European Medicines Agency
Communications and Networking

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Contract 2006/118-594

Multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007

Second Progress Report

to the

European Commission

Nov. 2006 – March 2007

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1. MANAGEMENT SUMMARY

This second progress report has been prepared in accordance with the standard terms and conditions applicable to the contract between the EMEA and the European Commission, reference 2006/118-594 and summarised activities performed under the terms of the contract from November 2006 to March 2007.

A contract of €700,000 was signed on 24 April 2006 between the Commission and the EMEA to be expended over 2006 and 2007. These funds assisted the National Competent Authorities in Croatia and Turkey in maintaining the alignment of their standards and practices with those obtained in the European Union in respect of the implementation of Community law.

This programme was initiated in July 2006 and activities already started immediately after the first meetings organised in both countries, followed by an information meeting held at the EMEA premises on 29 September 2006. The conference involved representatives of National Competent Authorities from Croatia and Turkey who deal with the regulation of medicinal products for both human and veterinary use.

A first progress report describing the aim and the objectives of the project, as well as the activities supported under the contract, in order to fulfil the objectives, was published in December 2006. This second report describes the activities performed during the following 5-month period, which consists mainly of the participation of representatives from Croatia and Turkey in EMEA meetings and training as observers. It also includes the organisation of conferences in both countries, such as the conference in Croatia on 2-3 April 2007, which will be described in the third report.

2. INTRODUCTION

2.1 Purpose of this report

This report has been prepared in accordance with the General Terms and Conditions applicable to contract reference 2006/118-594 and describes the activities initiated under the contract and the ways in which the programme's objectives have been addressed.

2.2 Context of the programme

The aim of this project is to build contacts and relationships between the EMEA and Croatia/Turkey for future collaboration in the EMEA's activities and its relationships with Member States.

This project aims therefore:

- to prepare the National Competent Authorities in Croatia and Turkey, which are active in the field of medicinal products relating to the work carried out by the EMEA, for their future participation in EMEA networks
- to contribute to the creation of communication and information exchange systems enabling the future participation of Croatia and Turkey in the EMEA's networks
- to support Croatia and Turkey in their communication activities
- to assist the National Competent Authorities in Croatia and Turkey, in a practical manner, in achieving a smooth transition to membership of the EU.

This programme will allow the two countries to prepare themselves for the participation in EMEA activities and to develop the confidence of the existing Members States in the systems in place in the two Candidate Countries.

In this context and 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 for the smooth transposition of their legislation into the EU *Acquis Communautaire* and participation in the EMEA activities.

More specifically, this translates into the following detailed objectives:

- to facilitate contacts with candidate countries to gain 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 Croatia and Turkey of scientific and procedural developments linked to the work of the EMEA and the participation of these countries in this work
- to assist the National Competent Authorities of Croatia and Turkey to participate in training initiatives undertaken
- to provide other training or assistance as required supporting the alignment of the standards and practices of Turkey and Croatia with those established in the European Union in the implementation of Community law.

2.3 Outline of the programme

The multi-beneficiary programme on participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007, comprises three types of activity to be carried out within the scope of this project:

- Participation, as observers, of Croatia's and Turkey's representatives in scientific and technical EMEA meetings, held at the EMEA premises in London.
- Provision of focused training on specific technical topics. This activity will involve participation of National Competent Authorities' experts in meetings and training sessions organised in London and in other Member States. Furthermore, Croatian and Turkish participants may also be invited to other meetings, which may be held in other parts of Europe as far as the subjects are considered relevant for achieving the project's objectives.
- Organisation of conferences in Split and Istanbul, in order 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, to identify the differences between existing legislation in each of these countries and to discuss issues that may be encountered with regards to moving towards accession, and in anticipation of membership of the European Union.

  These conferences will target scientific audiences and will include specific activities with a view to informing the full cross-section of stakeholders in Croatia and Turkey.

2.4 Format of this report

This report outlines the programme from a project management perspective and briefly describes the work performed during the second phase of the project.

3. PROJECT MANAGEMENT

The programme was launched by establishing contacts with the National Competent Authorities dealing with medicinal products for human and veterinary use in both Candidate Countries.

3.1 Initiation phase summary

After intensive communications with the appropriate National Competent Authorities in both Candidate Countries, visits were organised to promote collaboration and networking.
Then, on 29 September 2006, a kick-off meeting, to address the activities supported under the project, was organised in London. These activities are described in the First progress report.

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 and Turkey 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 Croatian and the Turkish Competent Authorities to maintain the accuracy of their knowledge through direct involvement, as observers, in EU regulatory community for pharmaceuticals.

Activity status

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

Invitations to participate in EMEA meetings have been sent to nominated representatives from Croatia and Turkey since August 2006.

This activity was welcomed by both Candidate Countries and nominations had to be streamlined in order to avoid inviting a higher number of observers per meeting compared to the number of active participants. The representatives' meeting attendances during these five months of activities are summarized in Appendix A.

It should be noted that the expenditure for this activity has reached its limit due to the number of meetings that representatives can attend as observers.

3.3 Training

Representatives of Croatia and Turkey have been invited to participate in trainings organised at the EMEA, e.g. for assessors on specific scientific topics, on aspects of the regulatory procedures, on Telematics issues, as well as on Quality Review of Documents. The provision of trainings on specific technical topics is scheduled for 2007.

In addition, participation of representatives in trainings organised in other Member States by external associations, e.g. Drug Information Association DIA has been supported under the scope of the project, upon request.

3.4 Conferences

Two Conferences will be organised in both Candidate Countries in 2007, in order to allow participation of representatives from the pharmaceutical industry and other interested parties. Focus in this respect will be given to building contacts and to developing a solid understanding of the work of the EMEA, to explain the role of and cooperation between the EMEA, Member States and the European Commission.

It was decided to organise a conference in Split (Croatia) on 2-3 April 2007 and in Istanbul (Turkey) on 22-23 October 2007, taking into account the dates of the Committee meetings organised at the EMEA and any other major meetings or events, thus allowing full participation and involvement of EMEA staff required.

The objectives of the conferences can be summarised as follows:

- 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
- To explain the role of the EU guidelines to candidate country regulators, and discuss specific areas in their application
- To identify the differences between the current legislations in each of these countries
- To discuss problems that may be encountered with regards to moving towards accession, and in anticipation of membership of the European Union.

These conferences will target scientific audiences and will include specific activities with a view to informing the full cross-section of stakeholders in Croatia and Turkey.

Conference on "Pharmaceuticals' Regulation – Croatia's Road to EU Membership" on 2-3 April, Split, Croatia

An emphasis was given on the organisation of the conference in Split on 2-3 April. Four Steering Committee meetings were held on 13 November and 4 December 2006, 12 January and 9 February 2007 with the participation of the Heads of Croatian National Competent Authorities dealing with medicinal product for human and veterinary use, EMEA Heads of Unit and Heads of Sectors or their representatives. During those meetings, 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
- Format of Conference report.

After agreement on both scientific and logistics aspects, the conference manager coordinated all organisational aspects for a smooth conference preparation running. The preparation of the conference required two full time staff members.

A dedicated conference website was designed on the EMEA website http://www.emea.europa.eu/euenlargement.htm, starting from December 2006.

Conference on "Human and Veterinary Medicinal Products' Regulation – Turkey's Road to EU Membership" on 22-23 October, Istanbul, Turkey

Negotiations for the organisation of the conference in Istanbul scheduled for 22-23 October 2007 have been initiated in order to better plan last-minute issues.

3.5 Financial implications

An amendment of the contract was signed on allowing a different budget repartition to reflect accurate costs per activity.
A total of € 161,991.44 was spent during the activity period, mainly for participation of representatives from both counties in meetings and training for an amount of € 126,416.52, including € 30,754.31for interim support to the project and € 4,820.61 for EMEA visits.

4. CONCLUSIONS

Expected results

The expected outcomes of this project are:

- better co-operation between the regulators of the European pharmaceutical market on a wider international basis
- the New Member States' Competent Authorities being better prepared to implement the requirements of the Acquis Communautaire, in specific identified areas
- the involvement of as many European regulatory authorities as possible contributing to homogeneous, reliable, and harmonised regulatory practices
- greater mutual confidence encouraging the future acceptance of research and development data, regulatory decisions and measures between these authorities
- greater understanding between these regulatory authorities, leading to agreement on regulatory positions and technical procedures within an expanded Europe
- integration, to the extent permissible prior to accession, of the two countries' National Competent Authorities into the EU Telematics projects and systems.

The results of this project will be mainly issued through activities progress reports published on the EMEA website.
The programme has also sought to provide practical assistance to the National Competent Authorities in order to render the transition to membership of the EU as smooth as possible.

5. APPENDICES

Appendix A: Summary of expenditure November 2006 - December 2006

Appendix B: Summary of expenditure January 2007 – March 2007

Appendix C: Actual costs November 2006

Appendix D: Actual costs December 2006

Appendix E: Actual costs January 2007

Appendix F: Actual costs February 2007

Appendix G: Actual costs March 2007

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Appendix A: Summary of expenditure November 2006 - December 2006

2006	Croatia	Turkey	**Total for CRTU Programme**
Travel	6,237.14	5,552.78	11,789.92
Other costs (DSA+ hotel)	12,470.94	7,640.63	20,111.57
Total for November 2006	**18,708.08**	**13,193.41**	**31,901.49**
Travel	4,919.09	3,825.00	8,744.09
Other costs (DSA+ hotel)	8,197.97	11,622.74	19,820.71
Total for December 2006	**13,117.06**	**15,447.74**	**28,564.80**
Missions (November-December)			**3,220.08**
Staff Support			**17,068.21**
Grand Total			**80,754.58**

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Appendix B: Summary of expenditure January 2007 – March 2007

2007	Croatia **Meeting costs**	Turkey **Meeting costs**	**Total meeting costs**	**Missions**	**Staff costs**	**Grand Total for the period (monthly)**
Travel	3,056.67	853.32	3,909.99			
Other costs (DSA+ hotel)	3,116.13	1,125.02	4,241.15			
Total for January	**6,172.80**	**1,978.34**	**8,151.14**	**0.00**	**4,610.30**	**12,761.44**
Travel	3,929.58	7,482.87	11,412.45			
Other costs (DSA+ hotel)	5,671.20	8,909.64	14,580.84			
Total for February	**9,600.78**	**16,392.51**	**25,993.29**	**0.00**	**4,570.18**	**30,563.47**
Travel	3,765.24	10,563.93	14,329.17			
Other costs (DSA+ hotel)	6,434.97	11,041.66	17,476.63			
Total for March	**10,200.21**	**21,605.59**	**31,805.80**	**1,600.53**	**4,505.62**	**37,911.95**
Grand Total (January - March 2007)	**25,973.79**	**39,976.44**	**65,950.23**	**1,600.53**	**13,686.10**	**81,236.86**

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Appendix C: Actual costs November 2006

Meeting ID	No	Travel - Croatia	Other costs - Croatia		Travel - Turkey	Other costs - Turkey	
	of days	Flight	DSA	Hotel	Flight	DSA	Hotel
CA/019/06 (2+1)	**2**	494.56	258.00	599.55	406.37	183.00	359.75
CA/020/06 (3+3)	**2**	1,004.01	732.00	1,880.04	874.98	399.00	588.67
CA/021/06 (2+2)	**2**	0.00	300.00	239.80	388.40	183.00	359.75
CA/022/06 (1+2)	**1**	394.33	108.00	290.48	772.66	183.00	587.30
CA/023/06 (3)	**1**	1,659.73	324.00	605.23	0.00	0.00	0.00
CA/025/06 (1+2)	**2**	232.09	183.00	776.10	1,001.49	366.00	776.10
CA/026/06 (3+3)	**3**	832.86	774.00	1,512.21	1,332.05	774.00	1,484.12
CA/028/06 (5+3)	**2**	1,379.95	915.00	2,013.53	776.83	516.00	880.94
CA/033/06 (1) Paris	**5**	239.61	960.00	0.00	0.00	0.00	0.00
Total travel €	**20**	**6,237.14**	4,554.00	7,916.94	**5,552.78**	2,604.00	5,036.63
Total other costs €				**12,470.94**			**7,640.63**

Appendix D: Actual costs December 2006

Meeting ID	No	Travel - Croatia	Other costs - Croatia		Travel - Turkey	Other costs - Turkey	
	of days	Flight	DSA	Hotel	Flight	DSA	Hotel
CA/024/06 (1+2)	**1**	397.75	108.00	340.78	776.80	216.00	590.06
CA/027/06 (1+1)	**1**	399.91	108.00	240.96	581.39	108.00	276.44
CA/029/06 (6+2)*	**1**	399.91	483.00	276.44	1,062.65	216.00	431.14
CA/030/06 (7+2)	**1**	2,169.26	756.00	2,644.09	961.34	216.00	560.26
CA/031/06 (3+1)	**3**	477.99	483.00	1,399.96	442.82	258.00	552.87
CA/032/06 (3)	**1**	1,074.27	324.00	1,033.74	0.00	0.00	0.00
Total travel €	**8**	**4,919.09**	2,262.00	5,935.97	**3,825.00**	1,014.00	2,410.77
Total other costs €				**8,197.97**			**3,424.77**

*most of the travel and hotel paid within CA/030/06

Appendix E: Actual costs January 2007

Meeting ID	No	Travel - Croatia	Other costs - Croatia		Travel - Turkey	Other costs - Turkey	
	of days	Flight	DSA	Hotel	Flight	DSA	Hotel
CA/001/07 (2+1)	**1**	795.94	216.00	547.83	509.13	108.00	317.02
CA/002/07 (3)	**1**	1,190.94	324.00	875.00	0.00	0.00	0.00
CA/004/07 (2+1)abroad*	**5**	665.12	700.00	0.00	344.19	700.00	0.00
CA/005/07 (1)	**1**	404.67	108.00	345.30	0.00	0.00	0.00
Total travel €	**1**	**3,056.67**	1,348.00	1,768.13	**853.32**	808.00	317.02
Total other costs €				**3,116.13**			**1,125.02**

*Hotel included in DSA

Appendix F: Actual costs February 2007

Meeting ID	No	Travel - Croatia	Other costs - Croatia		Travel - Turkey	Other costs - Turkey	
	of days	Flight	DSA	Hotel	Flight	DSA	Hotel
CA/006/07 (2)	**1**	876.27	216.00	415.04	0.00	0.00	0.00
CA/007/07 (2+3)	**1**	806.60	108.00	708.91	1,562.93	324.00	939.62
CA/008/07 (3+5)	**1**	1,209.90	324.00	881.64	2,108.59	540.00	1,559.56
CA/010/07 (1+2)	**3**	227.55	258.00	581.11	1,153.93	516.00	1,000.56
CA/013/07* (2)	**2**	289.15	0.00	0.00	848.45	366.00	1,035.90
CA/014/07 (3+3)	**3**	520.11	516.00	1,662.50	1,808.97	774.00	1,854.00
Total travel €	**11**	**3,929.58**	1,422.00	4,249.20	**7,482.87**	2,520.00	6,389.64
Total other costs €				**5,671.20**			**8,909.64**

*Canceletion fee - illness

Appendix G: Actual costs March 2007

Meeting ID	No	Travel - Croatia	Other costs - Croatia		Travel - Turkey	Other costs - Turkey	
	of days	Flight	DSA	Hotel	Flight	DSA	Hotel
CA/012/07 (1+3)	**2**	241.65	183.00	375.17	1,512.69	549.00	1,364.31
CA/016/07 (1+1)	**2**	205.43	183.00	507.64	582.61	183.00	375.21
CA/017/07 (2+4)	**2**	487.16	366.00	835.67	2,002.27	732.00	1,671.34
CA/018/07 (1*+1)	**1**	546.59	108.00	432.24	461.65	108.00	248.08
CA/019/07 (4+5)	**1**	1,211.84	399.00	813.57	2,813.78	540.00	1,345.39
CA/020/07 (2)Instanbul	**2**	0.00	0.00	0.00	633.59	680.00	0.00
CA/021/07 (4+5)	**2**	1,072.57	732.00	1,499.68	2,557.34	915.00	2,330.33
Total travel €	**12**	**3,765.24**	1,971.00	4,463.97	**10,563.93**	3,707.00	7,334.66
Total other costs €				**6,434.97**			**11,041.66**

*Also attended CA/019/07 - hotel paid from CA/018/07