Mutual Recognition Procedure Timetable

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ASPHALION
Knowledge from experience

PRE-SUBMISSION

90 days before submission: RMS updates Assessment Report (AR) and allocates procedure number

SUBMISSION

Day -14: Applicant submits the dossier. Validation of the application by RMS and CMSs

Start of the procedure

60 DAYS PROCEDURE

- **Day 0:** RMS starts the procedure
- **Day 30:** CMSs send comments
- **Day 40:** Applicant submits the response document
- **Until day 48:** RMS evaluates and circulates a report on the applicant's response to CMS
- **Day 55:** CMSs send their remaining comments
- **Day 55-59**: RMS and CMSs clarify if the procedure can be closed at Day 60

Day 60

If CMSs have no remaining comments, the RMS closes the procedure at Day 60.

In case a CMS has remaining comments, the applicant submits the response document

90 DAYS PROCEDURE

- **Until day 68:** RMS evaluates and circulates a report on the applicant's response.
- **Day 75:** CMSs send their remaining comments
- **Day 85:** CMSs send any remaining comments in case of break-out session
- **Day 90: CMSs** final position

Day 90

If CMSs have no remaining comments, the RMS closes the procedure at day 90.

If consensus is not reached (Less than 1% procedures)

REFERRAL

Within 7 days: The points for disagreement are referred to CMDh

Day 150

Final position by CMDh. If consensus is reached, the RMS closes the procedure

If consensus is not reached (Less than 1% procedures)

ARBITRATION

RMS refers immediately the matter to EMA for CHMP arbitration

NATIONAL PHASE

If consensus is reached, RMS closes the procedure:

- **7 days after EoP:** Applicant sends national translations of SmPC, PL and labelling to CMSs
- **30 days after EoP:** Granting of national Marketing Authorizations in the CMSs subject to submission of acceptable translations

NATIONAL MARKETING AUTHORISATION