European Medicines Agency
Communications and Networking

London, 11 July 2008
Doc. Ref. EMEA/368794/2008

Contract 2007/146-691

IPA Transition Assistance Programme

Second Progress Report

to the

European Commission

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1. MANAGEMENT SUMMARY

The European Commission has launched an IPA Transition Assistance Programme in order to support participation of the Candidate Countries, i.e. the former Yugoslav Republic of Macedonia, Croatia and Turkey in the activities of certain Community Agencies in 2008.
Basically, this programme was initiated to establish continuity between the Multi-beneficiary project, launched in 2006 for supporting Croatia and Turkey in European Agencies' activities, and the future IPA programme which will extend its support to Potential Candidate Countries.

Under this framework, a contract, reference 2007/146-691, of € 600,000 was signed on 20 December 2007 between the Commission and the EMEA for an initial twelve months implementation period. The purpose of this contract is to assist the National Competent Authorities in Croatia, Turkey and the former Yugoslav Republic of Macedonia in maintaining the alignment of their standards and practices with those obtained in the European Union in respect of the implementation of Community law.

In compliance with articles 2 and 15(1) of Annex II of this contract, reports are submitted on a quarterly basis. As this programme was initiated in January 2008, a first progress report covering the activities performed during the first three months was published. This second progress report describes the activities performed from April to June 2008 and the ways in which the programme's objectives have been addressed, from a project management perspective.

2. INTRODUCTION

2.1 Context of the programme

The aim of this project is to build contacts and relationships between the EMEA and the Candidate Countries, i.e. the Former Yugoslav Republic of Macedonia, Croatia and Turkey, for future collaboration in EMEA activities and its relationships with Member States.

This programme will allow the three Candidate Countries to prepare themselves for their participation in EMEA activities and to develop trust in the systems in the three Candidate Countries. Furthermore, this should enable the EMEA, the Member States and the Candidate Countries to be in a position to work as equal, mutually respected partners upon accession.

A solid understanding of EMEA activities is crucial in order to explain the roles/links between the EMEA, the Member States and the European Commission, and to facilitate the transposition of EU technical regulations and European technical acts into the national legislation of the participating Candidate Countries in the area of pharmaceuticals.

More specifically this aim translates into the following detailed objectives:

- to facilitate contacts with Candidate Countries, thus gaining a good understanding of the role of the EMEA as a mediator between the Member States and the European Commission
- to inform the National Competent Authorities of the Candidate Countries about scientific and procedural developments linked to the work of the EMEA
- to assist the Candidate Countries' National Competent Authorities in having access to regulatory data as it may be made available prior to accession to the European Union
- to assist the Candidate Countries' National Competent Authorities in participating in training initiatives undertaken
- to provide other training or assistance as required in order to support the alignment of their standards and practices with those established in the European Union in the implementation of the Community law.

2.2 Outline of the programme

The IPA transition programme on participation of representatives of Candidates Countries in EMEA activities comprises three types of activities to be performed within the scope of this project:

- Participation of representatives of the former Yugoslav Republic of Macedonia, Croatia and Turkey in scientific and technical EMEA non-product related meetings, as observers.

- Participation in trainings on specific technical topics organised by the EMEA or provided by external organisations. Support of short visits of Candidate Countries' representatives to the EMEA or to Member States' National Competent Authorities, for training purposes, where appropriate.

- Organisation of events, such as workshops, seminars or conferences in the Candidate Countries in order to give an overview of EU legislation governing the regulation of medicinal products and to provide feedback on the practical application of the *Acquis Communautaire* and legal aspects of its implementation.

3. PROJECT MANAGEMENT

The programme is a follow-up of the Multi-beneficiary project launched in 2006 in order to support participation of Croatia and Turkey in European Agencies' activities, with the addition of a further Candidate Country - the former Yugoslav Republic of Macedonia.

3.1 Initiation

A visit at Veterinary Directorate at the Ministry of Agriculture, Forestry and Water Economy of the former Yugoslav Republic of Macedonia was held on 24.04.2008.
During this meeting, the transition IPA programme and the activities proposed for 2008 were presented. The participation in meetings and trainings as observers was discussed and procedures explained.

3.2 Participation in meetings as observers

The purpose of this initiative is to enable the Candidate Countries' Competent Authorities to maintain the accuracy of their knowledge through direct involvement, as observers, in the EU regulatory community for pharmaceuticals.

3.2.1 Activity status

This activity requires a great deal of communication exchange, explanations, correspondence with National Competent Authorities and nominated persons, liaisons with the meeting organizers and meeting secretaries, administrative management of nominations and attendance, involving one staff member full time work.

Representatives of all Candidate Countries (where nominations were provided) were invited to participate in selected non-product related EMEA meetings, according to the European Commission requirements.

The representatives' attendance at meetings during these three months of activities is summarised in the table below.

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS					
	Meeting Name	**Meeting Code**	**Date**	**Invited Observers**	**Attendants**
April	Eudra GMP Database Sub-WG	IPA/019/08	03/04/2008	1 CR-H 2 MK-H	1 CR-H 2 MK-H
May	Eudra CT TIG & its JOG	IPA/030/08	15-16/04/2008	1 CR-H 1 MK-H	1 CR-H 1 MK-H
	HMPC Plenary	IPA/023/08	05-07/05/2008	2 CR-H 2 MK-H	2 CR-H 2 MK-H
	GMP-GDP Inspectors WG	IPA/034/08	20-22/05/2008	1CR-H 1 MK-H 1 TR-H	1CR-H 1 MK-H 1 TR-H
	EudraNet TIG	IPA/024/08	21/05/2008	1 CR-H 2 MK-H	1 CR-H 2 MK-H
June	Eudra CT TIG	IPA/040/08	05/06/2008	1 CR-H 2 MK-H	1 CR-H 2 MK-H
	QWP	IPA/026/08	10-12/06/2008	1 CR-H 2 MK-H 1 TR-H 1 TR-V	1 CR-H 2 MK-H 1 TR-H
	CVMP IWP	IPA/035/08	11-12/06/2008	2 TR-V	2 TR-V
	EudraVigilance TIG	IPA/039/08	12/06/2008	2 CR-H 2 MK-H	2 CR-H 2 MK-H
	Eudra Pharm TIG	IPA/027/08	17/06/2008	1 CR-H 2 MK-H	1 CR-H 1 MK-H
	GCP Inspectors WG	IPA/028/08	18-19/06/2008	1 CR-H 2 MK-H	1 CR-H 2 MK-H
	Pharmacovigilance Inspectors WG	IPA/041/08	20/06/2008	1 CR-H 2 MK-H	*see IPA/028/08*
	Telematics Implementation Groups	IPA/029/08	25-26/06/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 MK-H 1 TR-H

** *CR-H: Croatia Human NCA, TK-H: Turkey Human NCA, MK-H: The Former Yugoslav Republic of Macedonia Human NCA, CR-V: Croatia Vet NCA, TK-V: Turkey Vet NCA*

The information reported in this table shows:

- no attendance in meetings of representative from:
  - The Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy of the former Yugoslav Republic of Macedonia
  - The Croatian Veterinarian Institute and of the Ministry of Agriculture, Forestry and Water Management of Croatia
  - The General Directorate of Pharmaceuticals and Pharmacy of the Ministry of Health of Turkey
- no attendance in meetings of representatives from the General Directorate of Protection and Control - Veterinary Drug Department of the Ministry of Agriculture and Rural Affairs of Turkey in April 2008.
- high participation in meetings of representatives from the Croatian Agency for Medicinal Products and Medical Devices and from the Bureau for Medicinal Products of the Ministry of Health of the former Yugoslav Republic of Macedonia during this three-month period.

3.2.2 Further continuation

Further efforts were made in order to promote the participation of Candidate Countries' representatives in meetings and trainings, especially from the National Competent Authorities dealing with Veterinary medicinal products in Croatia, from the General Directorate of Pharmaceuticals and Pharmacy of the Ministry of Health of Turkey and from the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy of the former Yugoslav Republic of Macedonia, where the objectives of the programme were further explained.

3.3 Training

Representatives from the National Competent Authorities of Croatia, the former Yugoslav Republic of Macedonia and Turkey were invited to attend trainings organised at the EMEA or abroad. It should be noted that as for meetings only representatives from the Croatian Agency for Medicinal Products and Medical Devices and from the Bureau for Medicinal Products of the Ministry of Health of the former Yugoslav Republic of Macedonia, participated in trainings and workshops. The attendance of representatives is summarised in the table below.

ATTENDANCE OF OBSERVERS AT TRAININGS & WORKSHOPS		
	Event Name	**Date**
April	Workshop on Modelling in Paediatric Medicines	14-15/04/2008
	ENCePP	18/04/2008
	EudraVigilance DIA Training	21-23/04/2008
	EVMPD	24/04/2008
May	Management of MD Training	21/05/2008
	Joint PCWP/HCP WG Meeting	05/06/2008
	Conference sur les Developpements Recents en Pharmacovigilance Europeenne et la Gestion de Risque *(Vukovar)*	09-10/06/2008
June	4th SEE Pharmaceutical Symposium *(Istanbul)*	19-20/06/2008
	EudraVigilance Info Day	27/06/2008

3.4 Conferences

3.4.1 Seminar on "Les développements récents en Pharmacovigilance européenne et la gestion du risque"

A seminar on "Les développements récents en Pharmacovigilance européenne et la gestion du risque" was organised by the Croatian Agency for Medicinal Products and Medical Devices and the Croatian Society of Pharmacy in collaboration with the French Embassy on 9-10 June in Vukovar, Croatia. This initiative was supported by the programme, where speakers from the EMEA were invited as well as speakers from different countries.

3.4.2 Conference on "'EU Regulatory Network - Challenges and Opportunities for Croatia'"

A conference on 'EU Regulatory Network - Challenges and Opportunities for Croatia', will take place at the Croatian Cultural Centre at Sušak, in Rijeka, on 13 – 14 November 2008.
This conference is organised under the framework of the IPA-programme and the Croatian Agency for Medicinal Products and Medical Devices (ALMP) under the auspice of the Croatian Ministry of Health and Welfare.
The primary objectives of this conference are to continue the internationally open dialogue, to give an overview of EU legislation governing the regulation of medicinal products, to provide feedback on the practical application of the *Acquis communautaire* and legal aspects of its implementation. Furthermore, to identify the differences between existing legislation in Croatia and EU and to discuss issues that may be encountered with regard to moving towards accession and in anticipation of membership of the European Union.
This conference, organised for the 5th anniversary of the ALMP, is of great importance for Croatia's application to EU membership. It targets scientific audiences and will include specific activities with a view to informing the full cross-section of stakeholders in Croatia.

Negotiations for the organisation of this conference have been initiated with the cultural centre and different hotels in order to find the necessary room capacity during this event.
Discussions have been held on:

- Logistics preparation: Conference venue and date, interpretation, support, flights and accommodation bookings, administration, management
- Aim of the Conference and Conference title
- Establishment of the programme: format, session, panel discussion
- Invitation Strategy: Invited Speakers, Panellists, Invited Participants
- Presentation format
- External participants' fees
- Publication Strategy: Announcement, Programme publication, Printing, Press coverage.

4. CONCLUSION

As the attendance to meetings is less than expected, despite numerous efforts, and as no major events will be organised in the former Yugoslav Republic of Macedonia and in Turkey in 2008, an amendment of the budget and an extension of the programme will be requested.

This progress report will be published on the EMEA website.
http://www.emea.europa.eu/euenlargement.htm