European Medicines Agency
Post-authorisation Evaluation of Medicines for Human Use

London, 01 October 2009
Doc. Ref. EMEA/259449/2009

SECOND REPORT ON THE PROGRESS OF THE INTERACTION WITH PATIENTS' AND CONSUMERS' ORGANISATIONS AND ANALYSIS OF THE DEGREE OF SATISFACTION OF PATIENTS AND CONSUMERS INVOLVED IN EMEA ACTIVITIES DURING 2008

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Table of Contents

Executive Summary

Introduction

In 2005, at the time of endorsing a specific framework in the field of interaction between EMEA and Patients' and Consumers' Organisations (PCOs) (EMEA/354515/2005-Final), the EMEA Management Board requested that an annual report on the progress of the interaction should be presented to the Board in order to monitor activities defined in the Framework. It requested that this report be accompanied with the results of performance indicators developed to measure the degree of satisfaction for every patient and consumer involved in EMEA activities for each year.

The first report covered activities performed during 2007 and was presented to the EMEA Management Board in March 2008. It showed that all actions identified in the framework of interaction had been implemented, and that the work achieved so far has established the grounds towards a more systematic interaction and involvement of PCOs representatives at different levels of the Agency's work.

This present report describes the continued progress of this interaction during 2008, including the status of implementation of those actions and recommendations which were identified in the previous report. It also shows results of performance indicators for 2008 and its analysis.

Both the progress on the interaction with PCOs 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 5th March 2009. Outcomes and proposed recommendations were discussed and agreed. The final report is presented to the Board on 1st October 2009.

The report is divided in two sections:

Section 1: Overview of PCOs involvement in EMEA activities during 2008.

This section describes the progress of the interaction with PCOs during 2008, including the work undertaken by the PCWP, as well as the achievements related to the provision of information to the patients and the general public.

Section 2: Analyses of the degree of satisfaction of PCOs involved in EMEA activities during 2008.

To carry out this analysis, the EMEA developed a "performance indicator questionnaire" in conjunction with the PCWP which was distributed at the end of the year to every patient and consumer who participated in EMEA activities during 2008. The methodology, results and analysis of the feedback received is presented in this section.

Outcome

Progress on the interaction with PCOs during 2008

2008 has seen an important increase in the number of PCOs representatives who have been involved in EMEA activities (from **77** in 2007 to **165** in 2008). This is mainly attributed to the increase in participation in the review of the quality of product related information procedure, but also to an increase in participation at all levels of the Agency work (e.g. more members in scientific committees, more participation in working parties (WPs) and other EMEA events).

Conclusions from last year's report provided evidence that all actions identified in the Framework of Interaction had been implemented and contacts had been established between the PCOs and the EMEA Management Board, the EMEA Scientific Committees, Working Parties and Scientific Advisory Groups. However, although the groundwork had been done there remained the need to further formalise and improve on the procedural aspects of these interactions, such as the need for a more systematic approach towards PCOs involvement within the different areas of the Agency's work. In this regard, within the scope of the 2007 report, endorsed by the MB, the EMEA has been working during 2008-2009 on the preparation of a "Reflection Paper" which explores how to further develop the interaction in a more systematic way, and which proposes specific actions for implementation. The "Reflection Paper" will be presented to the EMEA Management Board later in 2009.

With regard to the provision of information, the EMEA has continued implementing measures aimed at improving the quality of the product related information adapted and oriented to patients. The scope of the procedure which was already in place has been extended during 2008, so that EMEA now involves PCOs representatives during the preparation of more documents. (i.e. review of EPAR summaries and Package Leaflets).

Analysis of the degree of satisfaction of patients/consumers involved in EMEA activities in 2008

The actions proposed last year as a result of analysis of 2007 performance indicators have been implemented for most of them (see table 4 in page 37).

The 2008 questionnaire was given to every patient/consumer who participated in an EMEA activity and includes questions on the overall interaction with the EMEA, the impact of their work both for the EMEA and for their organisations, as well as feedback on the use of EMEA facilities and the organisation of meetings by the Agency. In addition, part of the questionnaire has tested for the first time the level of satisfaction of patients/consumers who have participated in the review of the quality of product related information procedure.

The results and analyses of the performance indicators questionnaire show overall satisfaction. Following last year's approach, the analysis has been used to identify areas for improvement and to propose specific future actions which are listed in table 5 (page 39). These actions will be implemented during 2009/2010 and some will be incorporated in the PCWP Work Programme 2010. They have also been considered during the finalisation of the aforementioned "Reflection Paper".

Next steps

- The “Reflection Paper” on how to further involve PCOs in the EMEA activities will be presented to the EMEA Management Board later in 2009. It will define the strategy for interaction between EMEA and PCOs for the coming years. It will make specific proposals for actions which will be implemented by the EMEA further to the endorsement by the Board.

- PCOs representatives will continue to be involved in the preparation of information oriented to patients and the general public. The procedures in place will be operated, monitored and reviewed whenever necessary. The EMEA will ensure adequate support and training material to those PCOs representatives involved in the review procedure.

- The EMEA will explore the best way to involve patients/consumers in the preparation of additional EMEA information intended for the public (i.e. issues of critical interest to PCOs) and the best way to ensure timely and effective communication of this information.

- Actions identified through the analysis of the results of the compliance with the performance indicators will be implemented during 2009/2010. Some are already planned as part as the PCWP Work Programme for 2009 and some will be implemented in the PCWP Work Programme for 2010.

- The Management Board will be presented next year with a report on the progress achieved in 2009. It will also include an analysis of the compliance with the performance indicators during 2009.

Section 1

OVERVIEW OF PCOs INVOLVEMENT IN EMEA ACTIVITIES DURING 2008

Introduction

The first report on the progress of the interaction between EMEA and PCOs presented in 2008 identified the need to formalise the procedures which had been established and to further enhance the level of interaction. In this aspect, EMEA was requested to actively work together with the PCWP in exploring how to further develop a more systematic interaction and involvement of PCOs representatives at different levels of the Agency's work, paying particular attention to activities at the level of the different Scientific Committees. It was requested to develop a "Reflection Paper" with proposed actions on this aspect.

With regard to the provision of information, the 2007 report concluded that EMEA had implemented appropriate measures in order to improve the quality of the product information adapted and oriented to patients, and that procedures had been put in place to involve PCOs representatives in the preparation of such information (e.g. review of EPAR summaries and Package Leaflets). The EMEA was requested to continue involving PCOs representatives in the preparation of such information and in this respect, the procedures already in place were to be reviewed in order to introduce any necessary improvements and to extend the current scope of the exercise.

The following part of the report describes the different kind of activities in which PCOs representatives participated during 2008, and the contribution they made to each of them. It includes comparative analyses with the level of involvement during 2007. It also describes how the actions identified in the previous report have been implemented, and identifies the next steps in the interaction for this and the coming year (2010).

During 2008, the Agency incorporated more patients as formal members in its Scientific Committees (COMP, PDCO, CAT). The EMEA has also consulted patients on policy issues, product related matters, dissemination and preparation of information, as well as topics of general interest such as Work Programmes of Committees or Working Parties. These activities have very often been supported through the work of the PCWP but a wider network of organisations eligible to work with the EMEA has also been involved in many EMEA activities (see Table 1 in page 14 for the full list of activities).

1. EMEA MANAGEMENT BOARD (MB)

(Article 65 (1) of Regulation (EC) Nº 726/2004)

The MB membership includes two representatives from Patients and Consumers Organisations. The first mandate of three years was completed on 27 September 2008 by Mary Baker from the European Federation of Neurological Associations (EFNA) and Jean Georges from Alzheimer Europe (AE). Members are appointed by the Council after consulting the European Parliament.

For the next term of three years the PCOs representatives are Mary Baker and Mike O'Donovan from the European Patients Forum and they were officially nominated at the MB meeting on 5 March 2009.

A member from the Management Board has been attending the PCWP meetings during 2008 as an observer in order to maintain a link between the two groups.

2. EMEA SCIENTIFIC COMMITTEES

During 2008 more patients have become formal members of EMEA Scientific Committees. Additionally the different Committees have consulted PCOs representatives on specific issues when needed.

2.1. Committee for Orphan Medicinal Products (COMP)

(Article 4 (3) of Regulation (EC) Nº 141/2000)

The COMP includes in its membership two members nominated by the European Commission representing patients' organisations. In addition two patients' representatives attend regularly as observers. Their tasks during 2008 have included among others:

- Participation in the assessment of applications for Orphan Drug Designations and acting as coordinators for some of the applications.
- Participation in the Working Group on the review of the guideline on "Medical plausibility and significant benefit".
- Participation in the Working Group with interested parties.
- Present experience on patient involvement in the COMP to external parties, e.g. Health Canada.
- Providing advice on external experts when needed for the assessment of the Orphan Drug assessments.
- Collaboration in the preparation of PSOs (public summaries of opinion).

2.2. Paediatric Committee (PDCO)

(Article 4 (1.d) of Regulation (EC) Nº 1901/2006)

The PDCO includes in its membership three members and three alternates representing patients and consumers who are nominated by the European Commission. Their tasks during 2008 have included among others:

- Participation in the peer reviews of ongoing Paediatric Implementation Plan (PIP) applications, including presentation of their conclusions to the Committee in relation to the assessment of the PIP.
- Participation as PDCO representatives in other EMEA activities (e.g. drafting group on "Acceptance of clinical trials conducted in third countries, for evaluation in Marketing Authorisation Applications").

2.3. Committee for Advanced Therapies (CAT)

Article 21 (1.d) of Regulation (EC) Nº 1394/2007)

The composition of the Committee for Advanced Therapies foresees two members and two alternates. They were nominated by the European Commission for a renewable period of three years at the end of 2008.

The first meeting of the CAT was held on 15-16 January 2009.

2.4. Committee on Herbal medicinal products (HMPC)

There is currently no legal basis for patient membership in this Committee.

A member of the HMPC has regularly attended meetings of the PCWP as formal member of this Working Party.

Exploratory work on how to improve the way EMEA provides information on herbal medicines, on the need to involve patients in its preparation and on how to disseminate this information was initiated in 3/4Q2008. Further work on this aspect is to be performed during 2009.

2.5. Committee for Medicinal Products for Human Use (CHMP)

There is currently no legal basis for patient membership in this Committee. Interaction with CHMP and its Working Parties and Scientific Advisory Groups (SAGs) is based on article 78, indent (18) of Regulation (EC) Nº 726/2004. Participation of PCOs representatives has occurred in the following way:

- Participation in SAG meetings

  - One patient was invited to participate and contribute as an expert in the SAG for Tysabri.

- Participation in Scientific Advice Working Party (SAWP)

  - Patients as experts participated in 4 procedures for scientific advice during 2008. On three occasions they attended the meeting and in one case the patient attended via teleconference.

  - SAWP organised a discussion meeting on Duchene Muscular Atrophy, to which patients' representatives were invited to participate.

- Participation in guideline preparation (Gene Therapy Working Party (GTWP) and Efficacy Working Party (EWP))

  - Patients have participated actively in the preparation of two guidelines prior to their release for consultation: 1 expert collaborated in the "Guideline for HIV drug development" and 2 experts collaborated in the preparation of the "Guideline for follow-up of patients who have been administered gene therapy medicinal products". In the later case they attended the meetings of the GTWP.

- Participation in the Pharmacovigilance Working Party (PhVWP)

  - 2008 saw preparatory work for involvement of patients and consumers in the meetings of the PhVWP. Implementation of this proposal will be done during 2009. A pilot phase run for 3 consecutive months and two patient members of the PCWP attended the PhVWP as observers. Based on the experience acquired, a report will be prepared by October 2009.

  - The Pharmacovigilance Working Party (PhVWP) has sought the views of the patients and consumers on a proposed wording of the Package Leaflet of some medicines (e.g. antiepileptic).

3. ACTIVITIES IN RELATION WITH PROVISION OF INFORMATION TO PATIENTS/GENERAL PUBLIC

As expressed in the 'Framework on the Interaction between the EMEA and Patients' and Consumers' Organisations' (EMEA/354515/2005), to ensure that the Agency provides information in a way that fulfils patients' and the general public's expectations, the EMEA needs to set up adequate consultation with PCOs.

Patients have been regularly involved in several aspects regarding the provision of information on EMEA activities to patients and the general public. These activities include feedback from patients on the readability of information contained in product information, public statements and similar materials intended for the public.

The procedure for the review of EPAR summaries and PLs at the time of renewal was implemented as of May 2007 (EMEA/279083/2006 Rev 1) following the identification of a list of experts and the organisation of initial training on reviewing procedures. The purpose of this consultation is to ensure that the information is clear and understandable by the target audience, and that it fulfils their needs in terms of information content.

The analysis of the experience so far demonstrates that the majority of comments received are of high quality and useful and that in general their contribution increases the quality of the documents within the scope of this procedure.

Since the procedure was initiated, PCOs have been reviewing the PLs of those medicines for which a renewal application has been submitted (i.e. five years after initial authorisations). Further to the positive experience acquired and further to the proposal in the 2007 report to extend the scope of this review procedure, since September 2008 the review also includes PLs for *new* medicines (i.e. initial marketing authorisations). For EPAR summaries, PCOs will continue to be involved in the review of those for newly authorised medicinal products, as before.

In addition, as a follow-up from the recommendations from the previous report, training for experts involved in the review is now organised annually.

- **Review of EPAR summaries**

  During 2008 PCOs representatives reviewed a total of 39 new EPAR summaries.

- **Review of Package Leaflets**

  During 2008, PCOs representatives reviewed a total of 43 Package Leaflets (PL). This includes PLs at the time of renewal and also at the time of initial evaluation for marketing authorisation.

- **Involvement in EMEA safety communication**

  Appropriate safety information is provided when necessary to the general public, usually in the form of Q&A documents and press releases. Patients have been involved in the preparation and dissemination of EMEA communications of selected safety issues. Examples of this involvement are communication on Exubera, Viracept and Neupro.

  Feedback received from this interaction is very positive as patient contribution results in an added value to the outcome. Work towards a more systematic involvement of patients in safety communication by the EMEA will be performed during 2009.

- **The provision of additional information in relation to the Agency's activities**

PCOs were also involved during 2008 in the ongoing development of EudraPharm, the European database aimed at providing information to the public on all medicinal products authorised in the EU. PCOs carried out user-testing on proposals for improvements to the database and attended a plenary EudraPharm TIG meeting.

PCOs have also participated in the workshop on the EudraCT public website.

They have been also involved in different aspects of the ongoing reconstruction of the EMEA website during 2008, where their input has been of much value.

4. OTHER ACTIVITIES

4.1. EMEA Working Party with Patients' and Consumers' Organisations (PCWP)

The PCWP has continued to play an essential role in the progress of the interaction between the EMEA and PCOs. PCWP composition during 2008 has comprised:

- 10 members from PCOs and 8 alternates.

- 5 members from EMEA Scientific Committees (CHMP, COMP, PDCO, HMPC).

- 4 Observers (CMD(h)), HCP WG and Management Board).

PCWP activities during 2008 included four plenary meetings, one comprising all organisations which fulfil the eligibility criteria (following a recommendation in the 2007 report). In addition, one joint meeting with healthcare professionals and a one-day training session for experts involved in the review of product related information was organised. Different drafting groups on specific issues were also held (e.g. consultation meeting on website restructure, EudraPharm user-testing, EC legal proposal on Information to Patients, etc.).

PCWP was also consulted by other groups (PhVWP and CMD (h)) on the PL wording of certain medicines (e.g. oxycodone, antiepileptic drugs).

Through the PCWP, patients and consumers representatives have been involved in other projects, as in the case of the Innovative Medicines Initiative (IMI).

4.2. EMEA Conferences and Workshops

PCOs representatives have also participated in an increasing number of events organised by the EMEA in comparison with 2007. See table 1 on the next page for the full list of activities including complete details on these events.

Table 1: Activities involving patients at the EMEA during 2008

Management Board/Scientific Committees	MB (Members)
	COMP (Members & Observers)
	PDCO (Members)
Working Parties/ Working Groups	PCWP (Members & Observers)
	HCP WG (Observers)
	EWP - HIV Drug Development Guideline
	GTWP meeting (participants) - Guideline for follow-up of patients who have been administered gene therapy medicinal products
Ad Hoc/SAG meetings	SAG for Tysabri
	SAWP meeting on Duchene Muscular Dystrophy
	SAWP – participation as experts in the review of four SA requests
Safety communications	Viracept - Press release and Q&A (update)
	Exubera - Q&A - Safety communication
	Neupro - review a Q&A
Product information related activities	Review of new Package Leaflets
	Review of new EPAR summaries
	Review of mock-ups (multi-lingual packages) (Sprycel & Baraclude)
	Training on review of product information documents
	Review of new wording for section 5 (frequency definition of side effects) in PL
	Review of new wording to be added to PLs of erythropoietins
	PhVWP consultation on PL wording of anti-epileptic drugs and risk of suicide
	CMD(h) consultation on PL wording for Oxycodone
	Revision of Public Summary of Opinions for the COMP
Workshops	EudraCT Paediatrics Patient Group Consultation for Public Web Site Workshop
	EMEA Workshop on SMA Outcomes - EMEA/TREAT-NMD
	Workshop on user testing DIA-EMEA
Conferences	INFARMED: Annual Conference "New Therapies: The Challenges for Innovation" topic: "Clinical Trials: New Challenges"
Other meetings	European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
	Meeting on the EMEA on-line strategy and web-site design
	Drafting Group of Patients' and Consumers' Organisations members of the PCWP on **"**EC Legal Proposal on Information to Patients**"**
Input on other projects	EMEA website survey
	Update on the PCOs website
	IMI involvement
	EudraPharm development

5. ORGANISATIONS INVOLVED IN EMEA ACTIVITIES IN 2008

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 PCOs 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 from 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 which, 21 have received a positive outcome, 20 have received a negative one, and for 5 assessments are ongoing. The main reasons for a negative outcome related to a lack of fulfilment of the definition of Patients'/Consumers' organisation or a lack of EU representativeness.

As a consequence of this exercise, a growing number of patients' and consumers' organisations are now able to participate in EMEA activities. This ensures that the Agency has direct contact with a suitably wide range of PCOs, and that their views correctly represent the needs and concerns of PCOs representatives 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/161660/2005)", 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 evaluation and which organisations have been involved in different EMEA activities during 2008.

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

During 2008 a total of 26 Patients' or Consumers' Organisations were involved with the EMEA (during 2007 a total of 24 were involved).

	NAME OF ORGANISATION	FULFILMENT OF EMEA ELIGIBILITY CRITERIA*	Involvement in 2008
1	Alzheimer Europe (AE)	**YES**	√
2	European AIDS Treatment Group (EATG)	**YES**	√
3	European Cancer Patient Coalition (ECPC)	**YES**	√
4	European Consumers' Organisation (BEUC)	**YES**	√
5	European Federation of Neurological Associations (EFNA)	**YES**	√
6	European Genetic Alliances' Network (EGAN)	**YES**	√
7	European Heart Network (EHN)	**YES**	
8	European Multiple Sclerosis Platforms (EMSP)	**YES**	
9	European Myeloma Platform (EMP)	**YES**	√
10	European Organisation for Rare Diseases (EURORDIS)	**YES**	√
11	European Parkinson's Disease Association (EPDA)	**YES**	√
12	European Patients' Forum (EPF)	**YES**	√
13	European Public Health Alliance (EPHA)	**YES**	√
14	Health Action International (HAI)	**YES**	√
15	Insulin Dependent Diabetes Trust (IDDT)	**YES**	√
16	International Alliance of Patients' Organizations (IAPO)	**YES**	√
17	International Diabetes Federation (IDF)	**YES**	√
18	International Patient Organisation for Primary Immunodeficiencies (IPOPI)	**YES**	√
19	Myeloma Euronet (ME)	**YES**	√
20	Rett Syndrome Europe (RSE)	**YES**	√
21	Thalassemia International Federation (TIF)	**YES**	√
22	International Confederation of Childhood Cancer Parent Organisations (ICCCPO)	**NO**	√
23	The Jennifer Trust for Spinal Muscular Atrophy (JTSMA)	**NO**	√
24	TREAT-NMD Neuromuscular Network	**NO**	√
25	Muscular Dystrophy Association (MDA)	**NO**	√
26	SMA Trust - Spinal Muscular Atrophy (SMA)	**NO**	√
27	Association Francaise contre les myopathies	**NO**	√
28	United Parent Projects Muscular Dystrophy (UPPMD)	**NO**	√

6. OVERVIEW OF EMEA ACTIVITIES IN WHICH PCOS REPRESENTATIVES WERE INVOLVED DURING 2008

During 2008, 165 PCOs representatives were involved in EMEA activities. In some cases the same patient/consumer participated in more than one activity.

The activities have been split into three categories; activities requiring experts, activities requiring representatives of individual organisations and activities where patients are members (e.g. committees/working parties).

Table 3: activities involving PCOs representatives **at the EMEA during 2008**

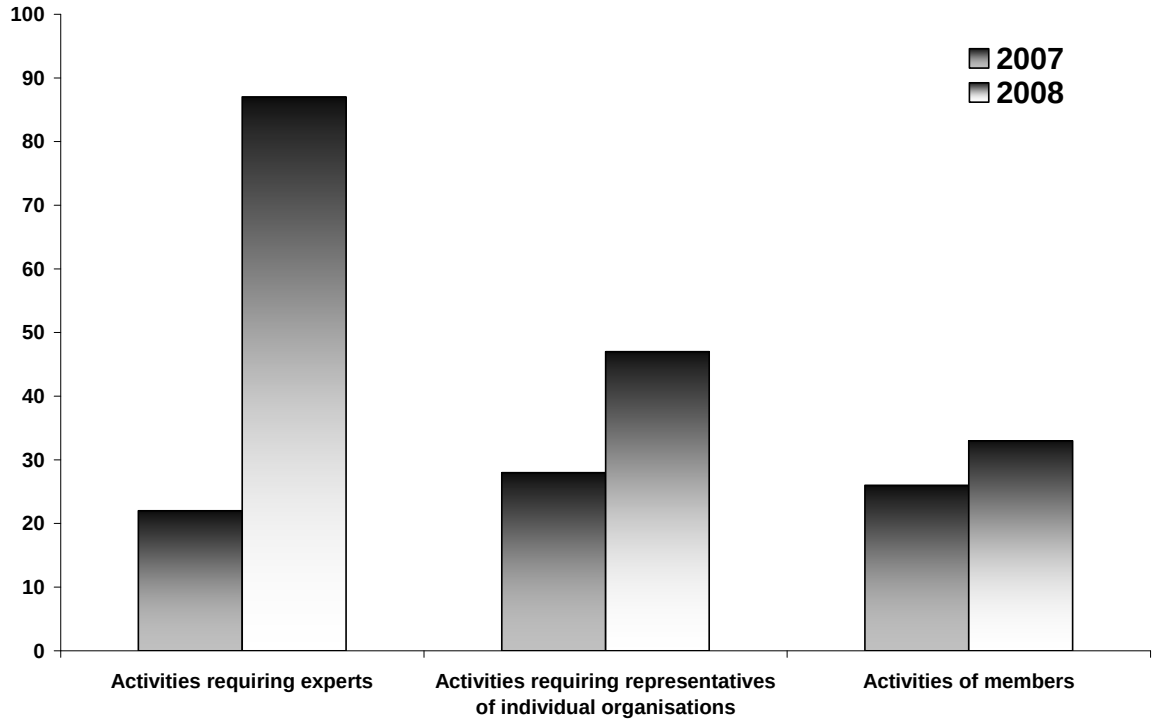
ACTIVITIES REQUIRING EXPERTS	**Nº OF EXPERTS**
SAG meeting on Tysabri	1
SAWP meeting on Duchene Muscular Dystrophy	1
SAWP – participation as experts in the review of four SA requests	4
Review of new wording to be added to PLs of erythropoietins	3
Neupro – review a Q&A	1
Viracept – Press release and Q&A (update)	1
Exubera – Q&A – Safety communication	1
GTWP meeting – Guideline for follow-up of patients who have been administered gene therapy medicinal products	2
Interest in joining Applicant Consortium for IMI	1
Training on review of product information documents	25
Review of mock-ups x 2	2
Review of 39 EPAR summaries	17
Review of 43 Package Leaflets	21
TOTAL	87

ACTIVITIES REQUIRING REPRESENTATIVES OF INDIVIDUAL ORGANISATIONS	**Nº OF REPRESENTATIVES**
Workshop on user testing DIA-EMEA	3
Meeting with research centres and interested parties on ENCePP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance)	1
EMEA Workshop on SMA Outcomes - EMEA/TREAT-NMD	8
INFARMED: Annual Conference "New Therapies: The Challenges for Innovation" topic: "Clinical Trials: New Challenges"	1
EudraPharm development – Participation in EudraPharm TIG meeting	1
EudraCT Paediatrics Patient Group Consultation for Public Web Site Workshop	9
Meeting on the EMEA on-line strategy and web-site design	13
Drafting Group of Patients' and Consumers' Organisations on **"**EC Legal Proposal on Information to Patients**"**	11
TOTAL	47

ACTIVITIES OF MEMBERS	Nº OF INDIVIDUALS
Members of the EMEA Management Board	2
Observers at the Healthcare professionals' Working Group	1
Members & Observers of the COMP	4
Members and alternatives of the PDCO	4
Patients and Consumers Organisations Working Party (members + alternates from the organisations) Other experts who attended PCWP	11 + 6 3
TOTAL	31
TOTAL NUMBER	**165**

NUMBER OF ACTIVITIES: COMPARATIVE ANALYSIS BETWEEN 2007 AND 2008

In the graph below we have compared the number of different activities involving patients/consumers as experts, representatives and members during 2008 with those of 2007.



We can see that, compared to 2007, there were significantly more participants in the different activities during 2008.

Experts:

There were 87 experts involved during 2008 compared to 22 in 2007 which can mainly be attributed to:

- Additional review of new Package Leaflets (previously only for renewals) at the time of initial evaluation for marketing authorisation.
- New training on the review of product information documents (no training in 2007).
- More participation in Scientific Advice activities.

- More participation in safety communications (only 1 example in 2007).

Representatives:

There were 47 Representatives involved during 2008 compared to 28 in 2007 which can mainly be attributed to an increase in participation of PCOs representatives in EMEA Conferences and Workshops, as well as other activities such as consultation on the website reconstruction.

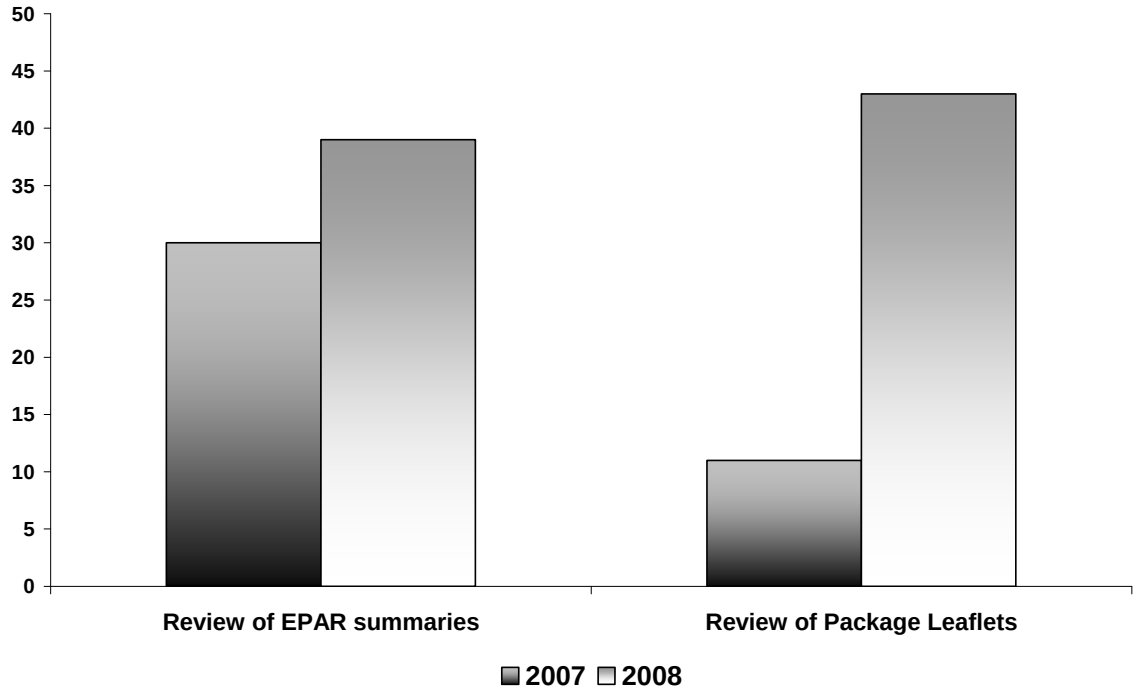
Members:

There was also an increased participation in the number of members involved due to the new members and alternatives for the PDCO (not in 2007).

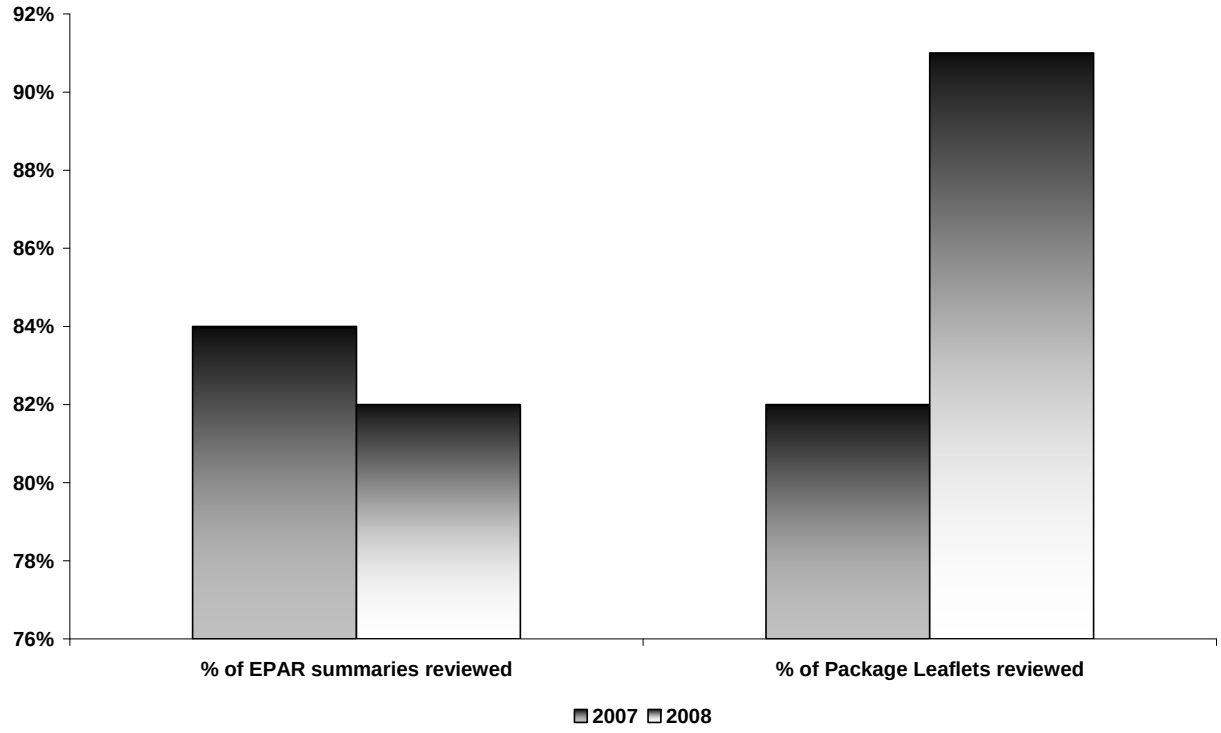
DOCUMENT REVIEW PROCEDURE (PACKAGE LEAFLET AND EPAR SUMMARIES):

COMPARATIVE ANALYSIS BETWEEN 2007 AND 2008

A) The graph below shows the number of reviews of EPAR Summaries and Package Leaflets carried out in 2007 compared to 2008. As already explained, the increase in the number of Package Leaflets reviewed is due to the extension of the scope of the procedure to cover Package Leaflets at the time of initial evaluation for marketing authorisation.



B) This second graph gives an overview of the difference between 2007 and 2008 on the percentage of documents (EPAR summaries and Package Leaflets) for which comments from patients/consumers were received out of the total number of documents sent to them for review.



7. CONCLUSIONS AND NEXT STEPS

2008 has seen an important increase in the number of PCOs representatives who have been involved in EMEA activities (from **77** in 2007 to **165** in 2008). This is mainly attributed to the increase in participation in the review of the quality of product related information procedure, but also to an increase in participation at all levels of the Agency's work (e.g. more members in scientific committees, more participation in WPs and other EMEA events).

Conclusions from last year's report evidenced that all actions identified in the Framework of Interaction had been implemented and contacts had been established between the PCOs and the EMEA Management Board, the EMEA Scientific Committees, Working Parties and Scientific Advisory Groups. However, although the groundwork had been done there remained the need to further formalise and improve on the procedural aspects of these interactions, such as the need for a more systematic approach towards PCOs involvement within the different areas of the Agency's work. In this regard, within the scope of the 2007 report, endorsed by the MB, the EMEA has been working during 2008-2009 on the preparation of a "Reflection Paper" which explores how to further develop the interaction in a more systematic way, and which proposes specific actions for implementation. The "Reflection Paper" will be presented to the EMEA Management Board later in 2009.

With regard to the provision of information, the EMEA has continued implementing measures aimed at improving the quality of the product related information adapted and oriented to patients. The scope of the procedure which was already in place has been extended during 2008, so that EMEA now involves PCOs representatives during the preparation of more documents (i.e. review of EPAR summaries and Package Leaflets).

Next steps

- The "Reflection Paper" on how further involve PCOs in the EMEA will be presented to the EMEA Management Board later in 2009. It will define the strategy for interaction between EMEA and PCOs for the coming years. It will make specific proposals for actions which will be implemented by the EMEA further to the endorsement by the Board.

- PCOs representatives will continue to be involved in the preparation of information oriented to patients and the general public. The procedures in place will be operated, monitored and reviewed whenever necessary. The EMEA will ensure adequate support and training material to those PCOs representatives involved in the review procedure.

- The EMEA will explore how best make patients/consumer participate in the preparation of additional EMEA information intended to the public (i.e. issues of critical interest to PCOs) and how best ensure timely and effective communication of this information.

Section 2

ANALYSIS OF THE DEGREE OF SATISFACTION OF PATIENTS/CONSUMERS INVOLVED IN EMEA ACTIVITIES DURING 2008

1. QUESTIONNAIRE ON DEGREE OF SATISFACTION

Since 2007 the EMEA has been measuring the degree of satisfaction of patients/consumers who have been consulted or involved in the EMEA activities. This has been considered as an essential tool to monitor the progress of the interaction, to identify areas for improvement and to propose specific actions. For 2008 a new questionnaire has been developed by the EMEA together with the PCWP, taking into account analyses and measures from previous years, but adapting to the specific activities in which the interaction is currently focusing.

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

A total of 41 valid questionnaires have been received and they form the basis for the current analysis. This figure does not represent the totality of patients/consumers who have been involved in the different activities, as not all participants responded; however it has notably increased compared with the number of questionnaires received last year.

The questionnaire includes 10 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 comments. The questions cover different aspects such as the value of the interaction between the EMEA and patients/consumers, and facilities and organisation of meetings by the EMEA. For the first time, this questionnaire explored the review procedure of product related information (Package Leaflet and EPAR summaries) after more than one year of operation.

In the last part of this section, all actions identified following analysis of last year’s performance indicators are presented. The implementation status for each action is specified. Finally, a new table of actions based on the results of 2008 analyses is presented.

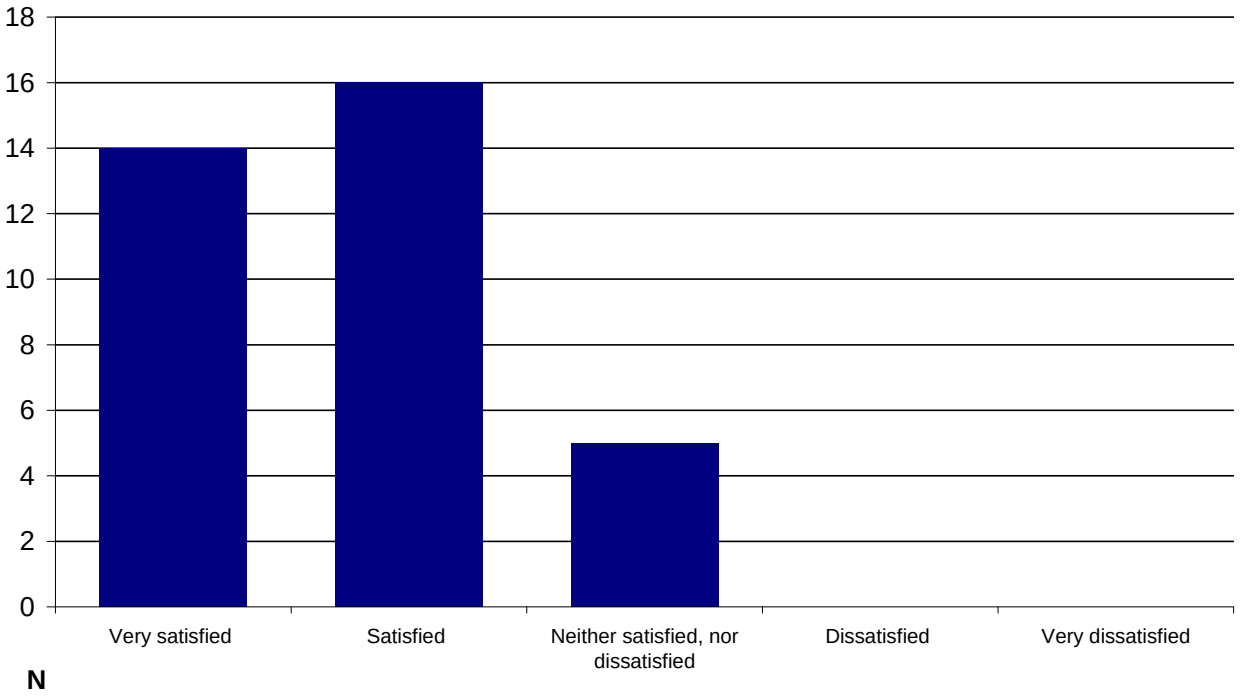
The questionnaire, attached in annex 1, could be filled in anonymously if preferred.

2. SCORING OF QUESTIONS AND SUMMARY OF COMMENTS RECEIVED

Question 1

Please indicate your level of satisfaction with:

The way the interaction between the EMEA and patients' and consumers' organisations has moved forward during 2008



Summary of comments received

Overall PCOs were very positive regarding the way the interaction between the EMEA and patients' and consumers' organisations has moved forward during 2008, in particular the responsiveness of the EMEA, its innovative and positive involvement of the PCO. They consider that EMEA is very good at communication, is transparent and informative and that the interaction is becoming more and more meaningful. *"We considered this interaction of prime importance and probably an example of how national authorities could have an interaction with patients' organisations".*

Many patients have commented that the interaction should be opened to more PCOs, and that they should be allowed to be represented in various EMEA activities.

In addition, feedback received shows a great interest from PCOs in enhancing the level of participation of PCOs representatives in EMEA activities. In this aspect, some patients noted some degree of disappointment since their organisation was not consulted for specific product related issues under evaluation by the Agency, which fell within the field of interest of his/her organisation.

Other comments referred to the need to increase the level of transparency of the Agency when it operates with PCOs. This refers to both the way the Agency communicates and interacts with PCOs.

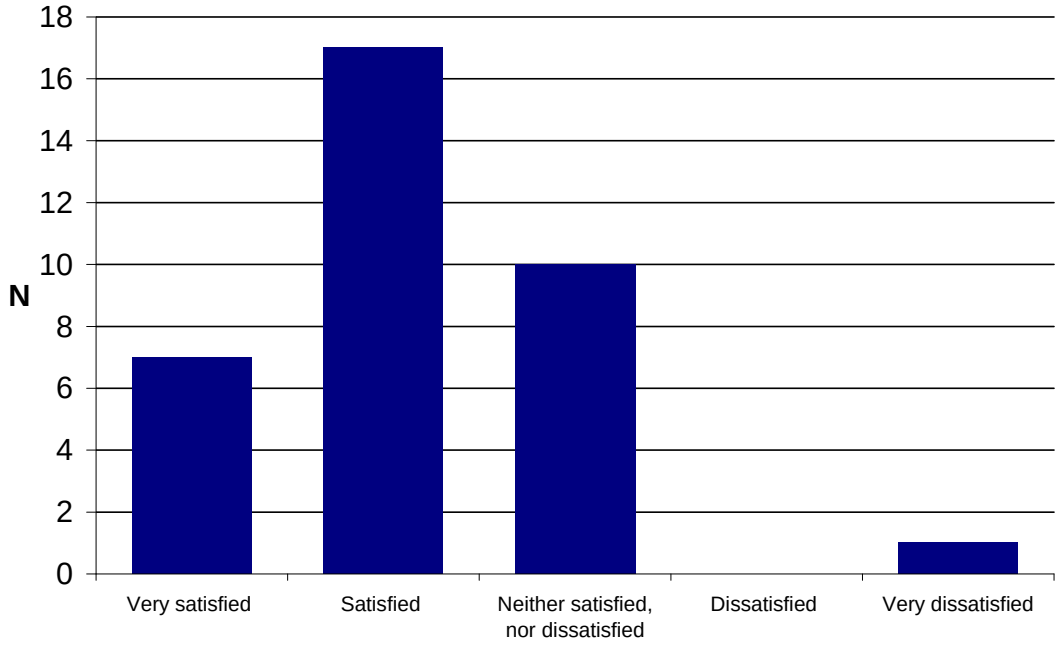
Areas for improvement have been suggested as follows:

- Further promote the EMEA selection criteria, so that more European PCOs may apply for eligibility.
- Increase the number of PCOs represented in the PCWP (enlarge PCWP membership).
- Increase the number of patients/consumers available in the EMEA network of experts in order to cover the maximum number of areas.
- Develop a strategy to further involve PCOs representatives in the work of the EMEA.
- Increase the level of transparency of the Agency when it operates with its stakeholders.
- Explore how to better promote the EMEA model of interaction with PCOs among regulatory authorities at national level.

Question 2

Please indicate your level of satisfaction with:

The impact of your involvement in EMEA activities during 2008 on your organisation



Summary of comments received

It was commented that it takes more time to increase awareness of EMEA activities within an organisation and that it is still a challenge to make people understand what EMEA is doing, and how things work. Also it seems that several organisations have difficulty in involving other members in some specific activities and that involvement takes a long time and there are limited resources. In this aspect some associations have organised training sessions to facilitate that patients members of their organisations can be involved in regulatory activities.

On a positive note it was found that the involvement in EMEA activities gives a good background on legal, regulatory and scientific aspects and being involved in EMEA activities is a way to express commitment to the needs of all patients in Europe. Several organisations felt that they could not comment due to not having been involved with the EMEA for very long.

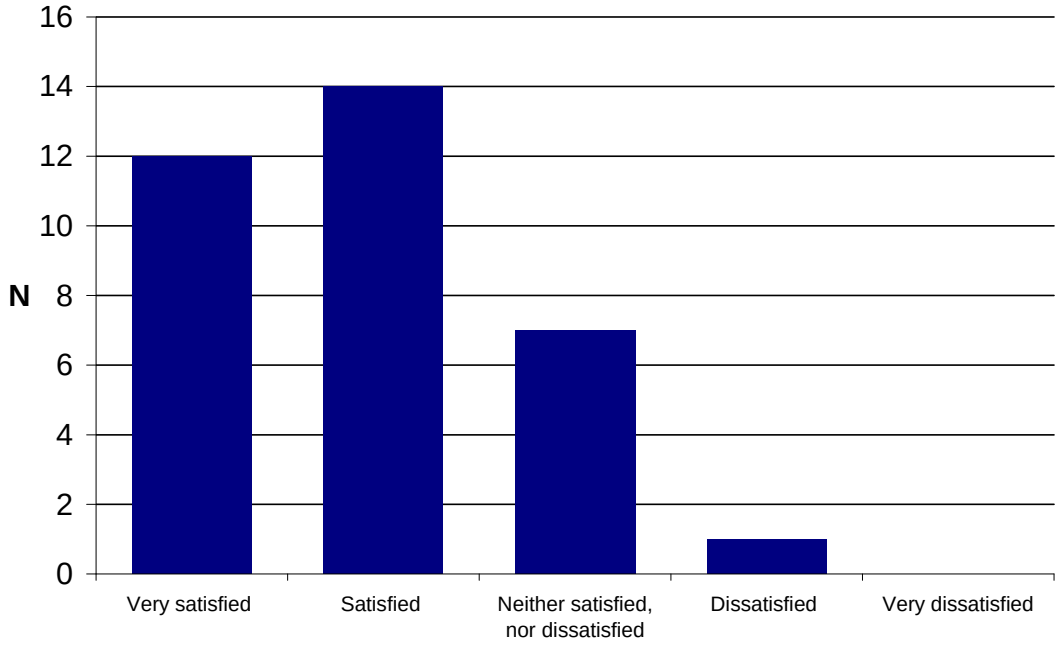
Areas for improvement have been suggested as follows:

- Ensure that involvement within EMEA activities is as 'straight-forward' as possible; that patients receive full support with regards to their involvement and understanding of specific activities.
- EMEA to support PCOs when they organise training sessions on regulatory activities.
- Further explore with PCOs how to maximise the impact of the work patients/consumers do at the EMEA within their organisations.

Question 3

Please indicate your level of satisfaction with:

The implementation of your input to EMEA activities in 2008



Summary of comments received

We can see that there was a good response in terms of the implementation of input to EMEA activities. PCOs representatives feel that their contribution has been taken into account in the different activities they have participated (e.g. Scientific Committee, Management Board, etc.). Another representative example of patient contribution to the EMEA is the work done in the context of benefit/risk communication.

However, some comments indicated that not enough feedback is received for some activities. This mainly relates to the review procedure and as such it will be analysed in this questionnaire later.

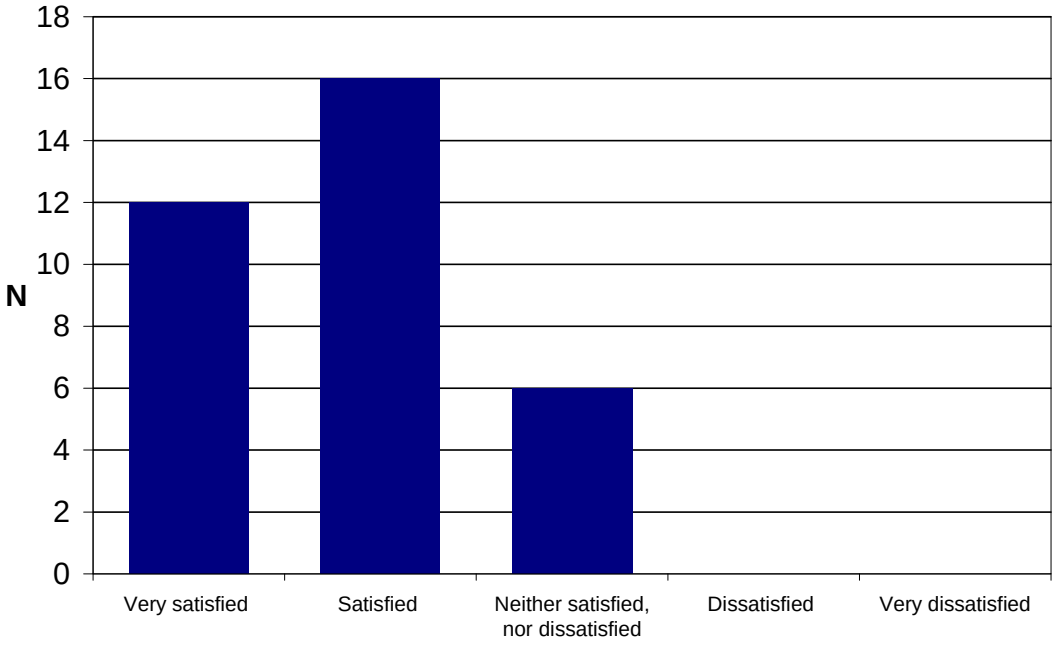
Areas for improvement have been suggested as follows:

- Investigate the feasibility to provide further feedback on the comments received on the reviews of package leaflets.

Question 4

Please indicate your level of satisfaction with:

The appropriateness and usefulness of documents provided by the EMEA for consultation



Summary of comments received

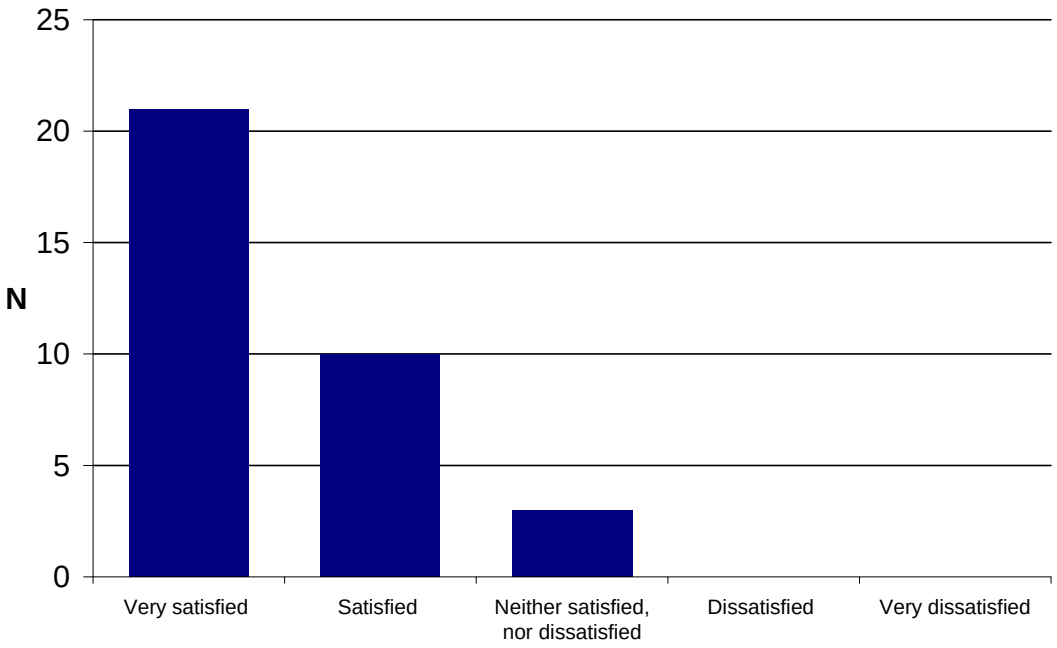
In general patients were very satisfied with the appropriateness and usefulness of the documents provided by the EMEA for consultation, mentioning that extensive information is given within the document which enables patients to be well prepared for the EMEA meetings and for the work that they are to perform. Patients have also declared that in general, documents are clear and understandable.

It is important to mention that PCOs representatives have not reported any problem in understanding the information provided through the documentation they have received, which evidences in general a good level of integration in the activities they have participated in.

Question 5

Please indicate your level of satisfaction with:

Practical arrangements and facilities provided by the EMEA (for example: invitations, travel arrangements, rooms, meeting services…) in 2008



Summary of comments received

Patients were extremely satisfied with the practical arrangements and facilities provided by the EMEA; in general they found that the organisation is excellent and that the services are of good quality and helpful.

It was also requested that the EMEA provides more training activities in 2009, specifically in the review of product related information, but also general training for new patients/consumers that participate in any EMEA activity for the first time.

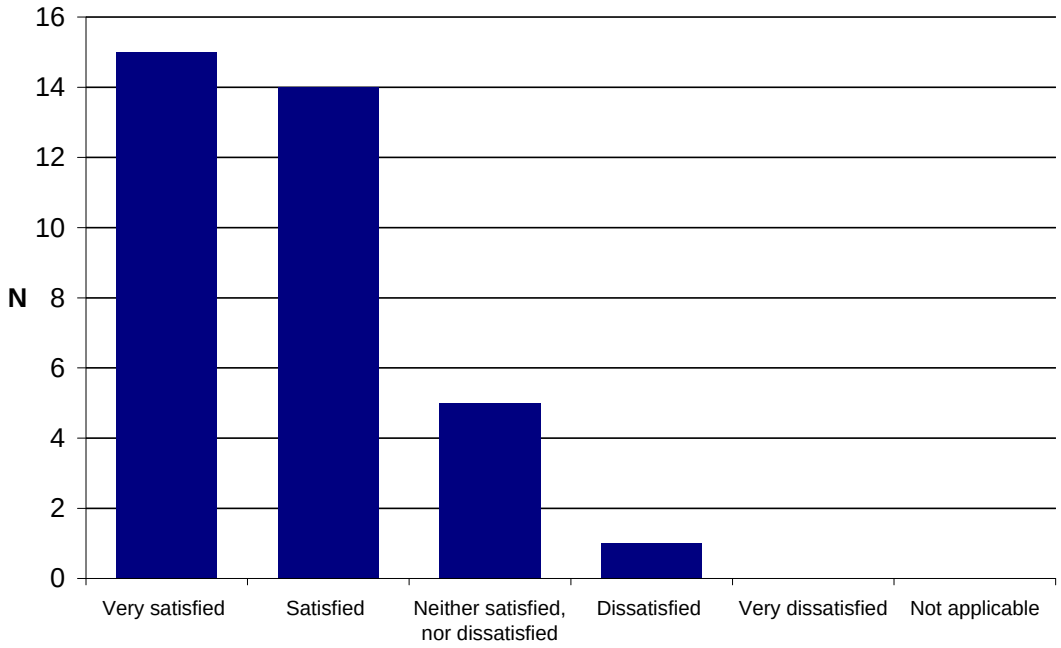
Areas for improvement have been suggested as follows:

- Continue to organise a training day on an annual basis (this year it will be held on 29/09/09), currently focused on the review of the quality of product related information.
- Prepare information/training material which can be systematically provided to any new patient/consumer which is involved in EMEA activities for the first time.
- Allocate a general introduction to the EMEA and its scientific committees in the annual PCWP meeting with all eligible PCOs organisations.

Question 6

Please indicate your level of satisfaction with:

The organisation of the EMEA meetings including the PCWP (for example: topics, agendas, minutes, documents circulated)



Summary of comments received

Overall patients were very satisfied with the organisation of EMEA meetings, citing that they were very professional and efficient and that documents sent before and after the meetings were very useful.

However, it was also mentioned that discussions can sometimes be long and incomplete, with long gaps in between and that meeting dates are often not announced enough in advance.

It was also pointed out that documentation is not always sent well in advance of meetings and should be sent at least one working week in advance. Patients/consumers more familiarised with EMEA procedures know that sometimes it is not always possible to give as much advance notice as it would be desirable (e.g. urgent safety issues and other procedures with tight timelines).

With regard to the PCWP, it has been requested that more transparency is applied when informing them of procedures to select experts and PCOs representatives to be involved in different areas of the EMEA.

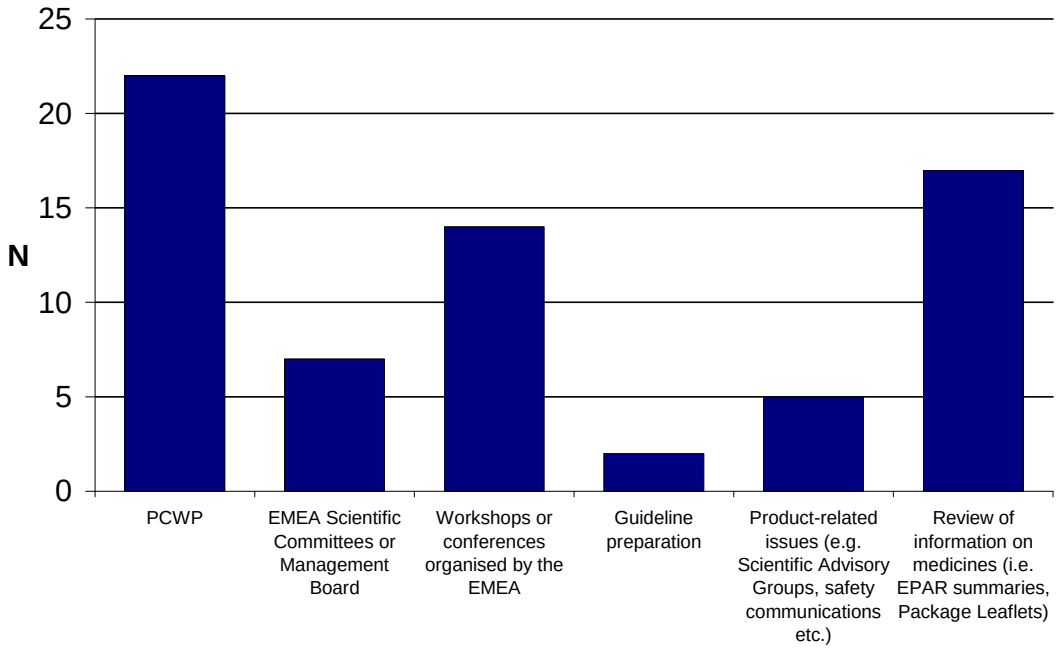
<u>Areas for improvement have been suggested as follows:</u>

- Ensure that all information regarding the procedure and nomination of experts for meetings/topics is conveyed to the PCWP in a transparent and timely manner.

- Ensure that documents are sent as much in advance of meetings as possible and at least to keep patients informed of the timing of such documents.

Question 7

What EMEA activities have you been involved in?



This graph shows the distribution of activities in which PCOs representatives who filled in the questionnaire have participated during 2008. In some cases, a same patient/consumer participated in several activities during the year.

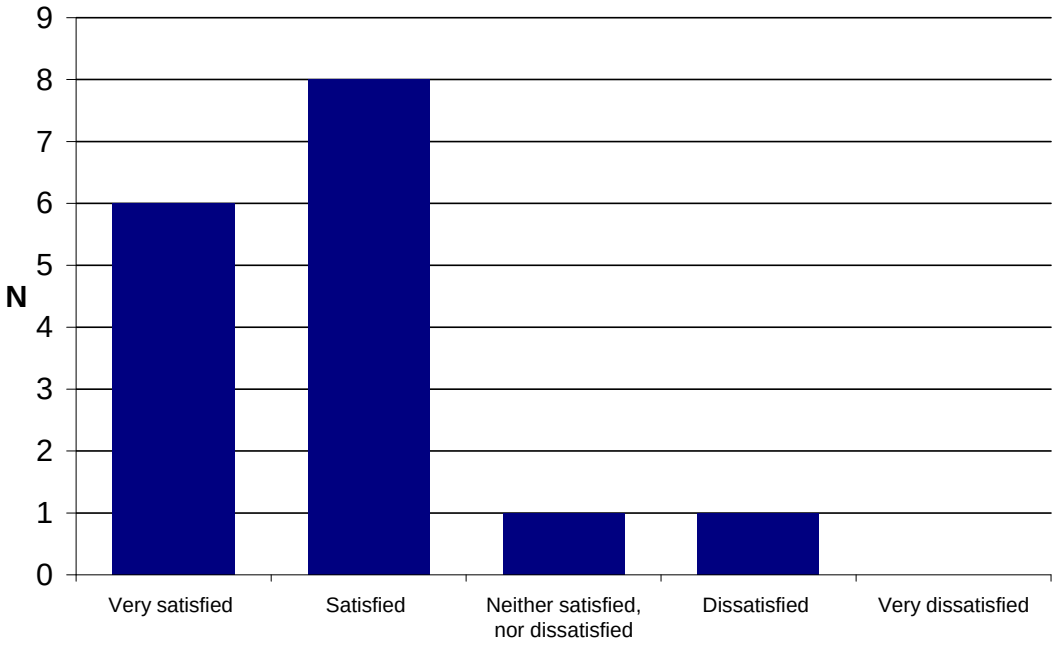
For those patients/consumers who were involved in the review of information in medicines (EPAR summaries and Package Leaflet) 4 additional questions were formulated. This was done with the intention to analyse for the first time the degree of satisfaction with the review procedure.

The analysis of the results of these 4 questions is presented below in question 8 to 11.

Question 8

Please indicate your level of satisfaction with:

The overall review procedure



Summary of comments received

The feedback indicates that most patients were happy with the overall review procedure and that comments provided by PCOs representatives are taken into account. Moreover, feedback received considers it as an important step in the overall interaction between EMEA and PCOs.

Some comments indicate that following smooth operation after more than 1 year, the scope of the procedure should be extended to cover other EMEA documents which are also intended to patients and the general public (e.g. safety communications, negative opinions, etc.).

Involvement of patients in the review procedure is also seen as an opportunity for patients to get initiated in regulatory activities, and as a way to interact with a higher number of PCOs on a regular basis (provided they all fulfil the eligibility criteria). The EMEA network of patients/consumers experts can serve as a source of potential experts for other EMEA activities.

Still more patients/consumers experts are needed in order to cover more areas.

Most comments, however, highlight the lack of sufficient feedback on the comments and the reasons behind the implementation (or not) of such comments.

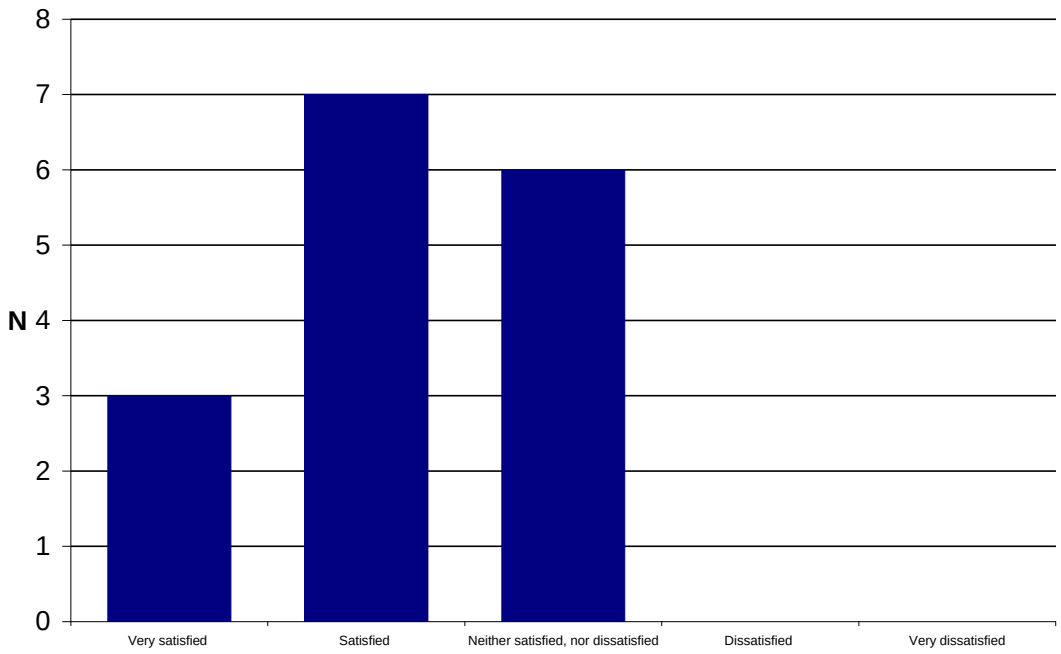
Areas for improvement have been suggested as follows:

- Continue operating the review procedure.
- Explore the possibility to extend the scope of the procedure so that patients can participate in the preparation of other EMEA documents intended for patients and the general public.
- Increase the number of experts available to participate in the procedure, especially for those areas which are currently not covered.

Question 9

Please indicate your level of satisfaction with:

The impact of your work on the final documents



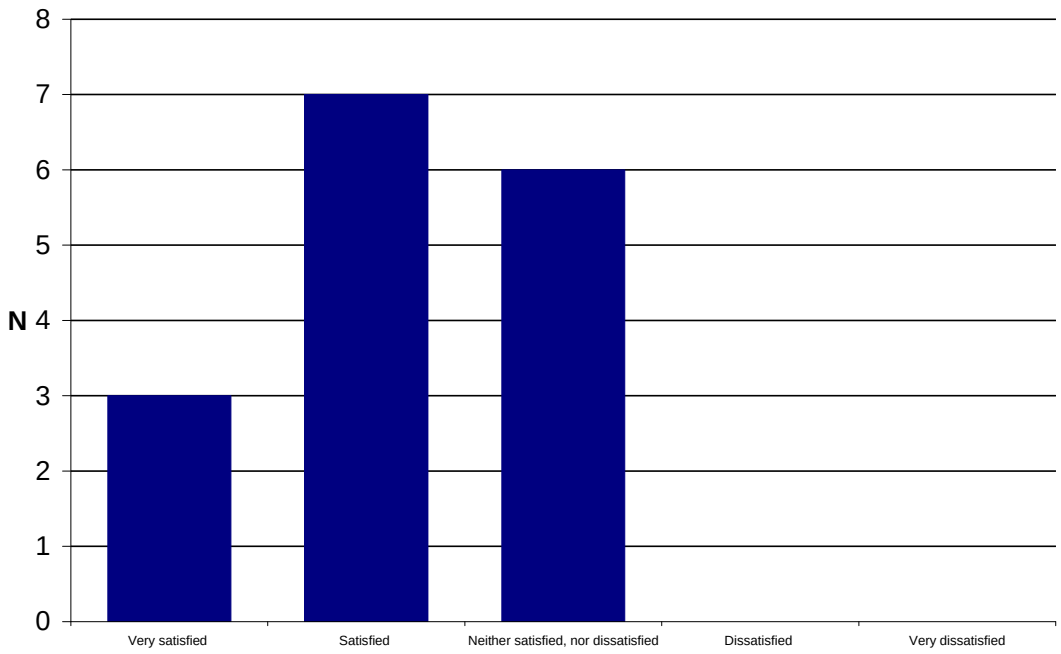
Summary of comments received

Overall most patients were satisfied or very satisfied with the impact of their work on the final documents, although several comments related again to the need for more individual feedback.

Question 10

Please indicate your level of satisfaction with:

The feedback you received on the documents you reviewed



Summary of comments received

Overall most patients were satisfied or very satisfied with the feedback. However, it has been mentioned by the patients/consumers involved in the review procedure that they would like to get further individual feedback.

So far, feedback which has been provided to them includes sending the final document (EPAR summary and PL). However, it is clear from the comments received that experts involved would like to have further information on the reasons why their comments have or have not been implemented. Resource implications have to be kept in mind when planning any action on this aspect.

In addition, during the training session on the review procedure, which is organised annually, a general feedback analysis is provided. It includes the display of relevant comments as examples, and the reasons for its acceptability are discussed.

Areas for improvement have been suggested as follows:

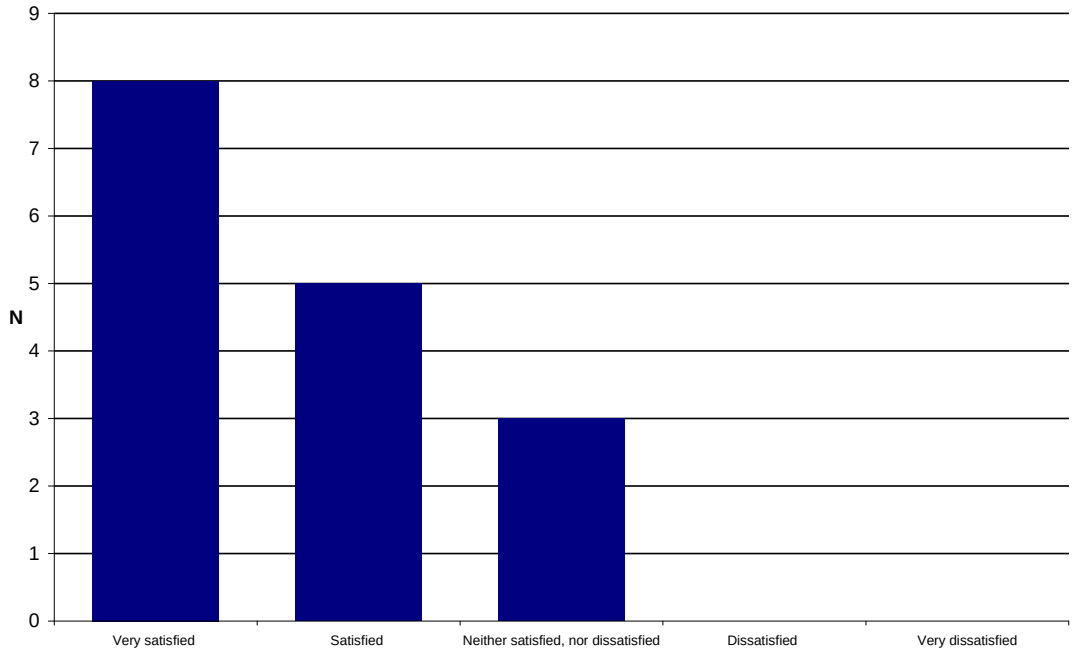
- Investigate the feasibility to provide further individual feedback on the comments received on the reviews of package leaflets and EPAR summaries.

- EMEA to continue providing general feedback analysis as part of the training material used in the training sessions on the review procedure annually organised.

Question 11

Please indicate your level of satisfaction with:

The training sessions and material offered by the EMEA to participate in the review



Summary of comments received

The feedback received indicates high level of satisfaction with the training sessions and with the material provided by the EMEA with regard to the review of documents. Some specific comments have mentioned that EMEA should continue organising theses sessions in order to maintain the outstanding level of quality.

Other comments also received indicated however that some of the documents included in the training material could be perhaps too rigid.

Areas for improvement have been suggested as follows:

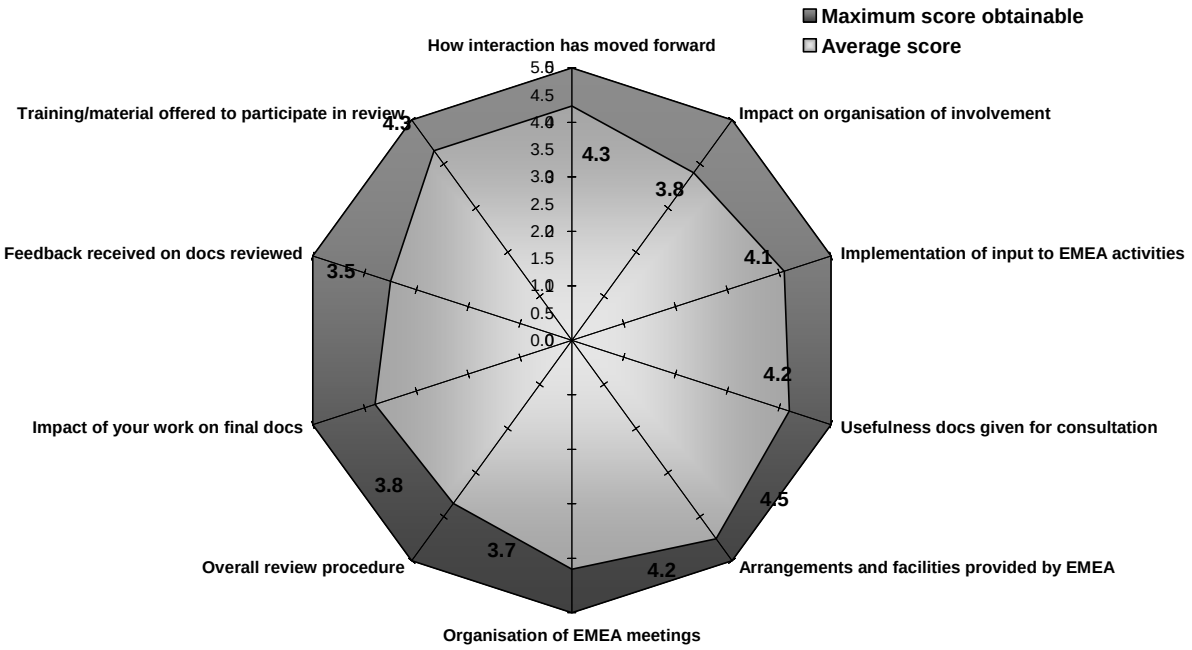
- Provide continued training sessions annually.
- Open up training sessions to new experts to the review procedure, and give them priority for participation.
- Update training material and adapt it to the extension of the scope of the procedure. PCWP to be involved in this update.

Final overview of comments collected

On average the scores reached for each question are quite satisfactory, reflecting that for the different aspects which have been investigated, PCOs representatives 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, as well as to facilitate the progress of the interaction.

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 (dark shade) represents the maximum possible score (5). The inner area (light shade) shows the average score measured in each question. The figure allows identifying which are the main areas which are more in need for further action.



3. STATUS OF IMPLEMENTATION OF ACTIONS IDENTIFIED IN 2008 REPORT

The analysis of the input received through the performance indicators last year, allowed the identification of areas for further improvement. These actions were proposed for implementation during 2008/2009.

The following table shows the status of implementation of these actions.

Table 4 – Table of actions identified in 2008 report and implementation outcomes

Action	Outcome
Publish report on the activities for which patients have participated during the year.	The report was published on the EMEA website following presentation to the Management Board in June 2008 (EMEA/478814/2007).
Further consideration on special needs of patients regarding travel arrangements and accommodation.	Internal work is ongoing to adapt current EMEA rules for reimbursement of experts and delegates to the identified special needs of PCOs representatives.
Need for clear identification of confidential/non-confidential nature of EMEA documents. Proposal to be made together with the PCWP	Topic to be considered for inclusion in the agenda of the PCWP meeting with all EMEA eligible organisations on December 2009.
Improvement of transparency for patients' organisations involved in EMEA activities. Proposal to be made together with the PCWP.	Leaflets on patient/consumer involvement available and translated in all EU languages. PCWP currently preparing summary describing each PCO, which will be available on the EMEA website. Patients and consumers organisations were invited to participate on the EMEA workshop on transparency held on 22nd January 2009.
Annual meeting with all EMEA eligible organisations, including discussion on involvement of more Patients' Organisations.	A first meeting with all EMEA eligible organisations was held on 6th June 2008. A second meeting is scheduled for 8th December 2009.
PCWP contribution to the drafting of a Reflection Paper on how to further develop procedures for involvement of patients in product related issues.	Preparation of Reflection Paper, currently ongoing, has involved PCWP. Further involvement of PCOs representatives in product related issues is addressed. Reflection Paper is expected to be presented to EMEA MB later in 2009.
PCWP contribution to the drafting of a Reflection Paper on how to further develop procedures for involvement of patients in guidelines preparation.	Reflection Paper prepared in collaboration with PCWP is expected to be presented to EMEA MB later in 2009.
Better coordination at each meeting for adequate provision of assistance and	Individual support provided by Medical Information Sector to PCOs representatives

support to new experts and representatives coming the first time. Monitor effectiveness of action through the 2008 performance indicator questionnaire.	participating in EMEA for the first time. 2008 performance indicators show high level of satisfaction in this area.
PCWP contribution to an eventual re-structure of the EMEA website which would facilitate access to patients.	PCWP involved in EMEA website reconstruction process, through regular updates in plenary meetings, as well as through specific Ad-Hoc meetings. User testing with individual PCOs representatives was also arranged.
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.	No translations were needed/requested during 2008.

4. 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 2008.

As it was done last year, the analysis of the input received has been used to identify areas for further improvement, and to propose specific actions which will be implemented during 2009/2010. To identify these actions, the status of implementation of actions identified in last year's report (2008) has also been taken into account. The identified actions are presented in the following "Table of Actions".

Table 5 – Table of actions for 2009

Action	Estimated timeframes for completion
Publish 2008 report on the activities for which patients have participated during the year.	2nd/3rd Quarter 2009
Further consideration on special needs of patients regarding travel arrangements and accommodation	2nd/3rd Quarter 2009
Improve transparency of the Agency with its stakeholders (including patients' and consumers' organisations). Ongoing initiatives to continue involving PCWP.	Throughout 2009
Enlarge PCWP membership (to allow participation of more PCOs).	3rd/4th Quarter 2009
Explore how better promote the EMEA model of interaction with PCOs at national level.	PCWP WP 2010
Increase the number of patients/consumers available in the EMEA network of experts in order to cover the maximum number of therapeutic areas.	Continued throughout 2009/2010
Present Reflection Paper to EMEA Management Board and initiate implementation.	3rd/4th Quarter 2009
Promote and support training initiatives on regulatory activities organised by PCOs.	Continued throughout 2009/2010
Continue to provide training sessions/material to PCOs involved in the EMEA: • Annual training session on review procedure (PL and EPAR summaries). • Update training material for PCOs involved for the first time.	3rd Quarter 2009 3rd/4th Quarter 2009
Investigate the feasibility to provide further individual feedback on the comments received on the reviews of package leaflets and EPAR summaries. Monitor effectiveness of action through the 2009 performance indicators.	3rd/4th Quarter 2009
PCWP to continue contributing to the reconstruction of the EMEA website.	Throughout 2009

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 2009 performance indicator questionnaire.	Continued throughout 2009/2010(if necessary)

Annex 1

EMEA PERFORMANCE INDICATORS QUESTIONNAIRE
INTERACTION WITH PATIENTS' AND CONSUMERS' ORGANISATIONS

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.

PCOs representatives 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.

EMEA questionnaire on degree of satisfaction for patients and

1. Introduction

Dear patient/consumer,

You have been asked to take part in this survey as you have been involved in one or more EMEA activities during 2008. Please answer to the following questions to help us understand how satisfied you are with your involvement. Click on 'next' to start...

2. General information

*** 1. My organisation is:**

Organisation

Name:

Other (please specify)

2. My name is (optional):

Name:

Email Address:

Phone Number:

3. Degree of satisfaction

Please let us know your degree of satisfaction with the following (please only tick 1 box for each question)

1. The way the interaction between the EMEA and patients' and consumers' organisations has moved forward during 2008

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

Please explain why:

2. The impact of your involvement in EMEA activities during 2008 on your organisation

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

Please explain why:

3. The implementation of your input to EMEA activities in 2008

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

If you feel that your contribution has not been taken into account, please provide details:

4. The appropriateness and usefulness of documents provided by the EMEA for consultation

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

Please give any comments:

5. Practical arrangements and facilities provided by the EMEA (for example: invitations, travel arrangements, rooms, meeting services...) in 2008

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

Please give any suggestions for improvement:

6. The organisation of the EMEA meetings including the PCWP (for example: topics, agendas, minutes, documents circulated)

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

Please provide any comments:

7. Please give any other comments or suggestion

4. Activities

1. What EMEA activities have you been involved in? (Please tick all that apply)

- ☐ PCWP
- ☐ EMEA Scientific Committees or Management Board
- ☐ Workshops or conferences organised by the EMEA
- ☐ Guideline preparation
- ☐ Product-related issues (e.g. Scientific Advisory Groups, safety communications etc.)
- ☐ Review of information on medicines (i.e. EPAR summaries, Package Leaflets)

Other (please specify)

5. Review of documents: Package Leaflets and EPAR summaries

If you have participated in the review of Package Leaflets or EPAR summaries, please indicate your level of satisfaction with:

1. The overall review procedure

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

Comments

2. The impact of your work on the final documents

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

Comments

3. The feedback you received on the documents you reviewed

- [ ] Very satisfied
- [ ] Satisfied
- [ ] Neither satisfied nor dissatisfied
- [ ] Dissatisfied
- [ ] Very dissatisfied

Comments

4. The training sessions and material offered by the EMEA to participate in the review

- [ ] Very satisfied
- [ ] Satisfied
- [ ] Neither satisfied nor dissatisfied
- [ ] Dissatisfied
- [ ] Very dissatisfied

Suggestion for improvement:

6. Thank you

Thank you for completing this survey. The outcome of this survey will be reported to the EMEA Management Board in 2009 and subsequently made public.

Annex 2

EMEA SCIENTIFIC COMMITTEES' WORKING PARTY WITH PATIENTS' AND CONSUMERS' ORGANISATIONS (PCWP) WORK PROGRAMME FOR 2009

European Medicines Agency

London, 20 November 2008
Doc. Ref.: EMEA/318023/2008

2009 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 2009

5th March	Plenary meeting
9th June	Joint meeting with HCP WG
29th September	Training session on the quality review of Package Leaflets and EPAR summaries
30th September	Plenary meeting
8th December	Meeting with all eligible patients' and consumers' organisations

2. INTRODUCTION

The EMEA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) has focused in previous years on the implementation of the 'Final Recommendations and Proposals for Action' (EMEA/149479/2004/Final), adopted by the CHMP and subsequently published on the EMEA website. For 2009, while ensuring that implementation of the "Recommendations" is concluded, the PCWP will move towards a further development and monitoring of activities already in place, in particular its contribution to the preparation of EMEA information adapted and oriented to patients and consumers.
The PCWP will work in the development of a more systematic interaction and involvement of patients and consumers at different levels of the Agency work, and particularly at the level of the different scientific committees and its working parties. The PCWP will examine whether this could be achieved within the current 'Framework on the interaction between the EMEA and patients' and consumers' organisations' (EMEA/354515/2005/Final) or whether there is any need to review it.

3. AREA OF PRODUCT INFORMATION

3.1 Quality Review of the Package Leaflet (PL)

Patients' and consumers' organisations have been involved on the review of the PL of centrally authorised medicines at the time of the renewal of marketing authorisation since 2007. Since September 2008, the procedure covers the PL at the time of the initial evaluation of marketing authorisation.

Action: report on the activity performed in 2008 and monitoring of the involvement of PCOs during 2009.

3.2 Quality Review of the EPAR summaries

Patients' and consumers' organisations have been involved on the review of the EPAR summaries for new authorised medicines since 2007.

Action: report on the activity performed in 2008 and monitoring of PCOs involvement in the review of EPAR summaries during 2009.

3.3 Review of Q&A documents

Patients' and consumers' organisations have been involved occasionally in the review of the Q&A documents regarding safety issues.

Action: proposal for a more systematic involvement in the preparation of the Q&A documents to be considered on the basis of the experience gained in 2/3Q2009.

3.4 Training of patients and consumers experts involved on the Quality Review of PLs and EPAR summaries

Every year a training session is offered to experts from patients' and consumers' organisation to be involved in the review.

Action: annual training session co-organised between the EMEA and the PCWP to be held at the EMEA in 3Q2009.

4. AREA OF PHARMACOVIGILANCE

4.1 Finalisation of the recommendations from the EMEA/CHMP Working Group with Patients' Organisations on Pharmacovigilance

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 and risk communication.

Action: the group has started some reflection and work for defining content of the training programme (headlines, objectives, main messages and definitions) – Finalisation is expected for 1/2Q2009.

4.1.3 Risk/benefit communication

Standardisation of quantitative measures for communicating benefit/risk of medicines in EMEA documents. Consideration of their ability to convey the most appropriate message to the public.

Action: a joint exercise involving patients, consumers, healthcare professionals and regulators has been undertaken during 2008. Outcome and any recommendation coming from this exercise will be considered. The opportunity to develop a glossary of effective words in communicating risks and benefits will be explored 1/2Q2009.

4.2 Other initiatives

4.2.1 European Risk Management Strategy (Work Programme for 2009)

Action: to provide input in various areas which requires interaction with patients' and consumers' organisations, such as:

- access to EudraVigilance database, including user requirements and technical specifications of the public interface (website).
- improved transparency on safety issues.

4.2.2 Safety communication

Maximise involvement of patients and consumers in safety communication aspects.

Action: proposal for a more systematic involvement of PCOs in safety communication will be considered in 2/3Q2009.

4.2.3 Participation of patients and consumers in the activities of the PhVWP

During a first pilot phase to be implemented in 2009, experts from patients' and consumers' organisations will participate as observers at the meetings of the PhVWP.

Action: monitoring of the implementation of the above mentioned initiative. Based on experience of the initial pilot phase, a report is to be prepared by 3/4Q2009.

5. AREA OF TRANSPARENCY AND DISSEMINATION

5.1 EU Telematics

5.1.1 European Database on Medicines

Action: to provide support to the EudraPharm project throughout 2009.

5.1.2 EudraCT website

Action: to provide support to the project throughout 2009.

5.1.3 EudraVigilance website

Action: to provide support to the project throughout 2009.

5.2 EMEA website

Action: to provide input and support to the restructure of the EMEA website and the EMEA public-facing online project throughout 2009.

5.3 EMEA transparency

Action: to provide support on further measures and initiatives to be developed by EMEA on this area throughout 2009.

5.4 EMEA awareness

Action I: continue exploring how to increase awareness at the level of patients' and consumers' organisations (e.g. distribution of EMEA information leaflets in different EU languages) - 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.

Action III: explore measures for dissemination of EMEA information in medicines specifically adapted to patients.

6. AREA OF INTERACTION BETWEEN THE EMEA AND PATIENTS' AND CONSUMERS' ORGANISATIONS

6.1 Involvement of member(s) of patients' and consumers' organisations in EMEA activities.

Action I: further to the conclusions coming from the first 'Report on the progress of the interaction with patients' and consumers' organisations and analysis of the degree of satisfaction of patients and consumers involved in EMEA activities' (EMEA/478814/2007), published in June 2008, the PCWP will contribute to develop a "Reflection Paper" with specific proposals for a more systematic interaction and involvement of patients and consumers at different levels of the Agency work, and particularly at the level of the different scientific committees and its working parties - 4Q2009. The "Reflection Paper" will explore if this interaction can be achieved within the current 'Framework on the interaction between the EMEA and patients' and consumers' organisations' (EMEA/354515/2005/Final) or whether there is any need to review it.
Action II: continue to monitor the involvement of PCOs in EMEA activities and to prepare a report in 4Q2009.

6.2 Eligibility criteria - EMEA interaction with patients' and consumers' organisations

Action I: monitoring of compliance with "EMEA eligibility criteria" by eligible PCOs. Status report to be presented to PCWP in 4Q2009.

Action II: all eligible patients' organisations with interest in regulatory activities but not represented in the PCWP, will be invited to a plenary meeting for 2009, to be held in 3Q2009.

Action III: based on expressed interest from PCOs fulfilling the criteria, enlargement of PCWP membership to cover areas currently not represented will be considered by 2/3Q2009.

6.3 Framework of interaction – performance indicators

Continuing implementation and monitoring of specific performances indicators. Conclusions and results will be analysed, and adequate measures will be put in place accordingly. Indicators for 2009 will monitor degree of satisfaction of measures already identified and put in place following analyses of performance indicators in 2007.

Action: Implementation throughout 2009 - Analyses report to be prepared by 4Q2009.

7. ORGANISATIONAL MATTERS

7.1 Interaction with healthcare professionals

Continue ensuring adequate level of interaction with representatives of healthcare professionals' organisations.

Action: annual joint meeting between PCWP and Healthcare Professionals' Working Group (HCP WG) to be held in 2Q2009.