EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

IPA Project Description

Introductory Meeting
1-2 February 2010

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An agency of the European Union

EU ENLARGEMENT PROGRAMMES

Introduction

1. EU enlargement pre-accession programmes
2. Transition IPA Programme for the Candidate Countries

IPA programme for Candidate & Potential Candidate Countries

1. Beneficiary Countries
2. Target groups
3. Objectives
4. Aims of the project
5. Activities

Conclusion Status of the project

2

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1.EU enlargement pre-accession programmes

1989 – 2007	PHARE programme
1999 – 2003	PERF project from 15 to 25 Member States
2004 - 2005	Multi-beneficiary for Bulgaria and Romania
2006 - 2007	Multi-beneficiary for Croatia and Turkey
2007	IPA programme
2008	Transition IPA for Croatia, Turkey and fYRoM
From 2009	IPA for Candidate Countries and Potential Candidate Countries (Albania, Bosnia-Herzegovina, Kosovo under UNSC Resolution 1244/99), Montenegro, Serbia

3

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2. Transition IPA for Candidate Countries (1.01.2008 – 15.09.2009)

Aims and objectives

- To build contacts and relationships for future collaboration and participation in the Agency's networks
- To provide training and assistance

Methodology and Activities

- Participation in meetings
- Provision of training
- Organization of conference "EU Regulatory Network - Challenges and Opportunities for Croatia", 13-14 Nov. 2008, Rijeka, 300 participants

4

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Programme for Candidate & Potential Candidate Countries

Instrument for Pre-Accession Assistance (IPA) programme for Candidate and Potential Candidate Countries

16.09.2009 – 16.09.2011

5

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1. Beneficiary Countries

- Candidate Countries

  Croatia, Turkey, the former Yugoslav Republic of Macedonia

- Potential Candidate Countries

  Albania, Bosnia-Herzegovina, Kosovo under UNSC Resolution 1244/99, Montenegro, Serbia

6

2. The target groups

The National Competent Authorities dealing with the regulation of medicinal products for both human and veterinary use.

7

3. Objectives

- Promoting harmonised pharmaceutical regulation in Europe
- Assisting National Competent Authorities in maintaining the alignment of their standards and practices with those obtained in the EU in the implementation of the Community law
- Building a platform for exchanging views and creating a mutual confidence
- Ensuring a smooth transition to full participation in the work of the Agency's committees on accession

8

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4. Aims of the project

- To build contacts and relationships for future collaboration in the Agency and the Member States' activities
- To prepare the NCA for future participation in the Agency's networks
- To contribute to the creation of communication and information exchange systems
- To support the beneficiary countries in their communication activities

9

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5. Activities

- Participation of representatives in meetings as observers
- Participation in training organized by the Agency and externally
- Organisation of conferences in the beneficiary countries

For new Potential Candidate Countries

- Assessment of what is harmonised with the EU legislation and of what needs to be done in each country
- Strategic training plan, based on identified needs per priority domains
- Request for involvement of the Commission and the Member States for sharing previous pre-accession experience

10

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Conclusion

➢Status of the project

- Taskforce on enlargement
- Formal launch of the project on 1-2 February 2010
- Nominations for meetings and training requested
- Conference organisation to be discussed

➢Programme prospective

- Pre-accession activities will be sustained for 10/15 years
- Accession to EU on a country by country basis
- General training programme to be set up, taking into account timeframes of accession

➢Progress reports published on the enlargement website

http://www.ema.europa.eu/htms/euenlargement/euenlargement.htm