EMA
EUROPEAN MEDICINES AGENCY

EU enlargement – EMA support to candidate countries

17th Industry Standing Group (ISG) meeting

29 June 2026

European Medicines Agency
International Affairs

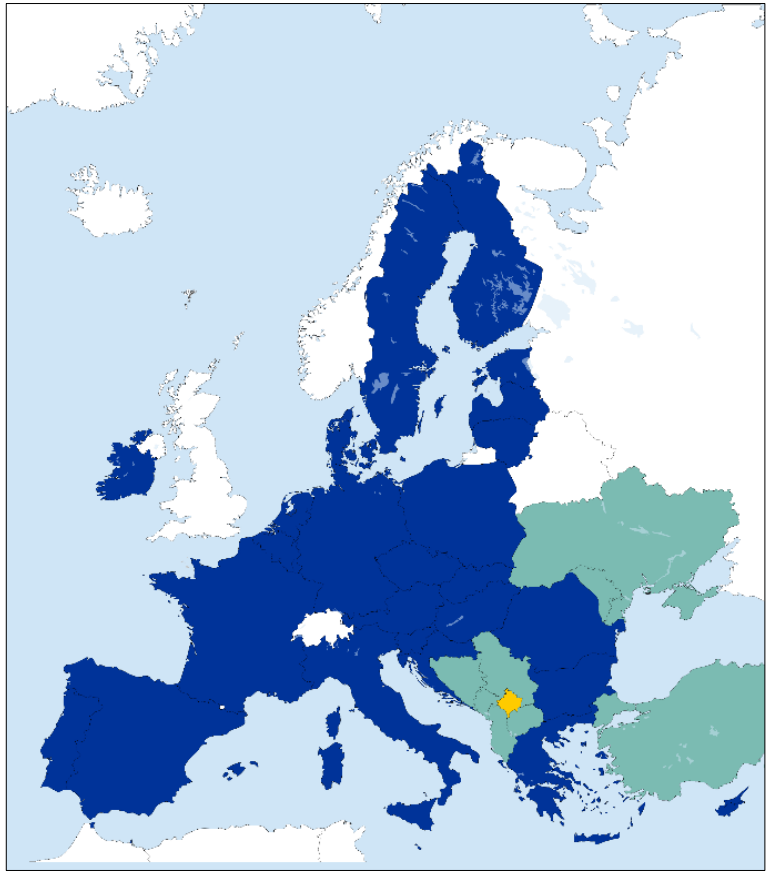
Instrument for Pre-accession Assistance - overview

Current IPA III cycle – from 2024-2026

Target authorities: Albania, Bosnia-Herzegovina, Kosovo, North-Macedonia, Montenegro, Serbia, Türkiye

Other EU candidate countries: Georgia, Moldova and Ukraine

Aim: Helping beneficiary national competent authorities in aligning their standards and practices with those established in the EU and to prepare beneficiaries for their future collaboration in the European medicines regulatory network.



IPA III – programme activities

I EMA training sessions on selected topics

Demand-driven trainings

Face-to-face / hybrid training sessions at EMA

Proactive invitation to all EMA workshops and events

Training focus in 2026: clinical trials, NPL, inspections

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 Group

Stakeholder engagement:

- Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP)

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 since 2024

High interest – over 300 registered users

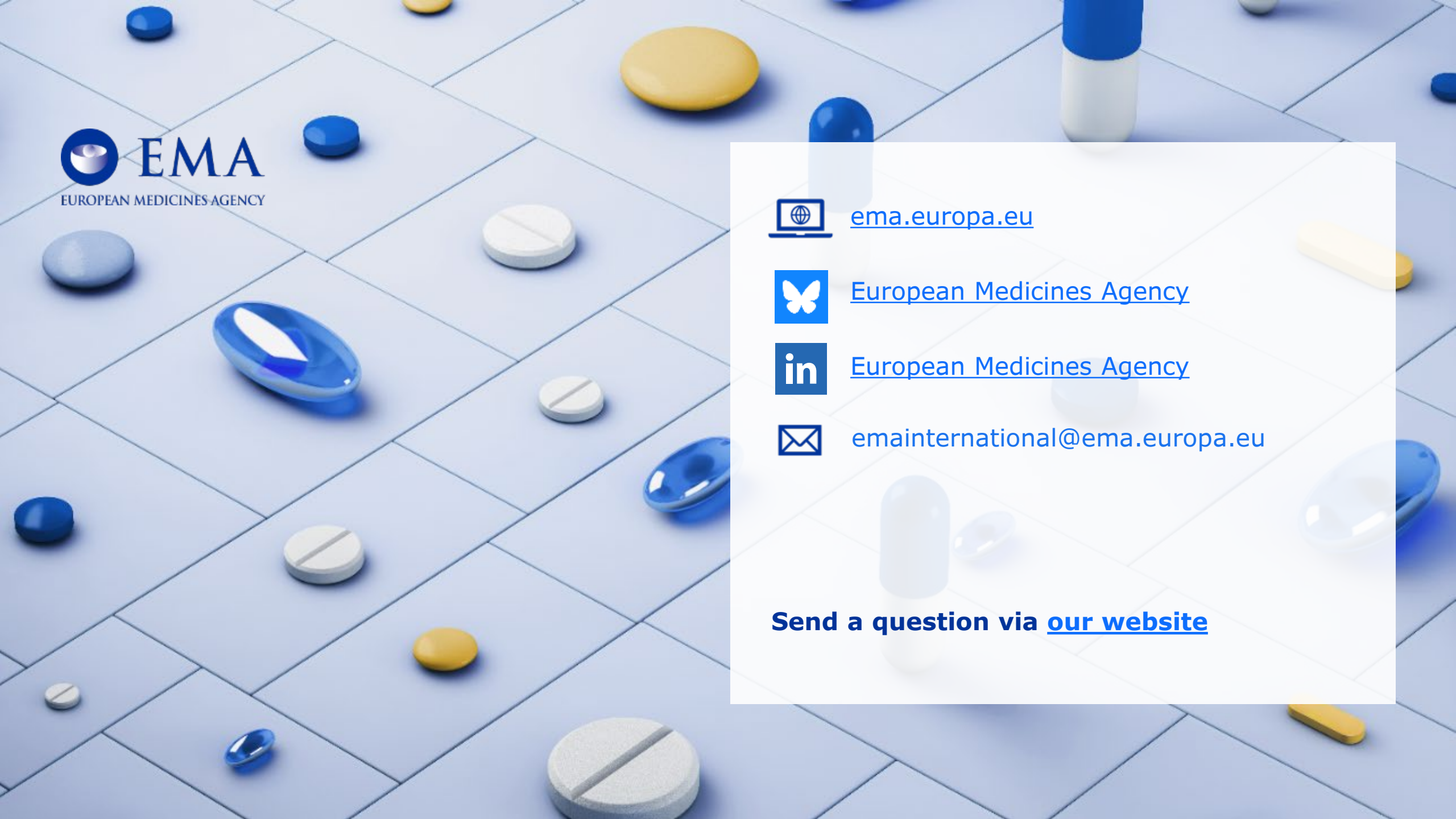
Catalogue of around 150 courses which is continuously expanded

IPA IV

- EU accession is a political decision
- IPA targets all candidate countries; if a country is confirmed to join the EU – separate actions
- Planning for next IPA iteration from 2027
    - Similar budget level, plus specific funding for Moldova and Ukraine for first time
    - Continue with the three main strands of activities: dedicated trainings, WP-WG observership, online training via EU NTC
    - Include as observers in the BEMA NCA benchmarking cycle (starts 2027)
    - Promote and support participation in joint EMA/WHO Post-Approval Changes reliance pilots
    - Foster alignment of medicinal product authorisations
    - Significant legislative updates in the coming years – include candidate countries from the start

Questions to industry

1) Based on your experience, what were the main challenges faced by candidate country National Regulatory Authorities (NRAs) in preparing for EU accession and their alignment with EU acquis and how could these challenges be better addressed in future enlargement rounds?
2) Reflecting on your experience, how effective was EMA's support (e.g. guidance, training, joint activities) in facilitating NRA and industry preparedness, and how could this support be improved or adapted going forward?
3) Looking ahead, which specific areas of regulatory alignment or capability should EMA prioritise to better support NRAs and industry and ensure a smooth and efficient transition at accession?



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Send a question via our website