EMA
EUROPEAN MEDICINES AGENCY

Actions arising from previous meeting and other updates

Presented by Maria Filancia, Industry liaison specialist

Actions arising from the 15th ISG meeting

Topic	Action	Follow up
Agency approach to the implementation of the revised pharmaceutical legislation and stakeholders' engagement	• Industry stakeholders to raise awareness within their members and subscribe to the newsletter "EMA Industry Highlights". • The Agency to update ISG with more details on the implementation when available.	• Link to Reform of the EU pharmaceutical legislation webpage. • Subscription link to EMA Industry Highlights.
Regulatory/HTA interface under the HTA Regulation	• Industry to ensure compliance with the parallel submission of the letter of intent. • Industry to follow up directly with HTA secretariat to further discuss companies' needs on the eligibility requests overview.	• Ongoing
Updates on Opening Procedures at EMA to Non-EU authorities (OPEN) initiative	• The EMA to update the Q&A with the agreed clarifications. • Industry stakeholders to raise awareness within their members and encourage participation in the OPEN framework. • Industry to provide feedback on the interest in having veterinary applications in the scope of this procedure.	• Q&A published and circulated to ISG
Cross-Industry feedback on HMA-EMA Catalogues of real-world data sources and studies	• The EMA to reflect on how to integrate the recommendations made.	• Ongoing

Actions arising from the 15th ISG meeting

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Update on Product Management Service	• The Agency to reflect on industry consultation on the working arrangement documents and on the PMS data quality and keep industry updated.
	• Industry stakeholders to follow up on:
	  • Enrichment of Manufacturer's data & structured pack size for non-CAPs (ULCM) by June 2026.
	  • Enrichment of Manufacturer's data for all non-CAPs on the company's portfolio by December 2026.
	  • Enrichment of pack sizes for all non-CAPs & structured pack sizes on the company's portfolio by June 2027.
	  • Optional submission of data carrier ID for non-CAPs by June 2027.
		• On PMS data quality: points raised addressed at the Quarterly Strategic Portfolio Review meeting and in today's agenda.

8. Report on Industry stakeholders survey on communication and engagement	• EMA to implement the recommendations and provide regular updates. • ISG to keep up to date Agency's Stakeholder Database and Industry Liaisons with the areas of interest. • ISG to raise awareness within their nominees contributing to Agency activities of the importance to keep the relevant trade updated.	• Ongoing

Other important updates and reminders

Topic	Details
Union list of critical medicines 2026 annual update- closed	• the call for input to propose active substance groups (ASG) for addition or removal from the current version of the Union list in the context of the 2026 annual update with a deadline of 27 March 2026 was circulated to the ISG.

Portfolio and technology meeting applications now open until 30/04/2026	• Large pharmaceutical companies are invited to take advantage of PTM meetings taking place in the second half of 2026.
	• PTM aims at:
	  • identify issues affecting the progress of product portfolios;
	  • assist the successful development of medicines;
	  • anticipate scientific and regulatory expertise needs.

EMA Industry Highlights

New quarterly newsletter providing regular updates on the Agency's regulatory and policy developments that may require action.

Helping industry stay informed and navigate the regulatory process more effectively.

31st March first issue will include:

- Welcome message from Melanie Carr (Head of Stakeholders and Communication)
- Steffen Thirstrup (Chief Medical Officer) vision on biosimilars
- Update on implementation plans for the Reform of EU pharmaceutical legislation

EMA Industry Highlights Newsletter

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