# Project Description

**ANNEX A**

## 1. Description

### *1.1 Title: IPA Transition Assistance Programme*

On participation of the Former Yugoslav Republic of Macedonia, Croatia and Turkey in certain Community Agencies in 2008 as the follow up of the Multi-beneficiary project launched in 2006 to support participation of Croatia and Turkey in EMEA activities.

### *1.2 Amount requested from the Commission:*

A budget of € 600,000 (six hundred thousand euros) is requested from the Commission to be spent over 2008.

### *1.3 Executive Summary:*

*a) The aim of the project*

The aim of this project is to build contacts and relationships between the EMEA and the Candidate Countries, e.g. the Former Yugoslav Republic of Macedonia, Croatia and Turkey and for future collaboration in the EMEA's activities and its relationships with Member States.

This project aims:

- to prepare the Competent National Authorities in the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, Croatia and Turkey in EMEA's networks
- to support the Former Yugoslav Republic of Macedonia, Croatia and Turkey in their communication activities.

This programme will allow the three Candidate 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 three countries. Furthermore, this should lead to the EMEA, the existing Member States and the Candidate Countries 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 the Community law. This means transposing the regulations

supporting the legislation into the EU *Acquis Communautaire* and establishing working procedures to make the laws and regulations operational.

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

*b) The target groups*

The target groups are the National Competent Authorities of the Former Yugoslav Republic of Macedonia, Croatia and Turkey 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:

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

- ***Training***
  Participation in training on specific technical topics, including linguistic reviews of translations of product information for centrally authorised products and on EU Telematics systems organised by the EMEA as well as short visits of Candidate Countries representatives at the EMEA or to Member States National Competent Authorities where appropriate.

- ***Conferences***
  Organisation of conferences in the Candidate Countries, in order 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
  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 with a view to informing the full cross-section of stakeholders in the Former Yugoslav Republic of Macedonia, Croatia and Turkey.

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 activity will involve participation of National Competent Authorities' experts in meetings and training sessions organised in London. Furthermore, Candidate Countries 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 different EU Member States' National Competent Authorities may be organised to provide a more extensive knowledge on particular specific activity domain or topic where appropriate.
- the third activity will involve travel within the European Union and to the Former Yugoslav Republic of Macedonia, Croatia and Turkey. The conferences will be organised in the Candidate Countries, 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, the Member States and the European Commission.

## *1.4 Objectives*

The overall purpose of the project is to assist the National Competent Authorities of the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, Croatia and Turkey 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 the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, 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.

| | |
|---|---|
| ***Former Yugoslav Republic of Macedonia*** | **Bureau for Medicinal Products**<br>Ministry of Health<br>Str. Vodnjanska bb 1000 Skopje, FYR Macedonia<br><br>***Agency for Medicinal Products and Medical Devices***<br>*To be created*<br><br>**Veterinary Directorate**<br>Ministry of Agriculture, Forestry and Water Economy<br>Leninova 2 1000 Skopje, FYR Macedonia |
| ***Croatia*** | **Agency for Medicinal Products and Medical Devices**<br>Ksaverska cesta 4 HR-10000 Zagreb<br><br>***Ministry of Health and Social Welfare***<br>Ksaver 200 HR-10000 Zagreb<br><br>**Croatian Veterinarian Institute**<br>Department for Quality of Pharmaceuticals<br>Savska c. 143 HR-10000 Zagreb<br><br>***Ministry of Agriculture, Forestry and Water Management***<br>Ulica grada Vukovara 78 HR-10000 Zagreb |
| ***Turkey*** | **General Directorate of Pharmaceuticals and Pharmacy**<br>Ministry of Health<br>Çankırı Cad No: 57 Dışkapı- Ankara -Turkey<br><br>**General Directorate of Protection and Control-Veterinary Drug Department**<br>Ministry of Agriculture and Rural Affairs<br>Akay Cad. No.:3 TK - 06100 Bakanliklar/Ankara |

The direct beneficiaries are the national 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 the Former Yugoslav Republic of Macedonia, 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 Candidate 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, the Former Yugoslav Republic of Macedonia, Croatia and Turkey 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 January 2008 to December 2008. 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
- 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
- the organisation of conferences, in the Candidate Countries 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.

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 non product related 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 the Former Yugoslav Republic of Macedonia, Croatia and Turkey will be financed through the project, like other invited participants, 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 Candidate Countries 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.
Meetings where representatives of Candidate Countries will be invited to participate in as observers are listed in Tables I and II.

*1.6.2 Training*

<u>Training</u>
The participation of Candidate Countries in meetings as observers could be envisaged either as a restricted participation in meetings as observers 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 Candidate Countries delegates is set out in Table II.

<u>Short visits</u>
Short visits at the EMEA or at the National Competent Authorities of selected Member States could be envisaged in order to provide focused training on specific issues.

*1.6.3 Conferences*

It is envisaged to organise conferences in the Candidate Countries 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 conferences 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 and each unit 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, as well as the Heads of National Competent Authorities from the Candidate Country concerned.

## *1.7 Methodology*

*a) Methods of implementation*

- Attendance by experts from the Former Yugoslav Republic of Macedonia, Croatia and Turkey as observers at EU regulatory meetings as far as allowed by current legislation and the proposed budget
- Training sessions and visits in specific domains
- Conferences 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 Candidate Countries Competent National Authorities.

*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 the Former Yugoslav Republic of Macedonia, 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 information technology work is designed to facilitate electronic communication between the Former Yugoslav Republic of Macedonia, 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.

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

*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), in the PHARE multi-beneficiary programme on the participation of Bulgaria and Romania in certain Community Agencies in 2005 and 2006 and in the multi-beneficiary programme on the participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007.

Pan-European Regulatory Forum on Pharmaceuticals

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.

PHARE multi-beneficiary programme on the participation of Bulgaria and Romania

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 aimed 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 acquired at the end of PERF III continue to be employed regularly.

The PHARE programme fulfilled its objectives in achieving a smooth transition to accession.

Multi-beneficiary programme on the participation of Croatia and Turkey

The multi-beneficiary programme on the participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007 was launched in 2006 in order to build contacts and relationships between the EMEA and the National Competent Authorities of the Candidate Countries, to contribute to the creation of communication and information exchange systems enabling their future participation of in the EMEA's activities and networks and to support preparatory measures prior to accession.

IPA-Transition Assistance Programme on participation of the Former Yugoslav Republic of Macedonia, Croatia and Turkey in certain Community Agencies in 2008

The aim of this programme supporting participation of the Former Yugoslav Republic of Macedonia, Croatia and Turkey in EMEA activities in 2008 is to continue the initiative undertaken in 2006 for Croatia and Turkey and to incorporate the Former Yugoslav Republic of Macedonia in the same support framework, thus providing 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.
- Progress reports will be available and published on the EMEA website (http://www.emea.europa.eu/htms/euenlargement) every 6 months
- Technical adherence to the plan of activities monitored on an ongoing basis by the EMEA.
- Progress of the conferences will be monitored by the Steering Committee and reports will be published after each conference.

*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 Candidate Countries, DG Enterprise and DG Enlargement at the Commission. The EMEA will support the logistical and practical arrangements for the attendance to meetings as observers, to the training sessions and the site visits, will organise the conferences, 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 Candidate Countries 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 the Former Yugoslav Republic of Macedonia, 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**

| **Coordination** | **Organisation** |
|---|---|
| **EMEA Secretariat**<br>Project manager<br>Budget coordinator<br>Project organiser | **Observers**<br>EMEA Head of Meeting Management<br>Meeting Secretaries<br><br>**Training**<br>EMEA Head of Meeting Management<br>EMEA Trainers<br>Meeting Secretaries<br><br>**Conferences**<br>EMEA Head of Meeting Management<br>Steering Committee<br>EMEA Speakers<br>Member State Speakers<br>Conference Organisers |

The Steering Committee proposed for implementation of the conferences will include:

- 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 the Candidate Countries.

It is also recommended that a fixed contact point in the Former Yugoslav Republic of Macedonia, Croatia and Turkey be defined.

### *1.8 Duration in months and indicative time schedule of actions*

The duration of the project should be 12 months from 1st January 2008 until 31st December 2008, as reported below:

| **Action 1**<br>**Observer** | **Action 2**<br>**Training** | **Action 3**<br>**Conferences** |
|---|---|---|
| From Month 1<br>to Month 12 | From Month 1<br>to Month 12 | From Month 4<br>to Month 12 |

Action 1: participation in meetings as observers
Representatives from the Former Yugoslav Republic of Macedonia, Croatia and Turkey will be invited to participate in some EMEA meetings scheduled on a monthly, or two-monthly basis, for 2 days at the EMEA's premises.

Activity 2: training and visits
Training sessions and visits to National Competent Authorities will be scheduled in 2008.

Action 3: conferences
Conferences will be organised in the Candidate Countries in 2008, for two days, involving one-day parallel sessions.

## 2. Expected results

### *2.1 Publications and other outputs*

The expected outcomes of this project are:

- building contacts and relationships with Regulatory Authorities in the Former Yugoslav Republic of Macedonia, Croatia and Turkey setting up a forum for discussion and information exchange
- encouraging greater understanding between the Former Yugoslav Republic of Macedonia, Croatia and Turkey and Member States' National Competent Authorities, leading to future co-operation and harmonisation of technical procedures within Europe

- building up the 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, e.g. progress reports and conferences presentations on the EMEA website.

## *2.2 Multiplier effects*

The programme is targeted at the National Competent Authorities in the Former Yugoslav Republic of Macedonia, 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 the Former Yugoslav Republic of Macedonia, Croatia and Turkey, 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 the Former Yugoslav Republic of Macedonia, 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 B.

| | |
|---|---|
| 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<br>PO Box 72<br>Bailey Drive<br>Gillingham Business Park<br>Gillingham<br>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 managed/implemented over the past five years*

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) Donors*

There were no other donors to this project.

<u>PHARE multi-beneficiary programme on the participation of Bulgaria and Romania in 2005-2006</u>

*a) The objectives of the project*

An amount of €800,000 was 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.

The aim of the project was to ensure:

- a smooth transition to full participation in the work of the Agency's committees upon accession
- 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

- that sufficient resources and planning are applied to the completion of the necessary translation checks to assure compliance with EU requirements upon accession.
- The maintenance of the alignment of their standards and practices with those established in the European Union with regard to the implementation of Community law.

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.

*b) Level of involvement in the project*

The EMEA proposed the programme, organised, coordinated, and reported upon the entire project.

*c) The results of the project and the project cost*

An amount of € 432,621.72 was spent during the contract period, starting from the initial date of the contract on 14 September 2005. Indeed the activities carried out under the project did not require the total amount of support allocated, as the main part of the budget was allocated to participation in meetings and training.
However, participants in the meetings consider that the high level objectives have been met. It is further considered that, amongst other specific objectives that have been achieved, the following are worthy of particular note:

- Mutual confidence between regulators has been fostered, leading to more efficient cooperation; and
- Many practical measures have been taken to facilitate accession in January 2007.

*d) Donors*

There were no other donors to this project.

<u>Programme on participation of Croatia and Turkey in EMEA activities in 2006 and 2007</u>

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.

*a) The object and location of the project*

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.

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.

*b) Expected results*

The expected outcomes of this project are:

- better co-operation between the regulators of the European pharmaceuticals 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, and
- greater understanding between these regulatory authorities, leading to agreement on regulatory positions and technical procedures within an expanded Europe.
- The other donors to the project

*c) Level of involvement in the project*

The EMEA proposed the programme, organised, coordinated, and reported upon the entire project.

*d) The project cost*

A budget of €700,000 (seven hundred thousand euros) is allocated from the Commission to be spent over 2006 and 2007.

*e) Donors*

There were no other donors to this project.

## Table 1 List of meetings for Human Medicinal Products for Human use

| |
|---|
| **GCP (Good Clinical Practice) Inspectors**<br>The GCP Inspections Services Group provides expert advice and support, on GCP inspection and GCP interpretation, to the EMEA, its scientific committees, the European Commission, its own membership and other parties as required. It draws its membership from the GCP inspectorates of the EU/EEA states and observers from the CADREAC countries and Switzerland. |
| **GMP (Good Manufacturing Practice) Inspectors**<br>The GMP Inspection Services Group consists of representatives of the GMP inspectorates of the EEA states, observers from EDQM, the inspectorates of the countries accessing to the EU and MRA partner countries. The meetings consider new and revised guidance on GMP, normally developed by drafting groups, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonization of GMP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Procedures are developed. |
| **QWP (Quality Working Party)**<br>The Joint CHMP/CVMP Quality Working Party (QWP) provides recommendations to the Committees on matters relating directly or indirectly to the quality of human or veterinary medicinal products. On request of the Committees, the QWP is involved in such areas as the preparation, review and update of quality guidelines, the provision of scientific advice on general and product-specific matters relating to quality, the resolution of national divergences regarding the assessment of quality issues, liaison with interested parties, international cooperation on quality-related matters, etc. All recommendations drawn up by the QWP are transmitted to the relevant Committee for adoption. |
| **HMPC (Committee on Herbal Medicinal Products)**<br>The HMPC's activities aim at assisting the harmonisation of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework. |
| **Training of Senior Assessors**<br>Environmental risk assessment |
| **COMP (Committee for Orphan Medicinal Products)**<br>Workshop on Orphan medicinal products |
| **SME info day**<br>Regulatory process (OD, SA, MAA) and data requirements. That may interest some Accession companies (SAOD). Scientific Advice, Orphan Designation, Paediatrics' regulation and SME will be expanded during the information session. |
| **QRD (Quality Review of Documents) activities**<br>Templates, terminology, standard terms, review of product information and the general role of the QRD group<br>*The representatives will not take part to the actual plenary, these are special trainings organized for them.* |
| **EudraVigilance TIG** |
| **EudraPharm TIG** |
| **EudraCT TIG** |
| **EudraNet TIG** |
| **TIGs** |
| **CJD Workshop** |

# Table II List of meetings for Veterinary Medicinal Products

**Immunologicals Working Party**

The Immunologicals Working Party (IWP) is established to provide recommendations to the Committee of Medicinal Products for Veterinary Use (CVMP) on all matters relating directly or indirectly to immunological veterinary medicinal products (IVMPs) and to perform the following tasks:

- Preparation, review and update of guidelines
- Support to dossier evaluation
- At the request of the CVMP, provision of scientific advice on general and product specific matters related to IVMPs
- Liaison with interested parties (IFAH Europe, European Directorate for the Quality of Medicines) See VI. Rules of procedure point
- International cooperation on IVMP related matters
- Setting up of drafting groups (see VI. Rules of Procedure, point 4)
- Liaison with other Working parties on IVMP related matters
- Advice, through the CVMP, to European Commission on IVMP related issues
- On request, advice, through the CVMP, to CMD(v) on IVMP related matters
- Focus and catalyst for training for IVMP assessment
- Contribution to IVMP related workshops and training

Liaison with the European Directorate for the Quality of Medicines to ensure consistency of approach in the development of European requirements for authorised IVMPs.

**Efficacy Working Party**

The Efficacy Working Party (EWP) provides recommendations on matters relating to efficacy and target animal safety of veterinary medicinal pharmaceutical products.

Observers from Turkey and Croatia could provide useful input in relation to different geographical regions with possible different disease patterns / target animal species / animal husbandry systems in place.

Possible problems further to those mentioned in the introduction would be the discussion of the EWP's internal data-collection, which is based on product related discussion. There is currently not much / no direct other product related discussion in EWP. If so, this could be scheduled e.g. for the first hour of the meeting only.

**Quality Working Party**

The Joint CHMP/CVMP Quality Working Party (QWP) provides recommendations to the Committees on matters relating directly or indirectly to the quality of human or veterinary medicinal products. On request of the Committees, the QWP is involved in such areas as the preparation, review and update of quality guidelines, the provision of scientific advice on general and product-specific matters relating to quality, the resolution of national divergences regarding the assessment of quality issues, liaison with interested parties, international cooperation on quality-related matters, etc. All recommendations drawn up by the QWP are transmitted to the relevant Committee for adoption.

**Safety Working Party**

**Ad-Hoc GMP**

The GMP Inspection Services Group consists of representatives of the GMP inspectorates of the EEA states, observers from EDQM, the inspectorates of the countries accessing to the EU and MRA partner countries. The meetings consider new and revised guidance on GMP, normally developed by drafting groups, work related to Mutual Recognition Agreements, how new legislation impacts GMP inspection activity and harmonization of GMP inspections. It is also where community-wide procedures relating to GMP inspections, known as the Compilation of Procedures are developed.

**EudraVigilance TIG**

**EudraPharm TIG**

**EudraNet TIG**

**TIGs**

| Annex B. Budget for the Action | Draft Budget 2008 | | | |
|---|---|---|---|---|
| **Expenses** | **Unit** | **# of units** | **Unit rate (in EUR)** | **Costs (in EUR)** |
| **1. Human Resources** | | | | |
| 1.1 Salaries (gross amounts, local staff) | Per day | 400 | 259 | 103600 |
| 1.3 Per diems for missions/travel | | | | |
| 1.3.1.1 Abroad ( to Croatia) | Per diem | 20 | 180 | 3600 |
| 1.3.1.2 Abroad (to Turkey) | Per diem | 20 | 220 | 4400 |
| 1.3.1.3 Abroad (to Skopje/Brussels/Zagreb) | Per diem | 10 | 180 | 1800 |
| 1.3.2 Local (staff assigned to the Action) | Per diem | 0 | 0 | 0 |
| 1.3.3 Seminar/conference participants in London | Per diem | 200 | 318 | 63600 |
| 1.3.4 Conference participants in Croatia/Turkey/Macedonia | Per diem | 1100 | 160 | 176000 |
| 1.3.3 Specialised training participants in (tbd) | Per diem | 30 | 286 | 8580 |
| ***Subtotal Human Resources*** | | | | **361580** |
| **2. Travel** | | | | |
| 2.1. International travel | Per flight | | | |
| 2.1.1 Zagreb - London - Zagreb | | 50 | 430 | 21500 |
| 2.1.2 Ankara - London- Ankara | | 50 | 480 | 24000 |
| 2.1.3 Skopje - London - Skopje | | 45 | 430 | 19350 |
| 2.1.4 Skopje - Zagreb - Skopje | | 20 | 430 | 8600 |
| 2.1.4 London - Zagreb - London | | 20 | 430 | 8600 |
| 2.1.4 London - Ankara - London | | 20 | 480 | 9600 |
| 2.1.5 Internal Istanbul-Ankara | | 100 | 100 | 10000 |
| ***Subtotal Travel*** | | | | **101650** |
| **3. Equipment and supplies** | | | | |
| ***Subtotal Equipment and supplies*** | | | | **0** |
| **4.Local office/Action costs** | | | | |
| 4.1 Venue/ Audio/Visual | Per venue | 3 | 19590 | 58770 |
| 4.2 Conference package | Per venue | 3 | 20000 | 60000 |
| ***Subtotal Local office/Action costs*** | | | | **118770** |
| **5. Other costs, services** | | | | |
| 5.1 Interpreters for the conferences | Per interpreter | 12 | 1500 | 18000 |
| ***Subtotal Other costs, services*** | | | | **18000** |
| **6. Other** | | | | |
| ***Subtotal Other*** | | | | **0** |
| **7. Subtotal direct costs of the Action (1-6)** | | | | **600000** |
| **8. Administrative costs (max. 7% of 7, total direct eligible costs of the Action)** | | | | **0** |
| **9. Total eligible costs of the Action (7+ 8)** | | | | **600000** |

## Expected sources of funding

| | | | Amount | Percentage |
|---|---|---|---|---|
| | | | EUR | of total |
| | | | | % |
| | | | | |
| | | | | |
| Applicant's financial contribution | | | 0 | 0 |
| | | | | |
| Commission contribution sought in this application | | | 600000 | 100 |
| | | | | |
| Contribution(s) from other European Institutions or EU Member States | | | | |
| | | | | |
| Contributions from other organisations: | | | | |
| *Name* | *Conditions* | | | |
| | | | | |
| | | | | |
| | | | | |
| | | | | |
| TOTAL CONTRIBUTIONS | | | 600000 | 100 |
| | | | | |
| | | | | |
| Direct revenue from the Action | | | 0 | |
| | | | | |
| OVERALL TOTAL | | | 600000 | |