EMA
EUROPEAN MEDICINES AGENCY

EMA's implementation of IPA programme

15th meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines

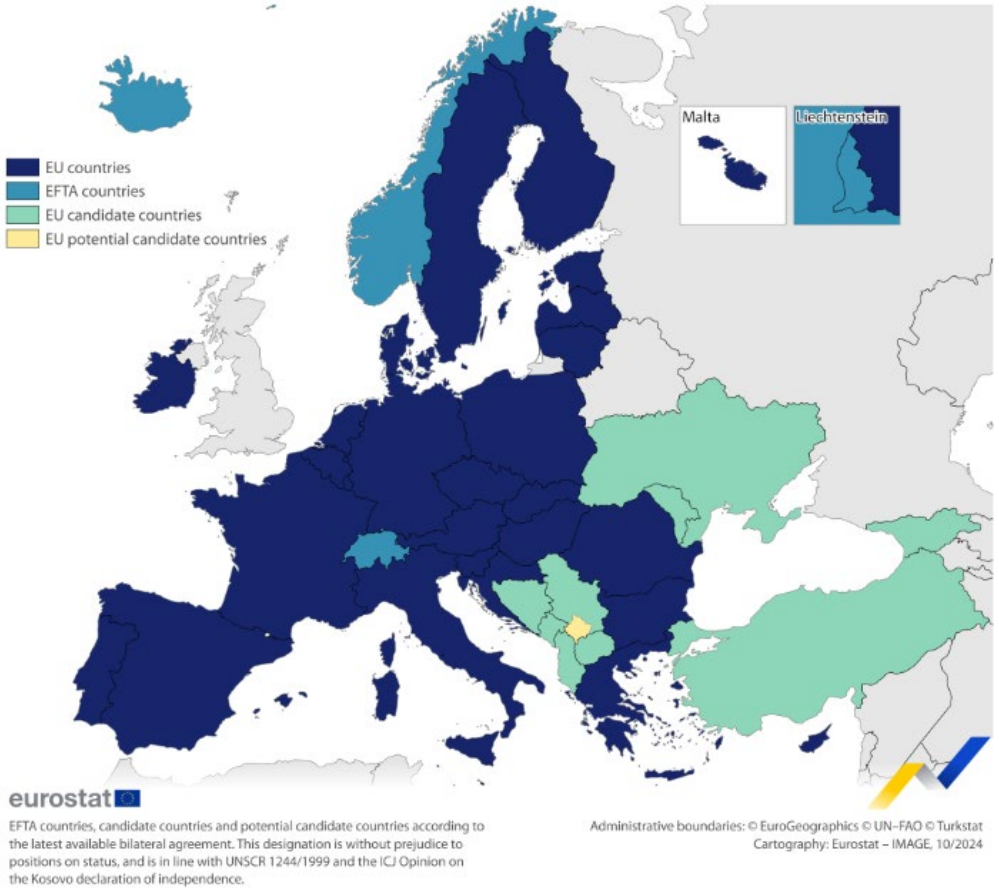
27 November 2025

European Medicines Agency
International Affairs Division

Instrument for Pre-accession Assistance programme (IPA)

- The European Commission's **Instrument for Pre-accession Assistance (IPA)** programme supports the preparation of enlargement countries in the work of selected EU agencies.
- Historical context: EMA engaged in IPA I (2008-2014), IPA II (2018-2023) and **IPA III (2024-2026)** ensuring continuity of assistance to the beneficiary countries.
- Aim: building working relationships with the beneficiary national competent authorities, to prepare for their future collaboration in the European medicines regulatory network.

IPA beneficiaries



- Albania
- Bosnia and Herzegovina
- Kosovo*
- Montenegro
- North Macedonia
- Serbia
- Türkiye

Georgia, Moldova and Ukraine also participate in the IPA activities

Instrument for pre-accession assistance training programme (IPA)

Areas of intervention:

- Strengthen the assessment capacity for medicinal products for human and veterinary use.
- Increasing scientific cooperation among national health products regulatory authorities of IPA countries as well as with EU Member States and EMA.
- Fostering preparedness and harmonization of medicines regulation in IPA countries with EU Acquis.

Achievements/results:

- Trained experts in medicines regulatory institutions IPA beneficiaries.
- Beneficiaries reported on improved alignment with medicines legislation with EU acquis.

Offering assistance to beneficiary national competent authorities in aligning their standards and practices with those established in the EU.

IPA III – programme activities

I EMA training sessions on selected topics

Demand-driven trainings

Face-to-face/ hybrid training sessions at EMA (one seminar per year)

Online training sessions

IPA III – programme activities

II Participation in selected EMA working groups

Shortages:

- Medicine Shortages Single Point of Contact (SPOC) Working Party

Inspections:

- Good Manufacturing Practice (GMP)/Distribution Practice (GDP) Inspectors Working Group
- Good Clinical Practice Inspectors Working Group
- Pharmacovigilance Inspectors Working

AMR and One Health:

- Environmental Risk Assessment Working Party
- Immunologicals Working Party
- Antimicrobials Working Party
- European Sales and Use of Antimicrobials for Veterinary Medicines Working Group (ESUAvet WG)

IPA III – programme activities

III Access to EMA's Learning Management System

Access to EU NTC from end of 2024

High interest – 250 users registered

Catalogue of over 100 courses which is continuously expanded

IPA III - challenges

- Uniform approach vs individual needs
- Further alignment of legislation while new EU Pharma legislation is coming
- Involvement of ‘new’ EU candidates: Georgia, Moldova and Ukraine without adjusted programme scope

IPA III – future

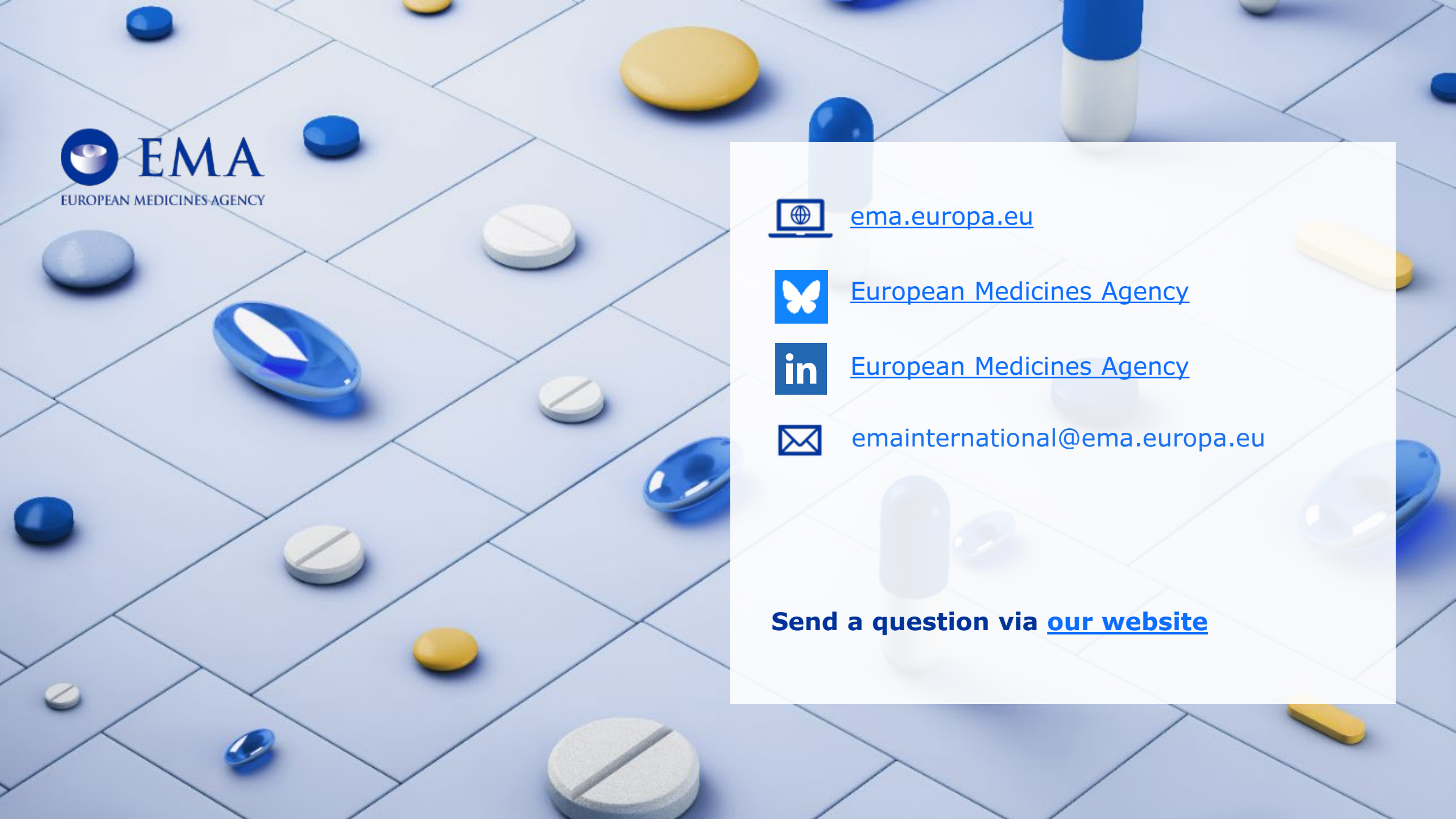
- EU accession a political decision
- Planning for next IPA iteration from 2027
  - Budget similar to current one
  - Funding for Moldova and Ukraine
  - Feedback form candidate countries on their needs
  - EU NTC courses allowing for tailored approach

Questions to Industry

1) How do you assess the current level of regulatory convergence between EU candidate countries and EU pharmaceutical standards?

2) What is your view on the attractiveness of these markets for pharmaceutical investment and innovation?

3) How can industry collaborate with regulators and governments in candidate countries to accelerate readiness?



EMA
EUROPEAN MEDICINES AGENCY

ema.europa.eu

European Medicines Agency

European Medicines Agency

emainternational@ema.europa.eu

Send a question via our website