolved disagreement.

2nd Assessment

Day 145: CMSs send comments to RMS, CMSs and applicant.
Day 150:

- RMS may close procedure if consensus is reached.
- If consensus is not reached, RMS communicates outstanding issues with applicant.

Day 160: Applicant sends the response document to RMS and CMSs.
Day 180: If consensus is not reached, RMS sends Day 180 Assessment Report.
Day 195: A Breakout Session (BOS) may be held at the EMA with the involved MSs to reach consensus on the major outstanding issues.

- *RMS consults with the CMSs and the applicant to discuss the remaining comments raised.*

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