European Medicines Agency
Administration

London, 17 March 2009
Doc. Ref. EMEA/459609/2009/Corr.

Contract 2007/146-691

IPA Transition Assistance Programme

Fourth 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.
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 quarter, was published followed by a second progress report describing the activities performed from April to June 2008, and the third progress report covered the July-September 2008 period from a project management perspective. This fourth progress report summarises the activities from July 2008 to May 2009.

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 and Training 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	1CR-H 2 TR-H

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS

	Meeting and Training Name	Meeting Code	Date	Invited Observers	Attendants*
	PhV 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
	TIGes	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
Oct	GMP/GDP Inspectors working Group	IPA/054/08	01-03/10/2008	1 CR-H 1 MK-H 2 TR-H 1 TR-V	1 CR-H 1 MK-H 2 TR-H 1 TR-V
	6th GCP Inspectors' Training Course	IPA/046/08	05-08/10/2008	2 CR-H 2 MK-H 2 TR-H	2 CR-H 2 MK-H 2 TR-H
	eCTD new major version requirement	IPA/061/08	06/10/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 MK-H 2 TR-H
	EudraCT TIG and its JOG	IPA/059/08	08/10/09	1 MK-H 2 TR-H	1 MK-H
	Eudrapharm TIG	IPA/057/08	09/10/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 TR-H
	European Review System (EURS)	IPA/062/08	23/10/2008	1 CR-H 1 TR-H	1 CR-H 1 TR-H
Nov	NRG/EFPIA WG	IPA/064/08	03/11/2008	2 CR-H 2 MK-H 1 TR-H	2 CR-H 1 MK-H 1 TR-H
	HMPC Plenary	IPA/063/08	05-06/11/2008	2 CR-H 2 MK-H 2 TR-H	2 CR-H 2 MK-H 2 TR-H
	EU Regulatory Network – Challenges and Opportunities for Croatia	IPA/056/08	13-14/11/2008	2 MK-H 7 TR-H	2 MK-H 7 TR-H
	EudraGMP Database Sub-working Group	IPA/065/08	13/11/2008	1 CR-H 1 MK-H 2 TR-H	2 TR-H
	ENCePP Scientific Convention	IPA/066/08	25/11/2008	1 CR-H 1 MK-H	1 CR-H

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS

	Meeting and Training Name	Meeting Code	Date	Invited Observers	Attendants*
	Eudravigilance TIG	IPA/067/08	25/11/2008	2 CR-H 1 MK-H 1 TR-H	2 CR-H
	GMP/GDP Inspectors working Group	IPA/068/08	25-27/11/2008	1 CR-H 1 MK-H 2 TR-H 1 TR-V	2 TR-H 1 TR-V
Dec	CHMP/CVMP Joint Quality WP	IPA/070/08	02-04/12/2008	1 CR-H 1 MK-H 1 TR-H	1 CR-H 1 TR-H
	GCP Inspectors Working Group	IPA/069/08	03-04/12/2008	2 CR-H 2 MK-H 1 TR-H	2 CR-H 2 MK-H
	TIGes	IPA/071/08	04-05/12/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 MK-H 2 TR-H
	EudraCT TIG	IPA/072/08	09/12/2008	1 CR-H 1 MK-H 2 TR-H	1 CR-H 1 TR-H
	EudraPharm TIG	IPA/073/08	10/12/2008	1 CR-H 1 MK-H 2 TR-H	1 TR-H
	PhV Inspectors Meeting	IPA/074/08	05/12/2008	2 CR-H 2 MK-H 1 TR-H	2 CR-H 2 MK-H
	EudraNet TIG	IPA/075/08	16/12/2008	2 CR-H 1 MK-H 2 TR-H	2 CR-H 1 MK-H 1 TR-H
	TOPRA - EMEA Annual Legislation update conference	IPA/076/08	02-03/12/2008	3 CR-H 1 MK-H 5 TR-H	3 CR-H 1 MK-H 5 TR-H
Jan	HMPC Plenary	IPA/001/09	14-15/01/2009	2 CR-H 2 TR-H	1 CR-H
Feb	CVMP IWP	IPA/006/09	27-28/01/2009	1 CR-V 2 TR-V	1 CR-V 1 TR-V
	EMEA Workshop for Micro Small and Medium-sized Enterprises (SMEs)	IPA/002/09	02/02/2009	2 CR-H 2 TR-H 2 MK-H	2 CR-H 2 TR-H 1 MK-H
	GMP-GDP inspectors Working Group	IPA/004/09	03-05/02/2009	1CR-H 1 TR-H 1 MK-H 1 TR-V	1 TR-H

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS

	Meeting and Training Name	Meeting Code	Date	Invited Observers	Attendants*
	EudraGMP Database Sub-working Group	IPA/005/09	02/02/2009	1CR-H 1 TR-H 1 MK-H	1CR-H
	Q&A Session on ATMP Regulation	IPA/003/09	03/02/2009	2 TR-H	2 TR-H
	EudraCT TIG, JOG and Paediatric Subgroup	IPA/007/2009	10-11/02/2009	2 TR-H 2 MK-H	2 TR-H
	CHMP/CVMP Joint Quality WP	IPA/008/09	10-12/06/2008	1 CR-H 1 CR-V 1 TR-H 1 TR-V 1 MK-H	1 CR-H 1 CR-V 1 TR-H 1 TR-V 1 MK-H
Mar	EudraNet TIG	IPA/011/09	03/03/2009	1CR-H 1 TR-H 1 MK-H	1CR-H 1 TR-H
	GCP Inspectors working Group	IPA/012/09	03-05/03/2009	2 CR-H 2 TR-H 2 MK-H	2 CR-H 2 TR-H 1 MK-H
	Eudravigilance TIG	IPA/013/09	04/03/2009	2 CR-H 1 TR-H 1 MK-H	2 CR-H
	TIGes	IPA/014/09	05-06/03/2009	1 CR-H 1 TR-H 1 MK-H	1 CR-H 1 TR-H
	Joint Human and Veterinary PhV IWG Mtg	IPA/016/09	11/03/2009	1 CR-H 1 CR-V 1 TR-H 1 MK-H	1 CR-H 1 TR-H 1 MK-H
	HMPC Plenary	IPA/015/09	11-12/03/2009	2 CR-H 2 TR-H 2 MK-H	1 CR-H 1 TR-H 2 MK-H
Apr	Workshop on Advance Therapies Medicinal Products (ATMP)	IPA/017/09	03/04/2009	1 CR-H 2 TR-H 1 MK-H	1 CR-H 2 TR-H 1 MK-H
	CVMP Safety	IPA/020/09	23-24/04/2009	1 CR-V 2 TR-V	1 CR-V 2 TR-V
	EudraCT TIG and its JOG	IPA/021/09	28-29/04/2009	2 TR-H 2 MK-H	1 MK-H 1 TR-H
May	HMPC Plenary	IPA/024/09	13-14/05/2009	2 CR-H 2 TR-H 2 MK-H	1 CR-H 2 TR-H
	GMP/GDP Inspectors working Group	IPA/036/09	18-20/05/2009	1 CR-H 1 TR-H 1 TR-V 1 MK-H	1 TR-H
	TIGes	IPA/026/09	28-29/05/2009	1 CR-H 1 TR-H 1 MK-H	1 CR-H

ATTENDANCE OF OBSERVERS AT EMEA MEETINGS					
	Meeting and Training Name	**Meeting Code**	**Date**	**Invited Observers**	**Attendants***
Jun	CHMP/CVMP Joint Quality WP	IPA/027/09	02-04/06/2009	1 CR-H 1 CR-V 1 TR-H 1 TR-V 1 MK-H	1 CR-H 1 TR-H 1 TR-V
	EV DIA Training	IPA/018/09	08-10/06/2009	2 CR-H 1 MK-H	2 CR-H
	Joint PCWP/HCP WG meeting	IPA/029/09	09/06/2009	2 CR-H 2 TR-H 2 MK-H	2 CR-H 1 TR-H
	Eudravigilance TIG	IPA/030/09	09/06/2009	2 CR-H 1 TR-H 1 MK-H	2 CR-H
	Human PhV IWG meeting	IPA/033/09	16/06/2009	1 CR-H 1 TR-H 1 MK-H	1 CR-H
	EudraGMP Database Sub-working Group	IPA/034/09	18/06/2009	1 CR-H 2 TR-H 1 MK-H	1 CR-H 2 TR-H
	GCP Inspectors Working Group	IPA/032/09	18-19/06/2009	2 CR-H 2 TR-H 2 MK-H	2 CR-H 2 TR-H
	HMPC Assessors Workshop/Training	IPA/038/09	19/06/2009	2 CR-H 2 TR-H	2 CR-H 1 TR-H
	Eudrapharm TIG	IPA/035/09	24/06/2009	1 CR-H 1 TR-H 1 MK-H	1 CR-H 1 TR-H
	EudraNet TIG	IPA/037/09	25/06/2009	1 CR-H 1 TR-H 1 MK-H	1 CR-H 1 TR-H
	European Review System (EURS)	IPA/039/09	30/06/2009	1 CR-H 2 TR-H	1 CR-H 1 TR-H
Jul	EudraVigilance Information Day	IPA/040/09	01/07/2009	2 CR-H	2 CR-H
	CVMP Safety	IPA/031/09	02-03/07/2009	1 CR-V 2 TR-V	2 TR-V
	HMPC Plenary	IPA/041/09	15-16/07/2009	2 CR-H 2 TR-H	1 CR-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 Candidate Countries:
  - The Veterinary Directorate of the Ministry of Agriculture, Forestry and Water Economy of the former Yugoslav Republic of Macedonia
  - The suspension of the participants from the Bureau for Medicinal Products of the Ministry of Health of the former Yugoslav Republic of Macedonia from May to September 2009.
  - The Croatian Veterinarian Institute and of the Ministry of Agriculture, Forestry and Water Management of Croatia
- 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.

3.1.2 Further continuation

Further communication are being made in order to favour 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.

3.3 Events

3.3.1 Conference on "'EU Regulatory Network - Challenges and Opportunities for Croatia'" on 13-14 November 2008.

The conference took place at the Croatian Cultural Centre at Sušak, in Rijeka. This city was chosen to host the conference as it is the second city in Croatia and also because the Croatian Agency for Medicinal Products and Medical Devices (ALMP) had several facilities within the city.

The conference, under the auspice of the Croatian Ministry of Health and Welfare, was also held to celebrate the 5th anniversary of the ALMP.

The following conference rationales were agreed:

- Logistics preparation: Conference venue and date, interpretation (only the welcome speeches), support, flights and accommodation bookings, administration, management;
- Aim of the Conference and Conference title;
- Establishment of the programme: format, session and panel discussion;
- Invitation Strategy: Invited Speakers, Panellists, Invited Participants;
- Presentation format;
- External participants' fees were fixed at €320;
- Publication Strategy: Announcement, Programme publication, Printing, Press coverage.

The software "Easy Event Suite" was developed in order to automate processes, i.e. customisation of the related databases. This web based software facilitated the automation of all types of registrants (delegates, speakers, external participants) and the production of lists such as 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.
Further developments and web hosting are being investigated with King Hall - the software producer.

Conference programme

EU Regulatory Network
Challenges and Opportunities for Croatia

5th Anniversary of the ALMP

13 – 14 November 2008

Croatian Cultural Centre at Sušak
Rijeka, Croatia

The Conference is co-organised by the Croatian Agency for medicinal Products and Medical Devices and the EMEA, with the support of the ALMP and of the transitional Instrument for Pre-Accession programme for supporting participation of Candidate Countries in EMEA activities

13 Nov 08	Topics	Speakers
09.30	**Moderation**	Gloria Fabijanić Jelović
09.30	**Welcome address EMEA**	Sylvie Bénéfice, EMEA
09.40	**Welcome address ALMP**	Sinisa Tomić , Croatian Agency for Medicinal Products and Medical Devices, Croatia
09.50-10.30	**Keynote address**	
09.50	Croatian Authorities	City and County of Rijeka
10.00	Initiative of the EU Commission: Public consultation	Martin Terberger, DG Enterprise, European Commission, Pharmaceuticals
10.15	Croatian Authorities	Ministry of Health and Social Welfare
10.30	Award in Pharmacovigilance	Health Care Professionals
	Musical interlude	Croatian Artists
10.45 – 11.15	***Coffee break***	

13 Nov 08	Topics	Speakers
11.15 – 12.45	**Pharmaceutical Regulation**	Chair Xavier Luria, EMEA Co-chair Milena Jadrijević Mladar Takač, FBF, Croatia
11.20	Pharmaceutical Policies	Milan Smid, World Health Organisation
11.40	New EDQM road	Susanne Keitel, EDQM
12.00	EMEA-CHMP Think-Tank Group on Innovation, Research and Drug Development	Xavier Luria, EMEA
12.25	Panel discussion	
12.45 – 14.00	***Lunch***	
14.00 – 16.00	**EU Regulatory Authorities**	Chair Arielle North, EMEA Co-chair Maja Jakševac Mikša, HFD, Croatia
14.05	The post-accession experience	Rodica Badescu, Romanian NMA, Romania
14.35	How can non-contributing agencies be encouraged to participate	Kristin Raudsepp, Estonian State Agency, Estonia
15.05	Transatlantic simplification of administrative procedures	Arielle North, EMEA
15.35	Panel Discussion	
15.45-16.00	***Coffee break***	
16.00– 18.00	**EU Regulatory Network**	Chair Aginus Kalis, Dutch Medicines Board Co-chair Siniša Tomić, ALMP, Croatia
16.05	Priorities of the Regulatory Authorities	Aginus Kalis, Dutch Medicines Board
16.35	Development of an efficient regulatory system in Europe – point of view of the NCA	Jean Marimbert, AFSSAPS, France
17.05	Advances in Croatia's rapprochement to the EU	Siniša Tomić, ALMP, Croatia
17.35	Panel Discussion	
19.00 – 22.00	***Welcome reception and conference dinner***	

14 Nov 08	Topics	Speakers
09.00 – 10.30	**Medicinal Products**	Chair Gérard Pons, Hôpital Saint-Vincent de Paul, Service de Pharmacologie Périnatale et Pédiatrique, France Co-chair Dinko Vitezić, MF Rijeka, Croatia
09.05	The role of the PDCO	Gérard Pons, Hôpital Saint-Vincent de Paul, Service de Pharmacologie Périnatale et Pédiatrique, France
09.25	Advanced therapies	Anthony Humphreys, EMEA
09.45	Revised Guidelines on Bioequivalence	Monica Edholm, MPA, Sweden
10.05	Panel discussion	
10.30 – 11.00	***Coffee break***	
11.00 – 12.30	**Regulatory affairs**	Chair Anthony Humphreys, EMEA Co-chair Anita Filipović Sučić, ALMP, Croatia
11.05	Overview of Review Process Interactions	Anthony Humphreys, EMEA
11.25	Impact on new variation system on NCAs	Susanne Winterscheid, BfArM, Germany
11.45	E- Submission	André Lhoir, AFMPS/FAGG, Belgium
12.05	Panel discussion	
12.30 – 14.00	*Lunch*	
14.00 – 15.15	**Pharmacovigilance**	Chair Thomas Goedecke, EMEA Co-chair Viola Macolić Šarinić, ALMP, Croatia
14.05	European Commission's proposal for Pharmacovigilance	Martin Terberger, European Commission, DG Enterprise, Pharmaceuticals
14.25	Eudravigilance	Thomas Goedecke, EMEA
14.45	Risk Management Plans	Stella Blackburn, EMEA
15.05	Panel discussion	
15.15 – 15.30	***Coffee break***	

14 Nov 08	Topics	Speakers
15.30 – 17.00	**Inspection**	Chair Gabriele Schwarz, BfArM, Germany Co-chair Hrvoje Tumir, ALMP, Croatia
15.35	GCP Inspection	Gabriele Schwarz, BfArM, Germany
15.55	Fighting the Pharmaceutical Crime and Counterfeit Medicines	Roy Vancauwenberghe, FAGG/AFMPS, Belgium
16.15	GMP	Lorraine Nolan, Irish Medicines Board, Ireland
16.35	Pharmacovigilance Inspection	Johanna Piper, MHRA, UK
16.55	Panel discussion	
17.15	***Closure of the conference***	Sinisa Tomić , ALMP, Croatia Sylvie Bénéfice, EMEA

Conference outcome
The conference was a great success and the tailor-made programme attracted a lot of participants. The maximum capacity was 350 and 294 participants attended the conference: 134 regulators were invited, 21 invited speakers from the EU National Competent Authorities, and 130 participants from Industry registered.

Publications post-conference
Session presentations are available on the EMEA website:
http://www.emea.europa.eu/htms/euenlargement/programs/IPA/events.htm
The event had a lot of media coverage in local press and television. The press-release is available on
http://www.emea.europa.eu/pdfs/news/60581908en.pdf

Conference Assessment
The conference evaluation forms were returned, all with a very positive feedback.
The conference run smoothly thanks to the team in place and the solid collaboration with the ALMP.

3.3.2 Support to two seminars organised by the ALMP

The EMEA invited on behalf of the ALMP a few speakers to give presentations for two seminars:

- 9-10 June 2008: Séminaire sur les développements récents en Pharmacovigilance européenne et la gestion du risque (Vukovar);
- 3-8 September 2008: 9th World Congress of Bioethics (Rijeka).

3.3.3 [1]

[1] Text deleted

4. CONCLUSION

Due to the current economic climate and despite the EMEA efforts to encourage the Candidates Countries to participate in the EMEA activities, the Macedonians have informed the EMEA about their decision to suspend their participation until August 2009.

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