



**EMA-CVM Parallel Scientific Advice (PSA) Timetable<sup>1</sup>**

<b>Day</b>	<b>CVM</b>	<b>EMA</b>
<b>Anytime</b>	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	
<b>~30 days</b>		Scientific advice (SA) request validation phase; EMA validates the SA request
<b>Day 0</b>	Procedure begins; EMA appoints a coordinator <sup>2</sup> for the procedure; the sponsor sends CVM the complete meeting package that has been validated by EMA	
<b>Day 0 - 70</b>	CVM internal meeting	SA coordinator prepares draft SA report
<b>Day 70</b>	CVM sends preliminary comments to EMA	EMA sends draft scientific advice report to CVM
<b>Day 71 – 77</b>	Bilateral CVM/EMA meeting	
<b>Day 74 – 80</b>	Send preliminary comments to applicant/sponsor	

<sup>1</sup> 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.

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

Day	CVM	EMA
<b>Day 78 - 84</b>	Trilateral meeting with applicant/sponsor, CVM, and EMA, followed by a short bilateral CVM/EMA meeting	
<b>Day 84 - 114</b>	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