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Post-authorisation Evaluation of Medicines for Human Use

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REPORT ON THE PROGRESS OF THE INTERACTION WITH PATIENTS' AND CONSUMERS' ORGANISATIONS AND ANALYSIS OF THE DEGREE OF SATISFACTION OF PATIENTS/CONSUMERS INVOLVED IN EMEA ACTIVITIES DURING 2007

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EXECUTIVE SUMMARY

Introduction

The EMEA Management Board endorsed in December 2005 a Framework of Interaction between the EMEA and Patients' and Consumers' Organisations (EMEA/354515/2005-Final). This framework defined the objectives to be achieved in order to better structure and formalise the interaction with patients and consumers and set up an implementation plan.
This report describes the outcome and progress of this interaction during 2007. The Management Board requested this report to be accompanied with results of performance indicators developed to measure the degree of satisfaction for every patient and consumer involved in EMEA activities during 2007.
Both the progress on the interaction with Patients' and Consumers' Organisations and the results of performance indicators were presented to the EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) at its meeting on 7th December 2007. Outcomes and proposed recommendations were discussed and agreed. The final report will be presented on 28th February 2008.

Outcome

Progress of the interaction with Patients' and Consumers' Organisations
Overall, all actions identified in the Framework of Interaction have been implemented.
With regard to the provisions addressing contacts between the Agency's fora and Patients' and Consumers' Organisations, these have been established at the level of the EMEA Management Board, the EMEA Scientific Committees, Working Parties and Scientific Advisory Groups. The work achieved so far has set up the grounds towards a more systematic interaction and involvement of patients and consumers at different levels of the Agency's work. However, there is still a need to formalise the procedures which have been established and to further enhance the level of interaction in the different areas.

With regard to the provision of information, the EMEA has implemented appropriate measures in order to improve the quality of the product information adapted and oriented to patients. Procedures have been put in place to involve patients and consumers in the preparation of such information. (e.g. review of EPAR summaries and Package Leaflets).

Analysis of the degree of satisfaction of patients/consumers involved in EMEA activities in 2007
The input has been collected through a questionnaire which was given to every patient/consumer having participated in an EMEA activity. The questionnaire included questions on the overall interaction with the EMEA, the impact of their work both for the EMEA and for their organisations, the EMEA website, as well as feedback on the use of EMEA facilities and the organisation of meetings by the Agency.

The results and analyses of the performance indicators questionnaire show overall satisfaction. Additionally, the analysis has been used to identify areas for improvement, and to propose specific actions. Some of these actions had been identified prior to the analysis and are already part of the EMEA Human Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP) Work Plan for 2008. Others have been outlined in the EMEA Road Map: 2008-2009 Implementation Phase (particularly those related to the provision of information to the Agency's stakeholders).

Next steps

- The EMEA will actively work together with the PCWP in exploring how to further develop a more systematic interaction and involvement of patients and consumers at different levels of the Agency's work. Particular attention will be paid to patient involvement in activities at the level of the different Committees (e.g. guideline preparation, product evaluation, etc). A Reflection Paper with proposed actions on this aspect will be developed.

- The EMEA will continue to work towards the provision of high quality information adapted and oriented to patients. Patients will continue to be involved in the preparation of such information. In this respect, the procedures already in place (e.g. review of EPAR summaries and Package Leaflet) will be reviewed in order to introduce the necessary improvements and to extend the current scope of the exercise.

- The analysis of the results of the compliance with the performance indicators has lead to a number of actions in various fields, ranging from the impact of the interaction for the Patients' and Consumers' Organisations up to the organisations of meetings by the EMEA.

- All recommendations for action are covered by either the EMEA Work Programme for 2008 (already adopted by the Management Board at its December 2007 meeting) or the EMEA Work Programme for 2009 (for adoption by the Management Board at its March 2009 meeting).

- The Management Board will be presented at the beginning of next year with a report on the progress achieved in 2008. It will also include an analysis of the compliance with the performance indicators during 2008.

INTRODUCTION

The EMEA has engaged in a dialogue with European Patients' and Consumers' Organisations (PCOs) ever since the Agency was created in 1995. As end-users of the medicines that the EMEA evaluates, PCOs have specific knowledge and expertise to offer. This makes them key stakeholders in the work of the EMEA, and the Agency is therefore committed to maintaining a strong working relationship with them.
Regulation (EC) No 726/2004 of European Parliament and of the Council has provided for the further development of appropriate contacts between the EMEA and representatives of PCOs at the level of its Management Board, its scientific committees and its working parties.

As part of the monitoring of activities defined in the Framework on the Interaction between the EMEA and Patients' and Consumers' Organisations (EMEA/354515/2005-Final) (http://www.emea.europa.eu/pdfs/human/pcwp/35451505en.pdf), the Management Board should be provided for information at the beginning of each year with the Work Plan of activities with Patients' and Consumers' Organisations, as agreed upon between the EMEA and Patients' and Consumers' Organisations. Such Work Plan should include performance indicators, jointly developed by the EMEA and Patients' and Consumers' Organisations. A report on the outcome and progress made at the end of each year has also to be presented, including an assessment of the performance indicators questionnaires collected during the year.

The present one is the first report produced, and it is presented in two sections:

Section 1: Framework of interaction: status of implementation as of 2007. This section describes the progress achieved so far in the interaction with PCOs, as planned in the mentioned framework of interaction, in particular through the work undertaken by the EMEA Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP), as well as the achievements related to the provision of public information.

Section 2: **Analyses of the degree of satisfaction of PCOs involved in EMEA activities during 2007**. To carry out this analysis, the EMEA has developed a "performance indicator questionnaire" together with the PCWP. This questionnaire has been used to get feedback from every patient and consumer who participated in EMEA activities in 2007. The methodology, results and analysis of the input received is presented in this section.

Section 1

FRAMEWORK OF INTERACTION: STATUS OF IMPLEMENTATION AS OF 2007

The EMEA Management Board endorsed in December 2005 a Framework of Interaction between the EMEA and Patients' and Consumers' Organisations. This framework defined the objectives to be achieved and set up an implementation plan.
The Management Board requested the EMEA to report at the end of each year on the outcome and progress of the Agency's interaction with Patients' and Consumers' Organisations. The following section will analyse the status of the implementation plan of the Framework on the Interaction between the EMEA and Patients' and Consumers' Organisations.

The same structure as used in the implementation plan will be followed. In this aspect, two main topics are distinguished: I) implementation of the New Pharmaceutical Legislation and II) identification of a Platform of Exchange with PCOs.
In addition a full list of activities (Table 1) is presented for easier identification.

1. IMPLEMENTATION OF THE NEW PHARMACEUTICAL LEGISLATION

1.1. Provisions addressing contacts between the Agency and Patients' and Consumers' Organisations

1.1.1. EMEA Management Board

Article 78 (1) of Title IV of Regulation (EC) N° 726/2004 states the following:
"The Management Board shall, in agreement with the Commission, develop appropriate contacts between the Agency and the representatives of the industry, consumers and patients and the health professions. These contacts may include the participation of observers in certain aspects of the Agency's work, under conditions determined beforehand by the Management Board, in agreement with the Commission."

The implementation of this Article has been undertaken as follows:

- The Agency, in agreement with the Management Board, has consulted Interested Parties, including Patients' and Consumers' Organisations, on policy issues or topics of general interest, through different fora - including workshops, conferences and info days. Some examples of these activities are: "the brainstorming meeting on the provision of information by the EMEA to its stakeholders", "the European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC)", "the Workshop on Naming, Labelling and Pack design of Insulin containing medical products", etc (for the full list of activities, please see Table 1).

- The Agency informed Patients' and Consumers' Organisations on issues of general interest such as Work Programmes of Committees or Working Parties, as well as progress in therapeutic or treatment areas, etc. These activities have mainly been undertaken through the work of the EMEA Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP).

- It was requested that |nterested Parties, including representatives of Patients' and Consumers' Organisations, should participate as observers in certain aspects of the Agency's work. So far patients' representatives have been observers in the newly created EMEA/CHMP Working Group with Healthcare Professionals' Organisations (HCP WG), as well as in the COMP (in addition to the patients who are full members of the COMP, other patients attend regularly COMP meetings as observers).

- In addition, it was agreed for the EMEA to draft specific frameworks on the interaction with its stakeholders. As a first step the Framework of Interaction for Patients' and Consumers' Organisations was developed, agreed by the EMEA Management Board, and subsequently published in 2006. Further to this, the EMEA

is working on the development of a Framework of Interaction between the EMEA and Healthcare Professionals' Organisations.

1.1.2. EMEA Scientific Committees

Article 78 (2) of Title IV of Regulation (EC) Nº 726/2004 states the following:

"The committees referred to in Article 56(1) and any working parties and scientific advisory groups established in accordance with that Article, shall in general matters establish contacts, on an advisory basis, with parties concerned with the use of medicinal products, in particular patient organisations and health-care professionals' associations. Rapporteurs appointed by these committees may, on an advisory basis, establish contacts with representatives of patient organisations and health-care professionals' associations relevant to the indication of the medicinal product concerned."

The implementation of such Article has been undertaken as follows:

- Consultation by the Committees

The Committees have consulted Patients' and Consumers' Organisations on specific issues of a scientific or technical nature. Examples of this consultation are the discussions with representatives of patients and victims of thalidomide to discuss the risk management plan for thalidomide and for Revlimid (lenalidomide). Patients were also consulted during the preparation of the communication plan at the time of the suspension of the marketing authorisation for Viracept (nelfinavir).

- Consultation by the Working Parties or the Scientific Advisory Groups

The Committee for Medicinal Products for Human Use (CHMP) requested a Scientific Advisory Group (SAG) to consult Patients' and Consumers' Organisations on issues related to disease management and the impact on the day-to-day life of the patients during the assessment of Tysabri (natalizumab).
The Pharmacovigilance Working Party (PhVWP) has sought the views of the patients on a proposed wording related to safety issues in order to update the Package Leaflet of some medicines (so far antidepressants and NSAIDs).
The Working Parties were advised to consider the need to consult Patients' and Consumers' Organisations during the development of guidelines. Procedures have been put in place and interaction for some guidelines has been planned or is ongoing.

- Consultation by the Rapporteurs

As per article 78 (2), the Rapporteurs appointed by the Committees (the experts each time nominated by the Committee as responsible for the assessment of a medicine) were to also establish contacts, on an advisory basis, with Patients' and Consumers' Organisations relevant to the indications of the medicinal products concerned. The contacts which have been done so far refer to those examples mentioned before (Consultation by the Committees, its Working Parties and Scientific Advisory Groups).

The EMEA was also requested to develop specific rules with regard to the interaction between the EMEA Scientific Committees, Working Parties, Scientific Advisory Groups, Rapporteurs and the Patients' and Consumers' Organisations. "Rules of involvement of members of Patients' and/or Consumers' Organisations in Committees related activities (EMEA/161660/05)" have been prepared accordingly. As per this document, members of Patients' and Consumers' Organisations can be involved in different EMEA activities either as experts or as representatives of their organisation. As regards the latter, they

will liaise with their organisation, as necessary, to come with the position of the organisation on the questions to be addressed.

1.2. Provisions in relation to public information

The framework addressed the need to provide for adequate consultation of Patients' and Consumers' Organisations in order to fulfil the patients'/general public's expectations in terms of provision of information on medicines.

1.2.1. The improvement of the quality of the information provided

The following has been implemented**:**

- An **EPAR summary** written in a manner that is understandable to the public (as a Q&A document)is being prepared for all new centrally authorised medicines (Article 13 (3) of Regulation (EC) Nº 726/2004). The PCWP was consulted during the preparation of the template of this document. In addition, since April 2007 PCOs representatives are involved in the review of the English version of all new EPAR summaries. They ensure that the information is clear and comprehensible for the general public. As of today, 30 EPAR summaries have been reviewed as part of this procedure.

- Consultation with target patient groups to ensure that the Package Leaflet is legible, clear and easy to use is systematically performed by the applicant for new applications (Article 59.3 of (EC) Nº726/2004). In addition, since May 2007, PCOs representatives are involved in the review of the Package Leaflet for centrally authorised medicines at the time of their renewal. They ensure that the information is clear and comprehensible for the general public. As of today, 10 Package Leaflets have been reviewed as part of this procedure.

1.2.2. The provision of additional information in relation to the Agency's activities

As requested in the Framework, specific explanatory documents and procedures, (regarding the implementation of legal provisions in Regulation (EC) Nº 726/2004)) have been developed. The following has been implemented**:**

- Publication of information on the **withdrawal of an application or refusal of a marketing authorisation** (Articles 11 and 12.3 of Regulation (EC) Nº 726/2004). As for the EPAR , a summary written in a manner that is understandable to the public has been prepared for each of these procedures. The PCWP has been consulted for the preparation of the template in the form of a Question & Answer (Q&A) document.

- Information on **compassionate use** programmes is provided (Article 83 of Regulation (EC) Nº 726/2004). In addition an explanatory document (in the form of a Q&A document) specifically for patients/general public has been produced. The PCWP was consulted during the preparation of this document.

- Information on **specific obligations and conditional approvals** (Article14.7 of Regulation (EC) Nº 726/2004) is provided through various EMEA documents (e.g. PL, SPC, EPAR and EPAR summaries). Additional measures are being taken to show clearly on the EMEA website for which medicines specific obligations apply. The PCWP was consulted.

- Appropriate **safety information** is provided on a general basis to the general public (Article 57. 1 (d, f) of Regulation (EC) Nº 726/2004), usually in the form of Q&A documents. Patients and consumers have been occasionally involved in the preparation of these documents (e.g. communication on Viracept) (See Table 1).

- Ongoing development of **EudraPharm**, the European database providing information to the public on all medicinal products in the EU (Articles 57.1 (l) and 57.2 of Regulation (EC) Nº726/2004). Patients' and consumers' representatives have been regularly consulted and updated throughout the development process in 2007, including participation of a PCWP representative in the Telematic Implementation Group (TIG).

Further communication tools have also been developed together with Patients' Organisations: the new dedicated section for Patients' and Consumers' Organisations within the EMEA website has been built with an active input from patients. In addition, a monthly e-mail to Patients' Organisations addresses their needs in terms of information about medicines evaluated by the EMEA Scientific Committees (only public information).

2. IDENTIFICATION OF A PLATFORM OF EXCHANGE WITH PATIENTS AND CONSUMERS

The work previously carried out by the EMEA/CHMP Working Group with Patients' and Consumers' Organisations has provided the basis for the creation of a permanent platform of exchange with PCOs. As requested in the Framework, the EMEA has extended the membership of the group, in particular to the representatives of the COMP and HMPC and other relevant Patients' and Consumers' Organisations. Representatives from the newly created Paediatric Committee (PDCO) will shortly be nominated. A representative from CMD(h) attends regularly the meetings of the group as an observer.
Finally, further to the experience achieved with the EMEA/CHMP Working Group with Patients' and Consumers' Organisations, the EMEA has officially created a Working Party to adequately reflect the widened scope of activities within the group: the EMEA Human Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP). Subsequently, the EMEA has revised the mandate of the group and the scope of its activities in relation to public information, addressed at the level of the various Committees dealing with human medicines.
The Working Party, met in December 2006 for the first time. It usually meets 4 times a year including a joint meeting with the EMEA/CHMP Working Group with Healthcare Professionals' Organisations where issues of common interest are discussed.

Table 1: Activities involving patients at the EMEA

Committes/Working Partie/Working Groups	PCWP (Members)
	COMP (Members & Observers)
	HCP **(**Observers**)**
	Management Board **(**Members**)**
	COMP-WGIP Representatives from Patients' Organisations
Workshops	First-in-man guideline-Workshop
	Workshop on Naming, Labelling and Pack design of Insulin containing medical products - 19 Nov 2007
Conferences	European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC) and Perspectives for the Future -
Ad Hoc/SAGs meetings	Viracept_Ad Hoc Expert Group Meeting - 18 June 2007- and Q&A
	Ad Hoc Meeting of Victims' and Patients' Organisations on Thalidomide
	Ad Hoc Meeting of Victims' and Patients' Organisations on Lenalidomide
	SAG meeting for Tysabri (natalizumab)
	SAG meeting on HIV/Viral diseases
Other meetings	Meeting of European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) - 28 June 2007-
	Telematics Implementation Group (TIG) for EudraPharm.
Product information related activities	Review of Package Leaflets at the time of renewal of MA
	Review of new EPAR summaries
	NSAIDS and trombotic risk: new wording for the package leaflet
	Antidepressant and suicidal risk: new wording for the package leaflet
Proactive consultation on EMEA documents (PCWP)	European Commission Guideline on the Readability of the Label and Package Leaflet of Medicinal Products for Human Use
	International Conference of Harmonisation (ICH) Draft Definition for Genomic Biomarkers, Pharmacogenomics, Pharmacogenetics, Genomic Data and Sample Coding Categories
	EudraCT Draft proposal from the EC
	Publication of paediatric trial details including results: proposal for data fields of EudraCT to be publicly available
	Guideline on the acceptability of invented names for human medicinal products processed through the centralised procedure
	Questions and Answers on biosimilar medicines
	Questions and Answers on generic medicines
	Pharmaceutical Forum Working Group on Information to Patients: Report on Pillar II: Statutory Information on Medicines
	EMEA template for Q&A on withdrawal, refusal of marketing authorisation application
Input from the PCWP for other projects	Access to information on specific obligations for products conditionally approved or approved under exceptional circumstances
	EMEA Website section for Patients' and Consumers' Organisations
	EudraPharm development

3. CONCLUSIONS AND NEXT STEPS

Overall, all the actions identified in the Framework of Interaction have been implemented as of 2007.

With regard to the provisions addressing contacts between the Agency's fora and Patients' and Consumers' Organisations, these have been established at the level of the EMEA Management Board, the EMEA Scientific Committees, Working Parties and Scientific Advisory Groups. The work achieved so far has set up the grounds towards a more systematic interaction and involvement of patients and consumers at different levels of the Agency's work. However, there is still a need to formalise the procedures which have been established and to further enhance the level of interaction in the different areas.

With regard to the provision of information, the EMEA has implemented appropriate measures in order to improve the quality of the product information adapted and oriented to patients. Procedures have been put in place to involve patients and consumers in the preparation of such information. (e.g. review of EPAR summaries and Package Leaflets).

Next steps:

- EMEA will actively work together with the PCWP in exploring how to further develop a more systematic interaction and involvement of patients and consumers at different levels of the Agency's work. Particular attention will be paid to patient involvement in activities at the level of the different Committees (e.g. guideline preparation, product evaluation, etc). A Reflection Paper with proposed actions on this aspect will be developed.

- The EMEA will continue to work towards the provision of high quality information adapted and oriented to patients. Patients will continue to be involved in the preparation of such information. In this respect, the procedures already in place (e.g. review of EPAR summaries and Package Leaflet) will be reviewed in order to introduce the necessary improvements and to extend the current scope of the exercise.

Section 2

ANALYSIS OF THE DEGREE OF SATISFACTION OF PATIENTS/CONSUMERS INVOLVED IN EMEA ACTIVITIES DURING 2007

1. ORGANISATIONS INVOLVED IN EMEA ACTIVITIES

In order to enable the Agency to establish contacts with the appropriate organisations on a transparent basis, the Management Board adopted during its September 2005 meeting a document defining the criteria to be fulfilled by Patients' and Consumers' Organisations in order to allow their involvement in EMEA activities. Since the publication of the criteria, all Patients' and Consumers' Organisations were in a position to express an interest in participating in the activities of the EMEA.

Upon request from an organisation, the EMEA secretariat evaluates whether the organisation fulfils the eligibility criteria. This evaluation is made possible through relevant information that the organisation provides through a predefined questionnaire which is available on the EMEA website.

Once the evaluation is finalised, the EMEA informs the organisation of the outcome of this evaluation and whether the organisation is eligible to participate in EMEA activities. In certain cases additional clarification or information on specific aspects is requested to the organisation before issuing a final outcome.

A list of the organisations found eligible after evaluation is published in the dedicated section for Patients' Organisations within the EMEA website. A link to each of their individual websites is also provided.

A negative outcome does not preclude the organisation to reapply at any time, and particularly once the issues raised during the evaluation are addressed.

So far, 46 organisations have applied for evaluation. Of them, 19 have received a positive outcome, 20 have received a negative one, and for 7 assessments are ongoing. The main reasons for a negative outcome related to lack of fulfilment of the definition of Patients'/Consumers' organisation or lack of EU representativeness (See Fig 1)

As a consequence of this exercise, a growing number of Patients' and Consumers' Organisations are able now to participate in EMEA activities. This ensures that the Agency has direct contact with a suitable wide range of PCOs, and that their views properly represent the needs and concerns of patients and consumers across Europe. All of them are not-for-profit organisations, involved at EU level. Some of them are general umbrella organisations, others have a particular focus on a specific patient/consumer-related area (such as rare diseases, HIV/Aids etc.).

In accordance with the "Rules of involvement of members of Patients' and/or Consumers' Organisations in Committees related activities (EMEA/161660/05)", in exceptional cases, the Committees have decided to consult organisations not fulfilling the criteria. However those organisations were fully transparent with regard to their activities and funding.

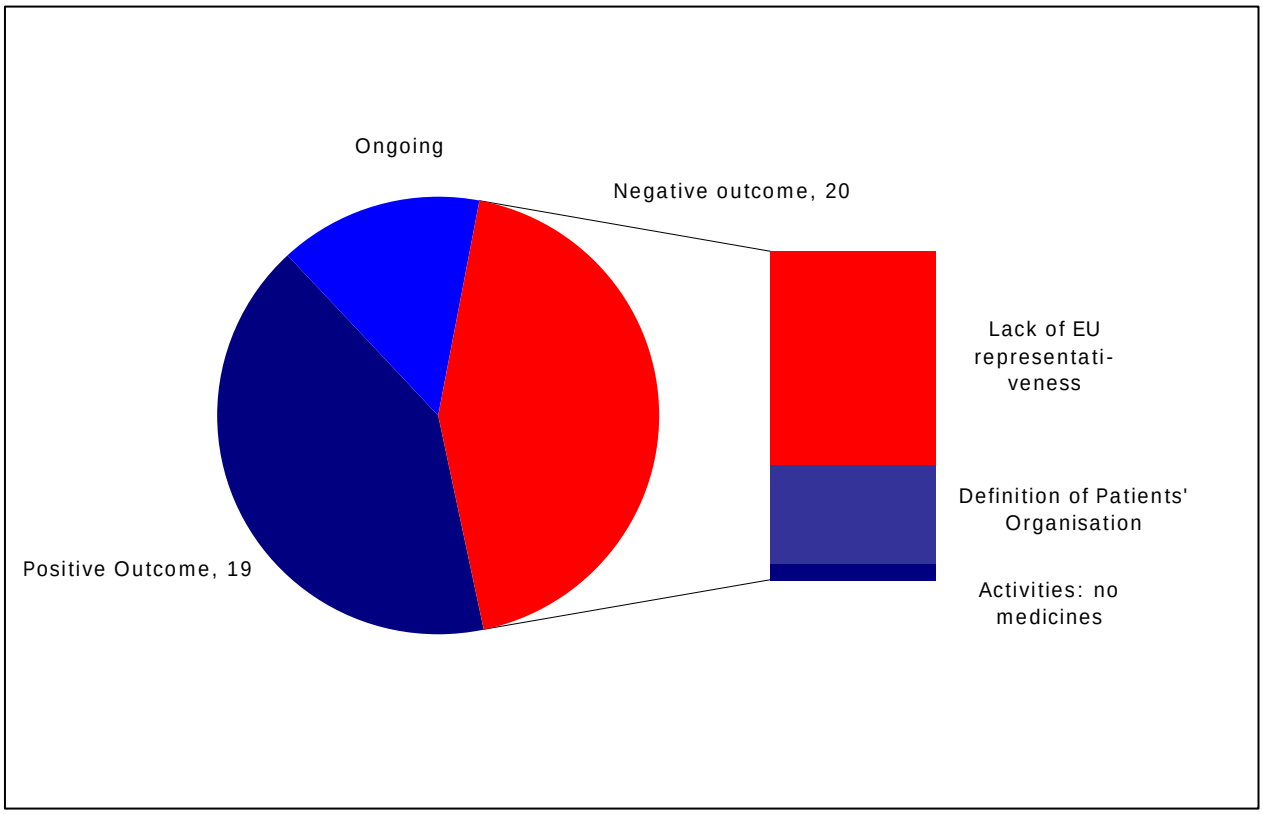
Table 2 gives an overview of the Patients' and Consumers' Organisations which so far fulfil the EMEA criteria after having being evaluated. It also indicates which organisations have been involved during 2007 in different EMEA activities.

Table 2: Patients' and Consumers' Organisations working with the EMEA

	NAME OF ORGANISATION	WEBSITE	FULFILMENT OF EMEA CRITERIA	Involvement in 2007
1	Alzheimer Europe (AE)	www.alzheimer-europe.org	**YES**	●
2	European AIDS Treatment Group (EATG)	www.eatg.org	**YES**	●
3	European Cancer Patient Coalition (ECPC)	www.ecpc-online.org	**YES**	●
4	European Consumers' Organisation (BEUC)	www.beuc.org	**YES**	●
5	European Federation of Neurological Associations (EFNA)	www.efna.net	**YES**	●
6	European Genetic Alliances' Network (EGAN)	www.egaweb.org	**YES**	●
7	European Myeloma Platform (EMP)	www.emp-myeloma.eu	**YES**	●
8	European Organisation for Rare Diseases (Eurordis)	www.eurordis.org	**YES**	●
9	European Parkinson's Disease Association (EPDA)	www.epda.eu.com	**YES**	●
10	European Patients' Forum (EPF)	www.eu-patient.eu	**YES**	●
11	European Public Health Alliance (EPHA)	www.epha.org	**YES**	●
12	Health Action International (HAI)	www.haiweb.org	**YES**	●
13	Insulin Dependent Diabetes Trust (IDDT)	www.iddtinternational.org	**YES**	●
14	International Alliance of Patients' Organizations (IAPO)	www.patientsorganizations.org	**YES**	●
15	International Diabetes Federation (IDF)	www.idf.org	**YES**	●
16	International Patient Organisation for Primary Immunodeficiencies (IPOPI)	www.ipopi.org	**YES**	●
17	Myeloma Euronet	www.myeloma-euronet.org	**YES**	●
18	Rett Syndrome Europe	www.rettsyndrome.eu	**YES**	

	NAME OF ORGANISATION	WEBSITE	FULFILMENT OF EMEA CRITERIA	Involvement 2007
19	Thalassemia International Federation (TIF)	www.thalassaemia.org.cy	**YES**	
20	Föreningen för de Neurosedynskadade	www.thalidomide.org	**NO**	●
21	Thalidomide UK	http://www.thalidomideuk.com	**NO**	●
22	Thalidomidici Italiani	www.thalidomidicionlus.it	**NO**	●
23	The Norwegian Thalidomide Association	_____	**NO**	●
24	The Thalidomide Society	_____	**NO**	●
25	Universitetssjukhuset i Lund	_____	**NO**	●
26	Irish Thalidomide Association	_____	**NO**	●

Figure 1 – Outcome of the evaluation of the organisations applying, as of 2007



2. OVERVIEW OF EMEA ACTIVITIES IN WHICH PATIENTS AND CONSUMERS WERE INVOLVED DURING 2007

In accordance to what is described in the framework of interaction, members of Patients' and Consumers' Organisations have participated during 2007 both as experts and also as representatives of their organisations in different EMEA activities. The two different types of consultation are defined in the "Rules of involvement of members of Patients' and/or Consumers' Organisations in Committees related activities (EMEA/161660/05)".
In case of a patient/consumer acting as a representative of the organisation, he/she will liaise with his/her organisation as necessary to come with the position of the organisation on the questions to be addressed.
During 2007, **42 different experts/representatives were involved in EMEA activities**. In some cases the same expert/representative has participated to more than one activity. **A total of 21 Patients' or Consumers' Organisations were involved.**

Table 3: activities involving patients at the EMEA in 2007

ACTIVITIES REQUIRING EXPERTS	Nº OF EXPERTS INVOLVED
Viracept_Ad Hoc Expert Group Meeting - 18 June 2007- and Q&A	1
SAG meeting on HIV/Viral diseases – 10 July 2007	1
Experts involved in the review of 30 EPAR summaries	12
Experts involved in the review of 11 Package Leaflets at the time of renewal	7
Workshop on Naming, Labelling and Pack design of Insulin containing medical products - 19 Nov 2007	1
TOTAL	22

ACTIVITIES REQUIRING REPRESENTATIVES OF THE ORGANISATION	Nº OF REPRESENTATIVES INVOLVED
Patients and Consumers Organisations Working Party (members and alternates from the organisations) –	18
COMP-WGIP Representatives from Patients' Organisations	3
Ad Hoc Meeting of Victims' and Patients' Organisations on Thalidomide	10
First-in-man guideline-Workshop	1
Meeting of European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) - 28 June 2007-	1
European Commission-EMEA Conference on the Operation of the Clinical Trials Directive (Directive 2001/20/EC) and Perspectives for the Future -	2
Brainstorming meeting on the provision of information by the EMEA to its stakeholders	11
Total	46

OTHER ACTIVITIES	Nº OF INDIVIDUALS INVOLVED
Members to the EMEA Management Board	2
Observers at the Healthcare professionals' Working Group	1
Members & Observers of the COMP	5
TOTAL	8
TOTAL NUMBER	**76**

3. QUESTIONNAIRE ON DEGREE OF SATISFACTION

The EMEA Management Board requested the EMEA to develop performance indicators to measure the degree of satisfaction of PCOs when having been consulted and involved in the different EMEA activities during 2007.
A performance indicator questionnaire has been developed by the EMEA together with the PCWP to measure the degree of satisfaction of PCOs which have been involved in the EMEA activities.

Every patient and consumer involved in any EMEA activities have been asked to complete this questionnaire at least once during the year and, whenever possible, for each individual activity that they participated.

A total of 27 valid questionnaires have been received and are the basis for the current analysis. 20 out of 27 experts/representatives who have provided an answer through the questionnaire, participated in more than one EMEA activity during 2007.

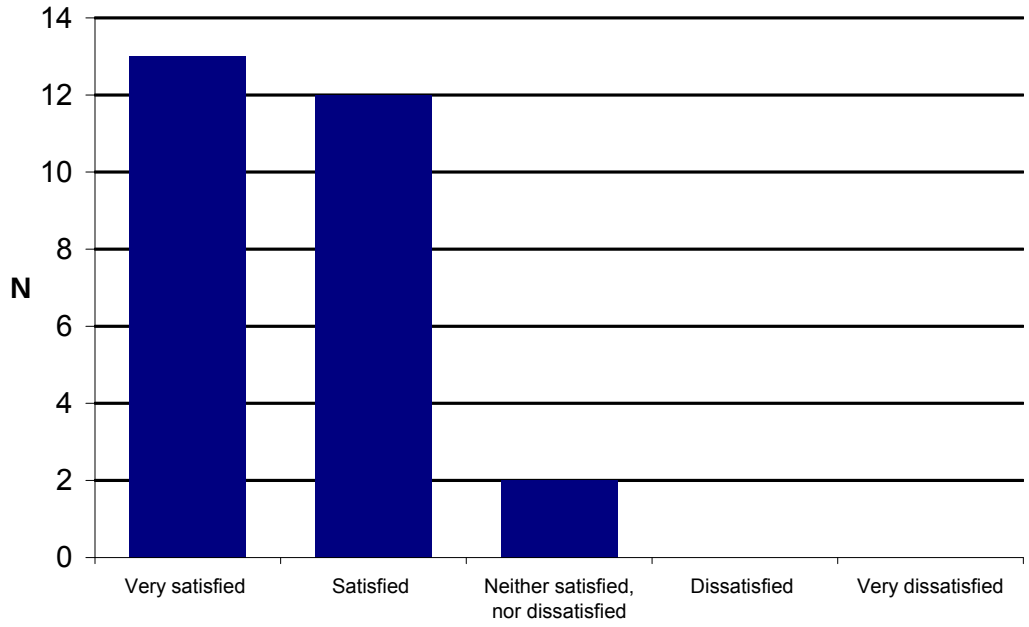
The questionnaire includes 8 questions, which can be answered by choosing among 5 grades of satisfaction rating from “Very satisfied” (5), the maximum score, to “Very dissatisfied” (1), the minimum. Each question provides an additional box where the interviewee is invited to add any comment. The questions cover different topics such as facilities provided by the EMEA, the dedicated section to patients within the EMEA website, organisation of meetings by the Agency, and input on the overall interaction of the EMEA with patients. The questionnaire, attached in Annex 1, offered the possibility to be filled in anonymously if preferred.

4. SCORING OF QUESTIONS AND SUMMARY OF COMMENTS RECEIVED

Question 1

Please indicate your level of satisfaction with:

Overall interaction with the EMEA



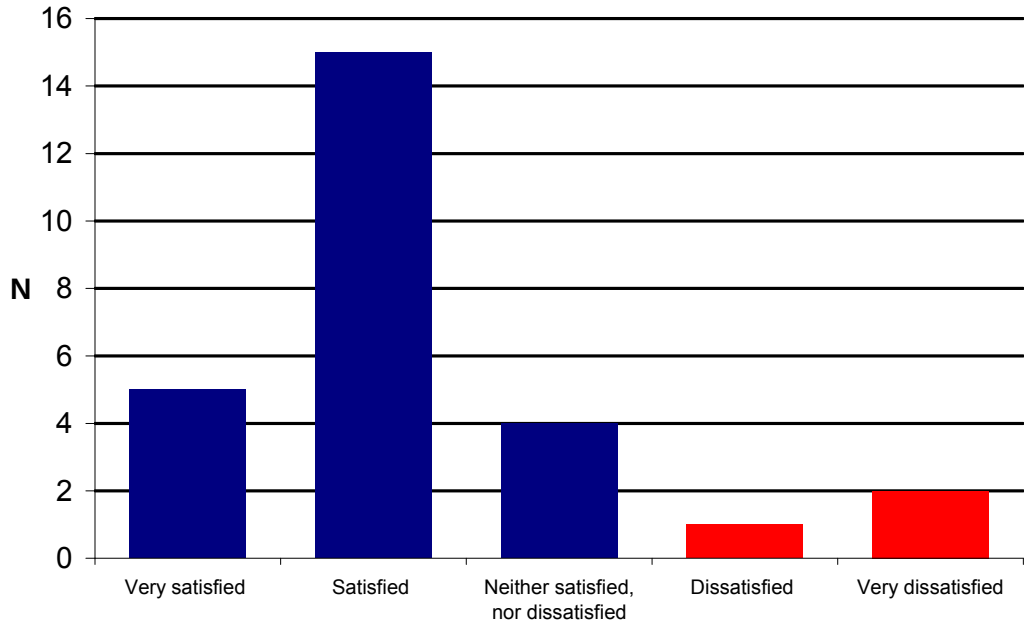
Summary of comments received

Overall Patients' Organisations regarded positively the current interaction with the EMEA, in particular the important achievement of actively involving patients in EMEA activities.
They have been "very impressed with the great willingness of the EMEA Management Board and the Working Party to take into account the comments made by patient representatives". In general they feel that their involvement is making a positive contribution, and that the exchange of information is productive.
In spite of this it is reminded that a further involvement would be welcomed, since product evaluation and guideline preparation are still carried out without any systematic involvement of relevant Patients' Organisations.

Question 2

Please indicate your level of satisfaction with:

The implementation of your contribution and input to the EMEA activities



Summary of supplementary comments received

Patients are generally satisfied with the way their comments are taken into account by the EMEA. Some patients felt uncomfortable when their proposal or comments were not (fully) implemented. This may have happened due to a misunderstanding on what was expected from them. The degree of satisfaction shows also great differences depending whether the input comes form patients as experts or when they participate as representatives of their organisation.

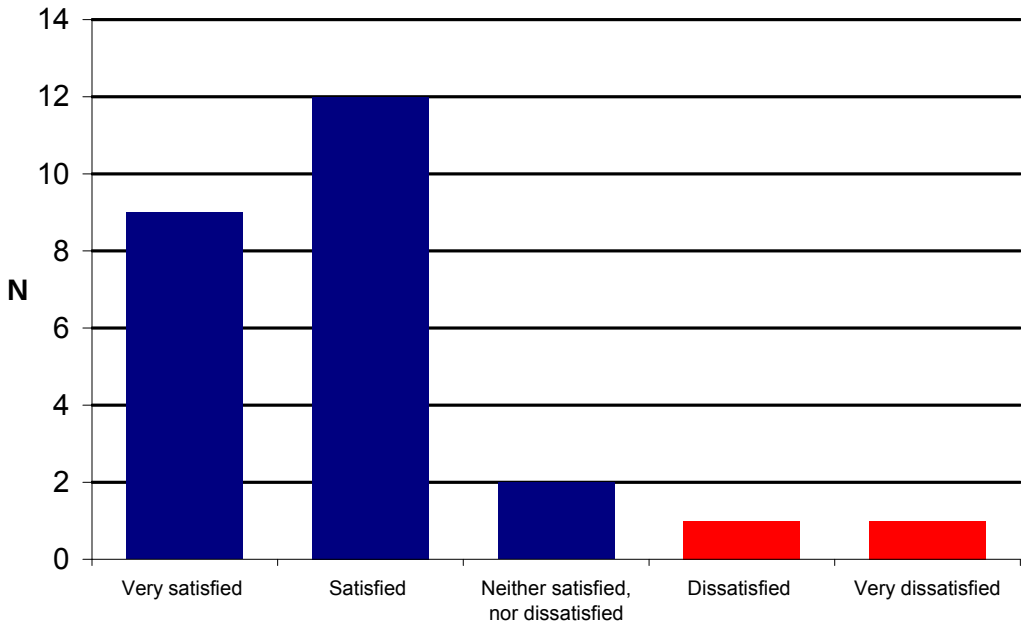
Areas for improvement have been suggested as follows:

- *The purpose of every consultation exercise, when involving patients, should always be clearly expressed at the beginning of each activity in order to let the patients know which kind of input is needed and therefore avoid disappointment in terms of the expectations of involved patients.*

Question 3

Please indicate your level of satisfaction with:

The consequences of the work carried out with the EMEA on your organisation



Summary of supplementary comments received

Patients have mentioned various consequences that the EMEA collaboration can have on their organisations:

- They can communicate and express the needs of individual members of their organisations so that they can be taken into account.
- This collaboration allows them to transfer information about EMEA activities, to improve the relations with the national and regional Health Authorities and Healthcare Professionals.
- The work at EMEA helps them to be informed about medicines and treatment options available to the patients. This surely contributes to the empowerment of patients through information, and to improve their awareness about the EU Health Policy, EU regulatory activities and the latest developments in the field of medicines.
- Many recognised the importance of being involved in European regulatory and policy issues, regarding, for instance, orphan diseases. Other issues such as the involvement in the review of guidelines and the evaluation procedure, for some products in the field of their interest, even has stronger consequences for their organisation.
- Finally, it was stressed that sometimes Patients' Organisations' representatives find it difficult to give to the other members of their organisation and to other patients in general, the amount of information necessary to understand how medicines are regulated and marketed in the EU.

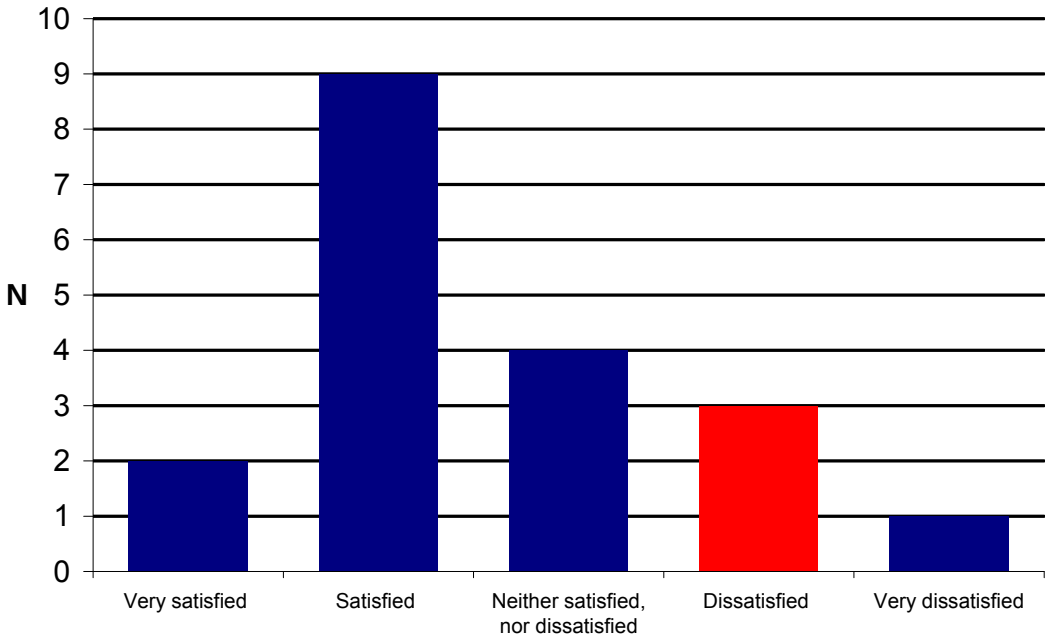
Areas for improvement can been identified as follows:

- *A further involvement of Patients' Organisations' representatives in the preparation of guidelines and in the evaluation procedure of medicines should be explored.*
- A *training programme based on already existing experiences in Patients' and Consumers' Organisations could be developed. This training program can be used afterwards for training of patients in the context of their respective organisations. The training could focus on topics such as pharmacovigilance, risk communication, etc.*

Question 4

Please indicate your level of satisfaction with:

The clarity and comprehension of the information available on the EMEA website for "patient groups"(http://www.emea.europa.eu/Patients/introduction.htm), if you have consulted it.



Summary of supplementary comments received

In general patients appreciate the web-pages that the EMEA has dedicated to Patients' Organisations. On the one hand the content is very appreciated; on the other hand the layout and access to the pages is found difficult and offers room for improvement. They pointed out that the target audience could be also patients themselves rather than only Patients' Organisations.

Specific suggestions were given on the page listing all eligible organisations. It is suggested that access to information on how well the organisations comply with the EMEA criteria could be given. Particular emphasis was given to information on transparency. The idea of including a declaration of interest, for each organisation, has been expressed. Those declarations could be updated on an annual basis, the same way that declarations of interests of EMEA experts and members of the EMEA Management Board need to be updated.

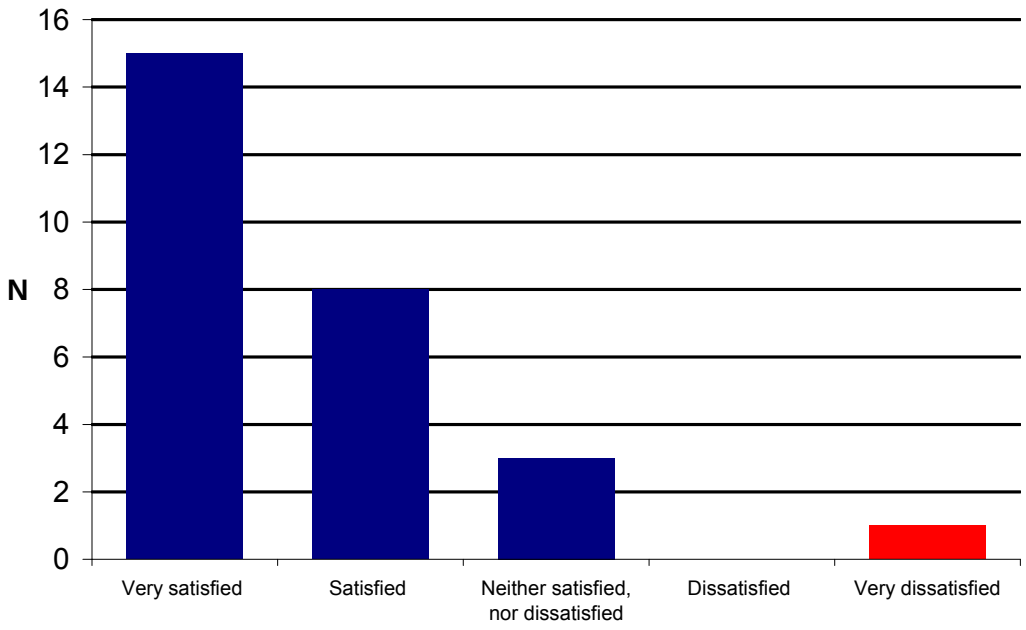
On the basis of comments received areas for improvement can been identified as follows:

- *An eventual re-restructure of the website should facilitate the access of patients to the information provided. There was also a request for clear graphics and presentations, easily downloadable, describing the main EMEA activities and procedures*.
- *It should be further explored how to improve transparency of the organisations involved in EMEA activities.*

Question 5

Please indicate your level of satisfaction with:

Appropriateness and usefulness of documents for participation in EMEA activities



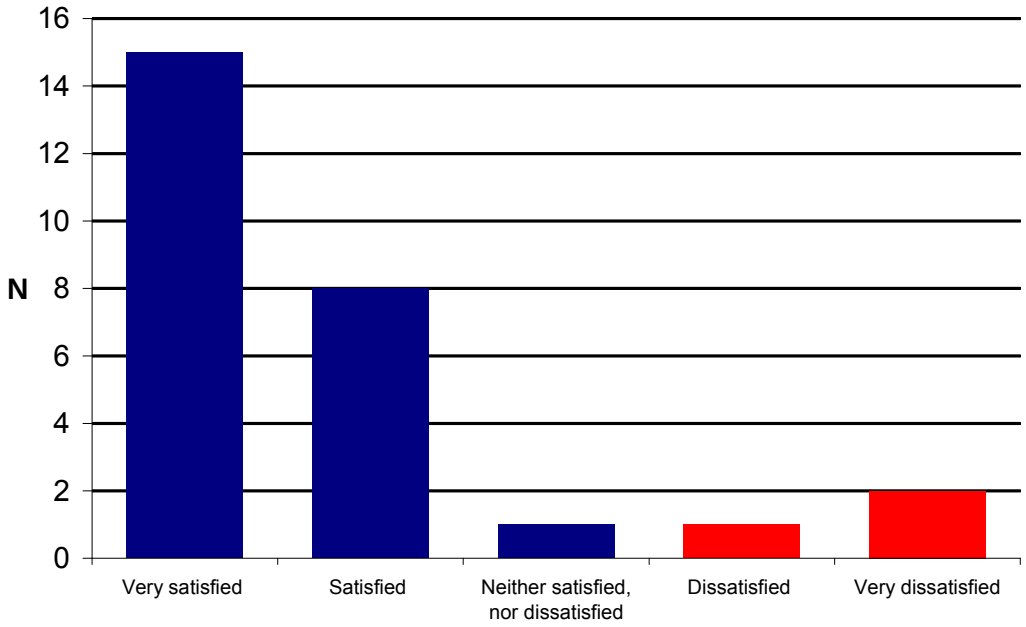
Summary of supplementary comments received

EMEA documents submitted to the Patients' Organisations are generally considered well written. The usefulness of a clear executive summary and instructions on which actions will be required (i.e. for adoption, for information, for comments etc) is acknowledged.
It is reminded that minutes of meetings should always come as early as possible in order to allow for comments in a reasonable time.

Question 6

Please indicate your level of satisfaction with

The supply of documents/information for participation in EMEA activities



Summary of supplementary comments received

Patients showed satisfaction with the comprehensiveness of the documentation provided for the different activities.
Overall it is recognised that documents usually come early enough. However, in some cases, late receipt of documentation could prevent patients to properly prepare their contribution. This can be an issue especially for rather scientific or technical documents. It needs to be specified that this situation has only happened occasionally, and mainly related to product related issues where timeframes were very tight.

Patients and consumers encourage EMEA to continue providing feedback and follow-up from relevant workshops or conferences.

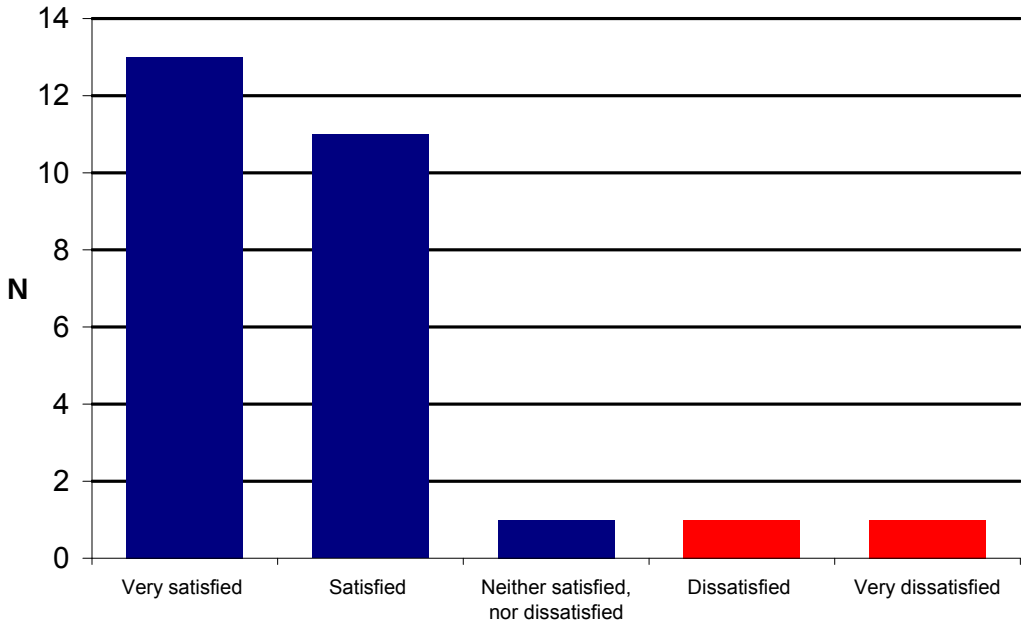
Areas for improvement have been suggested as follows:

- *There is a need to clearly identify the confidentiality/non-confidentiality nature of some documents circulated, in order to allow for a proper consultation and dissemination within the own Patients' Organisation.*

Question 7

Please indicate your level of satisfaction with:

The organisation of the EMEA meetings



Summary of supplementary comments received

Overall patients consider meetings to be well organised. The results show that perception and degree of satisfaction varies depending whether the patients come as experts or as representatives of their organisation, especially for permanent groups (e.g. PCWP).

It has been suggested to make the Reception services more aware of attendance of meetings by patients, particularly when they visit EMEA for the first time.
During the meeting, first time participants may not even know the Chair of the meeting and can feel a bit unsettled. EMEA staff is encouraged to take measures to identify first time participants in advance, so that adequate support can be provided.
It is more complex to provide the adequate level of assistance when it relates to sporadic attendances from patients to ad-hoc meetings rather than patients who participate regularly to permanent groups (e.g. PCWP).

Areas for improvement have been suggested as follows:

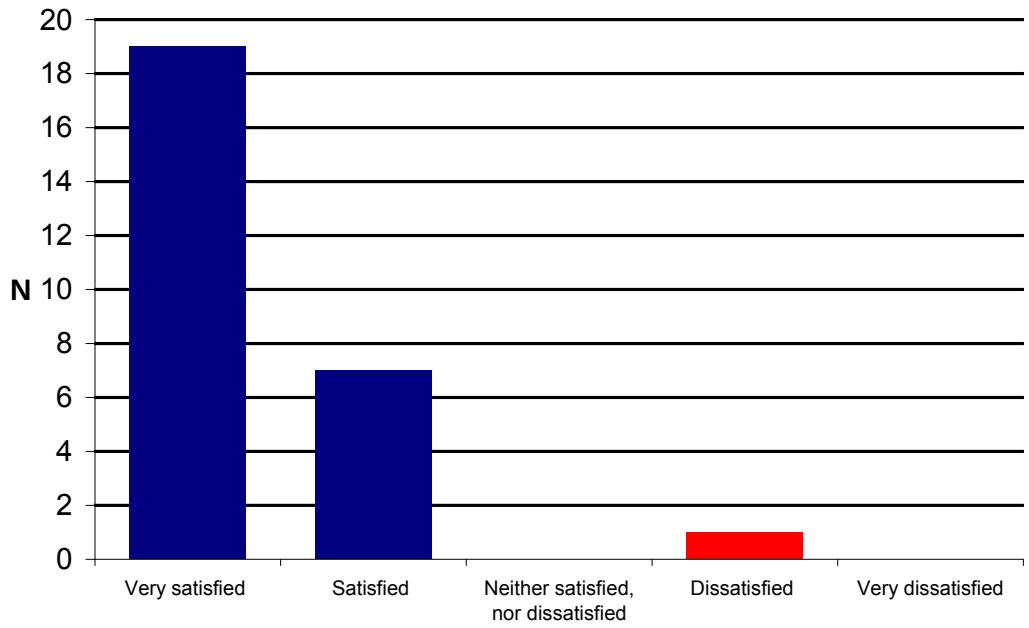
- *A public report, with all meetings open to patients[*] held at the EMEA during the previous year(s), should be prepared annually*
- *Translations during meetings (where they are foreseen): a short training/update to the translator on the matter to be discussed should be given in order to improve the outcome.*
- *EMEA staff should take measures to identify first time participants in advance, so that adequate support during the meeting can be provided (e.g the Chair of the meting should be introduced as soon as possible to new patients participating).*

[*] For which patient involvement has been requested.

Question 8

Please indicate your level of satisfaction with

Arrangements and facilities provided by the EMEA (for examples: invitations, travel arrangements, rooms, meeting services…)



Summary of supplementary comments received

The feedback received reflects patients' and consumers' satisfaction with EMEA facilities. Some refered to have been: "always impressed with the friendliness and effectiveness of the EMEA staff in helping us with travel arrangements and reimbursement". However, others would welcome some more flexibility in travel arrangements to better cover specific needs (e.g. some patient representatives with special requirements for travelling and accommodation due to medical conditions).

Some members of permanent groups, such as EMEA Scientific Committees, requested the invitation to be sent earlier, still understanding that sometimes the restricted timeframe does not allow that (e.g. product related activities).

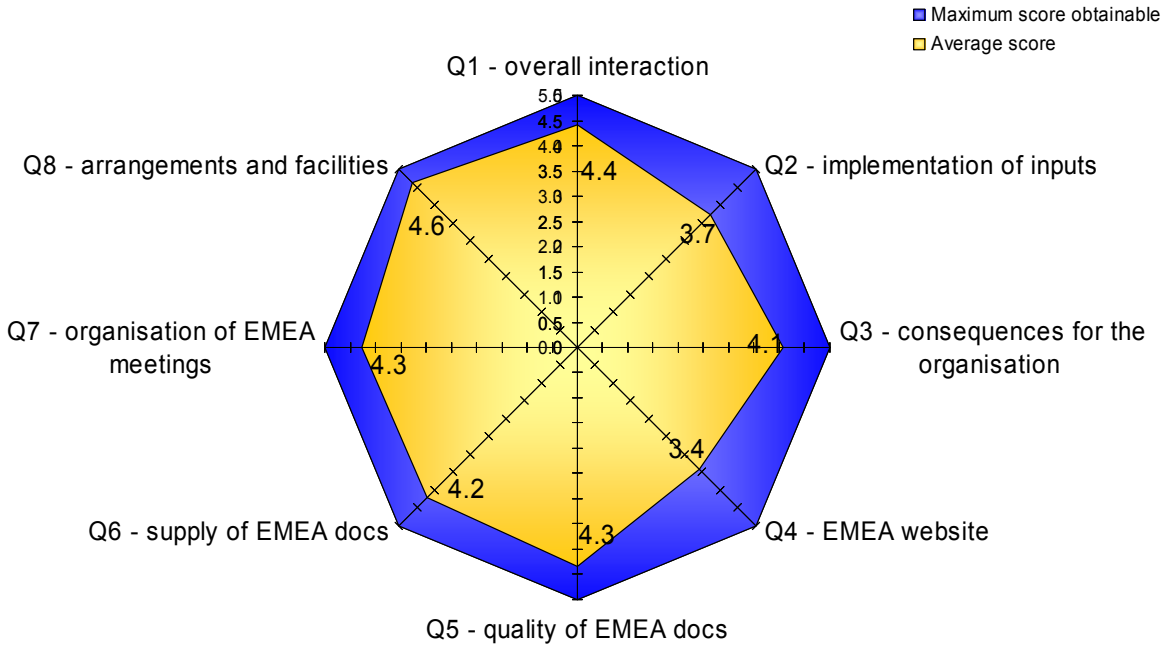
On the basis of the comments received, the following areas for improvement have been identified:

- *For the reimbursement of costs, it would be useful to receive a breakdown of how the costs have been calculated*
- *Special requirements due to medical needs of some patients should be further considered*
- *There is a need to ensure awareness of the needs of individual patients by the EMEA staff in charge of the organisation of any meeting where this patient was to participate. Any action should involve participation of EMEA Conferences services.*

5. FINAL COMMENTS COLLECTED

On average the scores reached for each question are quite satisfactory, reflecting that the patients involved so far value the collaboration with the EMEA.
Many comments collected through the questionnaire have been considered and will be implemented. This implementation is expected to increase the degree of satisfaction in the coming years.

The following figure illustrates simultaneously the average score achieved for each question, and puts it in comparison with the maximum possible score for each question (5). The total area (in blue) represents the maximum possible score (5). The inner area (in yellow) shows the average score measured in each question.



Some other general comments were collected in the final part of the questionnaire and related to the following issues:

Involvement of more Patients' Organisations
Many representatives asked to involve more organisations in the various activities. It is also suggested to organise once a year an EMEA event with all the PCOs' representatives present in the different Working Groups and Committees in order to improve the relations, the exchange of information, and the knowledge and the experience of the different EMEA activities. This could also give the opportunity to transfer experience and knowledge on the work done to the other PCOs representatives not so familiarised with EMEA activities.

More general involvement

While various members of the CHMP have indicated that they consider the contribution of patients very useful and many have made clear that the informed patients are ideally situated to provide a valid contribution during the evaluation of the benefit/risk ratio, their opinion is not usually requested during the evaluation of applications for authorisation. Another aspect where patient involvement can be useful refers to Risk Management Plans. Participation to the working of the SAGs in an expert's capacity should be reinforced.

Consideration on compensation to patients contributing to the work of the EMEA

Most of the time the involvement of a patient in the Agency's activities has a serious impact on the individuals' professional and personal life in terms of time, and thus money, spent to contribute to the EMEA work. Patient representatives, in fact, are in general not "professionals representatives" (paid staff of a patient organisation) but volunteers. Furthermore, even when they are staff members of a patient organisation, their involvement in the EMEA activities could have a considerable effect on the limited budget of the organisation itself.

This economic and professional impact certainly limits their capacity to be fully involved in the EMEA activities on the medium and long term and reduces the number of potential representatives who could be involved.

A remuneration/ compensation programme for such type of representatives involved in the Agency's work would certainly help to improve the present situation and ensure a wider involvement of patient representatives

Other suggestions

The EMEA has to increase its transparency and access to minutes and agendas. It also has to introduce public hearings when the evaluation leads to a difficult decision. Adequate procedures should allow the CHMP to consider the experts' and patients' opinions.

6. CONCLUSIONS AND NEXT STEPS

The results and analyses of the performance indicators questionnaire show overall satisfaction from PCOs' representatives which have been involved in EMEA activities during 2007.

The analysis of the input received has allowed to identify areas for further improvement. Some of these had already been identified and are part of the PCWP Work Plan for 2008. Others have been outlined in the EMEA Road Map: 2008-2009 Implementation Phase (particularly those related to the provision of information to the Agency's stakeholders). The remaining identified actions are presented in the "Table of Actions" (next page) for implementation.

The results obtained from the questionnaire, as well as the general perception from patients and consumers seems to show a difference depending whether the input comes from patients as experts or when they participate as representatives of their organisations. The performance indicator questionnaire will be adapted for next year in order to cover this difference and to enable it to extract specific conclusions for the two different scenarios.

Table 3 – Table of actions for 2008

Action	Estimated Timeframes for Completion
Publish report on the activities for which patients have participated during the year.	1st Quarter 2008
Further consideration on special needs of patients regarding travel arrangements and accommodation.	2nd Quarter 2008
Need for clear identification of confidential/non-confidential nature of EMEA documents. Proposal to be made together with the PCWP.	2nd/3rd Quarter 2008
Improvement of transparency for Patients' Organisations involved in EMEA activities. Proposal to be made together with the PCWP.	2nd/3rd Quarter 2008
Annual meeting with all EMEA eligible organisations, including discussion on involvement of more Patients' Organisations.	3rd Quarter 2008
PCWP contribution to the drafting of a Reflection Paper on how to further develop procedures for involvement of patients in product related issues.	PCWP WP 2008
PCWP contribution to the drafting of a Reflection Paper on how to further develop procedures for involvement of patients in guidelines preparation.	PCWP WP 2008
Better coordination at each meeting for adequate provision of assistance and support to new experts and representatives coming the first time. Monitor effectiveness of action through the 2008 performance indicator questionnaire.	Throughout 2008
PCWP contribution to an eventual re-structure of the EMEA website which would facilitate access to patients.	PCWP WP 2008 EMEA Road Map: 2008-2009 Implementation Phase
Translations during meetings (where they are foreseen): EMEA secretariat to provide training/update to the translator on the matter to be discussed – provision of documents in advance. Monitor effectiveness of action through the 2008 performance indicator questionnaire.	Throughout 2008

Annex 1

EMEA PERFORMANCE INDICATORS
INTERACTION WITH PATIENTS' AND CONSUMERS' ORGANISATIONS

Annex 1

London, 04 June 2007
Doc. Ref.: EMEA/345483/2006

EMEA Performance Indicators

Interaction with Patients' and Consumers' Organisations

Introduction:

As defined in the Framework on the Interaction between the EMEA and Patients' and Consumers' Organisations (http://www.emea.europa.eu/pdfs/human/pcwp/35451505en.pdf), the EMEA Management Board will be presented at the beginning of each year with the Work Plan of activities with Patients' and Consumers' Organisations, including performance indicators, jointly developed by the EMEA and Patients' and Consumers' Organisations.

Therefore, this questionnaire was developed to measure the degree of satisfaction by Patients' and Consumers' Organisations involved in EMEA activities.

It should be noted that this questionnaire only applies to the specific framework of interaction between EMEA and its Scientific Committees and Patients' and Consumers' Organisations.

Patients and consumers involved in EMEA activities will be asked to complete this questionnaire for each individual activity. In addition PCWP members/alternates will fill in this questionnaire annually.

The results from this questionnaire, together with any subsequent action proposed by the EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP), will be presented to the Management Board.

Questionnaire on degree of satisfaction* on the Interaction between EMEA and Patients' and Consumers' Organisations

***Please fill in all the "Explanation" boxes as it will help us to improve our interaction with you in the future**

Please indicate your level of satisfaction with the following*:

1. **Arrangements and facilities provided by the EMEA (for examples: invitations, travel arrangements, rooms, meeting services…)**

   ☐ Very satisfied
   ☐ Satisfied
   ☐ Neither satisfied nor dissatisfied
   ☐ Dissatisfied
   ☐ Very dissatisfied

Explanation:

2. **The supply of documents/information for participation in EMEA activities**

   ☐ Very satisfied
   ☐ Satisfied
   ☐ Neither satisfied nor dissatisfied
   ☐ Dissatisfied
   ☐ Very dissatisfied

Suggestion for improvement:

3. **Appropriateness and usefulness of documents for participation in EMEA activities.**

   ☐ Very satisfied
   ☐ Satisfied
   ☐ Neither satisfied nor dissatisfied
   ☐ Dissatisfied
   ☐ Very dissatisfied

Suggestion for improvement:

4. **The organisation of the EMEA meetings**

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Dissatisfied
- ☐ Very dissatisfied
- ☐ Not applicable

Suggestions for improvement:

5. **The implementation of your contribution and input to the EMEA activities**

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Dissatisfied
- ☐ Very dissatisfied

If your contribution has not taken into account, please provide details

6. **The consequences of the work carried out with the EMEA on your organisation**

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Dissatisfied
- ☐ Very dissatisfied

Explanation:

7. **The clarity and comprehension of the information available in the EMEA website for "patient groups" (http://www.emea.europa.eu/Patients/introduction.htm), if applicable.**

- ☐ Very satisfied
- ☐ Satisfied
- ☐ Neither satisfied nor dissatisfied
- ☐ Dissatisfied
- ☐ Very dissatisfied

Please explain why:

8. Overall interaction with the EMEA

☐ Very satisfied
☐ Satisfied
☐ Neither satisfied nor dissatisfied
☐ Dissatisfied
☐ Very dissatisfied

Please explain why:

9. Do you have any other comments or suggestions?

A) Which organisation(s) do you represent or you belong to? (optional)

B) In which EMEA activities have you been involved? (optional)

☐ Participation in PCWP
☐ Participation in other Working Parties? If yes, which one?
☐ Participation in workshop or other meetings organised by the EMEA
☐ Participation in review of documents (e.g. EPAR summaries, Patient Information Leaflet etc)
☐ Participation in a meeting or a consultation in relation to a specific marketing authorization procedure

Other, please specify:

Date completed :

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

Annex 2

EMEA SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) WORK PROGRAMME FOR 2008

Annex 2

London, 20 December 2007
Doc. Ref.: EMEA/478814/2007

2008 WORK PLAN FOR THE EMEA HUMAN SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS

CO-CHAIRPERSONS: ISABELLE MOULON (EMEA) - NIKOS DEDES (EATG)

1. MEETINGS SCHEDULED FOR 2008

- February 28th
- June 05th
- September 30th
- November 27th

2. INTRODUCTION

The 2008 Work Plan for the EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations aims to complete the implementation of the "Final Recommendations and Proposals for Action", adopted by the CHMP and subsequently published on the EMEA website.

The Working Party has been redefined, and its mandate and rules of procedure has been revised, taking into account the framework of interaction between the EMEA and Patients' and Consumers' Organisations, and the criteria to be fulfilled by Patients' and Consumers' Organisations prior to involvement in EMEA activities. On this basis, the Working Party will provide recommendations to the EMEA and its Human Scientific Committees on all matters of direct or indirect interest to patients in relation to medicinal products.

3. AREA OF PRODUCT INFORMATION

3.1 Quality Review of the Package Leaflet

- Patients' and Consumers' Organisations have been involved on the review of the PL at the time of the renewal.

  Action: Report on the activity performed in 2007 and monitoring of the involvement of PCOs during 2008. Discussion on the possible extension of the scope of the review.
  Consideration of proposal for the improvement of the content of the PL. 3/4Q2008

3.2 Quality Review of the EPAR Summaries

- **Action:** Report on the activity performed in 2007 and monitoring of PCOs involvement in the review of EPAR summaries, involvement in the review of Q&A documents. New proposal to be considered on the basis of the experience gained. 3/4Q2008

4. AREA OF PHARMACOVIGILANCE

4.1 Further progress on the recommendations from the EMEA/CHMP Working Group with Patients' Organisations on Pharmacovigilance

4.1.1 Patient Reporting

- Pilot experiences in some Member States, where patients themselves can report adverse reactions to the PhV systems, were presented during 2007.

  Action: further review the outcome of pilot exercises in the Member States where patients themselves can report adverse reactions to the PhV systems: presentation of the initiatives, and their comparison. 2/3Q2008

4.1.2. PhV Education Module

- The objective is to develop a training programme based on already existing experiences in PCOs, and which can be used afterwards for training of patients in the context of their respective organisations. The training will focus on pharmacovigilance, surveillance, risk communication

  Action I: The group will define a draft content of the training programme (headlines, objectives, main messages and definitions). 3/4Q2008

4.2 Other initiatives

4.2.1 European Commission Strategy to Strengthen the Community System for Pharmacovigilance

- **Action:** to provide support to the EC on the strengthening of the EU Pharmacovigilance system and on any legislative proposal, as requested by the Commission. 1/2Q2008

4.2.2 European Risk Management Strategy (Work programme 2008-2009)

- **Action:** to provide input in various areas which requires interaction with Patients' and Consumers' Organisations, such us:
  - access to EudraVigilance database,
  - how to further improve transparency and communication of safety issues to patients, including the PSUR evaluation reports

4.2.3 Risk/Benefit Communication

- Standardisation of quantitative measures for risk communication in EMEA documents.

  Action: review of the National Competent Authorities' studies on risk communication already presented to the group, in greater details. Discussion on concepts that need to be expressed, e.g. relative risks, absolute risks, frequency, and tools to better communicate on them, e.g. scales, charts. Explore the opportunity to develop a glossary of effective words in communicating risks and benefits. 3/4Q2008

5. AREA OF TRANSPARENCY AND DISSEMINATION

5.1 European Database on Medicines

- **Action:** to provide support to the EudraPharm project through all 2008.

5.2 EMEA Website

- **Action:** to provide input on the restructure of the EMEA website 2/3Q2008.

5.3 EMEA Awareness

- **Action I:** to explore and discuss the possibility to increase public awareness at the level of Patients and Consumers' Organisations 2/3Q2008.

  Action II: further promotion of "criteria to be fulfilled by PCOs involved in EMEA activities" to improve transparency in the process of selecting groups. In addition, eligible Patients' Organisations with interest in regulatory activities but not represented in the PCWP, will be invited to a plenary meeting once a year.

6. AREA OF INTERACTION BETWEEN EMEA AND PATIENTS' ORGANISATIONS

6.1 EMEA Interaction with Patients

- Involvement of member(s) of Patients' and Consumers' Organisations in EMEA Human Scientific Committees' related activities.

  Action I: Continue to monitor the involvement of PCOs in EMEA activities and to present a report in 4Q2008

  Action II: Explore how to further strengthen the interaction and participation of experts and representatives form PCOs in EMEA Human Scientific Committees/Working Parties' related activities. 1/2Q2008

6.2 Guidelines

- Procedure to flag guidelines under preparation or under revision with potential impact on product information to Patients' Organisations, so that input can be provided.

  Action: Proposal to be discussed by 1/2Q2008

7. ORGANISATIONAL MATTERS

7.1 Interaction with Health-Care Professionals

- Develop further interaction with HCPs. Identification of common areas of interest and possibilities for debate for the joint activities/meetings.

  Action: Proposal to be discussed by 1/2Q2008

7.2 Framework of Interaction – Satisfaction Questionnaire

- Continuing implementation and monitoring of specific performances indicators. Conclusions and results will be analysed, and adequate measures will be put in place accordingly

  Action: Implementation through 2008. Presentation of results to MB 4Q2008

Annex 3

EMEA ROAD MAP: 2008 – 2009 IMPLEMENTATION PHASE

European Medicines Agency

Annex 3

London, 22 November 2007
Doc. Ref. EMEA/515636/2007

EMEA ROAD MAP: 2008 – 2009 IMPLEMENTATION PHASE

I INTRODUCTION

The EMEA Road Map to 2010, which was launched in March 2005, is part of the Agency's longer term strategy. Its aim, as agreed in 2005 with the EMEA partners and stakeholders, is to contribute to better protection and promotion of public and animal health, to improve the regulatory environment for medicinal products, and to help stimulate innovation, research and development in the European Union (EU). This should be achieved within the context of the EU Regulatory System Network, hereafter called the "Network", through a close collaboration between the EMEA, the European Commission and the National Competent Authorities (NCAs) of the Member States.

Various initiatives have been undertaken since 2005 and progress made with the implementation of the EMEA Road Map has been described in two Status Reports which have been made publicly available, in May 2006 and October 2007 respectively (http://www.emea.europa.eu/htms/general/direct/roadmap/roadmapstatus.htm)

II SCOPE OF THE 2008 – 2009 EMEA ROAD MAP IMPLEMENTATION PLAN

The current EMEA Road Map Implementation Plan includes actions to be undertaken up to the end of 2007. Although excellent progress has been made (as shown in the aforementioned Status Reports), it should be noted that in some areas delays have been encountered. Such delays relate to certain aspects aiming at further strengthening the networking model, increasing the transparency of the EMEA activities, reinforcing the interaction with the Agency's stakeholders, and further improving the safety of medicines for veterinary use[1].

There are also a number of environmental changes which will impact on the operation of the EMEA and the Network over the next few years. The most important factors of a change relate to either the implementation of new Community legislation (advanced therapies) or the preparation for future Community legislation (in the fields of variations, pharmacovigilance, provision of information to patients, maximum residue limits). Alongside these legislative developments other factors which will affect the EMEA concern various initiatives undertaken by the European Commission to provide for better regulation and to reduce administrative burden, as well as new areas of EMEA activities which have emerged since 2005, notably in the field of paediatric and biosimilar medicines.

In addition, since the launch of the EMEA Road Map, Heads of Medicines Agencies (HMA) have developed an "HMA Strategy for the European Medicines Regulatory Network" (http://www.hma.eu/74.html) which will allow achieving a further strengthening

[1] For further details, please consult the document "Second Status Report on the Implementation of the EMEA Road Map" (http://www.emea.europa.eu/htms/general/direct/roadmap/roadmapstatus.htm).

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of the Network. Any initiatives as part of the further implementation of the EMEA Road Map to 2010 addressing networking aspects will have to be complementary to the actions identified in the context of the HMA Strategy Paper Work Plan.

The working methodology which has been applied for the elaboration of the next EMEA Road Map implementation phase takes due account of the aforementioned aspects, i.e. to (1) address not yet started / not yet completed initiatives identified in 2005, (2) complement, where relevant, actions undertaken within the frame of the HMA Strategy Paper Work Plan to strengthen the EU Regulatory System, and (3) cope with environmental changes which will impact on the EMEA over the next years.

III KEY INITIATIVES FOR THE 2008 – 2009 EMEA ROAD MAP IMPLEMENTATION PLAN

The key initiatives that are envisaged for the 2008 – 2009 implementation phase are described below. They have been presented as rather high-level initiatives and have been classified as per the EMEA priorities for the next two years.

Operation of the EU Regulatory System Network

An efficient operation of the Network is a prerequisite to ensure a successful implementation of the EMEA Road Map. Initiatives over the next years will be targeted to a further strengthening of various aspects of the networking model which should lead to a reinforcement of the already existing firm partnership between all EU Regulatory Authorities, ultimately resulting in a network of excellence.

Key Initiatives
• To further enhance the overall quality of the EU Regulatory System in the context of the work undertaken at EMEA level by - ensuring the availability of top quality scientific expertise (e.g. by strengthening the competence development and by formalising the process for workload and resource planning, both in collaboration with HMA), - strengthening and, where relevant, extending current peer review systems at the EMEA, - exploring within the context of the EMEA Process Improvement Exercise which areas could benefit from further process efficiency gains, - improving the current operation of an increasingly complex set of procedures interlinking the EMEA Scientific Committees and the Working Parties, and - exploring alternative practical ways to provide the EMEA Scientific Committees and the Working Parties with the necessary specialist input. • To provide for a high-quality EMEA Secretariat professional workforce by - in accordance with the new legal provisions, further clarifying the respective roles and responsibilities of the EMEA Secretariat and the EMEA Scientific Committees' members and experts, - further improving the operation of the Agency (including a reinforcement of corporate Information Technology (IT) tools) and implementing any necessary organisational changes, and - developing and implementing an EMEA Competence Development Strategy. • To deliver a high-quality IT infrastructure by progressing the implementation of the EU Telematics Master Plan and by addressing specific needs in the field of electronic submissions and inter-operability, in close collaboration with HMA.

Key Initiatives
• To provide for an appropriate funding of the Network in the context of the work undertaken at EMEA level by - implementing generally accepted international costing methods, - proposing to the EMEA Management Board alternative options for establishing a new remuneration scheme for services provided by the NCAs, and - subsequently liaising with the NCAs as regards the implementation of the approach agreed at Management Board level. • To progress work in the field of GXP[2] by - following-up on the 2007 Clinical Trials Conference and continuing to facilitate the implementation of the Clinical Trials legislation through support to the NCAs, and - developing and strengthening policies and procedures on pharmacovigilance inspections.

Safety of medicines

Further improving the safety of medicines by enhancing the management of risks continues to be a top priority for the next years. Activities will be undertaken by the EMEA in close collaboration with HMA within the context of the European Risk Management Strategy (ERMS) (for medicines for human use) and the European Surveillance Strategy (ESS) (for medicines for veterinary use). Although a further improvement of the operation of the EU Pharmacovigilance System will remain high on the agenda, there will also be particular focus on a strengthening of the science and the methodology that underpins the safety monitoring. This should enable to move-up the evidence in accordance with the principles of the best evidence concept.

Key Initiatives
• To progress the ERMS in accordance with the ERMS rolling two-year Work Programme[3]. • To progress the ESS in particular by - further developing EudraVigilance Veterinary through the introduction of additional functionalities (e.g. data analysis tools), - establishing the concept of risk management plans, adapted to the needs of veterinary medicines, - facilitating work-sharing initiatives, and - strengthening communication on product safety to the professional community.

Research and innovation

The EMEA will continue to provide support to the European Commission's efforts to stimulate research and innovation in the EU. This primarily will be undertaken in the context of the Innovative Medicines Initiative (IMI) and the 7th Framework Programme. In addition, a number of complementary initiatives carried out by the Agency should help addressing bottlenecks in the area of drug development. Such initiatives also come

[2] GXP refers to Good Clinical Practices, Good Laboratory Practices and Good Manufacturing Practices.

[3] Please consult the document "Implementation of the Action Plan to Further Progress the European Risk Management Strategy: Rolling Two-Year Work Programme (2008-2009)" for further information.

within the frame of the discussions held in the EMEA/CHMP Think-Tank group on innovative drug development.

Key Initiatives
• To implement the Action Plan resulting from the EMEA/CHMP Think-Tank group report on innovative drug development. • To further progress the Small and Medium-sized Enterprise (SME) concept by - introducing measures to tailor assistance to SMEs in the critical period between scientific advice and the marketing authorisation application, - collecting information on technologies/therapies under development by SMEs to better forecast the need for specific knowledge based expertise, and - developing and implementing the concept of SMEs within the Network.

Availability of medicines

Bringing medicines fast to the market will continue to be a key target for the EMEA. Although experience with the centralised procedure has shown the Agency's capability of delivering fast reviews, particular emphasis will have to be put on the monitoring of the implemented legal tools and the introduction of new legislative provisions in the field of Advanced Therapies. The Agency will also continue its efforts to introduce further improvements in the current regulatory licensing process for medicines for human use within the context of the EMEA Process Improvement exercise. In the field of veterinary medicines, the EMEA will respond to regulatory reform proposals expected from pharmaceutical industry.

Key Initiatives
• To implement new Community legislation on Advanced Therapies (e.g. by setting-up the new Committee on Advanced Therapies and by preparing the necessary guidance documents for regulators and pharmaceutical industry). • To progress work at the level of the CHMP/CVMP on a strengthening of the methodology for benefit/risk analysis to improve consistency of opinion-making at Committee level. • To extend the existing scientific advice procedure for human medicines to include biomarkers. • To progress work in the field of paediatrics by - monitoring the implementation of the new legal provisions and taking remedial action, whenever needed, - agreeing the strategy and establishing the EMEA network of paediatric research, and - establishing the inventory of paediatric needs based on the survey of off-label paediatric use at the level of the Member States.

Specific needs for veterinary medicines

The specificities of the veterinary sector will require efforts to be continued in 2008 and 2009 in order to address specific needs of medicines for veterinary use. Lack of availability of veterinary medicines especially for minor species and limited markets, concerns as regards the development of antimicrobial resistance in man and animals, as well as the environmental safety of medicines necessitate targeted actions over the next years.

Key Initiatives
• To progress the actions outlined in the HMA Action Plan on the availability of medicines for veterinary use[4]. • To work with relevant organisations in developing science based policies for the use of antimicrobials. • To continue and, if possible, extend the current pilot scheme for free scientific advice for veterinary medicines for minor species and limited markets. • To optimise good pharmacovigilance practice. • To balance, in the context of the implementation of Community legislation on environmental risks, the legislative requirements versus the impact on the availability of medicines for veterinary use.

Needs for specific classes of medicines

Specific classes of medicines (biosimilar and generic medicines, non-prescription medicines, herbal medicines) will require targeted actions to improve their management through the centralised licensing route. These actions come on top of initiatives undertaken in the context of the aforementioned EMEA Process Improvement exercise.

Key Initiatives
• To address specific needs for certain classes of medicines by - introducing the necessary measures to maintain consistency for opinions taken for centrally authorised biosimilar and generic medicines, - implementing in the case of non-prescription medicines a formal platform for regular interaction with non-prescription pharmaceutical industry to address potential hurdles in the submission of applications processed through the centralised licensing route, and - exploring for herbal medicinal products the possibility of complementary initiatives to progress the establishment of monographs and list entries, such as the involvement of academia alongside the resources made available by the Network.

Transparency

Openness of operation has since the start of the EMEA been an important feature. This has resulted in numerous initiatives to improve transparency of EMEA activities. Efforts over the next years will be directed to both transparency on product and non-product related issues. The Agency's partners and stakeholders will be involved in discussions on how to meet the increasing demands of patients/users of medicines and healthcare professionals on earlier information whilst respecting commercial confidentiality of proprietary information.

Key Initiatives
• To fully implement all outstanding transparency initiatives, such as the 2003 EMEA Transparency Policy measures (e.g. the revision of the EMEA website, publication of safety bulletins for medicines for human use), not yet completed initiatives stemming from the 2005 EMEA Road Map in the field of non-product related issues (e.g. publication of agendas and minutes/meeting summaries of EMEA fora), and access to the various Eudra databases.

[4] For further information, please consul the document "Report of the Task Force on Availability of Veterinary Medicines 2007" (http://www.hma.eu/203.html).

Key Initiatives
• To explore, through a debate with the Agency's partners and stakeholders, how to further improve transparency on product related issues. • To increase the transparency on the Agency's opinion-making, including the rationale for such opinion-making. • To also initiate a debate with the EMEA stakeholders on the draft EMEA Policy on access to EMEA documents.

Communication and provision of information

Communication and provision of information has been expanded and strengthened over the past years, resulting in an improved transparency of the Agency's work, more patient friendly information, as well as the launch of new tools for acquiring information on medicines (such as the EudraPharm database). In order to further progress in this field, there is a need to ensure an appropriate coherence and coordination in relation to the different types of information the EMEA provides, and the tools with which this information is communicated.

Key Initiatives
• To review the current EMEA communication tools, taking due account of a stakeholder analysis, and to subsequently implement the revised tools. • To develop a coherent communication platform at the EMEA, combining all communication tools, with primary focus on the revision of the EMEA website. • To maintain and further develop the various Eudra databases which provide input into the EMEA communication platform. • To initiate a debate with the NCAs on how the EMEA can better assist the NCAs in the provision of information as per current Community legislation (i.e. information about centrally authorised products to the public and healthcare professionals, and information concerning pharmacovigilance to healthcare professionals). • To develop a communication structure for dissemination of information through the Network.

Interaction with stakeholders

Since its establishment the EMEA has initiated interaction with its stakeholders (patients, consumers and users of medicines, healthcare professionals, pharmaceutical industry, academia and learned societies). It has to be recognised that such interaction has evolved over time. Over the next years the Agency will strive for a more homogenous approach, both in terms of the level of interaction with each stakeholder as well as the involvement of the stakeholders in the various fields of EMEA activity.

Key Initiatives
• To streamline the interaction between the EMEA (i.e. the EMEA Secretariat as well as the various EMEA Scientific Committees) and pharmaceutical industry by progressing the development of a Best Practice Guide and subsequently implementing it. • To strengthen, in the field of medicines for human use, the interaction with patients by identifying additional EMEA activities which could benefit from patients' involvement, and by monitoring the yearly "satisfaction survey" and introducing improvements, whenever necessary.

Key Initiatives
• To reinforce, in the field of medicines for human use, the interaction with healthcare professionals by establishing a dedicated EMEA Scientific Committees' Working Party with Healthcare Professionals' Organisations, building on the achievements made at the level of the current Working Group, by finalising and implementing a formal framework of interaction and by taking forward recommendations for action proposed by the Working Party. • To strengthen the interaction with academia and learned societies by including them in the provision of high-quality specialist training as per the joint EMEA/HMA Competence Development Strategy and by collaborating with these organisations in the field of outcome assessment in accordance with the EMEA Outcome Assessment Agenda. • To communicate with Health Technology Assessment Bodies on how to increase transparency with respect to the Agency's rationale for opinion-making.

International collaboration

Over the years the EMEA has been confronted with an increasing demand for collaboration with non-EU Regulatory Authorities, irrespective if this was undertaken within the context of formal Confidentiality Arrangements concluded between the EU and such Authorities, or through a less formal route of interaction. This phenomenon comes on top of an already existing international collaboration in the frame of fora such as the (V)-International Conference on Harmonisation (ICH), the Food and Agricultural Organisation (FAO), the Codex Alimentarius, the Office International des Epizooties (OIE) and Mutual Recognition Agreements (MRAs). It is envisaged for these international activities to become more important over the next years, alongside initiatives to further facilitate accession to the EU in the frame of pharmaceutical regulation. The EMEA, therefore, will focus its efforts on a strengthening of its involvement on the international scene with due respect of the Network in which it operates.

Key Initiatives
• To develop a framework for managing the Agency's international relationships and commitments. • To promote a greater visibility and involvement of the Network in international activities. • To progress activities on Confidentiality Arrangements with non-EU Regulatory Authorities in coordination with the European Commission. • To facilitate involvement of Accession and Candidate Countries in EMEA activities. • To identify, in cooperation with the World Health Organisation (WHO), possible measures to assist developing Countries on regulatory matters in the context of Article 58 provisions. • To strengthen the oversight of clinical trials (including ethical principles) performed outside the EU by developing links with local regulators. • To provide support in the areas of avoidance of duplication of inspections and prevention of double standards, and prevention of counterfeit medicines.

Forthcoming regulatory initiatives

In addition to the aforementioned actions, the EMEA will contribute to forthcoming regulatory initiatives such as the preparation and subsequent implementation of new Community legislation (e.g. in the fields of variations, information to patients, maximum residue limits, pharmacovigilance). The Agency will also provide support to policy

initiatives undertaken by the European Commission (e.g. the Transatlantic Administrative Simplification exercise).

IV PLANNING AND REPORTING

The same methodology for planning and reporting as adhered to so far will apply during the next two year period. The aforementioned key initiatives will be included, where applicable, in the 2008 and 2009 EMEA Work Programme respectively. Information on the follow-up to all initiatives undertaken within a specific year will be provided in a yearly Status Report which will be made publicly available.