## **Centralised Procedure Process Timetable**

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<ul> <li>Letter of Intent + Eligibility</li> <li>Invented Name</li> <li>(Co-)Rapporteurs Appointment Request</li> <li>Pre-Submission meeting</li> <li>eCTD compilation &amp; Publishing initial for MAA</li> </ul>	Start of the procedure	<ul> <li>CHMP (Co-)Rapporteurs AR</li> <li>PRAC Rapporteur AR</li> <li>Comments from CHMP &amp; PRAC on RMP AR</li> <li>Updated PRAC Rapporteur AR, PRAC Advice Adoption and early draft LoQ (for Peer review TC)</li> <li>Peer Review TC</li> <li>Draft LoQ</li> </ul>		Clock Stop	<ul> <li>Publishing activities connected with Response Document (day 121)</li> <li>Information to CHMP of the response submission date (-1 month)</li> </ul>		Restart of the clock	Joint Response Assessment Report from (Co-)Rapporteurs	
Pre-submission	Start	Assessment		LoQ or Opinion Clock stop Max. 6 months Respons			Submission of responses	Assessment of Responses	
	▦	Day 0		120			121		
Day 277					181			180	
Final EC decision			Final Opinion		Restart		ration of ponses	Clock Stop	
<ul> <li>Day 210 Adoption of CHMP Opinion and CHMP Assessment Report</li> <li>Day 215 at the latest - Presentation of translated product information</li> <li>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</li> <li>Day 237 Transmission of CHMP Opinion to applicant and Commission</li> <li>Post-Opinion - Submission of eCTD closing sequence including final adopted annexes</li> <li>Day 239-261 Draft Commission Decision</li> <li>Day 277 Final Commission Decision</li> </ul>					clock Submission of responses	Publishing activities connected with Response Document (day 181)		LoOI and/or oral explanation Clock stop Max. 1 month	