Decentralised Procedure Process Timetable

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Experts in Decentralized Procedures (DCP) in EMA More than 80 successfully submitted DCPs

- · 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.

Pre-submission

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.

Assessment step I

Clock Stop

 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

Preparation of Responses

Restart of the clock

Submission of responses

Day 120:

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

Assessment step II

Start of the procedure

Day 105 LoQ

Clock stop

Max. 6 months

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 mockups, 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.