



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8.3 EU enlargement – EMA support to candidate and potential candidate countries

Industry Standing Group (ISG) meeting, 25 March 2024





Instrument for Pre-accession Assistance programme (IPA)

- **Historical context:** EMA engaged in IPA I (2008-2014), IPA II (2018-2023) and IPA III (2023-2026) **ensuring continuity** of assistance to the beneficiary countries.
- **Responsible DG:** DG for Neighbourhood and Enlargement Negotiations (NEAR)
- **Objective:** Enhanced regulation of medicinal products for human and veterinary use in the region through revised and aligned standards and practices with those of the European Union



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:**

- Training of experts in medicines regulatory institutions IPA beneficiaries.
- Beneficiaries working to align with medicines legislation with EU acquis.
 - Current impact assessment ongoing.



IPA III project outline

- **Project title:** EU4 alignment on medicines regulation in the Western Balkans and Türkiye
- **Responsible DG:** DG for Neighbourhood and Enlargement Negotiations (NEAR)
- **Implementing partner:** European Medicines Agency
- **Target authorities:** national competent authorities in EU (potential) candidate countries: Albania, Bosnia-Herzegovina, Kosovo, North-Macedonia, Montenegro, Serbia, Türkiye
- **Other EU (potential) candidates:** Georgia, Moldova and Ukraine


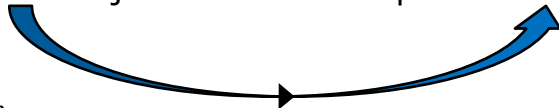



IPA III – description of action

- **Broader institutional context:** action contributes to the following EU Initiatives and Strategies
 - EU Pharmaceutical Strategy
 - One Health Action Plan Against Anti-Microbial Resistance
 - EU Health Union Initiative
 - EU Global Health Strategy
- **Scope:** Human and Veterinary Medicines

IPA III – description of action

- **Programme instruments:**

- EMA training sessions on selected (demand-driven) topics  *Continuation from IPA II*
 - Face-to-face/ hybrid training sessions at EMA (one seminar per year, three in total)
 - Online training sessions (at least one webinar per year, three in total)
- Participation as observer in identified EMA working groups- subject to available spots- *Reinstated*
 - Inspections (e.g. GCP IWG, GMDP IWG, Ph.Vig. IWG)
 - Shortages (SPOC working party, non-confidential workshops)
 - Veterinary (AMR, monitoring and supervision of antibiotics)- *NEW to be further explored*
- Access to (selected modules of) EMA's Learning Management System  *Continuation of EU NTC for non-European regulators pilot*
- Underlying modality: ad-hoc Confidentiality Arrangements with participating NCA's for duration of project



Any questions?

Further information

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