Project Description

1. Description

1.1 Title:

Participation of Croatia and Turkey in EMEA activities in 2006 and 2007

1.2 Amount requested from the Commission:

A budget of €700,000 (seven hundred thousand euros) is requested from the Commission to be spent over 2006 and 2007. The programme was initiated on 1st July 2005.

1.3 Executive Summary:

a) The aim of the project

The aim of this project is to build contacts and relationships between 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 competent bodies 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.

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 committees.
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.

b) The target groups

The target groups are the National Competent Authorities of Turkey and Croatia for the regulation of medicinal products for both human and veterinary use, in particular those with the same responsibilities as EMEA, their information officers, legal officers, scientists and stakeholders.

c) The main activities and their location

Main activities

This proposal 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 as observers
- Organisation of 3 mini-conferences in London, Zagreb and Ankara or Istanbul to:
  1. give an overview of EU legislation governing the regulation of medicinal products
  2. provide feedback on the practical application of the *Acquis Communautaire* and legal aspects of its implementation
  3. explain the role of the guidelines in the EU to candidate country regulators, and tackle specific areas in their application
  4. identify the differences between existing legislation in each of these countries; and
  5. 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 administrative and scientific audiences and will include specific activities targeted at such audiences with a view to informing the full cross-section of stakeholders in Croatia and Turkey
- 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.

Location

The location may vary according to the type of activity performed:

- the first activity will be performed at the EMEA's premises in London
- the second will involve travel within the European Union and to Croatia and Turkey. The first workshop will be organised in London, the next ones in Zagreb and Ankara or Istanbul, 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

- the third activity will involve participation of National Competent Authorities' experts in meetings and training sessions organised in London. Furthermore, Croatian and Turk 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. In addition visits in relation to EU Telematics systems will be organised in both countries in order to assist the two countries' National Competent Authorities to be part of the electronic network.

1.4 Objectives

The overall purpose of the project is to assist the National Competent Authorities of Croatia and Turkey to align their standards and practices with those established in the European Union. 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.

1.5 Justification

a) Identification of perceived needs and constraints in the target countries

In the area of medicinal products, there are a large number of directives and regulations, relating both to the issuing of marketing authorisations and to the economic regulation of the pharmaceutical market, that need to be applied, and implemented effectively. The body of knowledge relating to this implementation is constantly evolving as the EU scientific committees and their working parties develop guidelines and gain experience in new therapies and new technologies. Without involvement in these procedures, it is extremely difficult to acquire the necessary knowledge to be able to participate in the EU system.

This factor will contribute to difficulties associated with the implementation and enforcement of harmonised regulatory and technical requirements and procedures, including the continuing use of divergent practices existing within Croatia and Turkey. Constraints on participation in the work of the EU regulatory network therefore result in insufficient information being exchanged, limited understanding of the priorities and practices of others, and a need to overcome natural resistance to changes and new practices.

b) *List of target groups with an estimate of the anticipated number of direct and indirect beneficiaries*

The target groups are principally the National Competent Authorities in Croatia and Turkey, together with other institutions involved in the regulation of medicinal products. These are set out below, the lead agencies in each country (one for human medicines, a second one for veterinary medicines where appropriate) are recorded in bold type.

Croatia	**Agency for Medicinal Products and Medical Devices** Ksaverska cesta 4 HR-10000 Zagreb Ministry of Health and Social Welfare Ksaver 200 HR-10000 Zagreb **Croatian Veterinarian Institute** Department for Quality of Pharmaceuticals Savska c. 143 HR-10000 Zagreb Ministry of Agriculture, Forestry and Water Management Ulica grada Vukovara 78 HR-10000 Zagreb
Turkey	**General Directorate of Pharmaceuticals and Pharmacy** Çankırı Cad No: 57 Dışkapı- Ankara-Turkey **Ministry of Agriculture and Rural Affairs** General Directorate of Protection and Control-Veterinary Drug Department

The direct beneficiaries are the institutions listed above in bold and their employees. Indirect beneficiaries may be defined at different levels with the next level down including scientific academic and civil society organisations and ultimately could be defined as widely as to include the entire population of each of the countries involved.
Stakeholders other than regulators will be targeted during the conferences. All seminars will target regulators/National Competent Authorities.

c) Reasons for the selection of the target groups and activities

The target groups comprise the institutions in Croatia and Turkey in charge of the regulation of medicinal products.

The activities concentrate on the areas in which the National Competent Authorities in the countries concerned have determined that most benefit can be obtained from a collaborative approach to harmonisation with the EU.

d) Relevance of the project to the target groups

As candidate countries, Croatia and Bulgaria need to be in a position upon accession to assume the responsibilities and obligations of a Member State. The project is designed to provide the target groups with an ongoing detailed working knowledge of the practice of regulation of medicinal products in the context of EU legislation and guidelines. The project also seeks to advise candidate countries on the work necessary to ensure that regulatory work will be compliant with EU requirements. The EMEA's work with the Member States depends mainly on good working relationships, information exchanges, liaison and collaboration. In this way, the project will prepare the target groups in a practical manner to assume the duties and responsibilities of a Competent Authority of a Member State.

1.6 Detailed description of activities

In line with the methodology set out in section 1.7 (below), the nature of the activities described is dependent upon the timing of the implementation of the project. The activities described are planned on the assumption that the project will run from July 2006 to December 2007. Details of the final programme may differ, especially with regard to activities linked to pre-defined European meetings, should the timing of the project differ.

The programme proposal consists of three types of activities:

- the financing of participation of representatives in scientific and technical EMEA meetings as observers, in order to familiarise the National Competent Authorities with the work performed by the EMEA's scientific committees and their working parties
- the organisation of 3 mini-conferences, in London, Zagreb and Ankara or Istanbul in order to establish contacts in a structured forum, which shall be a platform for exchanging views, establishing a dialogue with interested parties and providing an overview of the EU legislation governing the regulation of medicinal products. These conferences will aim to provide feedback regarding actual experience of the application of the *Acquis Communautaire* and legal aspects of the implementation, to explain the role of guidelines in the EU to candidate country regulators, and tackled specific areas in their application, to identify the differences between the existing legislation in each of these countries and to introduce problems that may be encountered when moving towards accession, and in anticipation of membership of the European Union
- the provision of focused training on specific technical topics, e.g. legal aspects, assessors, EMEA structure including scientific activities and working parties, and on measures to integrate into the EU Telematics systems.

These are described in more detail below:

1.6.1 Participation in EMEA meetings as observers

It is proposed to invite one representative per candidate country to participate in EMEA Scientific Committee and Working Party Meetings, as observers on a voluntary basis. Invitations to Working Party Meetings will be sent to attendees in virtue of the Member State that they represent and not their scientific expertise. No additional experts will be invited.
The candidate countries' representatives will only have the status of observers and will not have responsibilities with regard to the assessment process.
The participation of observers from Croatia and Turkey will be financed through the project, as there is currently no other way of financing this participation.
The funds allocated for meetings and proposed participation will cover travel, daily allowances and hotel expenses for attendance at meetings, workshops and other visits. The purpose of this initiative is to enable the Croatian and Turk National Competent Authorities to develop their knowledge through direct involvement, albeit as observers, in the activities of the key committees in the EU regulatory community for pharmaceuticals.

1.6.2 Mini-conferences

It is envisaged to organise 3 mini-conferences in order to build contacts and to develop a deeper understanding of the work of EMEA, to explain the role of and cooperation between the EMEA, Member States and the European Commission.
The 3 mini-conferences (in London, Zagreb and Ankara or Istanbul) should:

- give an overview of the EU legislation governing the regulation of medicinal products,
- provide feedback regarding actual experience of applying the Acquis Communautaire and legal aspects of the implementation,
- explain the role of guidelines in the EU to candidate country regulators, and tackle specific areas in their application,
- identify the differences between the existing legislation in each of these countries, and finally,
- anticipate potential problems regarding the accession and membership of the European Union.

A Steering Committee created to establish the programme of each conference will include representatives from:

- the different EMEA activity sectors, e.g. medicinal products for human use and veterinary use, inspections, communication and networking, IT, legal affairs and executive support.
- Heads of National Competent Authorities from Member States and candidate countries.
- Commission representative(s) from DG Enterprise.

1.6.3 Training

<u>Training</u>

The participation of candidate countries in meetings as observers could be envisaged either as a restricted observership or as a training programme in order to facilitate accession to the European Union, depending on the expected outcome of the meeting.

Participation in training organised for assessors on specific scientific topics, on aspects of the regulatory procedures will be financed through the project. In addition, training will be provided on Telematics issues.

A schedule of the training sessions foreseen involving participation by Croatian and Turk delegates is set out in Annex II.

Integration into the EU Telematics systems

In the context of accession, a series of visits to the National Competent Authorities in the countries acceding in 2004 has been undertaken. It is proposed to extend the programme to Croatia and Turkey. The activities foreseen comprise:

- visits to assess the architecture in place with a view to implementing a connection to EudraNet.
- visits to assess the architecture in place with a view to implementing a connection to Eudravigilance.
- visits to assess the architecture and data models in place with a view to implementing the EuroPharm database.
- visits to introduce the European Review System (EURS)[1].

1.7 Methodology

a) Methods of implementation

- Attendance by experts from Croatia and Turkey as observers at EU regulatory meetings as far as allowed by current legislation and the proposed budget
- Meetings and workshops led by regulators from the EMEA and Member State National Competent Authorities. Directions will be set up by the Steering Committee. Priorities will be further defined and chosen following consultation with Competent National Authorities and the Commission
- IT training sessions, site visits and investment in information technology equipment.

b) Reasons for the proposed methodology

The proposed methodology is founded on the exchange of feedback on practical experiences of practising regulators in the EU and those in Croatia and Turkey, and participation in the ongoing regulatory activities of the EMEA and its Member State partners. In this way, harmonised regulatory standards and practices will be established in all participating countries.

Participation at selected meetings not only enables the observers to be informed of the most recent issues to be addressed within the EMEA, but also to become familiar with the medicinal product assessment process. Furthermore, the opportunity provided to extend the network of people with experience in the same field is very valuable.

The purpose of the mini-conferences is to provide a forum for discussion of methods to address working methods and practices at the EMEA and in the Member States.

[1] It should be noted that the main activity will be covered by participation in training organised at the EMEA's premises.

This will enable defined interested parties to be informed of the benefits and challenges surrounding accession, as well as the progress of the Programme as it is running. At the same time, the conferences will permit participants from the EMEA, Croatia, Turkey and EU Member States' National Competent Authorities to exchange views across disciplinary boundaries.
The Steering Committee uses the experience of EMEA Heads of Units and Heads of Sectors, as well as Heads of National Competent Authorities in both EU and the participating candidate countries, in order to provide direction to the project thus ensuring an appropriate focus.

The information technology work is designed to facilitate electronic communication between Croatia and Turkey and the EU networks, thereby facilitating the secure transmission of regulatory data. An area of emphasis is the monitoring of medicinal products already on the market, as far as allowed by current legislation.
The nature of the EMEA's activities leads to the building of networks. Therefore, the integration and the collaboration in the EMEA's work of the Member States and accession countries on a wide range of scientific data exchanges and bilateral collaboration has to be built up regarding scientific and institutional activities, so that upon accession the network is able to function. In order to facilitate all these activities it is important that there is a common understanding of the legal framework, constraints and context in which the EMEA operates.

c) How the project is intended to build on a previous project or previous activities

Previous activities under this programme were carried out within the framework of the Pan-European Regulatory Forum on Pharmaceuticals (PERF) and in the PHARE multi-beneficiary programme on the participation of Bulgaria and Romania in certain Community Agencies in 2005 and 2006.

The PERF programme comprised three phases as follows:

- The first PERF established the legislative position in each of the participating candidate countries and identified the differences between the existing legislation in each of these countries and the EU legislation governing the regulation of medicinal products. It also facilitated an understanding of the role of guidelines in the EU between candidate country regulators, and tackled specific areas in their application.

- PERF II extended the practical perspective, seeking to provide feedback on the practical experience of applying the Acquis Communautaire. At the same time, practical guidance and advice on problems that were being encountered in moving towards accession, and in anticipation of membership of the European Union, was provided through the work of the group concentrating on legal aspects of the implementation.

- PERF III built on the practical experience gained to reinforce the consistent application of standards and guidelines, while continuing to provide practical advice with respect to particular areas of difficulty. The programme assisted the candidate countries' National Competent Authorities to make a smooth transition, in practical terms, to membership of the EU.

PERF achieved the objectives described.

The PHARE multi-beneficiary programme on the participation of Bulgaria and Romania in certain Community Agencies in 2005 and 2006 was initiated in September 2005.
This programme aims to keep the Bulgarian and Romanian National Competent Authorities up-to-date and involved, such that the level of familiarity with and confidence in the EU regulatory procedures and practices attained at the end of PERF III continue to be employed regularly.

The aim of this programme for supporting participation of Croatia and Turkey in EMEA activities in 2006 and 2007 aims to provide knowledge for the alignment of their standards and practices with those in place in the European Union with regard to the implementation of Community law.

d) Procedures for internal evaluation

- Progress of the overall project will be monitored on a continuous basis by the EMEA project coordinator, the Head of the Meeting Management & Conferences Sector within the Communications and Networking Unit. Regular progress checks on the project will be carried out in order to ensure that goals are being met and that there is sufficient time remaining to carry out activities.
- Quarterly progress reports will be available and published on the EMEA website (http://www.emea.eu.int).
- Technical adherence to the plan of activities monitored on an ongoing basis by the EMEA.
- Progress of the mini-conferences will be monitored by the Steering Committee and reports will be published after each conference.
- Assessment reports and implementation reports will be provided after each National Competent Authorities Telematic systems visit.

e) Level of involvement and activity of other organisations in the project

The direct involvement of other organisations in the project organisation will be limited to National Competent Authorities from the Member States - in particular new Member States which may wish to share their experience with the candidates and DG Enterprise and DG Enlargement at the Commission. The EMEA will support the logistical and practical arrangements for the observership, organise conferences, training sessions and site visits, and will provide the secretariat facilities to the regulatory network. EU Telematics projects are managed and largely resourced through the EMEA, and therefore support to the Telematics portion of the proposed programme is expected to be provided by the EMEA.

Nevertheless, the participation of EMEA's regulatory partners in the regulatory processes, in which Croatian and Turk participants will be involved as observers, and in the training sessions, will be the primary ingredients for the success of the programme.

f) *Reasons for the role of each partner*

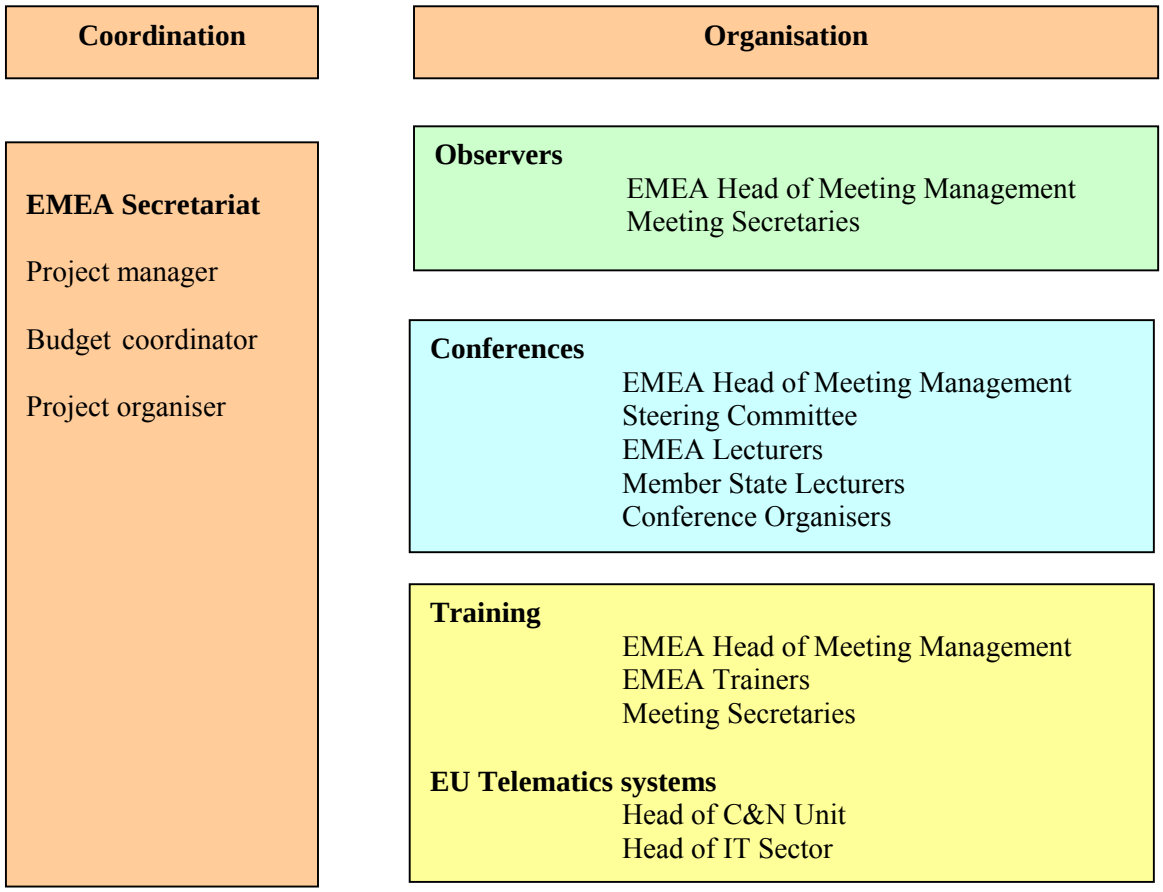
The EMEA coordinates the existing scientific resources of Member States with a view to evaluating and supervising medicinal products for human and veterinary use. Accordingly, the practical scientific evaluation is carried out by Member State experts. The future role of the participating experts from Croatia and Turkey will be the same, and therefore the experience of existing Member State experts is the most directly relevant.

Member States' involvement: The general understanding and problems are (more or less) similar in all EU Member States. By giving practical support instead of theoretical information they can add to the implementation and learning process.

g) *Team proposed for implementation of the project by function*

The organigramme of the project is set out below.

Organigramme



Steering Committee proposed for implementation of the mini-conferences:

- The project coordinator
- Representatives from the different EMEA activity sectors, e.g. medicinal products for human use and veterinary use, inspections, communication and networking, IT, legal affairs and executive support
- Heads of National Competent Authorities from both Member States and candidate countries
- Representative(s) from DG Enterprise.

It is also recommended that a fixed contact point in Croatia and Turkey be defined.

1.8 Duration (in months) and indicative time schedule of actions

The duration of the project should be 18 months from 1st July 2006 until 31st December 2007.

Duration

Action 1 **Observer**	**Action 2** **Conferences**	**Action 3** **Training** **EU Telematics systems**
From Month 1 to Month 18	From Month 4 to Month 18	From Month 6 to Month 18

Action 1: observers

Representatives from Croatia and Turkey will be invited to participate in EMEA Scientific Committee Meetings held 3 days per month on average and Working Party Meetings scheduled on a monthly, or two-monthly basis, for 2 days, organised at the EMEA's premises.

Action 2: mini-conferences

The mini-conferences will be organised in London, Zagreb and Ankara or Istanbul mainly in 2007, for two days, involving one-day parallel sessions.

Activity 3: training and integration into Telematics systems

Training sessions and visits to National Competent Authorities will be scheduled in 2007.

2. Expected results

2.1 Publications and other outputs

The expected outcomes of this project are:

- building contacts and relationships with Regulatory Authorities in Croatia and Turkey
- setting up a forum for discussion and information exchange
- encouraging greater understanding between Croatia, Turkey and Member States' National Competent Authorities, leading to future co-operation and harmonisation of technical procedures within Europe
- greater mutual confidence in order to encourage the future acceptance of research and development data and measures between these authorities
- better co-operation between the regulators of the European pharmaceutical market on a wider international basis

- the candidate countries' National Competent Authorities being informed practically of the implementation of 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 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 output of results of this project will mainly take the form of published activities progress reports on the EMEA website, including summary assessment reports after each National Competent Authorities' Telematics systems visit.
For each mini-conference, a report and press release as well as the slides from presentations at the conference will be sent to interested parties and published on the EMEA website.

2.2 Multiplier effects

The programme is targeted at the National Competent Authorities in Croatia and Turkey. The regulation of medicinal products for both human and veterinary use is included in the project. The extension of the project outcomes is envisaged through the improved regulation of pharmaceutical industry and better quality information for patient groups and professional organisations.

Replication of the programme within the pharmaceutical area is unlikely. The principle could be adapted to other regulatory environments. Such replication, however, is outside the scope of this project.

2.3 Sustainability

a) *Institutional sustainability*

The programme involves the National Competent Authorities of Croatia and Turkey, both of which will be responsible for the regulation of medicinal products during and after accession. The results of the project (harmonised standards and practices) will continue in the context of the exercise of the responsibilities and obligations of Member State National Competent Authorities within the European Union. At the end of the project our objective is to have built up contacts and relationships for future collaboration in respect of the EMEA's activities and its relationships with the Member States and, as such, this project will be important in bringing about this relationship. In addition the project will also put in place the necessary access links to the information exchange systems including access to IT systems, which facilitate the exchange of information between the EMEA and Member States.

b) *Sustainability of the policy*

Overall this project will lead to the improved exchanges and sharing of information across Europe on medicinal products regulation matters.
The project will also lead to the implementation of some of the appropriate legislation and the use of EU guidelines in Croatia and Turkey. The continuation of

work in the context of the real functioning of the European Union regulatory framework will lead to improved implementation of the *Acquis Communautaire* (including harmonised standards and methodologies).

3. Budget for the project

The budget for the total duration of the project is summarised in Annex V.

Account name:	EMEA
Bank account no:	59006776
Bank code:	Sort code: 30-12-18
SWIFT code:	LYODGB2LCTY
Name of bank:	Lloyds TSB PLC
Address of Bank:	City Office PO Box 72 Bailey Drive Gillingham Business Park Gillingham Kent ME8 0LS
Name of signatory:	Gerard O'Malley
Position of signatory:	EMEA Accountant

4. Capacity to manage and implement projects

4.1. Experience with similar projects.

Pan-European Regulatory Forum for Pharmaceuticals (PERF)

a) The object and location of each project

In the context of the PHARE multi-beneficiary programme on the Participation of the Central and Eastern European Candidate Countries (CEECs) in Community Agencies, the EMEA has run a series of programmes for the benefit of the Accession Countries since 1999 under the Pan-European Regulatory Forum for Pharmaceuticals (PERF) initiative.
The overall objective of the Pan-European Regulatory Forum for Pharmaceuticals PERF programme has been to facilitate the implementation of the *Acquis Communautaire* in the area of pharmaceuticals in the participating candidate countries. The project purpose has been to assist National Competent Authorities in the candidate countries in aligning their standards and practices with those in the European Union with regard to the implementation of Community law.

The first phase of the project, which ran from July 1999 to September 2000 (PERF I), was funded by PHARE through the PRAQ III programme, while the second phase from June 2001 to September 2002 (PERF II including extension) was funded through an earlier phase of the preparatory measures related to the future participation of Central and East European Countries (CEECs) in the European Agencies. The third phase of the project (PERF III) was funded in a similar manner.

b) The results of the project

The first PERF established the legislative position in each of the participating candidate countries and identified the differences between the existing legislation in each of these countries and the EU legislation governing the regulation of medicinal products; it also facilitated an understanding of the role of guidelines in the EU among candidate country regulators and tackled specific areas in their application.
PERF II extended the practical perspective, seeking to provide feedback on the actual experience of the application of the *Acquis Communautaire*. At the same time, practical guidance and advice on problems that were being encountered in moving towards accession and in anticipation of membership of the European Union were provided through the work of the group concentrating on legal aspects of the implementation.
The third phase of PERF, which ended in December 2003, built on the practical experience gained to reinforce the consistent application of standards and guidelines, while providing practical advice with respect to particular areas of difficulty. The programme aimed to assist the candidate countries' National Competent Authorities practically to achieve a smooth transition to membership of the EU. This third phase of PERF was the final phase of the pre-accession programme in this guise.

c) Level of involvement in the project

The EMEA proposed the programme and, following approval by the Steering Committee, organised, coordinated, and reported upon the entire project.

d) The project cost

PERF I: € 515,000
PERF II: € 1,837,000
PERF III: € 1,371,000

e) *The other donors to the project*

There were no other donors to the project.

Programme on participation of Croatia and Turkey in EMEA activities in 2006 and 2007

The aim of this project, for supporting participation of Croatia and Turkey in EMEA activities, is to:

- ensure a smooth transition to full participation in the work of the Agency's committees upon accession.
- 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 Bulgaria and Romania to be a part of the electronic network upon accession.
- ensure that sufficient resources and planning are applied to the completion of the necessary translation checks to assure compliance with EU requirements upon accession.
- maintain the alignment of their standards and practices with those established in the European Union with regard to the implementation of Community law.

An amount of €800,000 is allocated to the project for supporting participation of the National Competent Authorities in Bulgaria and Romania in the EMEA's activities, with regard to the regulation of medicinal products for both human and veterinary use from 15 September 2005 until 31 December 2006.