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

First Progress Report

to the

European Commission

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1. MANAGEMENT SUMMARY

This first 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 is submitted with the request for funding.

A contract of €700,000 was signed on 24 April 2006 between the Commission and the EMEA to be expended over 2006 and 2007 in order to assist 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. The first information meeting on participation of Croatia and Turkey in EMEA activities was held at the EMEA premises on 29 September 2006, involving representatives of National Competent Authorities from Croatia and Turkey, dealing with the regulation of medicinal products for both human and veterinary use.

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 with Turkey and Croatia and the EMEA 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 participation in the activities of the EMEA and to develop the confidence of the existing Members States in the systems in place in the two Candidate Countries. Furthermore, this should lead to the EMEA, the existing Member States and Croatia and Turkey being able to work as equal, mutually respected partners.

In this context and in the area of medicinal products, the project is designed to establish an internationally open dialogue, working mechanisms to facilitate the adoption of common technical requirements, to identify areas where additional action may be required to ensure the smooth

transposition of their legislation into the EU *Acquis Communautaire* and participation in the EMEA's activities.
Indeed, a solid understanding of the EMEA's work is necessary to explain the roles/links between the EMEA, the Member States and the European Commission 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 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 Turkey and Croatia 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 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 in having access to such regulatory data as may be made available to them prior to accession to the European Union
- 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 of representatives of Croatia and Turkey in scientific and technical EMEA meetings, held at the EMEA's premises in London, as observers
- Provision of focused training on specific technical topics, including linguistic reviews of translations of product information for centrally authorised products and on EU Telematics systems to assist the two countries' National Competent Authorities to be part of the electronic network. 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 3 conferences in London, 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 regard 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 first 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, via several means, e.g. letters, visits and information meetings, described below.

3.1 Communication

Contacts were initiated by sending information letters regarding the 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 Building up the relationship

Visits were organised in both Candidate Countries to promote collaboration and networking.

Visit of the National Competent Authorities in Croatia

A meeting was held in Zagreb on 11 July 2006, to introduce the Multi-beneficiary programme to support participation of Croatia and Turkey in EMEA activities to the National Competent Authorities dealing with medicinal products for both human and veterinary use.

An overview of the EMEA structure and responsibilities and the aim of the programme including the activities foreseen to fulfil the objectives were presented. These presentations were followed by a questions and answers session where preparations and developments in view of the accession of Croatia to the European Union were discussed as well as integration into the EU Telematics network.

Meetings were held at:

- the Croatian Agency for Medicinal Products and Medical Devices in the presence of the Head of Agency and the Heads of Departments
- the Ministry of Health and Social Welfare in the presence of the Assistant Minister and the responsible person for international cooperation
- the Croatian Veterinary Institute, in the presence of the Head of Veterinary Services and two other members of the Ministry of Agriculture, Forestry and Water Management, the Head of the Croatian Veterinary Institute and the Head of Department for Quality Control of VMP, who presented the structure and the organisation of the Veterinary activities including the regulation of medicinal products, as well as the activities of the Institute.

These meetings were very successful and the presentations of the Croatian representatives were very useful and informative. The atmosphere of the meetings was encouragingly enthusiastic, and future exchanges were expected to be positive.

Visit of the National Competent Authorities in Turkey

A mission took place at the General Directorate of Pharmaceuticals and Pharmacies at the Ministry of Health and at the General Directorate of Protection and Control at the Ministry of Agriculture and Rural Affairs in Ankara, on 17 July 2006, to introduce the programme and to present the EMEA activities to the National Competent Authorities dealing with medicinal products for both human and veterinary use, e.g.:

- the General Directorate of Pharmaceuticals and Pharmacies, where an introduction was given to the General Director, and to the four Deputy Directors responsible for registration, quality and inspections, including the programme coordinator
- the General Directorate of Protection and Control at the Ministry of Agriculture and Rural Affairs, in the presence of the Deputy General Director. The Director of the Veterinary Drug Department and her collaborators and the Director of Animal Disease Combat attended this meeting.

These meetings were very successful. The presentations of the EMEA were well received. However, many issues and questions were raised by the Turkish representatives who attended the meeting at the General Directorate of Protection and Control at the Ministry of Agriculture and Rural Affairs. The Turkish representatives were reserved and cautious in respect of the programme content, as they were not involved in its management and development. Further explanations were given on the aim and objectives of the programme designed for supporting participation in EMEA activities and details were given on why the programme was not designed to fund Turkish activities in specific domains.

Actions arising

National Competent Authorities from both Candidate Countries requested information on budget availability for the installation of a copy of the EudraVigilance Member State edition as a national electronic Pharmacovigilance system, of a total cost of €30,000 (hardware, software, installation, and support for the first year).
Their requests are relevant from a compliance point of view, as the installation of EudraVigilance would also make a significant contribution to public health.

3.3 Information meeting

A kick-off meeting for addressing the activities supported under the project took place on 29 September 2006.

3.3.1 Agenda

The four National Competent Authorities, e.g. the Croatian Agency for Medicinal Products and Medical Devices, the Croatian Ministry of Agriculture, Forestry and Water, the Turkish General Directorate of Pharmaceuticals and Pharmacy and the Turkish Ministry of Agriculture and Rural Affairs/General Directorate of Protection and Control, presented their activities, organisation and structure.

The aim and the objectives of the project were described as well as the activities supported under the contract, in order to fulfil the objectives; the main activity consisting of inviting representatives from Croatia and Turkey to participate in EMEA training and meetings as observers, and to organise Conferences in both countries.

Information was also given by EMEA on:

- The project description and relevant administrative information
- EMEA activities
- The Centralised procedure

- Ensuring consumer safety during authorization of veterinary medicines
- Acquis Communautaire
- Pharmacovigilance including Eudravigilance
- Inspections of Good Practices and associated groups
- EU Telematics implementation plan, Eudranet and Eudralink
- Benchmarking European Medicines Agencies.

3.3.2 Participants

Participants at this meeting included the Heads of National Competent Authorities, the Heads of Pharmacovigilance, Product Information, IT, Administration and the programme coordinators, and representatives of the National Competent Authorities for the regulation of medicinal products for both human and veterinary use from both Candidate Countries attended the meeting.
Simultaneous translations in Croatian and Turkish were provided.

3.3.3 Outcome of the meeting

The participants welcomed this initiative and the outcome was positive. The meeting was interactive and information on respective activities useful for future collaboration.

3.4 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.

3.4.1 Activity status

Letters requesting nominations of representatives and alternates to attend listed non-product related meetings were sent to the attention of the 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 European law.

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

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 and administrative management of nominations and attendance, involving one staff member full time work.

The representatives' attendance to meetings during the first four months of activities is summarized in Appendix A.

3.4.2 Financial implications

A total of € 66,004.80 were spent during the activity period, mainly for participation of representatives from both counties in meetings and training for an amount of € 51,276.81, including € 10212.49 for secretarial support to the project and € 4515.5 for EMEA visits.
It should be noted that the expenditure for this activity is very low, due to the limited number of meetings that representatives can attend as observers.

3.4.3 Further continuation

The number of representatives from Croatia and Turkey attending meetings should increase in 2007, as the respective National Competent Authorities have now nominated observers for all meetings.

3.5 Training

Representatives of Croatia and Turkey were invited to participate in training 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 focused training on specific technical topics is scheduled for 2007.

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

3.6 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 is proposed to organise a conference in Split (Croatia) in April 2007 and in Istanbul (Turkey) in 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.

3.6.1 Aim of the conferences

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 guidelines in the EU to candidate country regulators, and tackle specific areas in their application
- To identify the differences between existing legislation in each of these countries
- To discuss problems that may be encountered with regard 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.

3.6.2 Status of the conferences

A full dedicated person was recruited in October 2006 to organise the Conference in Split in April 2007, as well as a trainee in order to start the negotiations for the organisation of the conference in Istanbul under the supervision of the conference manager.

4. REPORTS

Progress is monitored by the EMEA project leader, the Head of Sector Meeting Management & Conferences within the Communications and Networking Unit.

Quarterly progress reports, including financial reports, will be available and published on the EMEA website http://www.emea.europa.eu/euenlargement.htm, starting from December 2006.

Technical adherence to the plan of activities is monitored on an ongoing basis by the EMEA.

5. 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 a practical manner, 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.