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

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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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