



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

27 May 2026  
EMA/116340/2026

Agenda – 16<sup>th</sup> Meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines.

15 June 2026, C.E.T.: 13:00–18:00 hybrid meeting: meeting room 01-A and WebEx

**Chair: Alberto Ganan Jimenez**

Item	Topics Nov 2025
	Welcome / Introductions
1.	Implementation of new pharmaceutical legislation <ul style="list-style-type: none"><li>• EMA update on NPL activities in stream 1, 5, 6</li><li>• Industry NPL considerations and priorities</li><li>• Variations and annex II</li></ul>
2.	Variations implementation feedback from industry
	<b>Coffee Break</b>
3.	Centralised Procedure topics: <ul style="list-style-type: none"><li>• Update on Revamp AR</li><li>• Submission predictability</li></ul>
4.	Pre-submission interactions group (PreSIG)
5.	Roll-out of ePI vaccines
	<b>Coffee Break</b>
6.	Post-authorisation changes reliance pilot
7.	Update on digitalisation initiatives affecting CP submissions
	Summary of follow-up item

