



European Medicines Agency
Communications and Networking

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Contract 2007/146-691

IPA Transition Assistance Programme

Third Progress Report

to the

European Commission

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.

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 regarding 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 followed by a second progress report describing the activities performed from April to June 2008. This third progress report will cover the July-September 2008 period 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

As mentioned and detailed in the previous reports, 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. Furthermore, this should enable the EMEA, the Member States and the Candidate Countries to be in a position to work as equal and mutually respected partners upon accession.

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 representatives of the Candidate Countries were invited to participate in selected EMEA meetings and training and to collaborate in the preparation of events where appropriate.

3.1 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.

3.1.1 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 summarized in the table below.

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS					
	Meeting Name	Meeting Code	Date	Invited Observers	Attendants*
July	HMPC Plenary	IPA/042/08	02-03/07/2008	2 CR-H 2 MK-H 2 TR-H	1 CR-H 2 MK-H
	European Review System (EURS)	IPA/044/08	08-09/07/2008	1 CR-H	1 CR-H
Sep	Eudravigilance TIG	IPA/048/08	03/09/2008	2 CR-H 1 MK-H 1 TR-H	2 CR-H
	HMPC Plenary	IPA/047/08	03-04/09/2008	2 CR-H 2 MK-H 3 TR-H	1 CR-H 2 TR-H
	PharmacoVigilance Inspectors Working Group	IPA/051/08	09/09/2008	2 CR-H 2 MK-H 1 TR-H	2 CR-H 2 MK-H 1 TR-H
	GCP Inspectors	IPA/050/08	10-11/09/2008	2 CR-H 2 MK-H 1 TR-H	2 CR-H 2 MK-H 1 TR-H
	EudraGMP Database Sub-working Group	IPA/049/08	11/09/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 MK-H 2 TR-H
	TIGs	IPA/052/08	18-19/09/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 2 TR-H
	EudraNet TIG	IPA/053/08	23/09/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 2 TR-H
	CHMP/CVMP Joint Quality WP	IPA/055/08	29/09-01/10/2008	1 CR-H 1 MK-H 1 TR-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 National Competent Authorities of the 3 Candidate Countries:
 - 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 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, the General Directorate of Pharmaceuticals and Pharmacy of the Ministry of Health of Turkey and from the Bureau for Medicinal Products of the Ministry of Health of the former Yugoslav Republic of Macedonia.

3.1.2 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, Turkey and the former Yugoslav Republic of Macedonia.

3.2 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	Attendance*
July	MedDRA Training for Regulators	08/07/2008	2 CR-H 2 TR-H

* CR-H: Croatia Human NCA, TK-H: Turkey Human NCA

3.3 Events

3.3.1 Connection of the Croatian Agency for Medicinal Products and Medical Devices to Eudranet

A 2 day-workshop was organised at the Croatian Agency for Medicinal Products and Medical Devices, in order to present the Eudranet network and to establish the connexion. On day one, a presentation was given to the IT staff, followed by a general discussion and a workshop with this group on EudraNet issues, general IT issues and the Videoconferencing pilot. In parallel, an EMEA consultant worked with the Croatian Agency's IT staff to start the implementation and the connection to EudraNet. On day two, a detailed presentation was given to the Head of Agency and a number of senior scientific and administrative staff on EU Telematics and an overview of EudraNet. Again in parallel to this presentation, the consultant worked with the Croatian Agency IT staff to successfully complete their connection to EudraNet.

3.3.2 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. 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.

During this period, negotiations with the cultural centre and 5 different hotels, in order to find the necessary room capacity during this event, were ongoing.

Discussions were 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.

In addition, a software “Easy Event Suite” was developed in order to automate processes, i.e. customisation of the Easy Event suite software for managing events and related databases.

This web based software will facilitate the automation of all types of registrants (delegates, speakers, external participants). It will produce: lists of participants, accommodation bookings and allotment, flight bookings, catering, allowances (daily, reimbursement form), printing (invitation letter, badge, invoice, and certificate of attendance) as well as budget control (suppliers and fees from external participants) and secured payments.

The first module of this application will be used for the conference, as a pilot.

350 participants are expected to attend this conference: 160 regulators will be invited, 22 invited speakers from the EU National Competent Authorities and 168 participants from Industry will be accepted for participation on payment of € 320 fees.

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>