



EMA-CVM Parallel Scientific Advice (PSA) Timetable¹

Day	CVM	EMA
Anytime	Applicant/sponsor submits a complete request for PSA to CVM and EMA One or both agencies decline → no PSA Both agencies accept → PSA proceeds, validation starts	
~30 days		Scientific advice (SA) request validation phase; EMA validates the SA request
Day 0	Procedure begins; EMA appoints a coordinator ² for the procedure; the sponsor sends CVM the complete meeting package that has been validated by EMA	
Day 0 - 70	CVM internal meeting	SA coordinator prepares draft SA report
Day 70	CVM sends preliminary comments to EMA	EMA sends draft scientific advice report to CVM
Day 71 – 77	Bilateral CVM/EMA meeting	
Day 74 – 80	Send preliminary comments to applicant/sponsor	

¹ This document shows a general timetable that reflects the stages and timing of PSA procedure in principle. An exact timetable will be designed for each PSA.

² A member of the veterinary Scientific Advice Working Party responsible for preparing EMA’s scientific advice report

Day	CVM	EMA
Day 78 - 84	Trilateral meeting with applicant/sponsor, CVM, and EMA, followed by a short bilateral CVM/EMA meeting	
Day 84 - 114	CVM issues final meeting minutes (30 days after trilateral)	EMA issues final scientific advice report (Following the CVMP meeting at which the report is adopted)

Expectations:

- High quality submission
- Intention to authorize the product in both jurisdictions
- Specific questions to development plan or study design
 - May include summaries of studies/data but no raw data for review