EMA
EUROPEAN MEDICINES AGENCY

# Actions arising from previous meeting and other updates

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# Actions arising from the 13th ISG meeting

| Topic | Action | Follow up |
|---|---|---|
| Regulatory/HTA interface under the HTA Regulation | Industry stakeholders to raise awareness among members on the need to ensure parallel submission of the letter of intent to EMA and the HTA secretariat | • Ongoing |
| REACH impacts on the healthcare industry | • EMA to facilitate dissemination of information on relevant ECHA regulatory procedures (restrictions, classifications) to industry.<br>• Industry stakeholders to monitor ECHA requirements. | • Ongoing |
| Innovation and reliance | • Industry stakeholders to raise awareness on QIG product support meetings and PQKMS pilots.<br>• EMA to further evaluate how to discuss regulatory aspects with the QIG. | • Ongoing |
| Beyond COVID-19 Monitoring Excellence (BeCOME) initiative | Further discuss the topic with the ETF and relevant pharmacovigilance colleagues. | - |
| Ecosystem information management | EMA to update the ISG upon completion of the pilots. | • Ongoing |
| Patient Experience Data reflection paper | EMA to provide an update on the PED reflection paper at the next ISG meeting. | • Update to be presented at 14th ISG.<br>• Survey on industry experience with use of PED launched until 19/10. |
| European Platform for Regulatory Science Research | EMA to update the ISG on Industry observer-ship at the European platform for regulatory science research. | • Update to be presented at 14th ISG. |

# Other important updates and reminders

| Topic | Details |
|---|---|
| PMS PUI and API functionalities release and extended data submission deadlines | • 22/09/2025: release of PMS PUI bulk write for non-CAPS: enabling MAHs to edit multiple products at a time by entering the data required for the ESMP and shortages use cases, including Manufacturers, Manufacturing Business Operations (MBOs), structured package details, and data carriers.<br>• 25/09/2025: PMS API for non-CAPs: enable MAHs to directly submit data for manufacturers and pack sizes data carrier ID in bulk through the API.<br>• New deadlines:<br>  • By December 2026: submit structured Manufacturer's data for all other non-CAPs on the company's portfolio using PMS PUI and API.<br>  • By June 2026: enrichment of structured Manufacturer's data and pack size for non-CAPs (part of Union list of critical medicines) using Product UI and API.<br>  • By June 2027: enrichment of pack sizes for all other non-CAPs using XEVMPD and structured pack sizes using PMS PUI and API on the company's portfolio. |
| Portfolio and Technology Meetings: applications for Q1-Q2 2026 | The applications for having a Portfolio and Technology Meeting in Q1-Q2 2026 are now open until the 14th of November 2025: Supporting Innovation. |
| EMA welcomes the publication of the EC new Variations Guidelines | New EC Variations Guidelines published and applicable to all variation applications submitted as of the 15/01/2026.<br>• EMA guidance: Guidance on the application of the revised variations framework \| European Medicines Agency (EMA) |

# Other important updates and reminders

| Topic | Details |
|---|---|
| EU Repurposing pilot report | A report is available on a pilot that provided tailored scientific advice to not-for-profit organisations and academics on repurposing authorised medicines for new indications. The report contains findings and recommendations from the pilot. EMA and Heads of Medicines Agencies (HMA) carried out this pilot between 2021 and 2024. |
| Guideline on the pharmaceutical quality of inhalation and nasal medicinal products | This guideline replaces the guideline on pharmaceutical quality of inhalation and nasal products (EMEA/CHMP/QWP/49313/2005 Corr) and Quality of medicines questions and answers: Part 2 Specific type of products – Dry product inhalers; Orally inhaled products; Storage – What are the requirements for storage orientation recommendations in the product information for pressurized metered dose inhalers. |
| A common Mandate, objectives and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains has been endorsed by the CHMP and CVMP | The document describes the tasks of EMA working parties (WPs) under the domains and addresses the WPs composition, nomination and appointment of members, rules of participation for members, and rules of procedure. An annex lists all WPs under the domains that are covered by this document.<br>• Mandate, objectives and rules of procedure for EMA working parties under the domains. |
| Working towards regulatory sandboxes | • As part of the Agency's monitoring horizon scanning on future innovative products, informal ITF meetings with medicine developers may help to identify, at an early stage during development, potential case studies that could inform a regulatory sandbox approach in the future (if endorsed by the co-legislators)<br>• Innovation Task Force briefing meetings \| European Medicines Agency (EMA) |

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# Thank you

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