European Medicines Agency
Communications and Networking

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Contract 2007/146-691

IPA Transition Assistance Programme

First 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.
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 will be submitted on a quarterly basis. As this programme was initiated in January 2008, this first progress report covers the activities performed during the first three months of the contract. It describes the activities initiated under the contract 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, e.g. the Former Yugoslav Republic of Macedonia, Croatia and Turkey, for future collaboration in the EMEA's activities and its relationships with Member States.

This programme will allow the three Candidate Countries to prepare themselves for participation in EMEA activities and to develop the existing Members States' trust in the systems, which are in place in the three countries. Furthermore, this should enable the EMEA, the existing Member States and the Candidate Countries to be in a position to work as equal, mutually respected partners.

In this context as well as in the area of medicinal products, the project is designed to establish an internationally open dialogue and working mechanisms to facilitate the adoption of common technical requirements, to identify areas where additional action may be required and to ensure the smooth transposition of their legislation into the EU Acquis Communautaire along with the participation in EMEA committees.
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. It is necessary in order 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.

Furthermore, this project will provide support for aligning their standards and practices with those established in the European Union with regard to the implementation of the Community law. This means transposing the regulations supporting the legislation into the EU Acquis Communautaire and establishing working procedures to make the laws and regulations operational.

This project will also ensure appropriate exposure and involvement in the EU's Telematics initiatives to foster compliance with legislated requirements (primarily, but not exclusively, Regulation 726/2004; Directive 2001/20/EC), and to enable the Former Yugoslav Republic of Macedonia, Croatia and Turkey to be a part of the electronic network upon accession.

More specifically, this translates into the following detailed objectives:

- to facilitate contacts with Candidate Countries thus gaining a better 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 and the participation of these countries in this work
- to assist the Croatian and Turkish National Competent Authorities in having access to such regulatory data as it may be made available to them prior to accession to the European Union
- to assist the Croatian and Turkish National Competent Authorities in participating in training initiatives undertaken
- to provide other training or assistance as required in order to support the alignment of the Turkish and Croatian 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 activity to be carried out within the scope of this project:

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

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

- Organisation of events, e.g. 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 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

Relationships with the National Competent Authorities of Croatia and Turkey were already initiated two years ago and therefore consolidated. Visits were organised in both Candidate Countries to promote collaboration and networking and to identify requirements.

Regarding the Former Yugoslav Republic of Macedonia, contacts were initiated with the National Competent Authorities by explaining the programme objectives, providing information on activities funded by the programme and by requesting nominations of representatives and alternates to attend meetings and trainings.
Communication via electronic mail was extensive during the period of reference.

3.2 Participation in meetings as observers

In line with an opinion of the legal service of the European Commission, Candidate Countries can appoint representatives as observers in non-product related meetings exclusively.
The participation of observers from Croatia, Turkey and the Former Yugoslav Republic of Macedonia is financed through the project, funds cover traveling, daily allowances and hotel expenses for attendance at meetings, workshops and other visits. 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 EU regulatory community for pharmaceuticals.

3.2.1 Activity status

Letters requesting nominations of representatives and alternates to attend listed non-product related meetings were sent to the attention of all Heads of National Competent Authorities. The provision of a declaration of interests and a signed confidentiality agreement were requested for each representative prior to meeting participation, in accordance with the European law.

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 EMEA meetings.

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

It should be noted that no representative from the Candidate Countries attended meetings in January. Nominations were received only for meetings held in February and March and not from all National Competent Authorities (see invited observers column where the Candidate Country concerned is indicated*) and among them attendance was further reduced (see column attendants).

**CR: Croatia, TK: Turkey, MK: the Former Yugoslav Republic of Macedonia*

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS					
	Meeting Name	**Meeting Code**	**Date**	**Invited Observers****	**Attendants**
February	MMD Training - EudraNet TIG	IPA/001/08	04/02/2008	1 CR-H	1 CR-H
	EudraNet TIG	IPA/002/08	05/02/2008	1 CR-H	1 CR-H
	EMEA Workshop Small & Medium Enterprise	IPA/011/08	08/02/2008	1 CR-H	1 CR-H
	PDA Conference: European GMP	IPA/015/08	20-21/02/2008	1CR-H 1 TK-H 1 MK-H	1CR-H 1 TK-H 1 MK-H
	TIG - Telematics Implementation Group	IPA/012/08	21-22/02/2008	1 CR-H	1 CR-H
	BEMA Assessors Training	IPA/016/08	22/02/2008	1 CR-H 2 TK-H	1 CR-H 2 TK-H
	Quality Working Party	IPA/006/08	26-28/02/2008	1CR-H 1CR-V 1 TK-V	1 CR-H
March	HMPC Plenary	IPA/014/08	05-06/03/2008	2 CR-H 2 MK-H	1 CR-H
	Eudravigilance TIG	IPA/017/08	06/03/2008	2 CR-H	2 CR-H
	EudraPharm TIG	IPA/018/08	11/03/2008	1 CR-H 1 MK-H 1 TK-V	1 CR-H
	Human and Veterinary Pharmacovigilance Inspector Meeting	IPA/010/08	11/03/2008	2 CR-H 2 MK-H	1 CR-H
	GCP Inspectors Working Group	IPA/009/08	12-13/03/2008	2 CR-H 2 MK-H	*see IPA/010*

*** 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:

- Higher participation of NCA representatives dealing with medicinal products for human use compared to those dealing with medicinal products for veterinary use.
- High participation of representatives from the Croatian Agency for Medicinal Products and Medical Devices.
- Reduced participation of representatives from all three the Directorate General of Turkey, the General Directorate of Pharmaceuticals and Pharmacy and, last but not least, the General Directorate of Protection and Control - Veterinary Drug Department, dealing with regulation of human and veterinary medicines respectively.
- The first participation of a representative from the Bureau for Medicinal Products of the Ministry of Health of the Former Yugoslav Republic of Macedonia dealing with regulation of human medicines
- No participation of representatives from the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy of the Former Yugoslav Republic of Macedonia dealing with regulation of veterinary medicines.

3.2.2 Further continuation

Further efforts will be made in order to promote the participation of Candidate Countries' representatives, especially from the Former Yugoslav Republic of Macedonia in meetings, as practical issues encountered with the Bureau for Medicinal Products of the Ministry of Health are resolved.
Contacts with the Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy dealing with the regulation of veterinary medicinal products will be reinforced and the objectives of the programme further explained.

3.3 Training

Representatives of Croatia and Turkey were invited to participate in training and workshops. The attendance of representatives is summarised in the table below.

ATTENDANCE OF OBSERVERS AT TRAININGS & WORKSHOPS		
Event Name	**Date**	**Attendants**
EudraNet TIG – MMD Training	04/02/2008	1 CR-H
2nd EMEA Workshop for Micro, Small and Medium-Sized Enterprises (SMEs)	08/02/2008	1 CR-H
EMEA – PDA Conference European GMP, Current Issues and Future Development	20-21/02/2008	1 CR-H 1 TK-H 1 MK-H
BEMA Assessors Training	22/02/2008	1 CR-H 2 TR-H
HMPC Assessors Training	06/03/2008	1 CR-H

4. CONCLUSION

Progress and technical adherence to the plan of activities is monitored on an ongoing basis, by the EMEA project leader, the Head of Sector Meeting Management & Conferences within the Communications and Networking Unit.

The results of this project will be mainly issued through quarterly activities progress reports, published on the EMEA website http://www.emea.europa.eu/euenlargement.htm

The programme has also sought to provide practical assistance to the National Competent Authorities in order to smooth the transition to membership of the EU.