EMA
EUROPEAN MEDICINES AGENCY

Actions arising from previous meeting and other updates

Presented by Maria Filancia, Industry liaison specialist

Actions arising from the 12th ISG meeting

Topic	Action	Follow up

2.1 Update on the development of the European Monitoring Platform	• MAHs to complete submission of packages in XEVMPD by end of May 2025.
	• MAHs to complete submission of manufacturers and structured pack size data in PUI/PMS API.
	  • For centrally authorised medicines (CAPs): submission not required as data is available, MAHs should confirm that PMS data is correct
	  • For non-CAPs included in the union list of critical medicines submission required until end of December 2025.
	  • For other non-CAPs submission required until end December 2026.
		• Ongoing

2.3. Cross-industry learnings on Union list of critical medicines	EMA to share the feedback received with the MSSG	• Ongoing
5 Regulatory/HTA interface under the HTA regulation	Industry stakeholders to ensure parallel submission of letter of intent to both EMA and HTA secretariat was stressed	• Ongoing
6. Cross-industry presentation: Survey results on Opening Procedures at EMA to Non-EU authorities (OPEN)	EMA to reflect on the feedback provided by industry stakeholders and provide an update to ISG when possible.	• Ongoing
7. Update on ePI	Industry stakeholders to participate to the public consultation on the Reflection paper on linking to electronic product information (ePI) from EU medicine packages by 30 June 2025.	• Reflection paper; public consultation ending on 30/06.
9. Industry stakeholders survey on communication and engagement	Industry stakeholders to submit 1 nomination per trade by the 11th of April.	• Nominations received from 12 organisations. Survey launched on 12/05. Consolidated feedback by 15/07. Interviews concluded in June. Report expected in Q4.

Other important updates and reminders

Topic	Action
Call for 2 Industry Subject Matter Experts nominations for ESMP extension to ensure compliance with the proposed pharmaceutical legislation and the Critical Medicines Act.	Each Industry stakeholder organisations to submit 1 nomination each by 25th July 2025 to availabilitySPOC@ema.europa.eu (CC PMO@ema.europa.eu; emaindustryliaison@ema.europa.eu) .
Agency 2024 annual report published	For awareness.
CHMP re-start face to face oral explanations	For awareness. As announced at the latest CP platform meeting (23/06/2025), a 1-year pilot on the re-introduction of in person oral explanation meetings will be launched in July 2025. The scope will include CHMP, CVMP, PRAC.
ICH M4Q(R2) Guideline on the Common Technical Document for the registration of pharmaceuticals for human use: Quality	For awareness. Public consultation open until 24/10/2025.

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Thank you

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