Centralised Procedure Process Timetable

www.asphalion.com

ASPHALION

20 years providing vision and experience to manage global submissions

Experts in Centralized Procedures (CP) in EMA

More than 40 successfully submitted CP

Pre-submission

- Letter of Intent + Eligibility
- Invented Name
- (Co-)Rapporteurs Appointment Request
- Pre-Submission meeting
- eCTD compilation & Publishing initial for MAA

Start of the procedure

Assessment

- CHMP (Co-)Rapporteurs AR
- PRAC Rapporteur AR
- Comments from CHMP & PRAC on RMP AR
- Updated PRAC Rapporteur AR, PRAC Advice Adoption and early draft LoQ (for Peer review TC)
- Peer Review TC
- Draft LoQ

Clock Stop

LoQ or Opinion

Clock stop
Max. 6 months

Preparation of Responses

- Publishing activities connected with Response Document (day 121)
- Information to CHMP of the response submission date (-1 month)

Restart of the clock

Submission of responses

Assessment of Responses

Joint Response Assessment Report from (Co-)Rapporteurs

Day 0 — 120 — 121 — 180 — 181 — Day 277

Final Commission Decision

Final EC decision

Final Opinion

- Day 210 Adoption of CHMP Opinion and CHMP Assessment Report
- Day 215 at the latest - Presentation of translated product information
- Day 235 at the latest - Presentation of final translations of SmPC, Annex II, labelling and package leaflet, and Annexes IV and 127a if applicable; in the 25 languages by Eudralink
- Day 237 Transmission of CHMP Opinion to applicant and Commission
- Post-Opinion - Submission of eCTD closing sequence including final adopted annexes
- Day 239-261 Draft Commission Decision
- Day 277 Final Commission Decision

Restart of the clock

Submission of responses

Preparation of Responses

Publishing activities connected with Response Document (day 181)

Clock Stop

LoOI and/or oral explanation

Clock stop
Max. 1 month

info@asphalion.com