EMA
EUROPEAN MEDICINES AGENCY

Actions arising from previous meeting and other updates

Presented by Maria Filancia, Industry liaison specialist

Actions arising from the 17th ISG meeting

Topic	Action	Follow up
Regulatory/HTA interface under the HTA Regulation	• Industry to participate to HTA evaluation of rules consultation. • EMA/HTA secretariat to reflect on additional guidance.	• NA
Update on COMBO	• COMBO to reflect on simplifications and NBOs risk-based approaches	• ongoing
Instrument for Pre-accession Assistance (IPA) plans with candidate countries	• Industry to provide feedback to EMA on the experience with candidate countries	• ongoing
Revision of Framework for interaction with industry stakeholders and related documents	• EMA to circulate revised documents for consultation	• Update to be provided at ISG.

Other important updates and reminders

Topic	Details
Updated Guidance for industry on implementing Shortage Prevention Plans (SPP) - link	Guidance published on the 17th of July following consultation with stakeholders.
ICH E6(R3) Annex 2 on Good Clinical Practice published	ICH E6(R3) Guideline for Good Clinical Practice Step 5
Payment by SEPA Direct Debit Business-to-Business - link	Guidance to for marketing authorisation holders and applicants now available medicines
Pre-submission activities now on IRIS	As of 19th of August several pre-submission activities for Human (H) and Veterinary (V) centrally authorised products (CAPs) and including companion diagnostic and medical devices with an ancillary medicinal substances ~~will be~~ are managed via IRIS platform. As of 1st September initial marketing authorisation applications (iMAA) for both human and veterinary CAPs are managed on the IRIS platform.
Updated pre-authorisation procedural advice for users of the centralised procedure - link	**New** The applicants notify the HTA Secretariat by providing the IRIS generated forms for **eligibility and intent** (downloaded from IRIS) through the HTA IT platform. This will enable the JCA pre-submission phase to start in parallel to the MAA pre-submission phase. Also see the HTA unit published guidance on submission of early information
Open call Q1-Q2 2027 Portfolio and technology meetings by 30/10/2026	EMA invites large pharmaceutical companies to apply for a meeting by filling in the application: Portfolio and technology meetings Q1-Q2 2027- Application form by 30/10/2026.
Submitting ePI for centralised procedures – guidance published	Guidance for applicants published: Electronic product information (ePI) | European Medicines Agency (EMA)

EMA Industry Highlights

Nex issue sneak peek (30th September)

- Spotlight “Understanding Global reach of EMA Assessment” – Martin Harvey-Allchurch (Head of International affairs)
- EU pharmaceutical legislation: overview of latest discussions and activities (ISG updates; publication of SPP guidance).
- Call to action: EU-IN survey on TEC guidance; Open call for Portfolio and Technology Meetings

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