

Candidate countries observing EMA activities

PCWP/HCPWP joint meeting
4 February 2026

European Medicines Agency
International Affairs Division



Work with EU candidate countries at EMA – overview

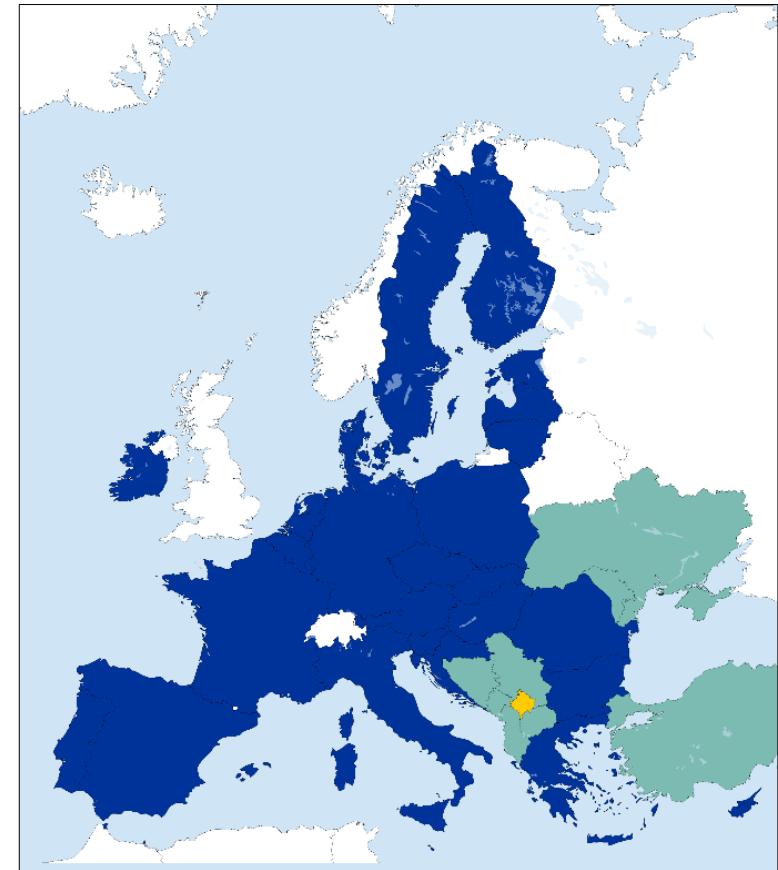
Instrument for Pre-accession Assistance (IPA)

III – from 2024-2026

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

Other EU candidates: Georgia, Moldova and Ukraine

Aim: to prepare beneficiaries for their future collaboration in the European medicines regulatory network



Activities under IPA III programme

Three main activities:

Advanced trainings

- → At least one face to face a year

Access to EMA's digital catalogue

- → Access to EU NTC – over 250 users

Participation as observers in selected EMA working groups and parties

- → Observing eight different WGs- WPs – inspections, shortages, AMR and One Health



Proposal – candidate countries as observers in PCWP/HCPWP meetings

- Steps towards enlargement of the EU
- Planning for next iteration of the Instrument for Pre-accession Assistance programme (2027-2029)
- Step by step integration into more EMA's activities
- **Proposal:**
- candidate countries as observers in PCWP/HCPWP
- online attendance, in-person attendance to a limited extent
- 1 year 'trial period'



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