Project Description

ANNEX A

1. Description

1.1 Title: IPA Assistance Programme

Preparatory measures for the participation of the Candidate Countries, e.g. Croatia, the former Yugoslav Republic of Macedonia and Turkey as well as the Potential Candidate Countries[1] namely Albania, Bosnia and Herzegovina, Montenegro, Serbia and Kosovo under UNSC Resolution 1244/99 in EMEA activities.

1.2 Amount requested from the Commission:

A budget of € 900,000 (nine hundred thousand euros) is requested from the Commission to be spent over two years.

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 and Potential Candidate Countries mentioned above, for future collaboration in the EMEA's activities and its relationships with Member States.

This project aims:

- to prepare the Competent National Authorities (NCA) in the Candidate and Potential Candidate Countries, 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 Candidate and Potential Candidate Countries in EMEA networks.

This programme will allow the Candidate and Potential Candidate Countries to prepare themselves for participation in the activities of the EMEA and to develop the Member States' confidence in the systems in place. Furthermore, this should enable the EMEA, the Member States and the beneficiary Countries to work as equal, mutually respected partners.

In the context of medicinal products, the project is designed to establish with the beneficiary countries an internationally open dialogue and working mechanisms. This would facilitate the adoption of common technical requirements in order to identify areas where additional action might be needed to ensure the smooth transposition of their legislation into the EU *Acquis Communautaire* and participation in EMEA 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. This will facilitate the transposition of EU technical regulations and European technical acts into the national legislation of the participating Candidate and Potential Candidate Countries.

[1] All references to potential candidate countries include Albania, Bosnia and Herzegovina, the former Yugoslav Republic of Macedonia, Montenegro and Serbia, as well as Kosovo as defined by the United Nations Security Council Resolution 1244 of 10th June 1999;

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 them to be a part of the electronic network upon accession.

b) The target groups

The target groups are the National Competent Authorities dealing with 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 different types of activities to be carried out within the scope of this project, according to the needs of the Country concerned, such as:

For Candidate Countries that have already benefited from the transition preparatory measures and for the Potential Candidate Countries that can be immediately involved in:

- Participation in meetings as observers:
  Participation of representatives of the Candidate and Potential Candidate Countries as observers, in scientific and technical EMEA non product related meetings

- Organisation of Conferences:
  Organisation of conferences in the Candidate and Potential Candidate Countries, in order to:
  - Give an overview of EU legislation governing the regulation of medicinal products;
  - Provide feedback on the practical application of the Acquis Communautaire and legal aspects of its implementation;
  - Explain the role of the EU guidelines to candidate country regulators and tackle specific areas in their application;
  - Identify the differences between existing legislation in each of these countries;
  - 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 in informing the full cross-section of stakeholders in these countries.

- Training
  - Short visits of Candidate Countries representatives to Member States' NCA or to the EMEA where appropriate;
  - 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.

For the Potential Candidate Countries where awareness-raising and needs assessment actions are required

A step-by-step approach will be set up as follows:

- Meetings will be set up in order to establish, and in most cases, to strengthen the links with NCA, in order to gain a better understanding about the gaps that need to be filled allowing the beneficiaries to fully benefit from participation in the Agency and/or its activities.

- Organisation of various trainings in predefined priority areas according to identified real needs to fulfil the gaps.

Location

The location may vary according to the type of activity performed:
- The first activity will be performed at the EMEA premises in London.
- The second activity will involve travelling within the European Union and to the Candidate and Potential Candidate countries. The conferences will be organised in the Candidate and Potential Candidate Countries, to engage participation of representatives from the Pharmaceutical Industry and other interested parties. Focus in this respect will be given to build contacts and to develop a solid understanding of the work of the EMEA. A further goal is to explain the role of and cooperation between the EMEA, the Member States and the European Commission.
- The third activity will involve participation of National Competent Authorities' experts in training sessions organised in London. Furthermore, Candidate Countries' participants may also be invited to attend meetings and trainings, which may be held in other parts of Europe as long as the subjects are considered relevant for achieving the project's objectives. In addition, visits to different EU Member States' NCAs may be organised to provide a more extensive knowledge on specific activity domains or topics where appropriate.

1.4 Objectives

The overall purpose of the project is to assist the National Competent Authorities of the Candidate and Potential Candidate Countries 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 the Candidate and Potential Candidate Countries in order 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 these countries about scientific and procedural developments linked to the work of the EMEA and the participation of these countries;
- To assist the NCA in having access to such regulatory data as may be made available to them prior to accession to the European Union;
- To assist the NCA of the Candidate and Potential Candidate Countries to participate in training initiatives undertaken;
- To provide other training or assistance as required supporting the alignment of the standards and practices of these countries 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 any involvement in these procedures it is extremely difficult to acquire the necessary knowledge to be able to participate in the EU system. This could lead to difficulties associated with the implementation and enforcement of harmonised regulatory and technical requirements as well as procedures, including the continuing use of divergent practices existing within the Candidate and Potential Candidate Countries. 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 mainly the National Competent Authorities in the Candidate and Potential Candidate Countries, together with other institutions involved in the regulation of medicinal products. The National Competent Authorities identified so far, 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** Ministry of Health Str. Vodnjanska bb 1000 Skopje, FYR Macedonia ***Agency for Medicinal Products and Medical Devices*** *To be created* **Veterinary Directorate** Ministry of Agriculture, Forestry and Water Economy Leninova 2 1000 Skopje, FYR Macedonia
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
	General Directorate of Pharmaceuticals and

Turkey	**Pharmacy** Ministry of Health Çankırı Cad No: 57 Dışkapı- Ankara -Turkey **General Directorate of Protection and Control-Veterinary Drug Department** Ministry of Agriculture and Rural Affairs Akay Cad. No.:3 TK - 06100 Bakanliklar/Ankara
Albania	**National Center Drug Control Druga e Dibres** Prane Fakutetit te Mjekesise Tirana , Albania **Ministry of Agriculture, Food and Consumer Protection** Sheshi Skenderbej 2 Tirana, Albania
Bosnia-Herzegovina	**Zavod za kontrolu lijekova Feceracije Bonse i Herzegovine (Medicines Agency)** Marsala Tita 9 71001 Sarajevo Bosnia and Herzegovina **Federal Ministry of Agriculture, Water Management and Forestry** Marsala Tita 15 Sarajevo Bosnia and Herzegovina **Agencija za ljekove Republike Srpske** **Ul Veljika Mladenovica bb** 78000 Banja Luka Republika Srpska **Vlada Republike Srpske – Ministarstvo zdravstva i socijalne skrbi (Ministry of Health and Social Welfare)** Trg RS 1 Banja Luka Republika Srpska **Ministry of Agriculture, Forestry and Water Management of Republic Srpska** Kralja Petra I-og 100 Banja Luka Republika Srpska
Serbia	**Agencija za lekove i medicinska sredstva Srbije** Ulica Vojvode Stepe 458 111152 Belgrade Serbia **Ministry of Agriculture, Forestry and Water Management of Serbia** Nemanjina 22-26 11000 Belgrade Serbia **Serbia, Autonomous Province of Vojvodina Provincial Secretariat of Agriculture, Water Economy and Forestry** Bulevar Mihajla Puhina 16 21000 Novi Sad Serbia
	Uprava sa ljekove i medicinske sredstva Crne Gore (Medicines Agency)
Montenegro	Bracana Bracanovica bb, 81000 Podgorica Montenegro **Ministry of Agriculture, Forestry and Water Management of Montenegro** Trg. Vektra 81000 Podgorica Montenegro

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 unlike 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 Candidate and Potential Candidate Countries in charge of the regulation of medicinal products.

The activities focus on areas in which the National Competent Authorities in the Candidate and Potential 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

Candidate Countries 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 and Potential 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 doing so, 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 type of activities suggested and described depends on the situation of the Candidate and Potential Candidate Countries regarding the implementation of the *Acquis communautaire.*

This project will be split in two phases, as follows:

- **Phase 1: from September 2009 to September 2010**
  - Participation of representatives of Candidate and Potential Candidate Countries in EMEA selected meetings and trainings;
  - Organisation of a general conference at the EMEA and a conference in one Candidate Countries where appropriate;
  - Visits of the NCAs to the Potential Candidate Countries for assessing their needs.

- **Phase 2: from September 2010 to September 2011**
  - Participation of representatives of Candidate and Potential Candidate Countries in EMEA selected meetings and trainings;
  - Organisation of two conferences in two different beneficiary Countries;

- Visits of the National Competent Authorities of the Potential Candidate Countries where appropriate;
- Organisation of training in specific areas.

The activities described are planned on the assumption that the Potential Candidate Countries will be ready to participate in the second phase of the project. Details of the final programme may differ, especially with regard to activities involving the participation of Potential Candidate Countries in the implementation of the project.

Activities to be carried out throughout the project are described in more detail below:

Phase 1

1.6.1 Participation in EMEA selected meetings and training as observers

It is proposed to finance one representative per Candidate and Potential Candidate Country to participate, as observers, in EMEA non-product related Meetings, on a voluntary basis, in order to familiarise the NCA with the work performed by the EMEA. Invitations to Working Parties 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
As observers, the Candidate and Potential Candidate Countries' representatives will not have responsibilities with regard to the assessment process.
The participation of Candidate Countries in trainings organised for assessors on specific scientific/technical topics and on aspects of the regulatory procedures, will be financed through the project. In addition, training will be provided on Telematics issues.
Due to financial constraints, the involvement of these observers will be financed through the project, like other invited participants.
The funds allocated for attendance at meetings, workshops and other visits will cover travel, daily allowances and hotel. For training organised outside the EMEA, participation fees will be reimbursed where appropriate. The purpose of this initiative is to enable the Candidate and Potential Candidate Countries NCA 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 applicable to this phase are listed in Table I & Table II, and trainings in Table III below.

1.6.2 Conferences

It is envisaged to organise a one-day conference at the EMEA at the end of 2009/beginning 2010. As a kick-off initiative, to address the activities supported under the project, up to five representatives per NCA/ Institution of each Candidate and Potential Candidate Country will be invited.
The aim and the objectives of the project will be described as well as the activities supported under the contract.

In addition, it is planned to organise one conference in 2010 in one of the Candidate or Potential Candidate Countries in order to:

- Build contacts and to develop a deeper understanding of EMEA work, to explain the role of and cooperation between the EMEA, Member States and the European Commission;
- 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.

This conference 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. It will also tackle specific areas in their application to identify the differences between the existing legislation in each of these countries, to introduce problems that may be encountered when moving towards accession, and in anticipation of membership of the European Union.
The programme of the conference will be established by a Steering Committee including 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 or Potential candidate Country concerned.

1.6.3 Visits of the Potential Candidate Countries' National Competent Authorities

Short visits of representatives of National Competent Authorities of Candidate and Potential Candidate Country at the EMEA or at a National Competent Authority of a Member State can be supported throughout the project up to one month.
The funds allocated to this activity will cover travel, daily allowances and hotel expenses.

Phase 2

In addition to the activities described above, it is envisaged to organise two conferences in 2011: one in Croatia (prior to accession) and one in another Candidate or Potential Candidate Country.

Moreover, organisation of more focused activities, tailored to real needs can be organised as follows:

1.6.4 Training
According to the outcome of the assessment regarding the implementation of the *Acquis communautaire*, carried out during the first phase of the project, it is envisaged to set up training sessions per defined priorities areas according to the needs of the Candidate and Potential Candidate Countries. Sessions will be organised per domain in the different beneficiary countries. Contributions will be requested from DG Enterprise at the Commission and from the Member States, where experts and speakers can be supported in the framework of the programme.

1.7 Methodology

a) Methods of implementation

- Attendance by experts from the beneficiary countries as observers at EU regulatory meetings as far as allowed by the 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 stems from the exchange of feedback on experiences of regulators in the EU and those in the beneficiary countries, as well as 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 about 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 Candidate and Potential Candidate Countries 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 activities facilitates networks with the Member States. In order to be part of the network upon accession, the integration of the accession countries in EMEA activities is crucial. 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 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 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 and Potential Candidate Countries and EU Member States' National Competent Authorities to exchange views across disciplinary boundaries.

The Steering Committee draws on experience of the EMEA Heads of Units and Sectors, as well as Heads of National Competent Authorities in both the EU and the participating Candidate Countries, in order to provide direction to the project and 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, in the Multi-beneficiary programme on the participation of Croatia and Turkey in certain Community Agencies in 2006 and 2007 and the Transition IPA programme in 2008, extended to 14 September 2009.

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 support of the group focusing 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, so 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.

PHARE 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 2006/07 was launched in 2006. The goal was to build contacts and relationships between the EMEA and the NCAs of the Candidate Countries, to contribute to the creation of communication and information exchange systems enabling their future participation in EMEA activities and networks as well as to support preparatory measures prior to accession. This programme was very successful. Representatives from both countries participated in EMEA activities and a conference was organised in each country with more than 380 participants.

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. In doing so, knowledge is provide for the alignment of their standards and practices with those in place in the European Union with regard to the implementation of Community law. The contract was extended to 14 September 2009 and activities further developed. A conference was held in Rijeka, Croatia on 13-14 November 2008 with more than 350 participants.

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 Administration 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) on a yearly basis.
- Technical adherence to the plan of activities will be 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 and the Potential 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. The EMEA will also organise the conferences and provide secretariat facilities to the regulatory network. EU Telematics projects are managed and largely resourced through the EMEA. Therefore support to the Telematics portion for the proposed programme is expected to be provided by the EMEA.

Nevertheless, the participation of EMEA partners in the regulatory processes (in which Candidate and Potential Candidate Countries' participants will be involved as observers) and in the training session will be the primary ingredients for the success of the programme.

f) Reasons for the role of each partner

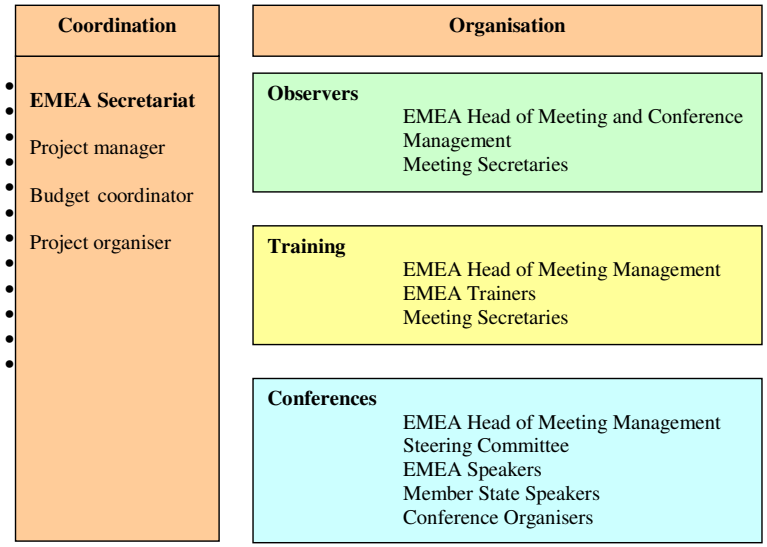
The EMEA coordinates the existing scientific resources of Member States with a view to evaluating and supervising medicinal products for human and veterinary use. Accordingly, the practical scientific evaluation is carried out by Member State experts. The future role of the participating experts from the beneficiary countries remains 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 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



The steering committee of the conferences organisation 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 and Potential Candidate Countries.

It is also recommended that a fixed contact point in the beneficiary countries should be defined.

1.8 Duration in months and indicative time schedule of actions

The duration of the project should be 24 months from 1st September 2009 until 1st September 2011, as reported below:

Phase 1 **September 2009 - September 2010**	**Phase 2** **September 2010 - September 2011**
➢ Participation of representatives of Candidate and Potential Candidate Countries in EMEA selected meetings and trainings ➢ Organisation of a general conference at the EMEA and a conference in one Candidate Country where appropriate ➢ Visits of the National Competent Authorities of the Potential Candidate Countries to assess their needs	➢ Participation of representatives of Candidate and Potential Candidate Countries in EMEA selected meetings and trainings ➢ Organisation of 2 conferences in two different beneficiary Countries ➢ Visits of the National Competent Authorities of the Potential Candidate Countries where appropriate ➢ Organisation of training sessions in specific areas

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 Candidate and Potential Candidate Countries setting up a forum for discussion and information exchange;
- Encouraging greater understanding between the beneficiary countries and the Member States' National Competent Authorities, leading to future co-operation and harmonisation of technical procedures within Europe;
- Building up mutual confidence in order to encourage the future acceptance of research and development data and measures between these authorities;
- Establishing better co-operation between the regulators of the European pharmaceutical market on a wider international basis;
- Informing Candidate Countries' NCAs about the implementation of the requirements of the *Acquis Communautaire* in specific identified areas;

- Involving as many European regulatory authorities as possible, contributing to homogeneous, reliable, and harmonised regulatory practices;
- Creating understanding between regulatory authorities, leading to agreement on positions and technical procedures within an expanded Europe;
- Integrating beneficiary countries and NCAs,, to the extent permissible prior to accession, 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 Candidate Countries, namely Croatia, the former Yugoslav Republic of Macedonia, and Turkey, as well as the Potential Candidate Countries[2](Albania, Bosnia and Herzegovina, Montenegro, Serbia, and Kosovo under UNSC Resolution 1244/99). 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

2.4

a) *Institutional sustainability*

The programme involves the National Competent Authorities of Croatia, the former Yugoslav Republic of Macedonia, Turkey, Albania, Bosnia and Herzegovina, Montenegro, Serbia, and Kosovo under UNSC Resolution 1244/99, 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 beneficiary countries. 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).

[2] All references to potential candidate countries include Albania, Bosnia and Herzegovina,, the former Yugoslav Republic of Macedonia, Montenegro and Serbia, as well as Kosovo as defined by the United Nations Security Council Resolution 1244 of 10th June 1999;

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 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 managed/implemented over the past five years

PHARE Multi-beneficiary programme on the participation of Bulgaria and Romania in 2005-2006

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 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;
- An 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;
- 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 on 14 September 2005. Indeed the activities carried out under the project did not require the total amount of support provided, as the main part of the budget was allocated for the 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;
- Many practical measures have been taken to facilitate accession in January 2007.

d) Donors

There were no other donors to this project.

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

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

a) The objectives 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 EMEA 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 Croatia and Turkey's NCAs about scientific and procedural developments, linked to the work of the EMEA, and the participation of these countries in the Agency's activities;
- To assist NCAs of Croatia and Turkey in having access to the regulatory data as it may be made available prior to accession to the European Union;
- To assist the NCAs 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 outcomes of this project were:

- 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;
- Greater understanding between these regulatory authorities, leading to agreement on regulatory positions and technical procedures within an expanded Europe.

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) was allocated from the Commission to be spent over 2006 and 2007, of which €564,994 were spent.

e) Donors

There were no other donors to this project.

IPA 2008 – 2009

a) The objectives of the project

A transition Instrument for Pre-accession Assistance programme was launched in certain Community Agencies in 2008 as the follow up of the Multi-beneficiary project, launched in 2006, in order to continue supporting participation of the Candidate Countries, namely the former Yugoslav Republic of Macedonia, Croatia and Turkey in EMEA activities.

The aim of this project is to build contacts and relationships between the EMEA and the Candidate Countries, (former Yugoslav Republic of Macedonia, Croatia and Turkey), to foster future collaboration in EMEA activities and to improve their relationships with Member States.

This programme will allow the three Candidate Countries to prepare themselves for participation in EMEA activities. In addition, it will develop the Member States' confidence in the systems in place in the three countries. Furthermore, this enables the EMEA, Member States and the Candidate Countries to work as equal, mutually respected partners.

b) The results of the project

The expected outcomes of this project are:

- Building contacts and relationships with Regulatory Authorities in the Candidate and Potential Candidate Countries setting up a forum for discussion and information exchange
- Encouraging greater understanding between the beneficiary countries and the Member States' National Competent Authorities, leading to future co-operation and harmonisation of technical procedures within Europe

- Building up mutual confidence in order to encourage the future acceptance of research and development data and measures between these authorities
- Establishing better co-operation between the regulators of the European pharmaceutical market on a wider international basis
- Informing Candidate Countries' NCAs about the implementation of the requirements of the *Acquis Communautaire* in specific identified areas;
- Involving as many European regulatory authorities as possible, contributing to homogeneous, reliable, and harmonised regulatory practices;
- Improving understanding between regulatory authorities, leading to agreement on positions and technical procedures within an expanded Europe;
- Integrating beneficiary countries and NCAs,, to the extent permissible prior to accession, into the EU Telematics projects and systems.
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c) Level of involvement in the project

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

d) The project cost

A budget of €600,000 (six hundred thousand euros) was requested from the Commission to be spent over 2008. An extension of the contract was requested until 14 September 2009, due to lack of participation of the National Competent Authorities dealing with regulation of medicinal products for veterinary use.

e) Donors

There were no other donors to this project.

Table I List of meetings for Human Medicinal Products for Human use

GCP (Good Clinical Practice) Inspectors Working Group The GCP Inspectors Working 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 EU accession countries and Switzerland.	24-25 Feb, 09-10 Jun, 08-09 Sep, 01-02 Dec 2010 01-03 Mar, 14-15 Jun, 13-15 Sep, 28-30 Nov, 05-07 Dec 2011
EU Good Clinical Practice Inspectors Working Group training course This is an annual, 3-day training course for EU GCP inspectors, organised by the CGP IWG in conjunction with one of the Member States GCP inspectorates. It takes place in a different Member State each year.	
Ad Hoc PhV (Pharmacovigilance) Inspectors Working Group The PhV IWG provides input and recommendations on all matters relating directly or indirectly to the preparation, conduct and follow up of PhV inspections in the context of post-authorisation processes and irrespective of the marketing authorisation procedure. Its main goals are to promote an effective management of PhV inspections in the Community, to establish proficient communication and information exchange and to provide input into PhV legislation preparation. The group meets 4 times/year, twice as Human Ad Hoc PhV IWG and twice as Joint Human and Veterinary Ad Hoc PhV IWG.	23 Feb 08 Jun 07 Sep 30 Nov 2010 24-25 Mar 16-17 Jun 29-30 Sep 01-02 Dec 08-09 Dec 2011
EU Pharmacovigilance Inspectors Working Group training course This training will take place in 2009 for EU PhV inspectors, organised by the PhV IWG in conjunctions with one of the Member States PhV inspectorate.	
GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group The GMP/GDP Inspectors Working 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) 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.	02-04 Feb, 01-03 Jun 07-09 Sep, 22-24 Nov 2010 (Joint QWP/GMDP IWG meting 24 November) 01-03 Feb, 30May-01 Jun, 05-07 Sep, 29 Sep-01 Oct 2011

HMPC (Committee on Herbal Medicinal Products) 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.	13-14 Jan, 10-11 Mar, 05-06 May, 14-15 Jul,15-16 Sep, 24-25 Nov 2010 26-27 Jan, 30-31 Mar, 25-26 May, 13-14 Jul, 14-15 Sep, 23-24 Nov 2011
HMPC Assessors Workshop/Training	
NRG (Name Review Group) As part of the EMEA's role in evaluating the safety of medicinal products in the centralised marketing authorisation procedure, it is obliged to consider whether the invented name proposed for a medicinal product by its manufacturer could create a public-health concern or potential safety risk. The NRG performs reviews of invented names and updates the relevant guideline on the acceptability of invented names. *The representatives will not take part to the actual plenary, but can participate in the Interested Parties Workshop.*	
EMEA/CHMP Working Group with Healthcare Professionals The EMEA CHMP Working Group with Healthcare Professionals' Organisations' (HCP WG) is to set up a framework of interaction between EMEA, its Human Scientific Committees and HCPs, and prepare recommendations and proposals for actions in information on medicines addressed to HCPs, pharmacovigilance, involvement of HCPs in EMEA Scientific Committees related activities. (In addition, the HCP WG will contribute to contacts and exchange of information between the EMEA, the CHMP and Healthcare Professionals)	25 Feb 2010 28 Oct 2010
Joint meeting between the EMEA/Scientific Committees' WP with Patients' and Consumers' Org. (PCWP) and the EMEA/CHMP Working Group with Healthcare Professionals The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (more commonly known as the Patients' and Consumers' Working Party, or PCWP) has been established to provide recommendations to the EMEA and its human scientific committees on all matters of interest to patients in relation to medicinal products. The EMEA CHMP Working Group with Healthcare Professionals' Organisations' (HCP WG) is to set up a framework of interaction between EMEA, its Human Scientific Committees and HCPs, and prepare recommendations and proposals for actions in information on medicines addressed to HCPs, Pharmacovigilance, involvement of HCPs in EMEA Scientific Committees related activities. (In addition, the HCP WG will contribute to contacts and exchange of information between the EMEA, the CHMP and Healthcare Professionals)	16 Jun 2010
QRD (Quality Review of Documents) activities Templates, terminology, standard terms, review of product information and the general role of the QRD group. *The representatives will not take part to the actual plenary, these are special trainings organized for them.*	
EudraGMP database sub-working group	
In order to assist from a technical perspective, the EudraGMP TIG delegates some of its work to a subgroup (EudraGMP database sub-working group) composed of IT specialists from Member States with systems in place and of GMP inspectors. In particular the sub-working group is in charge of the definition of the technical requirements for the EudraGMP project	
EV TIG EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).	
EUTCT	09 Feb, 04 May, 27 Jul, 09 Nov 2010
RDM The aim of the RDM project is to develop a common understanding of information (semantic interoperability) within existing information systems, and allow the information exchange (syntactic interoperability) within the European Medicines Regulatory Network (EMRN) framework.	
ENCePP Academic Centres Annual Meetings This includes both the ENCePP General Assembly and scientific meetings. The General Assembly intends to inform all ENCePP partners about the current status and the recent developments of ENCePP and to discuss the next steps and key aspects of the network. The scientific meetings shall help to promote pan-EU partnerships and professional exchange of opinions and experience in order to strengthen EU excellence in the field of PhV and PEpi	
EudraPharm TIG EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA).	
EudraCT TIG / JOG and Paediatric subgroup	
EudraNet TIG EudraNet II is a managed virtual private IP network (IP VPN) based on encrypted tunnels over the public Internet. It is a star shaped network with the EMEA being the central site.	
TIGs The main objective of this IT strategy is the reinforcement of appropriate exchange of information between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.	

Table II List of meetings for Veterinary Medicinal Products

Immunologicals Working Party (NK) 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.	02-03 Feb, 09-10 Jun 05-06 Oct 2010 , 02-03 Feb, 31 May-1Jun , 05-06 Oct 2011
Ad Hoc PhV (Pharmacovigilance) Inspectors Working Group The PhV IWG provides input and recommendations on all matters relating directly or indirectly to the preparation, conduct and follow up of PhV inspections in the context of post-authorisation processes and irrespective of the marketing authorisation procedure. Its main goals are to promote an effective management of PhV inspections in the Community, to establish proficient communication and information exchange and to provide input into PhV legislation preparation. The group meets 4 times/year, twice as Human Ad Hoc PhV IWG and twice as Joint Human and Veterinary Ad Hoc PhV IWG.	23 Feb, 08 Jun, 07 Sep, 30 Nov 2010 24-25 Mar, 16-17 Jun, 29-30 Sep, 01-02 Dec, 08-09 Dec 2011 (not all meetings will be joint with Vet)
EU Pharmacovigilance Inspectors Working Group training course This training will take place in 2009 for EU PhV inspectors, organised by the PhV IWG in conjunctions with one of the Member States PhV inspectorate.	
Efficacy Working Party (BC) 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.	02-03 Mar, 06-07 Jul, 05-06 Oct, 14-15 Dec 2010 01-02 Mar, 21-22 Jun, 20-21 Sep, 13-14 Dec 2011
QWP (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.	02-04 Feb, 01-03 Jun, 07-09 Sep, 22-24 Nov 2010 (Joint QWP/GMDP IWG meting 24 November) 01-03 Feb, 30May-01 Jun, 05-07 Sep, 29 Sep-01 Oct 2011
Safety Working Party (NJ) The CVMP Safety Working Party (SWP-V) provides scientific expertise to the CVMP on all issues regarding the safety of veterinary medicinal products in the context of consumer and operator safety (excluding environmental-risk assessment and target-animal safety). This includes providing expertise on the establishment of maximum residue limits (MRLs) and on the preparation of guidelines relating to safety of veterinary medicinal products and to user safety.	
GMP/GDP (Good Manufacturing Practice/Good Distribution Practice) Inspectors Working Group The GMP/GDP Inspectors Working 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.	
EudraGMP database sub-working group In order to assist from a technical perspective, the EudraGMP TIG delegates some of its work to a subgroup (EudraGMP database sub-working group) composed of IT specialists from Member States with systems in place and of GMP inspectors. In particular the sub-working group is in charge of the definition of the technical requirements for the EudraGMP project	
EV TIG EudraVigilance is a data processing network and management system for reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA).	
EUTCT	09 Feb, 04 May, 27 Jul, 09 Nov 2010
RDM The aim of the RDM project is to develop a common understanding of information (semantic interoperability) within existing information systems, and allow the information exchange (syntactic interoperability) within the European Medicines Regulatory Network (EMRN) framework.	
EudraPharm TIG	

EudraPharm is intended to be a source of information on all medicinal products for human or veterinary use that have been authorised in the European Union (EU) and the European Economic Area (EEA).	
EudraNet TIG EudraNet II is a managed virtual private IP network (IP VPN) based on encrypted tunnels over the public Internet. It is a star shaped network with the EMEA being the central site.	
TIGs The main objective of this IT strategy is the reinforcement of appropriate exchange of information between stakeholders (general public, industry, Member States, European Commission and EMEA) to support pharmaceutical regulatory activities for both human and veterinary medicines.	

Table III List of Trainings and Workshops

Event's Name	Location
3rd EMEA Workshop for SME's "Focus on Non-clinical Aspects" This workshop will include an overview of non-clinical data requirements, highlighting key success factors and practical advice from an EU assessors' perspective.	EMEA
First Workshop on Advanced Therapy Medicinal products (ATMP)	EMEA
DIA - Excellence in Pharmacovigilance: Clinical Trials and Post Marketing	Abroad
DIA - EudraVigilance Member States Training	EMEA
DIA - EVMPD (EudraVigilance Medicinal Products Dictionary)	EMEA
GCP Inspectors' Training Course	Abroad
PhV Inspectors' Training Course	Abroad