



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU enlargement programme

An agency of the European Union



About the IPA programme

The Instrument for Pre-accession Assistance (IPA) programme was launched by the European Commission in 2009 to support the participation of beneficiaries in the activities of the European Medicines Agency.

Following Croatia's accession to the European Union (EU) on 1 July 2013, the programme beneficiaries are:

- Albania;
- Bosnia and Herzegovina;
- the former Yugoslav Republic of Macedonia;
- Iceland;
- KOSOVO (under UNSC Resolution 1244/99);
- Montenegro;
- Serbia;
- Turkey.

About the Agency

The European Medicines Agency is the EU body responsible for the scientific evaluation and monitoring of medicines within the 'centralised procedure', a procedure that allows a marketing authorisation (licence) to be obtained for a medicine simultaneously in all EU countries, on the basis of a single application.

Scope of the IPA programme

In the context of medicinal products, the IPA programme is designed to establish between the Agency and the beneficiaries an open dialogue and working mechanisms that facilitate the harmonisation of technical standards, the adoption of legislative requirements, and the smooth integration of the beneficiaries' representatives into the work of the Agency.

In the EU legislative framework for medicines, there are a large number of directives and regulations relating to the issuing of marketing authorisations and to the economic regulation of the pharmaceutical market that need to be applied and implemented effectively.

The body of knowledge relating to this implementation is constantly evolving as the EU scientific committees and their working parties develop guidelines and gain experience in new therapies and new technologies.

Without any involvement in these procedures, it is extremely difficult to acquire the necessary knowledge to be able to participate in the EU regulatory system for medicines.

Target groups

The target groups are the beneficiaries' national competent authorities dealing with the regulation of medicines for human and veterinary use, their information officers, legal officers, scientists and stakeholders.


Aims of the programme

The main aim of the IPA programme is to build contacts and relationships between the Agency and the beneficiaries' national competent authorities responsible for medicines, in preparation for their future collaboration in the EU regulatory network. This should enable the Agency, the existing Member States and the beneficiaries to work as equal, mutually respected partners from the day of accession.

To achieve this aim, the programme offers assistance to the beneficiaries' national competent authorities in aligning their standards and practices with those established in the EU.

A specific activity of the project is to contribute to the creation of communication and information exchange systems that enable the effective participation of the beneficiaries in the networks of the EU regulatory system for medicines.

Programme activities

- Invitation of representatives of the beneficiaries to participate in Agency meetings and training courses as observers, as well as in external training courses.
 - Organisation of ad hoc training events to establish contacts in a structured forum for exchanging views, providing an overview of the EU legislation governing the regulation of medicinal products, and identifying areas where additional action might be needed.
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Further information

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