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Contract 2006/118-594

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

Fourth Progress Report

to the

European Commission

September 2007 - December 2007

Contents

1. MANAGEMENT SUMMARY

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

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

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

A first progress report describing the aim and the objectives of the project, as well as the activities supported under the contract, in order to fulfil the objectives, was published in December 2006. A second report illustrated the activities performed during the following five-month period, which consisted mainly of the participation of representatives from Croatia and Turkey in EMEA meetings and training as observers. A third report covered programme from a project management perspective and focused on the conference organised in Split, Croatia on 2-3 April 2007.
This fourth report covers the period from September to December 2007. It outlines the programme from a project management perspective and describes the work performed during the third phase of the project. It focuses on the conference organised in Istanbul, Turkey, on 22-23 October 2007, which is described in details.

2. INTRODUCTION

This report describes the activities initiated under the contract and the ways in which the programme's objectives have been addressed.

The project is designed to establish an internationally open dialogue in the area of medicinal products and working mechanisms, to facilitate the adoption of common technical requirements, to identify areas where additional action may be required for the smooth transposition of their legislation into the EU *Acquis Communautaire* and participation in the EMEA activities.

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

The objectives can be summarised as follows:

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

In order to fulfil the objectives, the following activities were agreed to be carried out within the scope of this project:

- Participation, as observers, of Croatia's and Turkey's representatives in scientific and technical EMEA meetings, held at the EMEA premises in London.
- Provision of focused training on specific technical topics. This activity would involve participation of National Competent Authorities' experts in meetings and training sessions organised in London and in other Member States. Furthermore, Croatian and Turkish participants might also be invited to other meetings, which could be held in other parts of Europe as far as the subjects were considered relevant for achieving the project's objectives.
- Organisation of conferences in Split and Istanbul, in order to give an overview of EU legislation governing the regulation of medicinal products, to provide feedback on the practical application of the Acquis Communautaire and legal aspects of its implementation, to identify the differences between existing legislation in each of these countries and to discuss issues that may be encountered with regards to moving towards accession, and in anticipation of membership of the European Union.
  These conferences target scientific audiences and include specific activities with a view to informing the full cross-section of stakeholders in Croatia and Turkey.

3. PROJECT MANAGEMENT

The programme was launched in July 2006 by establishing contacts with the National Competent Authorities dealing with medicinal products for human and veterinary use in both Candidate Countries.

3.1 Summary of Initiation phase

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

3.2 Participation in meetings as observers

Nominated representatives of the Candidate Countries were appointed as observers in non-product related meetings exclusively. The participation of observers from Croatia and Turkey in these meetings is financed through the project.
The purpose of this initiative is to enable the Croatian and Turkish Competent Authorities to maintain the accuracy of their knowledge through direct involvement, as observers, in the EU regulatory community for pharmaceuticals.

Since August 2006, letters requesting nominations of representatives and alternates to attend listed non-product related meetings have been sent to the Heads of National Competent Authorities on a bi-annual period basis. The provision of a declaration of interests and a signed confidentiality agreement is requested for each representative prior to meeting participation, in accordance with European law.

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

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

3.3 Training

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

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

3.4 Conferences

As part of the programme, two conferences were organised: one in Split (Croatia) on 2-3 April 2007 and another in Istanbul (Turkey) on 22-23 October 2007.

These conferences are organised in order to allow the participation of representatives from the pharmaceutical industry and other interested parties. Focus in this respect is given to making contacts, to developing a profound understanding of the work of the EMEA as well as to explaining the role of and cooperation between the EMEA, the Member States and the European Commission.

The objectives of these conferences can be summarised as follows:

- To give an overview of EU legislation governing the regulation of medicinal products
- To provide feedback on the practical application of the Acquis Communautaire and legal aspects of its implementation
- To explain the role of the EU guidelines to Candidate Country regulators, and discuss specific areas in their application
- To identify the differences between their current and the EU legislation
- To discuss obstacles that may be encountered with regards to moving towards accession, and in anticipation of membership of the European Union.

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

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

The aim of the conference was to establish a dialogue between the parties involved and to encourage co-operation prior to accession.
The objective of the Conference was to stimulate the discussion of issues relevant to the enlargement of the European Union and to contribute to informing the Candidate Country stakeholders of their obligations pre- and post- accession.

Organisation

Istanbul was chosen to host the conference according to the presence of the pharmaceutical industry in the area. The preferred date was in October, after the Ramadan period and also in order to minimise the cost and taking into account the dates of the Committee meetings organised at the EMEA as well as the dates of other major meetings or events, thus allowing full participation and involvement of EMEA staff and the availability of the Executive Director and EMEA senior management.
Three Steering Committee meetings were held on 16 April, 4 and 26 June 2007 with the participation of the Heads of Turkish National Competent Authorities dealing with medicinal products for human and veterinary use, EMEA Heads of Unit and Heads of Sectors or their representatives. During those meetings, discussions were held on:

- Logistics preparation: conference venue and date, interpretation, support, flights and accommodation bookings, administration, management
- Aim of the conference and conference title

- Establishment of the programme: format, session, panel discussion
- Invitation Strategy: Invited Speakers, Panellists, Invited Participants
- Presentation Format
- External participants' fees
- Publication Strategy: Announcement, Programme publication, Printing, Press coverage
- Format of conference report.

The following conference rationales were agreed:

- To organise a two day conference with two break-out sessions in the morning of the second day to allow the organisers to include all topics that need to be discussed, particularly for Veterinary medicines-specific issues;
- To tailor the programme to the requirements of the Turkish National Competent Authorities and to include relevant topics proposed by the Turks;
- To propose speakers on relevant topics for presentations of 15 to 20 minutes allowing discussions and flexibility regarding timings in respect of different topics;
- To invite 130 Croatian delegates and to cover their accommodation and conference package expenses for two days;
- To invite 10 representatives from the Turkish National Competent Authorities and to reimburse their expenses;
- To invite the Pharmaceutical Society and the Chambers in Turkey responsible for human and veterinary medicines, representatives from the European Commission (DG Enterprise and DG Enlargement), Pharmaceutical Industry, Consumer groups, the Turkish National Competent Authorities, the Turkish Ministries, existing EU Member States and the EMEA as well as representatives from the Croatian National Competent Authorities;
- To request a fee of € 420 for external participants, e.g. Industry and Consumer group attendees to cover the costs of lunches, coffee breaks, documentation, conference material and conference room rental;
- To provide interpretation in Turkish for all sessions for the two-days conference, in both directions by interpreters who have the appropriate knowledge with regards to technical terms;
- To invite the Mayor of Istanbul, the Minister of Health and the Minister of Agriculture to give a key note address;
- To inform journalists about the conference;
- To provide a conclusion report in both English and Turkish
- To include the presentations given at the conference on the Enlargement webpage.

After agreement on both scientific and logistics aspects, the conference manager coordinated all organisational aspects for a smooth running of the conference preparation. The organisation of the conference required two full time staff members.
A dedicated conference website was designed on the EMEA website http://www.emea.europa.eu/htms/euenlargement/croatiaturkey/index.htm , including all necessary information about the conference, abstracts and presentations.

Human & Veterinary Medicinal Products Regulation
Turkey's Road to EU Membership

22-23 October 2007

Barceló Eresin Topkapi Hotel
Istanbul, Turkey

The conference is supported by the European Commission in the framework of the multi-beneficiary programme for participation of Croatia and Turkey in EMEA activities, and is being held under the auspices of the Ministry of Health and the Ministry of Agriculture and Rural Affairs of Turkey.

22 October 2007	**Topics**	**Speakers**
09.30 – 10.30	**WELCOME AND KEYNOTE ADDRESS**	
09.30	Welcome address	Thomas Lönngren, EMEA
	KEYNOTE ADDRESS	
09.40	European Commission Delegation in Turkey	Frédéric Misrahi, EC, Delegation in Turkey
09.50	European Commission	Georgette Lalis, EC, DG Enterprise
10.00	Turkish Authorities	Erman Tuncel, Assistant to the Mayor of Istanbul, Turkey
10.10		Nihat Pakdil, Ministry of Agriculture and Rural Affairs, Turkey
10.20		Orhan Fevzi Gümrükçüoğlu, Ministry of Health, Turkey
10.30 – 11.00	*Coffee break*	
11.00 – 12.30	**PERSPECTIVES AND CHALLENGES**	
11.00	Turkish Ministry of Health's views	Mahmut Tokaç, General Directorate of Pharmaceuticals and Pharmacy, Turkey
11.15	Turkish Ministry of Agriculture and Rural Affairs' views	Muzaffer Aydemir, General Directorate of Protection and Control, Turkey
11.30	Responsibilities and mandate of National Competent Authorities as scientifically independent entities—an established Member State	Olga Apaligan, Federal Agency for Medicines and Health Products, Belgium

11.45	Responsibilities and mandate of National Competent Authorities as scientifically independent entities—a new Member State	Tamás Paál, National Institute of Pharmacy, Hungary
12.00	EMEA Structure and working principles	Vincenzo Salvatore, EMEA
12.15	EMEA Transparency policy	Vincenzo Salvatore, EMEA
12.30 – 14.00	*Lunch*	
14.00 – 16.00	**ACQUIS COMMUNAUTAIRE – PERSPECTIVES FOR REGULATORS**	Chair Eric Abadie, Chair of CHMP, French Health Products Safety Agency, France Co-chair Gabriel Beechinor, Irish Medicines Board, Ireland
14.05	The role of the Commission in the Regulatory System	Matus Ferech, EC, DG Enterprise
14.20	Centralised Procedure Theory/Practice	Eric Abadie, Chair of CHMP, French Health Products Safety Agency, France
14.35	Mutual Recognition Procedure and DCP Theory/Practice	Christa Wirthumer-Hoche, AGES PharmMed, Austria
14.50	Dossier upgrading & pre EU accession activities	Rodica Badescu, National Medicines Agency, Romania
15.05	Compliance of products already on the market with EU Marketing Authorisation	Rodica Badescu, National Medicines Agency, Romania
15.30	Panel discussion	
16.00 – 16.30	Coffee break	

22 October 2007	Topics	Speakers
16.30 – 18.30	**ACQUIS COMMUNAUTAIRE – CHALLENGES FOR INDUSTRY**	Chair Kerstin Franzen, EFPIA Co-chair Declan O'Brien, IFAH-Europe
16.35	Effect of a single market and availability of medicines	Hubertus Cranz, AESGP Greg Perry, EGA Kerstin Franzen, EFPIA
17.40	Orphan Europe experience from an SME company	Marie-Christine Fortun, Orphan Europe
17.50	Turkish views	Nurgün Örgen, Association of Research-based Pharmaceutical Companies, Turkey Murat Salihoğlu, Pharmaceutical Manufacturers Association, Turkey Burhan Haci, Association of Veterinary Health Product Industries, Turkey
18.00	PANEL DISCUSSION	
20.00 – 21.00	Welcome reception	
21.00 – 23.00	**Conference Dinner**	

23 October 2007	Topics	Speakers
09.00 – 12.00	**Breakout sessions**	
09.00– 10.00	Session I: Access to medicines	Chair Melanie Carr, EMEA Co-chair Fahri Ovali, Zeynep Kamil Research Hospital Eda Cindoğlu, General Directorate of Pharmaceuticals and Pharmacy, Turkey
09.05	**Biosimilars: Guidelines and current experience**	Peter Richardson, EMEA
09.20	**Incentives for** • **Orphan drugs** • **Paediatric medicines** • **SMEs** **Panel discussion**	Melanie Carr, EMEA
09.00 – 10.00	Session II: Safety of veterinary medicines	Chair Gabriel Beechinor, Irish Medicines Board, Ireland Co-chair Nihat Pakdil, Ministry of Agriculture and Rural Affairs, Turkey
09.05 09.20	• MRLs and consumer safety • Environmental risk assessment, user safety and antimicrobial resistance	Jos Olaerts, EMEA **Gabriel Beechinor, Irish Medicines Board, Ireland**
09.35	• EU Veterinary Pharmacovigilance specific issues Panel discussion	Jos Olaerts, EMEA
10.00 – 10.30	*Coffee break*	
10.30 – 12.00	**SESSION III: SPECIFIC REGULATORY ISSUES**	Chair Zaide Frias, EMEA Co-chair Ahmet Basaran, General Directorate of Pharmaceuticals and Pharmacy, Turkey Hülya Karahasanoğlu, General Directorate of Pharmaceuticals and Pharmacy, Turkey Hubertus Cranz, AESGP
10.35	• Borderline Products, legislation, implementation	Hubertus Cranz, AESGP

23 October 2007	Topics	Speakers
11.00	• Clarification on traditional herbal products, and fast track registration process	Lucia D'Apote, EMEA
11.25	• Classification issues and possible switch to OTC	Zaide Frias, EMEA
11.50	• Licensing Of The Borderline Products Panel discussion with industry associations	Hülya Karahasanoğlu, General Directorate of Pharmaceuticals and Pharmacy, Turkey
10.30 – 12.00	**SESSION IV: AUTHORISATION OF VETERINARY MEDICINAL PRODUCTS**	Chair Jill Ashley-Smith, EMEA Co-chair Muzaffer Aydemir, General Directorate of Protection and Control, Turkey
10.35	• Effect of a single market and availability of veterinary medicines	Christian Van Beek, IFAH-Europe / Intervet
10.50	• Challenges for veterinary generics	Rob Joosten, EGGVP
11.05	• Immunologicals	Tibor Soós, DVMP, Central Agricultural Office, Directorate of Veterinary Medicinal Products, Hungary
11.20	• Genetically modified organisms (GMOs)	Jill Ashley-Smith, EMEA
11.30	• Quality of veterinary medicines • Panel discussion	Teresa Potter, EMEA
12.00 – 13.30	*Lunch*	
13.30 – 15.30	**SESSION V: PHARMACOVIGILANCE**	Chair François Maignen, EMEA Co-chair Demet Aydinkarahaliloglu, General Directorate of Pharmaceuticals and Pharmacy, Turkey
13.35	• Outline of the EU Pharmacovigilance system	François Maignen, EMEA
14.00	• EudraVigilance and Risk Management within the EU Pharmacovigilance system	François Maignen, EMEA
14.25	• Technical aspects of EudraVigilance	Hans-Georg Wagner, EMEA
14.50	• Pharmacovigilance system in Turkey Panel discussion	Demet Aydinkarahaliloglu, General Directorate of Pharmaceuticals and Pharmacy, Turkey

23 October 2007	Topics	Speakers
13.30 – 15.30	**SESSION VI: GCP INSPECTIONS AND RELATED ACTIVITIES**	Chair David Cockburn, EMEA Co-chair Berna Terzioglu, General Directorate of Pharmaceuticals and Pharmacy, Turkey
13.35	• Clinical trials and GCP inspections findings	Adina Pirvu, National Medicines Agency, Romania
13.55	• Ethics Committees	Mats Ericson, Wyeth Pharmaceuticals, France
14.35	• Implementation of GLP principles in the EU	Rob Jaspers, Food and Consumer Products Safety Authority, The Netherlands
14.55	• GLP inspection system and findings	Andrew Gray, Medicines and Healthcare products Regulatory Agency, UK
15.00	• GCP in Turkey Panel discussion	Berna Terzioğlu, General Directorate of Pharmaceuticals and Pharmacy, Turkey
15.30 – 16.00	Coffee break	
16.00 - 18.00	**GMP INSPECTIONS AND RELATED ACTIVITIES**	Chair Katrin Nodop, EMEA Co-chair Fatma Bekar, GD of Pharmaceuticals and Pharmacy, Turkey
16.05	• GMP Inspections in Turkey	Fatma Bekar, General Directorate of Pharmaceuticals and Pharmacy, Turkey
16.25	• GMP inspection system in the EEA EudraGMP	Katrin Nodop, EMEA
	• Role of the qualified person Training and qualification of inspectors	David Cockburn, EMEA
16.45	• Rapid alert procedure and product defects	Katrin Nodop, EMEA
17.05	• Anti-counterfeit initiatives	
17.25	• Medicinal gases – Expectations and experiences during GMP-inspection in Germany Panel discussion	Christa Färber, Trade and Industrial Inspection Agency of the State of Lower Saxony - Agency Hannover, Germany
18.00 – 18.30	**CLOSE OF CONFERENCE** Summary conclusions	Mahmut Tokaç, General Directorate of Pharmaceuticals and Pharmacy Muzaffer Aydemir, General Directorate of Protection and Control, Turkey Sylvie Bénéfice, EMEA

Outcome of the conference

The conference was a great success in terms of participation and content relevance. The extensive overview of the EU legislation governing the regulation of medicinal products and the description of the practical application of the acquis communautaire and legal aspects of its implementation were welcomed by the participants.
The Participation to the conference had to be limited to 450 participants according to the conference room capacity. Therefore, the attendance from Pharmaceutical Industry was limited to 235 participants bringing the number of participants to 435.

Conference budget

The total cost of the conference is reported in the table below.

Conference in Turkey	Total €
Invited speakers and invited delegates (re-imbursed)	13,600.00
Conference expenses and social event	28,620.00
Interpretation	4,705.00
Contract with hotels	78,670.00
Total Conference	**125,595.00**
Conference fees	101,849.00
Actual costs	**23,746.00**

The transport from the Ministries to Istanbul and the entertaining singer during the conference dinner were supported by the Ministry of Health and the Ministry of Agriculture and Rural Affairs of Turkey.

Publications post-conference

All presentations are published on the EMEA website
http://www.emea.europa.eu/htms/euenlargement/conferences/turkey/programme.htm
Session summary reports are included under the title of the different sessions with all related presentations. Shortly the pod cast of the sessions held in the main auditorium, the Ballroom, will be available.
A summary report was also published in the Croatian Pharmaceutical Gazette.

Conference assessment

Evaluation forms were distributed during the conference to all participants and feedback requested on a regular basis. Only 12% of the questionnaires were returned and most of them with a positive feedback. The conference was well appreciated indeed.

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

The location was chosen to allow the participation of the pharmaceutical Industry mainly based in Istanbul. The date of this conference was determined taking into account the dates of religious events, the dates of the Committee meetings organised at the EMEA, the dates of any other major meetings or events, thus allowing full participation and involvement of the EMEA staff required and the availability of the Executive Director and the EMEA senior management.

Negotiations for the organisation of the conference in Istanbul on 22-23 October 2007 were initiated in April 2007, in order to find a suitable venue. Six hotels were visited and several facilities to host the conference investigated. According to the budget allocated for this event and to the chosen dates

taking into account all parameters mentioned above and hotel availability, the Barceló Eresin Topkapi Hotel was the best location, cost versus quality, to host the conference. A contract agreement was signed in July with the Barceló Eresin Topkapi Hotel and with the nearby Holiday Inn hotel to increase the room capacity as the number of rooms available during this event is limited due to prior hotel commitments.

For organising this conference, two Steering Committee meetings were held in London on 16 April and 4 June 2007 with the participation of the General Director of Pharmaceuticals and Pharmacy, the Ministry of Health and a nominated project coordinator, as well as a representative from the General Director of Protection and Control of the Ministry of Agriculture and Rural Affairs.
During those meetings, discussions were held on:

- Logistics preparation: Conference venue and date, interpretation, support, flights and accommodation bookings, administration, management
- Aim of the Conference and Conference title
- Establishment of the programme: format, session, panel discussion
- Invitation Strategy: Invited Speakers, Panellists, Invited Participants
- Presentation Format
- External participants' fees
- Publication Strategy: Announcement, Programme publication, Printing, Press coverage
- Format of Conference report.

A third Steering Committee meeting was held in Ankara on 26 June, where all remaining questions were answered and agreed. Both General Directors of Pharmaceutical and Pharmacy (Ministry of Health) and of Protection and Control (Ministry of Agriculture and Rural Affaires) attended the meeting as well as representatives from their respective departments.
During this meeting, an amendment of the conference budget was requested and agreed. 130 Turkish delegates (80 from the Ministry of Health and 50 from the Ministry of Agriculture and Rural Affairs) will be invited instead of 100, as originally planned for budgetary reasons. It was also agreed to pay only 2 nights' accommodation (21-22 October 2007) and 2 days delegate package (22-23 October 2007) per participant, with no additional reimbursement, e.g. travel (kindly supported by the Turkish Authorities) and daily allowance.

In summary, the following conference rationales were agreed:

- To organise a two days conference with six break-out sessions in the morning of the second day including all topics that need to be discussed;
- To tailor the programme to the requirements of the Turkey National Competent Authorities and to include relevant topics proposed ;
- To suggest speakers on relevant topics for presentations of 15 to 20 minutes allowing discussions and flexibility regarding timings in respect of different topics;
- To invite the Mayor of Istanbul, the Minister of Health and the Minister of Agriculture to give a key note address;
- To invite the Pharmaceutical Industry Associations and Research based associations dealing with human and veterinary medicines, representatives from the European Commission (DG Enterprise and DG Enlargement), Pharmaceutical Industry, Consumer groups, the Turkish Ministries, the Turkish National Competent Authorities, existing EU Member States and the EMEA, representatives from the Croatian National Competent Authorities, under the Multi-beneficiary programme budget;
- To request a fee of € 420 for external participants, e.g. Industry and Consumer group attendees to cover the cost of lunches and coffee breaks, documentation, conference material and other conference costs
- To provide interpretation in Turkish and English;
- To include the presentations, given at the conference, on the Enlargement webpage ;
- To inform journalists, radio and TV about the conference.

The Turkish Authorities confirmed their financial support for the transport from Ankara to Istanbul and music entertainment during the social dinner on 22 October 2007.

3.5 Financial implications

A total of € 183,456.28 was spent during the activity period - mainly for the organisation of the conference in Split € 101,128.09 plus € 16,485.84 for the EMEA speakers making the presentations, the participation of representatives from both counties in meetings and trainings for an amount of € 51,592.77, including € 31,241.17 for interim support to the project.

4. CONCLUSION

Expected results

The project results are:

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

The results of this project will be mainly issued through activities progress reports published on the EMEA website.

The programme has also provided practical assistance to the National Competent Authorities in order to render the transition to membership of the EU as smooth as possible.