EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Fourth report on the progress of the interaction with patients' and consumers' organisations (2010)

and

Results/analysis of the degree of satisfaction of patients and consumers involved in EMA activities during 2010

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1. Executive summary

Introduction

The present report describes in detail the various activities in which patients' and consumers' organisations (PCOs) have been involved during 2010, together with the status of implementation of the actions and recommendations that have been identified in previous reports.

Also included are details of the work carried out by the "EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations" (PCWP), and activities related to the provision of information to patients and the general public.

In 2005, at the time of endorsing a framework of interaction between the EMA and the patients' and consumers' organisations, the Agency's management board (MB) requested that each year an annual report be prepared in order to monitor the progress of interaction.

This report was presented to the PCWP during its meeting on 13 September 2011 and to the EMA MB during its meeting on 6 October 2011.

Please find herewith a link to our glossary of definitions of acronyms.

Progress on the interaction with patients' and consumers' organisations during 2010

Year upon year, the number of PCO representatives who have been involved in EMA activities has increased, and 2010 is no exception; from 77 in 2007, to 307 in 2010. If we take into account of the number of *occasions* that patients/consumers have participated (for example the number of times that Committee members attend meetings), the total figure becomes 479.

This increase can be attributed to an enhanced involvement at many levels of the Agency work, such as increased participation of patient experts in scientific advisory group (SAG) meetings, an increase in the number of CHMP consultations as well as the participation of patient representatives within the Pharmacovigilance working party. Additionally there has been an enhanced participation in the review of EMA documents which now includes safety communications, as well as continued involvement in other long-term projects such as ENCEPP, Eudravigilance, clinical trial related activities and EnprEMA (see below for more details).

The conclusions from previous reports have provided evidence that the actions originally identified in the aforementioned 'Framework of interaction' have been implemented and that formal interaction has been established between patients'/consumers' organisations and the EMA. There remains further scope to broaden the extent of involvement, such as an enhanced participation in benefit/risk evaluations, the need to define the role for patients involved in the different scientific committees, as well as the need to provide adequate support to facilitate patient involvement.

With regard to the provision of information on medicinal products, the Agency continuingly strives to improve the quality of product-related information intended for patients and the general public. The scope of the review of such information by PCOs, initiated in 2007, has since been extended to include a wider range of documents (i.e. EPAR summaries, package leaflets, 'question and answer' documents and press releases). During 2010 PCOs have also been involved in the revision of the package leaflet QRD template.

In line with the increased scope of patient involvement in so many of the Agency's activities and the need to cover a wider range of therapeutic areas, the PCWP membership has been enlarged during 2010 and now includes 5 additional patient and consumer organisations; giving a total of 15 PCO members. In addition, the number of organisations applying and becoming eligible to work with the Agency is also increasing, from 19 in 2007 to 29 by the end of 2010.

The EMA has developed "performance indicators" in conjunction with the PCWP, which measured the degree of satisfaction of patients who participated in the Agency activities during 2010, and the impact of some of the new or updated activities. The results of this questionnaire are included within section 2 of this document and have helped to identify further areas for improvement/enhancement, such as increased involvement in benefit/risk evaluations (revision of framework), increase the network of patient experts and eligible organisations, investigate additional areas of involvement which are of mutual benefit and enhance the current training offered to patients/consumers. The implementation of these actions will continue during 2011/2012.

Next steps

During the next two years the focus will be on revising the "Framework of interaction" between the EMA and PCOs, which will incorporate:

- The role of patients within the scientific committees;
- Their involvement in benefit/risk evaluation;
- A strategy for training and support.

PCO representatives will continue to be fully involved in the many varied activities within the Agency, i.e. PCWP related activities, scientific advisory group meetings, CHMP consultations, other Committee/Working party consultations, the review of information oriented to patients/general public, as participants in general conferences and workshops and as patient representatives in the different committees, working parties and the EMA MB.

The new pharmacovigilance legislation (effective July 2012), will be an opportunity to strengthen the interaction, for example in the preparation of risk management plans and direct patient reporting methods. The work on the implementation of this legislation, together with all stakeholders will commence early 2011 and PCOs will be invited to stakeholder meetings throughout the year and will continue to be actively involved during the following years.

The management board will be presented with the next annual report on the interaction with patients' and consumers' organisations in 2012.

This report is divided in two sections:

Section 1: Overview of patients' and consumers' organisations involvement in the activities of the European Medicines Agency during 2010.

Section 2: Analyses of the degree of satisfaction of PCOs involved in EMA activities during 2010.

Section 1:
Overview of patients' and consumers' organisations involvement in the activities of the European Medicines Agency during 2010

2. EMA activities involving patients and consumers during 2010

2010 has been a very busy year with an ever-increasing number of patient representatives being involved in an expanding range of Agency's activities. This report provides a detailed summary of all the EMA activities in which PCOs have been involved in during 2010 and compares this involvement with that of preceding years. It also discusses actions identified in earlier reports and highlights future steps for the interaction between the Agency and PCOs.

Patients are included as formal members in the Agency's Scientific Committees (COMP, PDCO, CAT) and following a 3-month pilot phase during 2009, patients'/consumers' representatives received endorsement from the management board to be included as permanent representatives in the PhVWP as of April 2010 (more details below). As of July 2012 they will also be members of the new Pharmacovigilance committee (PRAC).

There has been an increased involvement of PCOs in the benefit / risk evaluations carried out by the CHMP. For example, specialised patient/consumer organisations have been able to provide information related to the use of specific medicinal products in the market, which then has contributed to the overall data reviewed by the CHMP when making its final recommendations. In addition patients have participated in many of the scientific advisory group meetings convened at the request of the CHMP, where they were able to provide a patient perspective to the product-specific benefit-risk deliberations.

More patients have been involved in the preparation of the Agency's safety communications. Since 2008 PCOs have reviewed some "question and answer" documents concerning safety issues (e.g. withdrawal, suspension of marketing authorisations for safety reasons, or a product defect or supply shortage). Moreover since 2010 a formal procedure has been put in place to ensure the systematic involvement of patient experts in the preparation of all safety-related Q and A documents.

PCOs have also been very much involved in several ongoing EU-wide initiatives, such as EudraCT (EU clinical trials register), Eudravigilance (publication of data), ENCEPP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), and more recently Enp-EMA (European Network of Paediatric Research). They have also been very involved in the working group on clinical trials in 3rd countries (concept paper). More specific details on these activities are provided later in this report.

The Agency has also consulted patients on policy issues (e.g. transparency project, roadmap to 2015), and also on the formulation of the new EMA website. Many of these activities have been carried out by the PCWP, but the wider network of organisations eligible to work with the European Medicines Agency has also been involved in many activities (see Tables 1 and 3 below for the full list of activities).

Over the years, the Agency has been building a 'network of experts' from patients' and consumers' organisations. This now extensive network was able to reach over 200 experts during 2010 within many different therapeutic areas, for participation in specific Agency activities. This network is an extremely valuable resource for the Agency and has been constantly expanding due to the increasing number of organisations eligible to participate in EMA activities. The added value that the contribution of 'lay experts' brings to the activities of the Agency has been well acknowledged on many occasions. An up-to-date list of eligible organisations is published on the Agency website.

The 'reflection paper on the further involvement of patients and consumers in EMA activities' took into account the experience already gained and the interests and capabilities of the patient organisations. Two specific actions are proposed: the first concerns the need to revise the current framework of interaction, which will be finalised during 2011/2012, including how and when PCOs can be further involved in benefit/risk evaluations and their specific role as committee members. The second is aimed

at providing additional financial support in specific cases to experts and delegates from patients'/consumers' organisations which has been put in place during 2010.

2.1. EMA management board (MB)

Since 2005, two representatives of patients' organisations are members of the Agency's management board. The legal basis for their membership is found in article 65 (1) of Regulation (EC) Nº 726/2004.

For the current term of three years the PCOs representatives are Mary Baker from the European Federation of Neurological Associations and Mike O'Donovan from the European Patients Forum.

The representatives of patients' organisations have been fully integrated into the work and activities of the Board and have actively participated both in the discussions and the decisions taken, providing their views as users of medicines and as representatives of civil society. There were 4 board meetings held at the Agency during 2010.

A member from the management board also attends the PCWP meetings as an observer which maintains a link between the two groups.

2.2. EMA scientific committees

Patients are formal members of three EMA Scientific Committees; the COMP, the CAT and the PDCO. Additionally, all the Committees consult PCO representatives on specific issues when needed.

2.2.1. Committee for Orphan Medicinal Products (COMP)

The COMP (as per Article 4 (3) of Regulation (EC) Nº 141/2000) includes in its membership "three members nominated by the Commission". The current members were nominated on 1 July 2009 for a term of three years, which is renewable.

Their tasks include, among others:

- Participation in the assessment of applications for Orphan Drug Designations and acting as coordinators for some of the applications;
- Providing advice on the identification of external experts when needed for the assessment of applications for orphan drug designation;
- Collaboration in the preparation of public summaries of opinion (PSOs) for orphan designations.

COMP consultations with PCOs

4 additional patients' representatives were consulted as patient experts in procedures concerning orphan designations.

2.2.2. Paediatric Committee (PDCO)

The PDCO (as per Article 4 (1.d) of Regulation (EC) Nº 1901/2006) includes in its membership "three members and three alternates appointed by the Commission". The current members were nominated on 31 July 2008 for a renewable term of three years.

Their tasks include, among others:

- Participation in the peer reviews of ongoing Paediatric Investigation Plan (PIP) applications.

2.2.3. Committee for Advanced Therapies (CAT)

The CAT (as per Article 21 (1.d) of Regulation (EC) Nº 1394/2007) includes in its membership "two members and two alternates appointed by the Commission". The current members were nominated at the end of 2008 for a renewable period of three years.

- Act as Rapporteur, Co-rapporteur or Peer reviewer for marketing authorisation applications for ATMPs.

2.2.4. Committee on Herbal Medicinal Products (HMPC)

There is currently no legal basis in Community legislation for patients to be members of this Committee, although interaction is possible through provisions in Article 78 (2) of Regulation (EC) Nº 726/2004. A HMPC member regularly attends the meetings of the PCWP to maintain a link between the two groups.

The HMPC has previously consulted the PCWP on the way the Agency communicates information on herbal medicines to the general public. Following a meeting between the HMPC and representatives of patients'/consumers' organisations, it was clear that such information is of interest to patients and the general public. In the future, PCO representatives with a specific interest/expertise in herbal medicines could contribute to the preparation of this type of information.

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

There is currently no legal basis in European legislation for patients to be members of this committee. Interaction with the CHMP, its working parties and scientific advisory groups (SAGs) is based on Article 78(2) of Regulation (EC) Nº 726/2004.

During 2010 participation of PCOs representatives occurred as follows:

- **CHMP consultation with PCOs on products under evaluation**

The CHMP consulted with several organisations to obtain the viewpoint of patients and consumers with reference to particular medicinal products under evaluation. The products were: Zeffix (wording for therapeutic indication), Fabrazyme (product supply shortage/treatment recommendations), Cellcept (wording in PL on pregnancy prevention), and a patient representative participated in a CHMP oral presentation concerning Ammonaps (potential supply shortage).

In each case, the organisations are asked to respond in writing to a list of questions adopted by the Committee, and in one case were subsequently invited to participate in the relevant CHMP discussion. The information obtained was then taken into account by the CHMP during the evaluation process and for the final opinions.

- **Third party intervention with CHMP**

One patient organisation presented their concerns to the CHMP with regard to the product NeoRecormon and the discontinuation of some of the presentations (cartridges/Recopen). These concerns were forwarded to the marketing authorisation holder for consideration and were also included within the assessment report.

- **Participation in SAG / ad-hoc expert group meetings**

SAGs are groups of European experts convened by the CHMP to provide advice during the evaluation of a specific product or treatment. During 2010, a total of 14 patients participated as patient experts in 11 different SAG/expert meetings to give their views on specific questions. The areas covered were: major depressive disorder (seroquel XR), chronic obstructive pulmonary disease (daxas), glioma (cerepro), growth hormone/JIA (genotropin), breast cancer (tamoxifen & fulvestrant), schizoaffective disorder/schizophrenia (paliperidone), diabetes (Avandia), multiple sclerosis (fampridine), hepatitis guideline, sleep disorder (modafinil) and lipoprotein lipase deficiency (glybera).

Following a review by the EMA and the CHMP of this work, it was proposed to carry out a one year pilot phase systematically involving patients in SAG meetings wherever possible. The pilot phase began on 1 October 2010, and during the one year period after each meeting a questionnaire will be sent out to both the patient representative and the Chair and Rapporteur of the specific SAG in order to obtain feedback on their involvement. An analysis report will be prepared by the end of 2011, together with the CHMP. It will be the basis for deciding the way forward.

- **Interaction with the Scientific Advice Working Party (consultation)**

13 patients' representatives participated as experts in specific scientific advice requests. These requests were related to requests to EMA for protocol assistance (for orphan drugs) and involved consultation either through attendance at a SAWP meeting or by submitting comments in writing.

- **Participation in the Pharmacovigilance Working Party (PhVWP)**

During 2009 a pilot phase was carried out whereby two patients' representatives participated as observers in 3 consecutive PhVWP meetings. The subsequent analysis report, endorsed by the management board and the Heads of Medicines Agencies, proposed the permanent inclusion of patients'/consumers' representatives in the PhVWP, as observers.

Following a call for expression of interest and a selection procedure in 2010, the Agency nominated one patients' representative to join the PhVWP as an observer (from IAPO), and a second representative to stand as alternate (from EMP) with a yearly renewable membership. This participation officially began in May 2010.

2.3. EMA Working Party with Patients' and Consumers' Organisations (PCWP)

The PCWP has continued to play an essential role in the interaction between the EMA and patients'/consumers' organisations. One of the key features during 2010 was the enlargement of this group.

The need to further widen the composition of the group with additional patients/consumers' organisations had been previously highlighted following feedback received from performance indicators, as well as the need for a wider range of expertise and also interest expressed by organisations (non PCWP) in becoming full members.

In accordance with the "*Mandate, objectives and rules of procedure of the PCWP"* the composition of the group could be increased to 20 core representatives (5 are members of the committees, giving a maximum of 15 members from patients' and consumers' organisations).

Organisations were selected based on a predefined set of criteria related to their appropriateness in the subjects covered within the scope of the working party's mandate and on the declared expression of interest received from eligible organisations.

The final composition of the PCWP during 2010 was as follows:

- 15 members and 13 alternates representing PCOs;
- 5 members from the EMA Scientific Committees (CHMP, COMP, PDCO, HMPC & CAT);
- 1 member from the EMA secretariat;
- Observers from the CMD-h, the HCP WG and the EMA management board.

There were four plenary PCWP meetings during 2010, including one meeting with all 'eligible' organisations (fulfil EMA eligibility criteria), and one joint meeting with the Healthcare Professionals' Working Group (HCP WG). In addition, a one-day training session for all experts involved in the review of product-related information was held towards the end of the year.

The PCWP was also consulted concerning a question and answer document on the compassionate use of medicines which is now available on the Agency website. They were additionally consulted on the EMA roadmap to 2015 and on the development of the new corporate website. Furthermore some PCWP members participated in a webinar dedicated to innovative medicines.

Through the PCWP, patients and consumers representatives have been involved in other initiatives, as in the case of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP), the Pharmacoepidemiological Research on Outcomes of Therapeutics (PROTECT), the implementation of the public clinical trials register, the clinical trials in 3rd countries working group and also the EudraPharm implementation study.

2.4. Activities related to clinical trials

2.4.1. EMA Working Group on Third Country Clinical Trials

The revision to the EU pharmaceutical legislation in 2004 increased the emphasis on ethical standards for clinical trials conducted outside the EEA and included in marketing authorisation applications submitted within the EEA.

At the end of 2008 the EMA published a strategy paper "Acceptance of clinical trials conducted in third countries for evaluation in marketing authorisation applications" (EMA/228067/2008) and established a working group which included 6 representatives from the PCWP. The working group subsequently drafted a reflection paper ("Reflection paper on ethical and GCP aspects of clinical trials of medicinal products for human use conducted in third countries and submitted in marketing authorisation applications to the EMA") (EMA/712397/2009).

The paper was released for public consultation between May and September 2010 and as part of the consultation process an international workshop was also held in September. Participation included a wide range of stakeholders' associations; patients' representatives, ethics committees, national competent authorities, commercial and non-commercial sponsors' associations, CROs and researchers.

The paper is being revised in the light of all comments and discussions and will be finalised towards the end of 2011.

2.4.2. Development of EudraCT

Since 2004, all clinical trials carried out within the EU are registered in the EudraCT database. None of this information was previously accessible to the general public; however, in line with the new EU legislation (Article 57(2) of Regulation No. 726/2004 and Article 41 of Regulation No. 1901/2006),

from March 2011 some of the information from EudraCT has become publically available within the new EU Clinical Trials Register.

10 patients'/consumers' representatives are part of the EudraCT JOG (joint operational group) which held two meetings at the Agency during 2010 and were involved in the development of the new public interface, specifically to ensure that it is 'public-friendly'. Patient/consumer representatives were also involved in the user testing of the database prior to its launch and additionally 6 organisations provided their online glossaries for use in the preparation of the online glossary within this public register.

2.5. Activities related to the provision of information to patients and the general public

The EMA provides information about medicines it evaluates, including information directed to patients and the general public. During the preparation of this information, the Agency consults with PCOs to ensure that it is adequately formulated and comprehensible to the target audience. The purpose of this consultation is to ensure that the information is clear and understandable, and that it fulfils the needs of patients in terms of information content.

Patients and consumers are regularly involved in the review of package leaflets (PLs), EPAR summaries, question and answer documents, public statements, press releases and similar materials intended for the public.

The procedure for the review of PLs at the time of renewal of the marketing authorisations and EPAR summaries has been in place since May 2007 (EMA/279083/2006 Rev 1). It has since been expanded to also include PLs for new medicines, Q and As and press releases on safety issues.

Each eligible organisation identifies a list of experts available for reviewing such documents, who are then invited to attend a training session on the review procedure held by the EMA each year. There is also a 'procedure for review' document as well as a 'training manual' available for perusal on the EMA website.

The analysis of the experience acquired so far confirms the relevance of comments received. It is found that in general the patients' and consumers' contribution increases the quality of the documents within the scope of this procedure.

- **Review of EPAR summaries**

During 2010 PCOs representatives reviewed a total of 14 new EPAR summaries.

- **Review of package leaflets**

During 2010 PCOs representatives reviewed a total of 41 package leaflets (PLs).

- **Review of EMA safety communications**

During 2010 PCOs representatives reviewed a total of 11 Q and A documents.

- **Training on the 'Review of European Medicines Agency documents addressed to the general public by patients and consumers'**

The annual training session on the review of EMA documents was held at the Agency on 29 November 2010. In addition to the usual training on the review of package leaflets and EPAR summaries; this years' training also included guidance on the new procedure regarding PCO involvement in the preparation of safety communications (question and answer documents, press releases). An invitation to attend was sent to all eligible organisations and their nominated experts, 28 "patient experts", attended the training session.

All experts, nominated by organisations eligible to work with the Agency, are provided with a CD ROM and a training manual containing all information needed to perform the review of these documents. Upon request from the PCOs representatives, the EMA will explore in 2011 the possibility to expand this training to include other topics, such as a general information session on the Agency and its activities.

- **Involvement in the preparation of other documents addressed to the general public**

During 2010 patients and consumers have also participated in the preparation of other documents directed to patients and the general public, such as “Questions and answers on the compassionate use of medicines” and “class statements” in EPAR summaries.

2.6. Other activities

- **Involvement in EMA workshops, conferences and expert meetings**

PCOs have been involved in several conferences, workshops and expert meetings throughout the year:

The first international scientific workshop on nanomedicines was hosted by the EMA in September 2010, with over 200 European and international participants from 27 countries including Australia, Canada, India, Japan and the United States, and which also included representatives from three patient organisations. The workshop discussed benefits and challenges arising from the application of nanotechnologies to medicines.

Joint European Commission / EMA conference on the outcome of the assessment of the EMA PCOs had contributed to the evaluation by completing a survey or answering questions during interviews, which formed part of the assessment. The conference was organised following the completion of the evaluation in 2009, to discuss the outcomes and recommendations with partners and stakeholders. During the conference patient representatives thanked the Agency for a close and productive interaction with their organisations and the EMA highlighted that it is looking to develop further this interaction to increase ways in which representatives can contribute and participate in the process of communication and provision of information to patients and to take part in the assessment process.

"Regulatory science: are regulators leaders or followers?" This one-day regulatory science conference was held by the Agency in December 2010. The conference highlighted a range of scientific topics related to the role the Agency can play to best support regulatory sciences, including models to support benefit-risk assessment, the regulation of biotechnological products, addressing the efficacy-effectiveness gap, the use of health data to support medicines regulation, ongoing efforts on safety detection and statistical methodologies for clinical trials.

Expert meeting on familial neurodegenerative diseases; although the possibility to identify the gene mutations which determine neurodegenerative diseases can create stress for the affected individuals, it can also provide an opportunity to attempt to delay or stop the progression of the disease if the right tools are developed. The scientific communities that study these diseases and the families of those affected are eager to advance in this field; however there are several challenges to overcome in designing relevant clinical trials in these populations.

This meeting, comprising academics, regulators, industry and patients, aimed to provide a forum of discussion among stakeholders to provide a first proposal for the resolution of the issues mentioned.

EMA meeting with Christopher’s Smile charity to discuss issues related to paediatric research in general.

- **Involvement in Eudravigilance**

A user-group, including 8 patient representatives was created during 2010 to assist in the implementation of the Eudravigilance access policy and the development of the public portal giving access to Eudravigilance data. The group met once during 2010 and will continue to be actively involved during 2011.

- **Involvement in EudraPharm implementation study**

EudraPharm is the database intended to hold information on all medicinal products for human or veterinary use that have been authorised in the EU and EEA. It currently contains all centrally authorised medicines for human and veterinary use as well as some national data from several national competent authorities.

During 2010 the Agency decided to carry out a study to assess the extent to which the requirements of legislation have been met by EudraPharm so far, to analyse the challenges in meeting the requirements and/or expectations of the stakeholders and to establish the foundations upon which decisions will be taken to progress with its implementation.

As part of this implementation study of EudraPharm, 12 PCO representatives took part in telephone interviews with the association commissioned to carry out the study.

- **Involvement in ENCePP**

Patients'/consumers' representatives have participated in the meetings of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and one PCO representative is a member of the steering group since the beginning of 2010. The aims of this initiative are to bring together the available expertise in the fields of pharmacovigilance and pharmacoepidemiology, to strengthen post-authorisation monitoring of medicinal products in the EU and to facilitate the conduct of post-authorisation safety studies. Since 2010 ENCePP has set up a Code of Conduct setting out rules on access to data, agreed upon a list of methodological standards and launched an online database. There is also a publically available ENCePP e-register of studies. ENCePP will continue during 2011-2012 to reinforce itself as an important and internationally known resource in this field and PCOs will continue to be fully involved.

- **Involvement in PROTECT (IMI)**

Patient representatives are involved in the PROTECT project (Pharmacoepidemiological Research on Outcomes of Therapeutics), funded by the Innovative Medicines Initiative Joint Undertaking. It is a collaborative European project which aims to develop innovative methods in pharmacoepidemiology and pharmacovigilance. PROTECT will look at limitations of current methods used in pharmacovigilance and pharmacoepidemiology in order to strengthen the monitoring of the benefit/risk balance of medicines marketed in Europe.

Table 1. Activities involving patients/consumers at the European Medicines Agency during 2010

Management board/scientific committees
MB (members)
COMP (members and observers) and ad-hoc consultations with patient experts on specific topics
PDCO (members)
CAT (members)
CHMP ad-hoc consultation on medicinal products under evaluation / participation in CHMP oral explanations
Working parties/working groups
PCWP (members and observers)
PhVWP (observers)
HCP WG (observers)
SAWP – participation as experts in the review of Protocol Assistance requests
Working Group on Clinical Trials in Third Countries (members)
EudraCT Joint Operational Group (public clinical trial registry) (members)
Eudravigilance Users Group (members)
SAG/ad hoc expert group meetings
SAGs – regular participation as patient experts
Ad-hoc expert group meeting on a gene therapy product
Product information related activities
Review of package leaflets (new and renewal MA applications)
Review of new EPAR summaries
Review of safety communications: Q and A documents and press releases
Training on the review of documents addressed to patients and the general public
Review of the new package leaflet template
Other meetings
European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) – Steering group meeting
Webinar on innovative medicines
Expert meeting on familial neurodegenerative disorders
Expert meeting on Alzheimer
PDCO meeting on SIT with Academy of Allergy and Clinical Immunology (EAACI)
EMA meeting with child cancer charity on paediatric research
Workshops
International Workshop on Nanomedicines
Workshop on Nanomedicines
Joint EC/EMA Conference on the outcome of the EMA assessment
DIA ENCePP info day
International workshop on clinical trials in third countries
EMA regulatory science conference
Input on other initiatives
Public consultation on EMA Road Map to 2015
EudraPharm implementation study

General Q and A on compassionate use of medicines
Provision of glossary data for EudraCT public portal
Consultation on class statements in EPAR Summaries
PhVWP report on risks of first-generation antihistamines
Pharmacoepidemiological Research on Outcomes of Therapeutics – Innovative Medicines Initiative (PROTECT – IMI)
European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

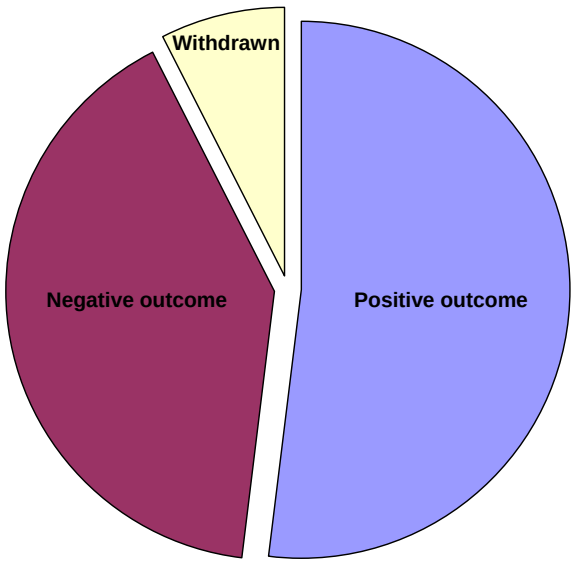
3. Organisations involved in the EMA activities during 2010

All patients' and consumers' organisations are welcome to express an interest to participate in the activities of the European Medicines Agency. Their involvement helps the Agency to conduct its activities with a proper understanding of patients' and consumers' interests in the field of medicines regulation.

Any interested patients' or consumers' organisation must fulfill the 'Criteria to be fulfilled by patients' and consumers' organisations involved in the European Medicines Agency activities'. These criteria are formulated to ensure that the Agency establishes contacts only with appropriate organisations that are genuinely acting in the interests of European patients and consumers.

A list of the organisations eligible to interact with the EMA is published in the dedicated section 'Working with patients and consumers' within the Agency website. Links to the organisations' websites are also provided, together with a short summary of their expertise and main activities.

A negative outcome does not preclude the organisation to reapply at any time, particularly if the issues raised during the evaluation have been addressed. As of end December 2010, 55 organisations have applied for evaluation. Of them, 29 have received a positive outcome, 22 have received a negative outcome and for 4 organisations the application was withdrawn. Finally 1 application was being assessed. The majority of the negative outcomes relate to 2006/07 (initial 'batches' of applications) and were mainly due to having limited EU representation, already being a member of another EU organisation and not being patient/medicine focused.



As a result of this exercise, a growing number of patients' and consumers' organisations are now able to participate in the Agency activities. This allows the Agency to have direct contact with a suitably wide range of PCOs, and guarantees that their views represent the needs and concerns of patients and consumers across Europe. All the eligible PCOs 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 to the "Rules of involvement of members of patients'/consumers' organisations in Committees' related activities" (EMA/483439/2008 rev.1), there have been exceptional cases when the Committees consulted organisations not fulfilling the criteria. However, as per the rules, organisations involved were fully transparent with regard to its activities and finding. They are identified and presented in table 2b.

During 2010, a total of 52 patients'/consumers' organisations interacted with the Agency (41, during 2009, 26 during 2008 and 24 during 2007). Table 2 on the following page gives an overview of the patients' and consumers' organisations which fulfil the European Medicines Agency criteria after evaluation, and also the organisations that have been involved in different EMA activities.

Table 2a: Eligible patients' and consumers' organisations working with the EMA

	Name of organisation	Involvement during 2007	Involvement during 2008	Involvement during 2009	Involvement during 2010
1	Alzheimer Europe (AE)	√	√	√	√
2	Debra International				√
3	European AIDS Treatment Group (EATG)	√	√	√	√
4	European Cancer Patient Coalition (ECPC)	√	√	√	√
5	The European Consumers' Organisation (BEUC)	√	√	√	√
6	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)			√	√
7	European Federation of Neurological Associations (EFNA)	√	√	√	√
8	European Genetic Alliances' Network (EGAN)	√	√	√	√
9	European Headache Alliance (EHA)				√
10	European Heart Network (EHN)		√	√	√
11	European Institute of Women's Health (EIWH)				√
12	European Multiple Sclerosis Platform (EMSP)		√	√	√
13	European Myeloma Platform (EMP)	√	√	√	√
14	European Older People's			√	√

	Platform (AGE)				
15	European Organisation for Rare Diseases (EURORDIS)	√	√	√	√
16	European Parkinson's Disease Association (EPDA)	√	√	√	√
17	European Patients' Forum (EPF)	√	√	√	√
18	European Public Health Alliance (EPHA)	√	√	√	√
19	European Prostate Cancer Coalition (EUomo)				√
20	Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)			√	√
21	Health Action International (HAI)	√	√	√	√
22	Insulin Dependent Diabetes Trust (IDDT)	√	√	√	√
23	International Alliance of Patients' Organizations (IAPO)	√	√	√	√
24	The International Confederation of Childhood Cancer Parents Organisations (ICCCPO)		√	√	
25	International Diabetes Federation (IDF)	√	√	√	√
26	International Patient Organisation for Primary Immunodeficiencies (IPOPI)	√	√	√	√
27	Myeloma Euronet (ME)	√	√	√	√
28	Rett Syndrome Europe (RSE)		√	√	
29	Thalassaemia International Federation (TIF)		√	√	

Table 2b: Other organisations who interacted with the EMA during 2010 (e.g. participated in workshop/conference, product consultation with CHMP)

1	Brain Tumour Trust
2	Hypophosphatasie Europe
3	Gorlin Syndrome Group
4	GEISER Foundation
5	Fondation Internationale TIerno et Mariam
6	Salud y Fármacos
7	Parkinson Pipeline Project
8	Alliance for Patients' Mutual Help Organizations
9	MS Society UK
10	European Gaucher Alliance
11	Kidney Alliance

12	Society for Mucoolysaccharide diseases
13	Fabry International Network
14	Christopher's smile
15	Norwegian Huntington Patients Association
16	European Huntington's Disease Network
17	Huntington's Disease Support Club
18	Myelom Euronet Romania
19	EuroAtaxia Association
20	German HAE association
21	BAG Selbsthilfe (Federal Association of Self-help for physically and/or mentally disabled, people with chronic illnesses, and their families)
22	BAGSO – German National Association of Senior Citizens' Organisations
23	DVMB – National Association Morbus Bechterew

4. Number of patients and consumers involved in EMA activities during 2010

During 2010, patients/consumers have been involved in the activities of the Agency on 479 occasions. In some cases the same patient/consumer participated in more than one activity.

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

Table 3: Activities involving patients/consumers at the European Medicines Agency during 2010

Membership of committees	**Members / alternates**	**No. of meetings**	**Numbers attended***
MB	2	4	7
COMP	3 / 2	11	47
PDCO	3 / 2	12	20
CAT	2 / 2	11	33
Total	**14**	**38**	**107**

Membership of working parties	**Members / alternates / observers**	**No. of meetings**	**Numbers attended***
PCWP members / alternates	15 / 13	5	71
PhVWP	1 / 1	7	12
HCP WG	2	2	4
			21
Total	**32**	**14**	**87**

*The total number of members' attendance during the year

Participation in scientific advisory / ad-hoc expert group meetings	**No. of meetings**	**Experts**
Scientific Advisory Group meetings	10	13
Ad-hoc expert group meetings	1	1

Total	**11**	**14**

Other activities requiring experts	**Experts**
Experts who attended PCWP meetings	3
Ad-hoc observers who attended PCWP meetings	21
Experts who participated in SAWP consultations	13
Experts who participated in COMP consultations	4
Consultation on class statements in EPAR summaries	1
Working Group on Clinical Trials in third countries (3 meetings)	13
EudraCT Joint Operational Group (3 meetings)	16
EudraVigilance Users Group (1 meeting)	8
EudraPharm implementation study	12
Q and A / press release review (consultation on safety communications)	11
Review of EPAR summaries	14
Review of package leaflets	41
Training on the review of documents	28
Total	**185**

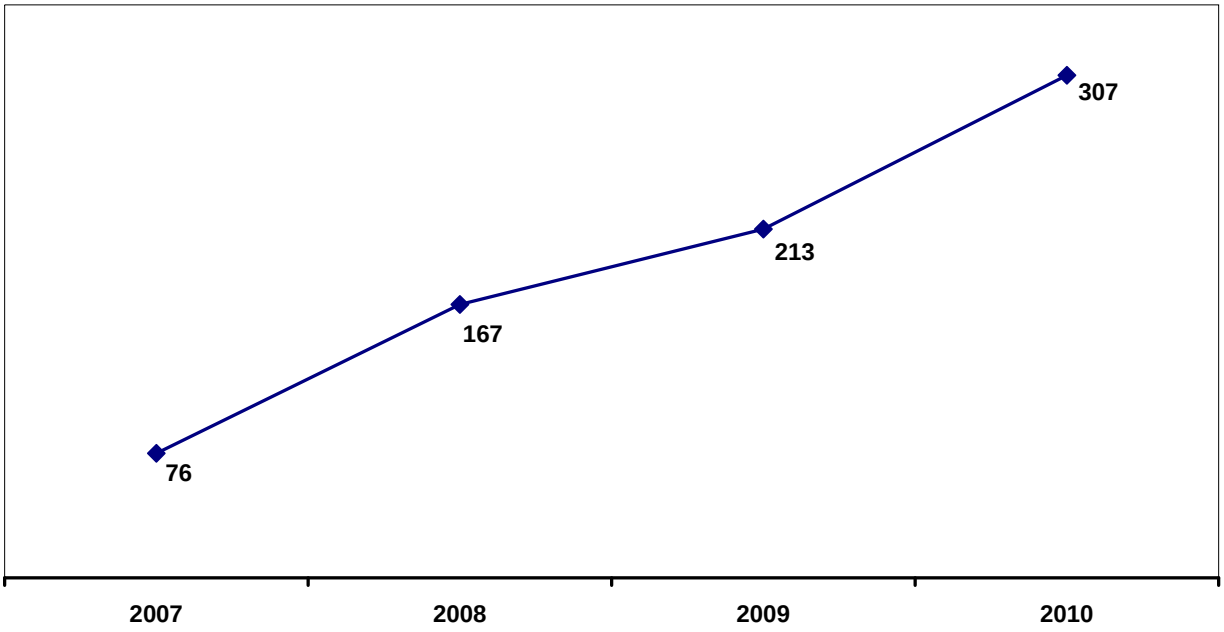
Activities requiring organisations' representatives	**Nº of Representatives**
CHMP consultation on products under evaluation	8
Organisation consultation with CHMP on products under evaluation	1
Road Map to 2015 - consultation	8
Compassionate use Q and A	8
ENCePP Steering Group (4 meetings)	1
DIA ENCePP info day	4
Provision of glossaries for EudraCT	6
Report on risks of first-generation antihistamines	1
Meeting on paediatric research (PDCO)	2
Expert meeting in familial neurodegenerative disorders	4
PDCO meeting on SIT	1
Alzheimer meeting	1
EMA/EC Conference on outcome of EMA assessment	12
International workshop on nanomedicines	3
International workshop on clinical trials in 3rd countries	6
Regulatory Science Conference	10
IMI PROTECT	3
Workshop on the revision of the QRD template	3
External consultation on the revision of the English annotated QRD template	3
External consultation on the translations of the QRD template	1
Total	**86**

Total number of patients/consumers involved during 2010 (i.e. member of COMP = 1)	**307**
Total number of *occasions* patients/consumers involved during 2010 (i.e. member of COMP = number of times attended COMP meetings)	**479**

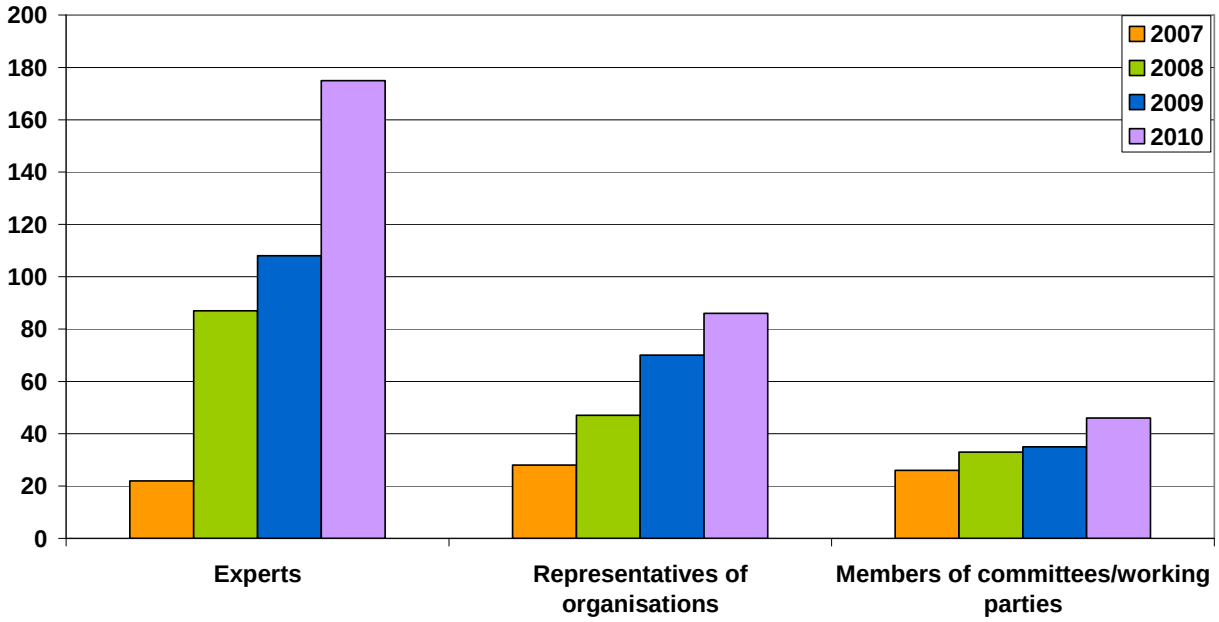
4.1. Involvement of patients/consumers in EMA activities: comparative analysis of data from previous years.

In the graphs below, the number of patients/consumers who have been involved in the activities of the Agency is compared with previous years.

Comparison of overall involvement of patients and consumers in the EMA activities 2007-2010



Comparison of involvement as Experts, Representatives and Committee/WP members 2007-2010



The evidence shows that, compared to previous years a more significant number of patients and consumers participated in the different activities of the Agency during 2010.

- **Members:**

The increased participation in the number of members is due to the new members and alternates for the PCWP and the observers for PhVWP.

- **Experts:**

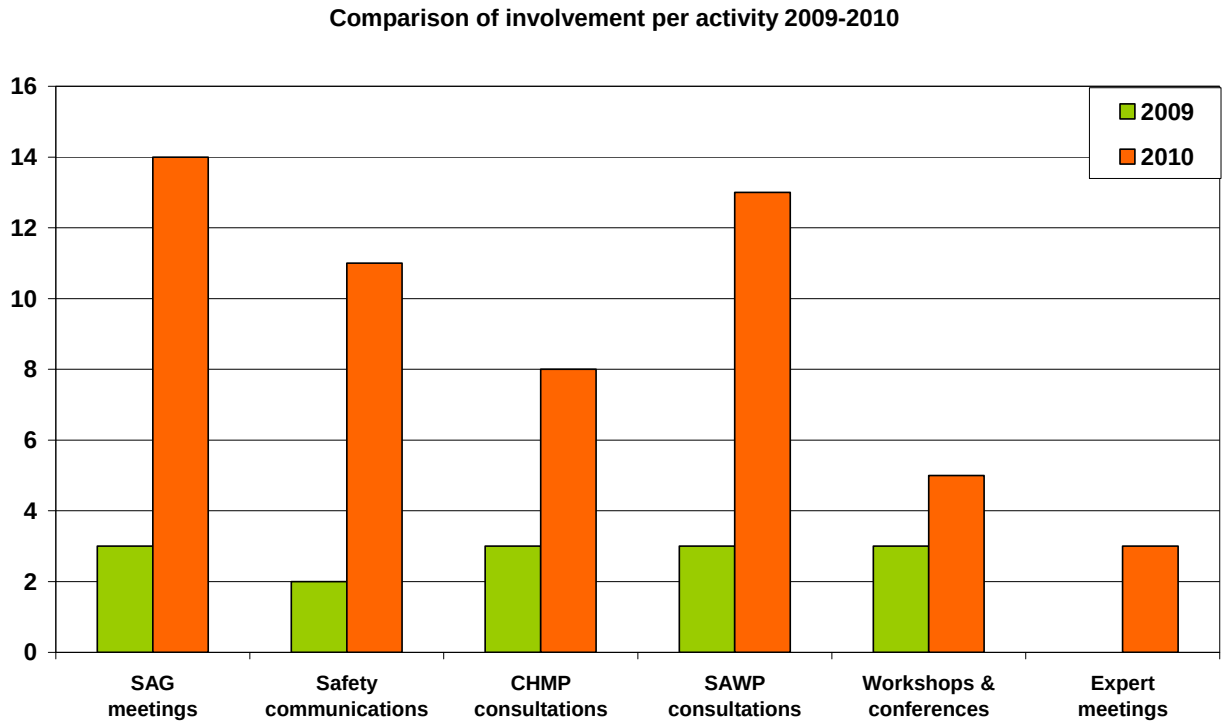
There have been 175 experts involved during 2010, compared to 108 in 2009, 87 in 2008 and 22 in 2007, which can mainly be attributed to:

- Increased participation in SAG meetings (3 meetings in 2009, 14 in 2010);
- Increased participation in the activities of the Scientific Advice Working Party (3 occasions in 2009, compared to 13 in 2010);
- Increased number of package leaflets reviewed (from 33 in 2009 to 41 in 2010);
- More participation in the preparation of safety communications (Q and As) and press releases (3 in 2009, 11 in 2010).

- **Representatives:**

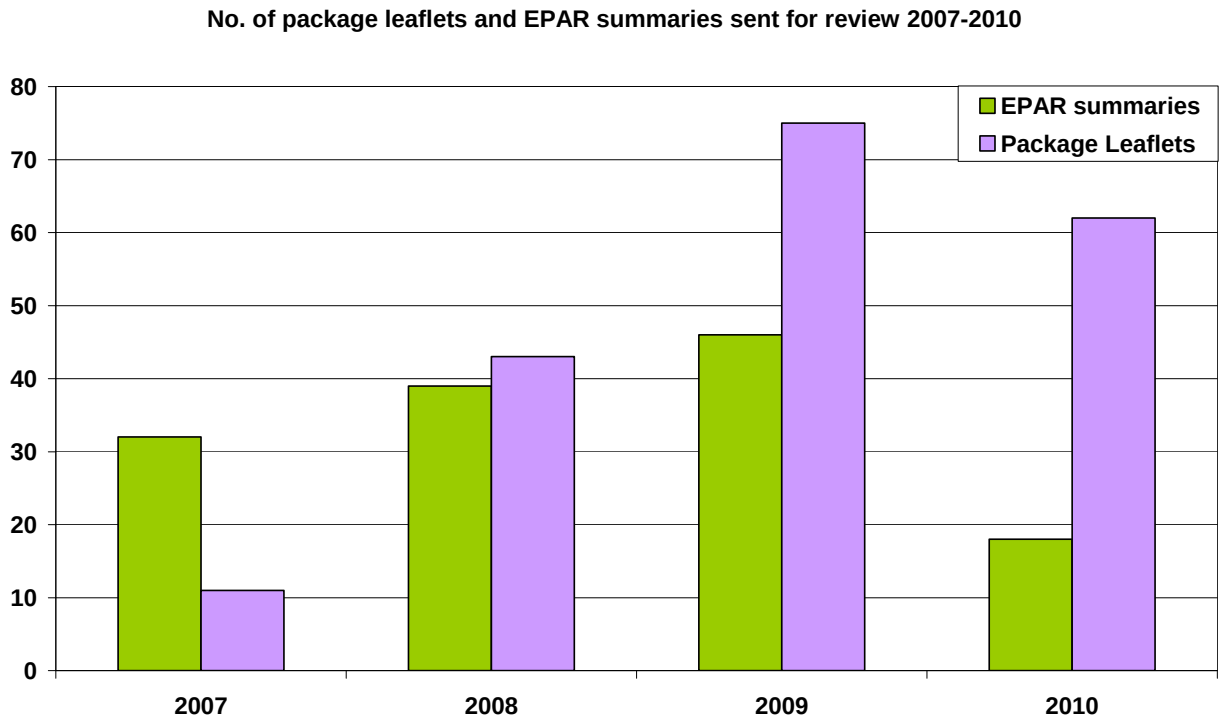
  There were 52 different organisations who interacted with the Agency during 2010 with 86 organisations' representatives, compared to 70 in 2009, 47 in 2008 and 28 in 2007. This can mainly be attributed to a more systematic participation of patients'/consumers' representatives in workshops, conferences, expert meetings and other events organised by the Agency, as well as an increasing number of CHMP and COMP consultations on product specific issues;

  - A higher number of CHMP consultations directly with patient/consumer organisations were carried out during 2010 (3 in 2009; 8 in 2010);
  - Increased involvement in several working group meetings (e.g. clinical trials in third countries, EudraCT JOG, EudraVigilance users group, ENCEPP related meetings and activities);
  - Increased attendance of specialised topic meetings, workshops and conferences (e.g. workshops on nanomedicines, workshop on revision of QRD template, Alzheimer workshop, expert meeting on familial neurodegenerative disorders, etc).

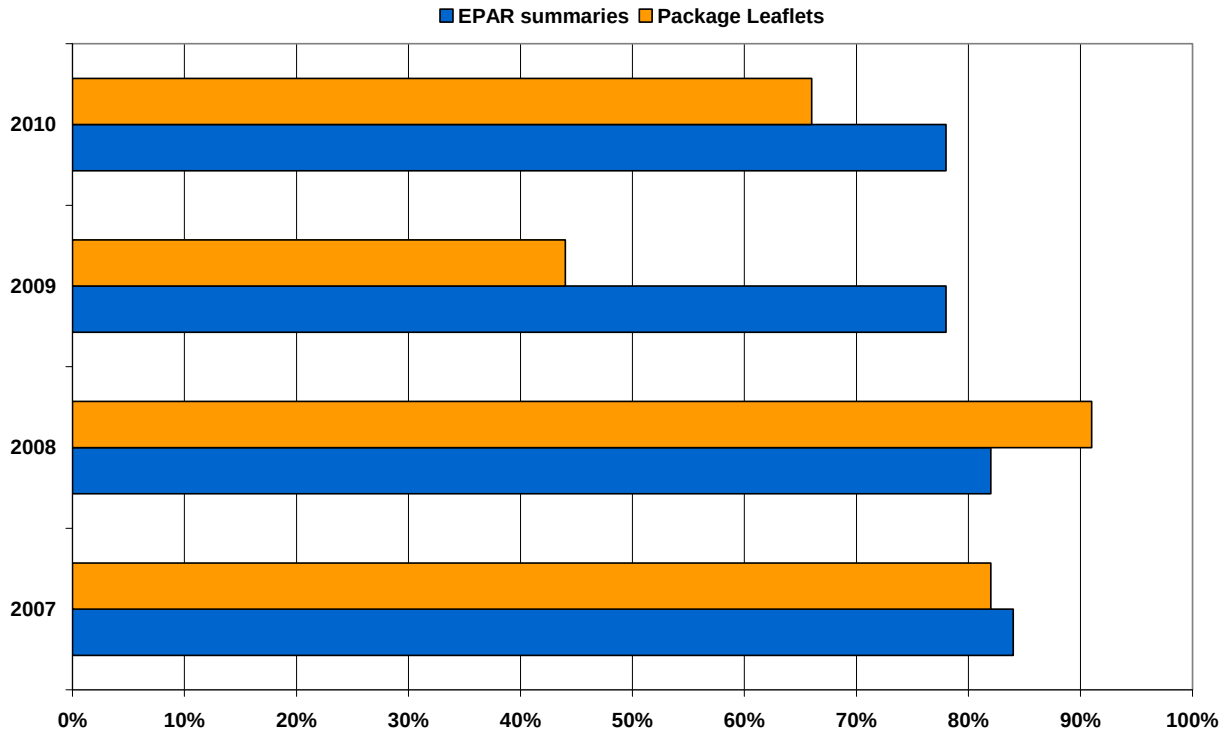


4.2. Document review procedure: comparative analysis of data between 2007 and 2010

The graph below shows the number of EPAR summaries and package leaflets sent for review in 2010, compared to the three previous years. The decrease in the number of EPAR summaries sent in 2010 is due to the reduction in marketing authorisation applications to the Agency; the same trend is not as high for the PLs because renewals (as well as new authorisations) are also reviewed.



The graph below shows the percentage of EPAR summaries and package leaflets reviewed (in relation to the number sent out), which confirms the optimal operation of the process.



5. Conclusions and next steps

2010 has again seen an important increase in the number of patients and consumers who have been involved in EMA activities; from **77** in 2007, **165** in 2008, **213** in 2009 to **307** in **2010** (if we take into account the *number of occasions* that patient representatives attended regular meetings (e.g. MB, scientific committees, working parties and groups), then the overall figure is 479). This is due to an increase in participation at many levels of the Agency's work (e.g. more participation in scientific advisory group meetings, representatives in the PhVWP and other working groups, increased CHMP consultations on product specific consultations, further involvement in the review of safety communications, scientific advice, as well as continued involvement in Agency projects like Clinical Trials in 3rd countries, Clinical Trial public portal, Eudravigilance, ENCePP and PROTECT).

In the reflection paper, which was endorsed by the EMA management board in December 2009, the Agency experience in involving patients and consumers in different areas was analysed, and the added value of the participation of patients and consumers in the work of the Agency was acknowledged and confirmed. This acknowledgment included the recognition of the efforts of the individuals as well as of the organisations in contributing to the Agency activities, and it translated into a proposal to provide financial support to patients/consumers in specifically defined circumstances. This was put in place during 2010 for those attending meetings at the Agency. Feedback on the implementation of this measure have been analysed within the performance indicator questionnaire.

One of the actions which had been proposed by PCOs concerned the enlargement of the PCWP. Following this recommendation, and considering the need to involve more PCOs in order to cover more therapeutic areas, the PCWP was enlarged during 2010 to include an additional 5 patient and consumer organisations.

With regard to the provision of information, the Agency now involves PCOs in a wider range of product related information adapted and oriented to patients and the general public. The scope now covers the systematic review of safety communications, such as Q and As, but also direct patient communications as well as the review of proposed 'safety' wording on package leaflets.

The Agency roadmap to 2015 highlighted the added value of patients and consumers in benefit/risk considerations; that they enrich regulatory decisions by complementing them with the views of those directly affected by such decisions and that the decision-making process can be improved by taking account of patient experience, thus contributing to the rational use of medicines. Aspects that will require particular consideration include how best to address the complexity of the benefit/risk data, as this requires careful interpretation, and determining the most appropriate time point for communication when new information emerges.

Next steps

- Following the endorsement by the management board of the proposals for action in the "Reflection p aper", implementation of the remaining defined actions will continue during 2011/2012.
- The "Framework of interaction" between the EMA and PCOs will be revised during 2011/2012, including the following:
  - The Agency will explore how patients and consumers can be further involved in the benefit/risk assessment of medicinal products, defining criteria for involvement, with implementation aimed for 2012.

  - The specific role of patients and consumers within the different scientific committees of the Agency will also be defined within a specific paper during 2011.
  - The Agency will additionally investigate how to provide further training in different areas (e.g. regulatory procedures, clinical trials, innovative medicines) which are considered of interest by patients'/consumers' organisations.
  - PCOs representatives will continue to be involved in the preparation of information oriented to patients and the general public, including EPARS, PLs, safety communications and press releases where appropriate.
- The Agency will be looking to further increase the network of experts and eligible organisations in order to cover as many therapeutic areas as possible and thus to investigate additional areas for PCO involvement, which are of mutual benefit.
- The Agency, in line with the Roadmap to 2015, will be aiming to strengthen the involvement of patients' organisations in the process of guidelines development, for example the organisation of early workshops, so that PCOs can actively contribute towards the medical, regulatory and scientific thinking, will be explored.
- The adoption of the new pharmacovigilance legislation (Regulation (EU) No 1235/2010 and Directive 2010/84/EU) at the end of 2010 (effective July 2012), will lead to PCOs being further involved in regulatory activities. The work on the implementation of this legislation will commence during 2011 and PCOs will continue to be involved during the following years.
- The next progress report will be presented to the management board in 2012.

Section 2:
Analyses of the degree of satisfaction of PCOs involved in EMA activities during 2010.

Since 2007 the Agency has been measuring the degree of satisfaction of patients/consumers who have been involved in EMA activities, as requested by the EMA management board. This is considered an essential tool to monitor the progress of the interaction, to identify potential areas for improvement and to propose future actions. A new questionnaire, building on previous recommendations, was developed for 2010 to take into account additional specific activities such as the recent provision of extra financial support to patients/consumers.

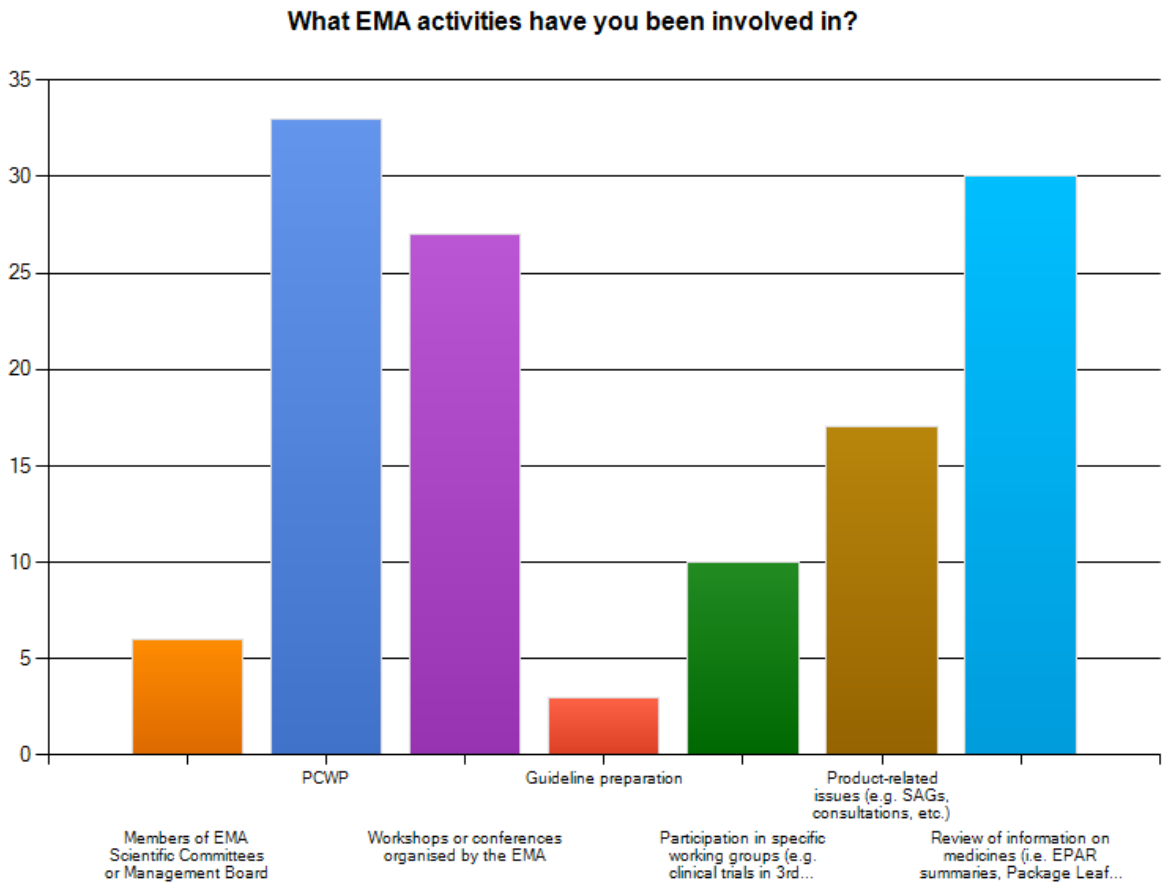
Every patient and consumer involved in EMA activities during 2010 has been asked to complete this questionnaire (132 sent) and a total of 71 responses have been received - 54% (100% from PCWP members). The questionnaire could be filled in anonymously if preferred.

The questionnaire consists of 15 questions, which can be answered by choosing among 5 grades of satisfaction rating from “Very satisfied”, to “Very dissatisfied” and each question also provides an additional box where the respondent is invited to add additional comments.

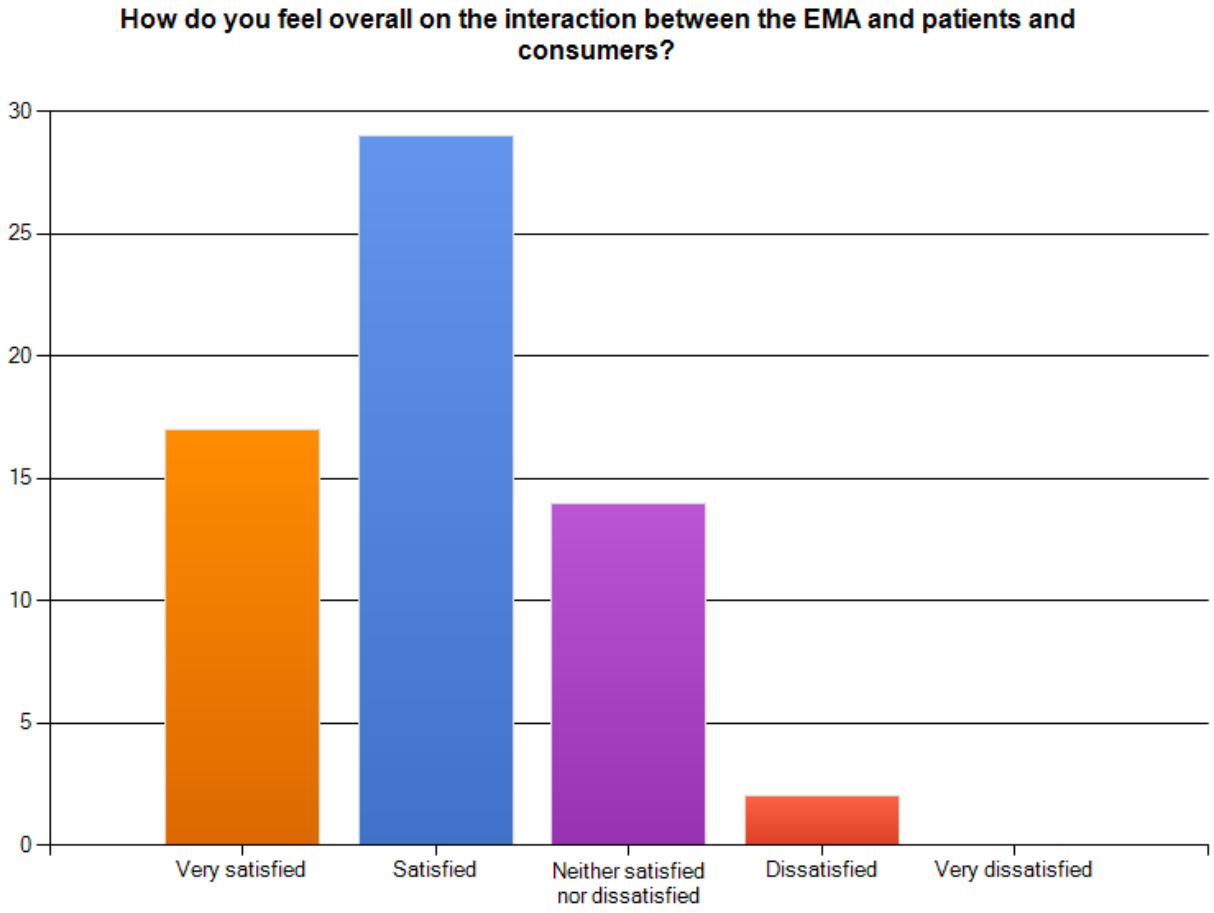
There are 4 main sections, Activities, general interaction, review of documents, logistics / practical arrangements and financial support.

The results were collected and analysed and are shown in the graphs below.

1. Activities

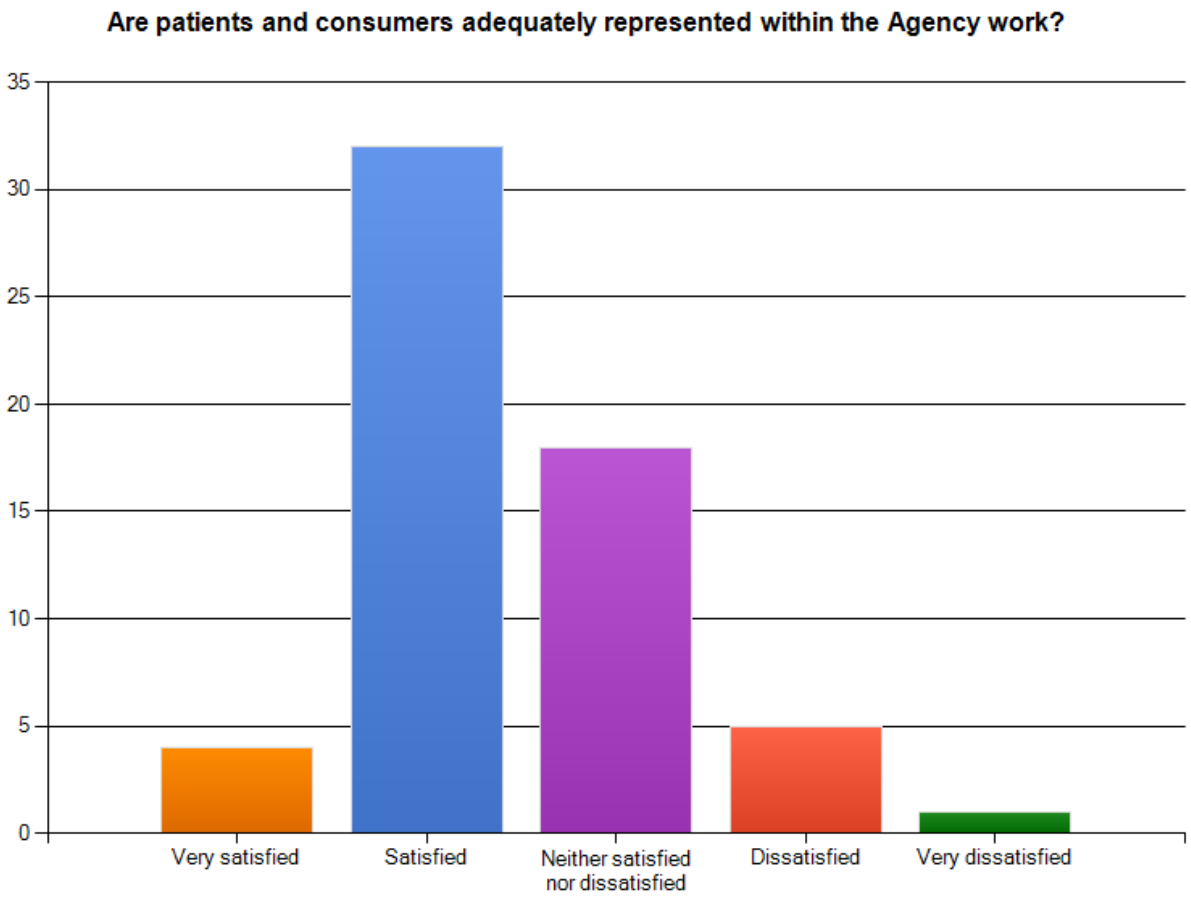


2. General interaction



Summary of comments received

Many patients indicated that they were very satisfied with the overall interaction between the EMA and PCOs, mentioning that the EMA can be “an example for other organisations on how to include patients in a meaningful way”. Some other comments include “I am very satisfied with the very ambitious work-plan and mandate of the PCWP and also of the achievements up until now”, “Has improved during the last year “, “worthy attempt but only partly successful”, “improvements can and should still be made”.



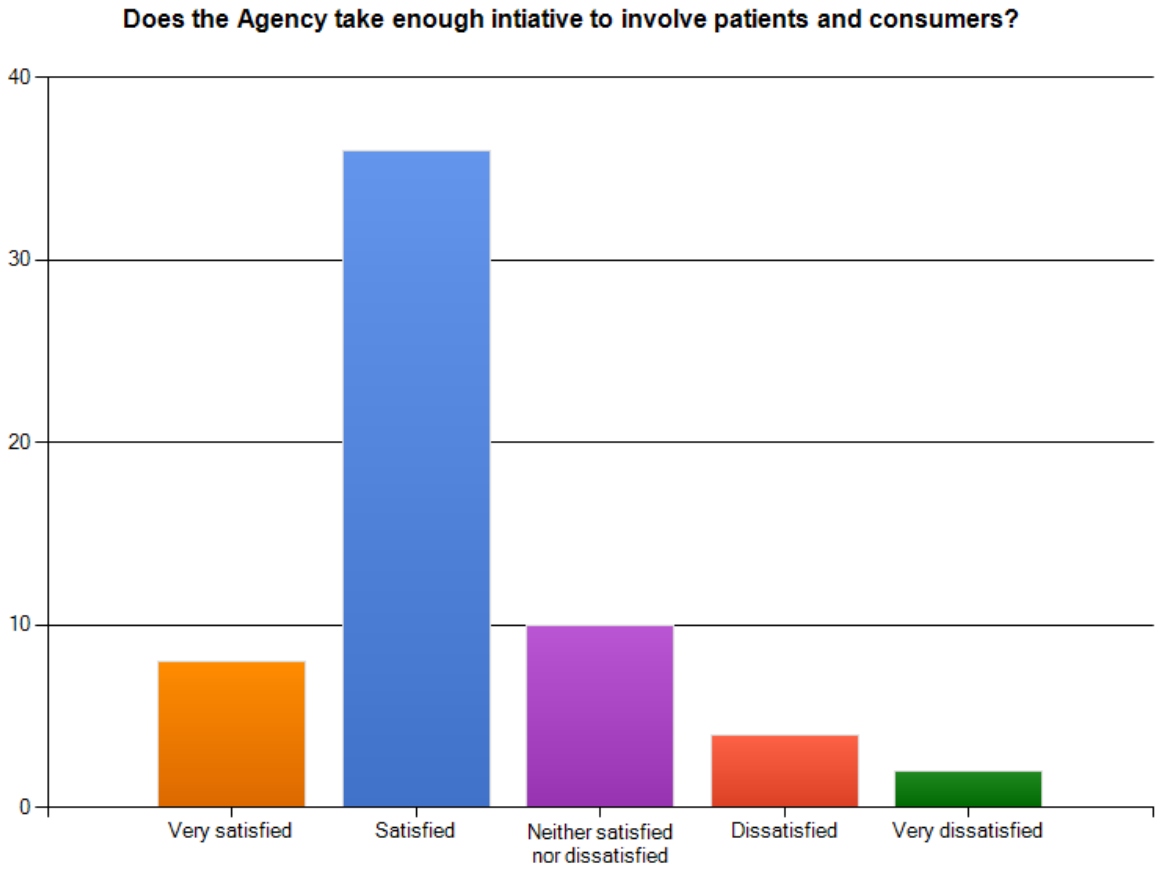
Summary of comments received

Most responders were satisfied with how patients and consumers are represented within the Agency work; however it was mentioned that in some places there can still be improvements. In particular responders mentioned the lack of patient representation in the CHMP. It was also highlighted that further training and support for new members would facilitate more extensive participation within different activities.

The plans for further involvement were appreciated and also the fact that patients are becoming equal step by step with scientific experts. It was also mentioned that the new policy on "conflicts of interest" may prevent the participation of some patient representatives in some areas and scientific committees.

Areas for improvement have been suggested as follows:

- Further involvement in benefit-risk evaluations (revision of framework).
- Systematic involvement in cases such a product shortages.
- Increasing the network of groups already involved within the Agency and look to expand the eligible organisations.



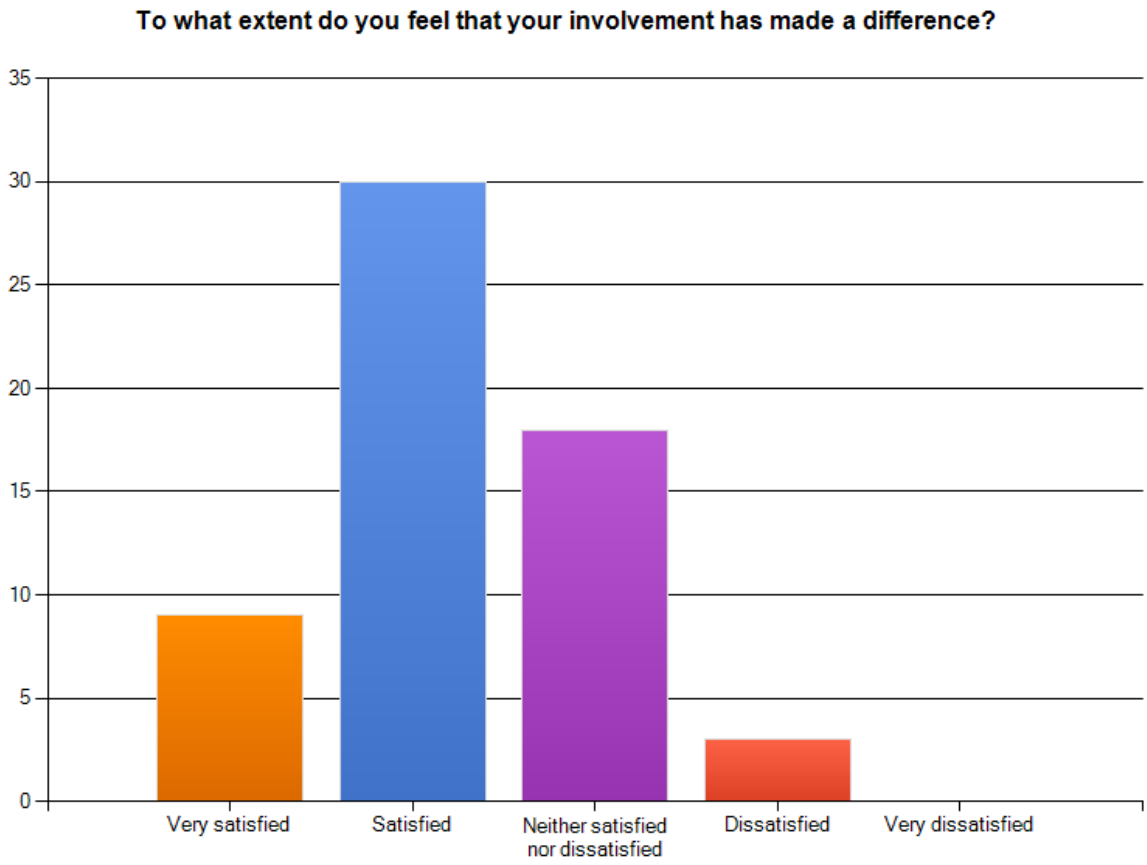
Summary of comments received

Most responders were satisfied with the way that the Agency takes initiative to involve PCOs in its work. It was mentioned that a wider audience should be reached, with more PCO representatives involved, but on the other hand for PCOs to find patient expertise within their organisations/networks is arduous work and time-consuming. Some felt that more could be done to involve patients and consumers and although the political willingness to involve more patient representatives exists, solutions to make this happen on a more sustainable scale may be limited (i.e. support to volunteers, greater difficulties for patient organisations to have members in the scientific committees.)

It was also highlighted that the financial support for their time was very welcome and encourages more people to give their time.

Areas for improvement have been suggested as follows:

- Continue to provide financial support for PCOs coming to the Agency (where appropriate).
- The Agency to continue looking at additional areas in which PCOs involvement can be of benefit for the Agency's outcome, e.g. SAWP, SAGs, benefit/risk evaluations, pharmacovigilance.
- Need to rationalise the benefit of the interaction vs. the work effort invested from both PCOs and the Agency.



Summary of comments received

Many responders were satisfied that their involvement had made a difference, although a number responded by being neither satisfied or dissatisfied, and mentioned that it was difficult to know if their involvement made a difference, which would indicate that perhaps more feedback would allow PCOs to better judge their involvement.

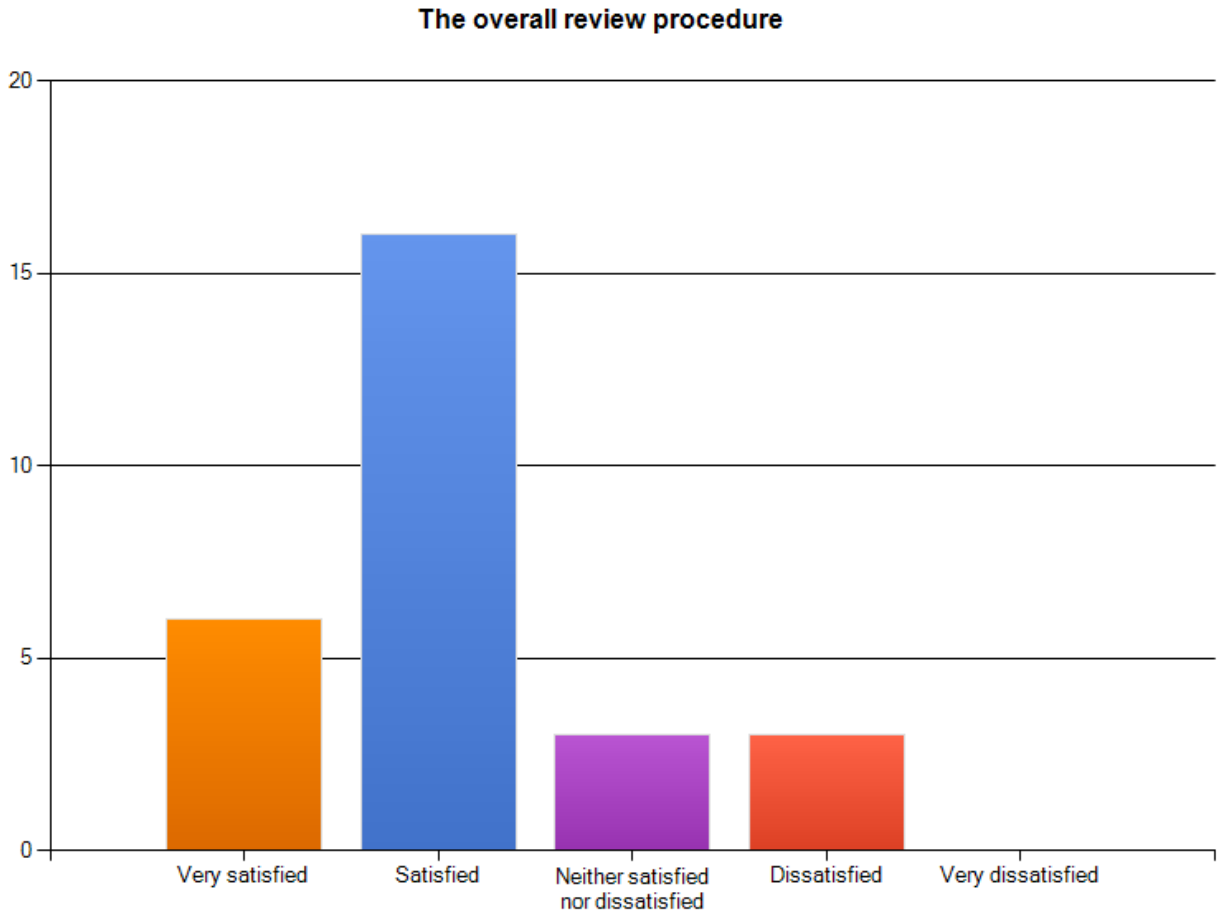
It was highlighted that the perception when patients participate in, e.g. any working group/party is that the perspective of patients is needed to come to the best possible decisions and that this is not merely understood by the patients, but also by the representatives of EMA and the NCA's. Patients and consumers bring a wealth of personal knowledge in dealing with public health. Another respondent felt that the “giving and taking of know-how between the Agency and patient representatives is very fruitful”.

Areas for improvement have been suggested as follows:

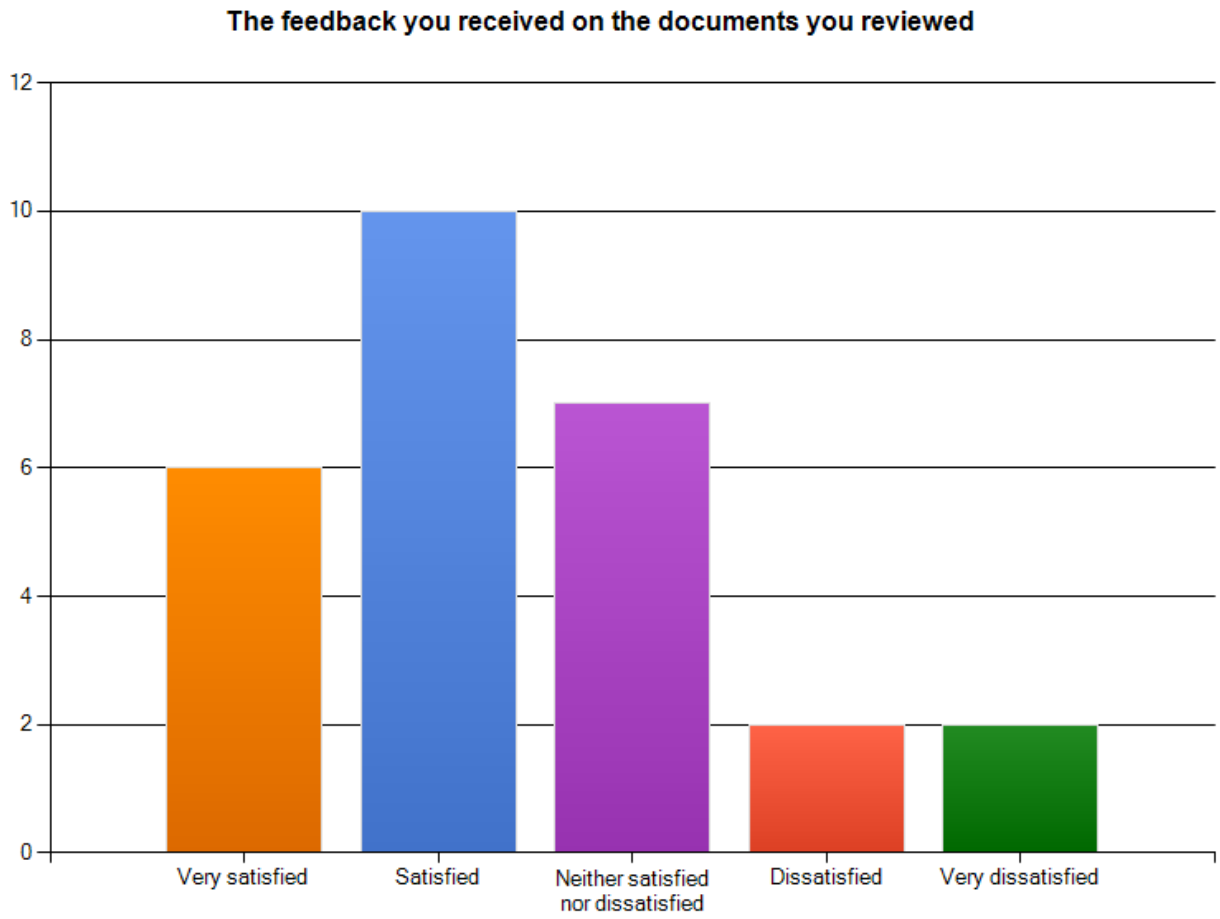
- The Agency will continue to provide feedback on patient involvement wherever feasible.

3. Review procedure

The following part of the questionnaire refers only to the review of documents and so was only applicable to those PCOs who had been involved in such procedures.



The majority of responders were either very satisfied or satisfied with the overall review procedure.

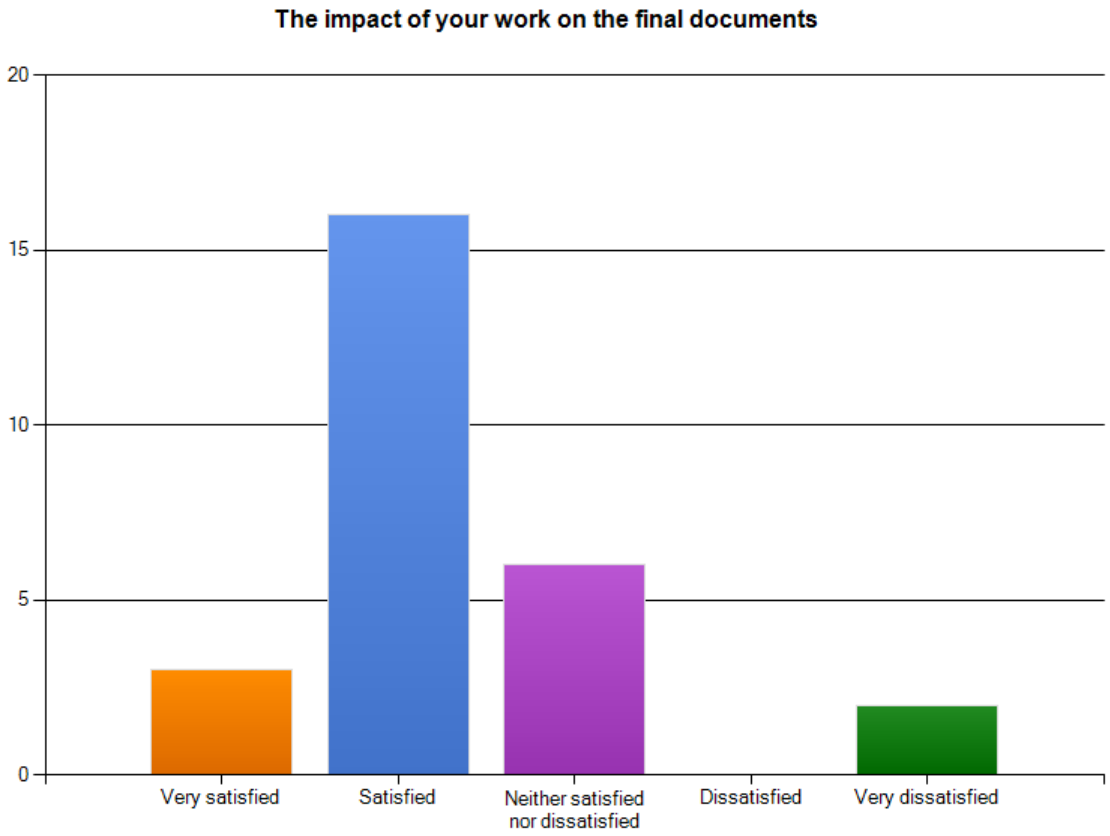


Summary of comments received

Although most responders were either very satisfied or satisfied with the feedback they received, some felt that they received very little or no feedback and that it this more related to procedures than content. However the scores indicate an improvement compared to previous performance indicators.

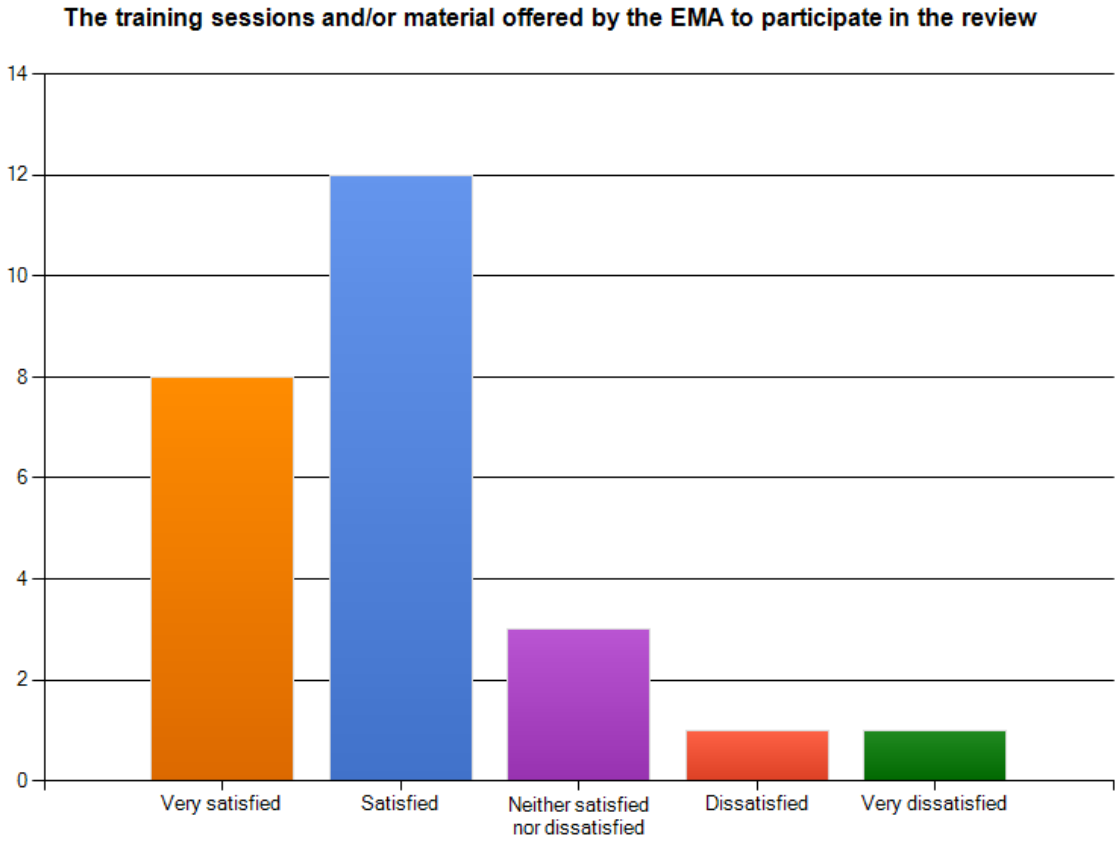
Areas for improvement have been suggested as follows:

- Since 2010, once a patient/consumer has reviewed a package leaflet, they are sent the version with all accepted comments (after discussion at the QRD review group). It is hoped that this will improve the level of feedback received by PCOs when reviewing documents (individual feedback is already given on reviews for EPAR Summaries).
- The impact of this initiative will be analysed in further performance indicators.



Summary of comments received

Again most responders were either very satisfied or satisfied with the feedback they received, some responses were neutral and it was mentioned that “did not have time to compare it with my comments”, “did not see the final document or that not many comments had been taken on board”.



Summary of comments received

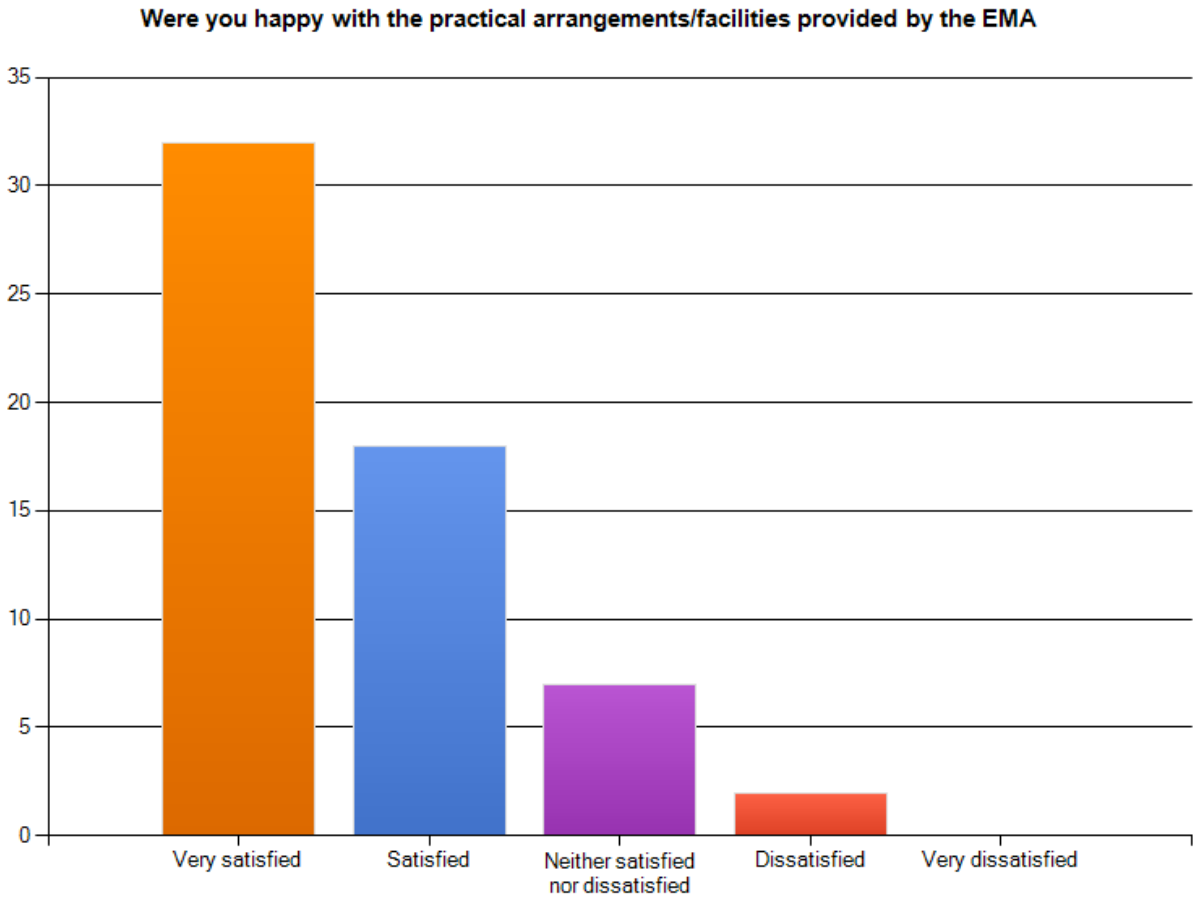
Many PCOs were very satisfied with the training sessions and material provided for the review of documents. It was requested to have a 'reviewers help desk' or similar.

Areas for improvement have been suggested as follows:

- Following a ‘brainstorming session on training’ during the June 2011 PCWP meeting, it was agreed that the Agency, together with the organisations, will look at alternative topics, methods and materials for enhancing the current training, which will be incorporated from 2011/2012.
- Changes in the structure of the current training will be evaluated within future performance indicators.

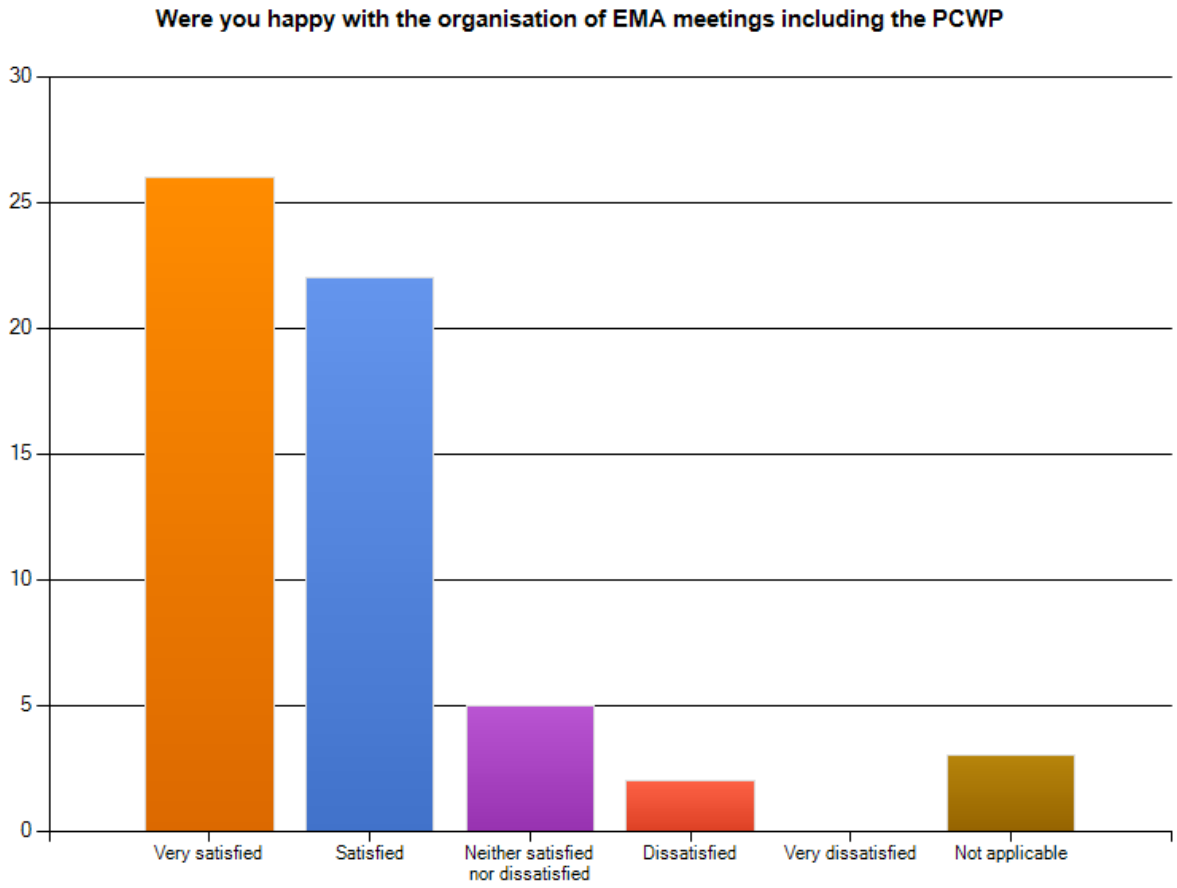
4. Logistics/practical arrangements

The following section refers to the practical arrangements with regards to invitations/booking/travel/accommodation etc, and also the facilities provided at the EMA offices



Summary of comments received

The majority of responders were very satisfied with the practical arrangements and facilities provided by the Agency. It was mentioned that reimbursement of expenses can take quite a while.



Summary of comments received

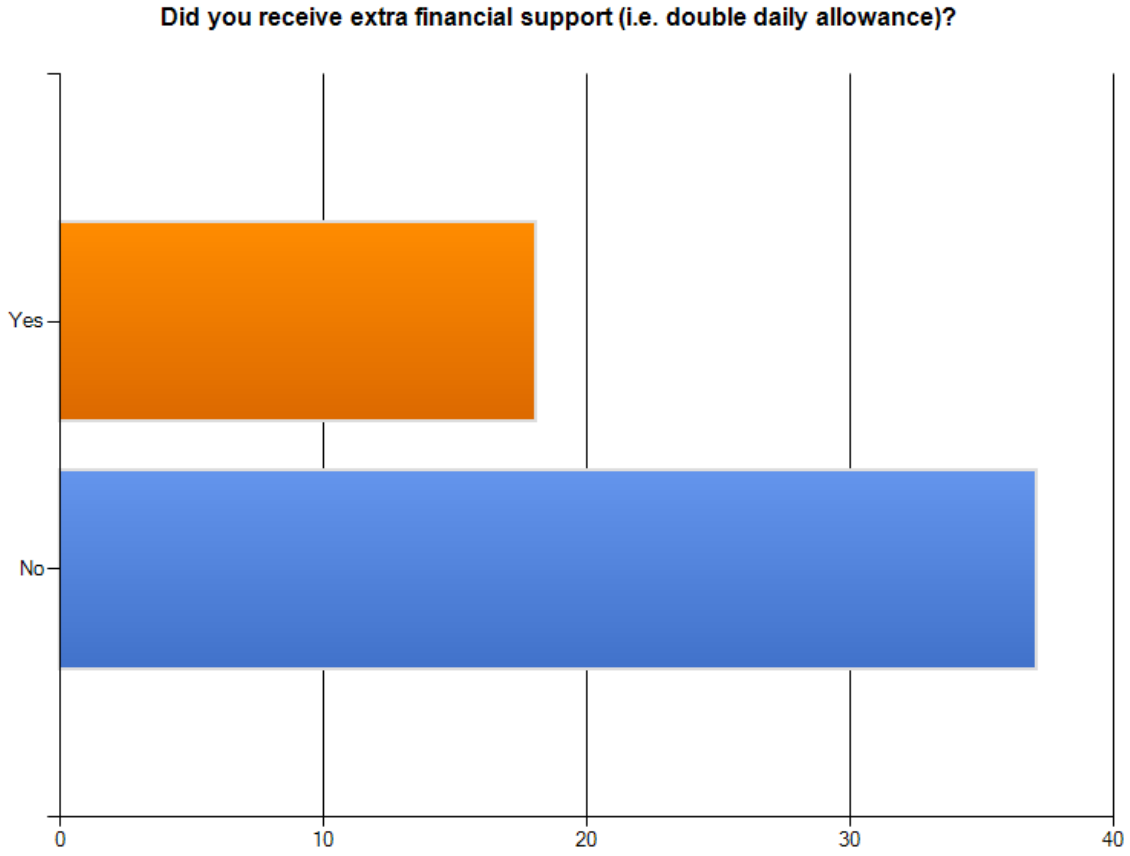
Again the majority of responders were very satisfied with the organization of EMA meetings. It was mentioned that it would be appreciated to receive meeting documents further in advance and also if more time could be allocated for speakers during meetings.

Areas for improvement have been suggested as follows:

The Agency will endeavour to allow more time for each topic on the agenda of the PCWP (and joint) meetings and to ensure that documents are sent out as far in advance as possible.

5. Financial support

The reflection paper, endorsed by the EMA MB in December 2009, included the proposal to provide financial support to patients/consumers in specifically defined circumstances. This was put in place during 2010 for those attending meetings at the Agency and this section of the questionnaire has been included in order to obtain specific feedback on the implementation of this measure.

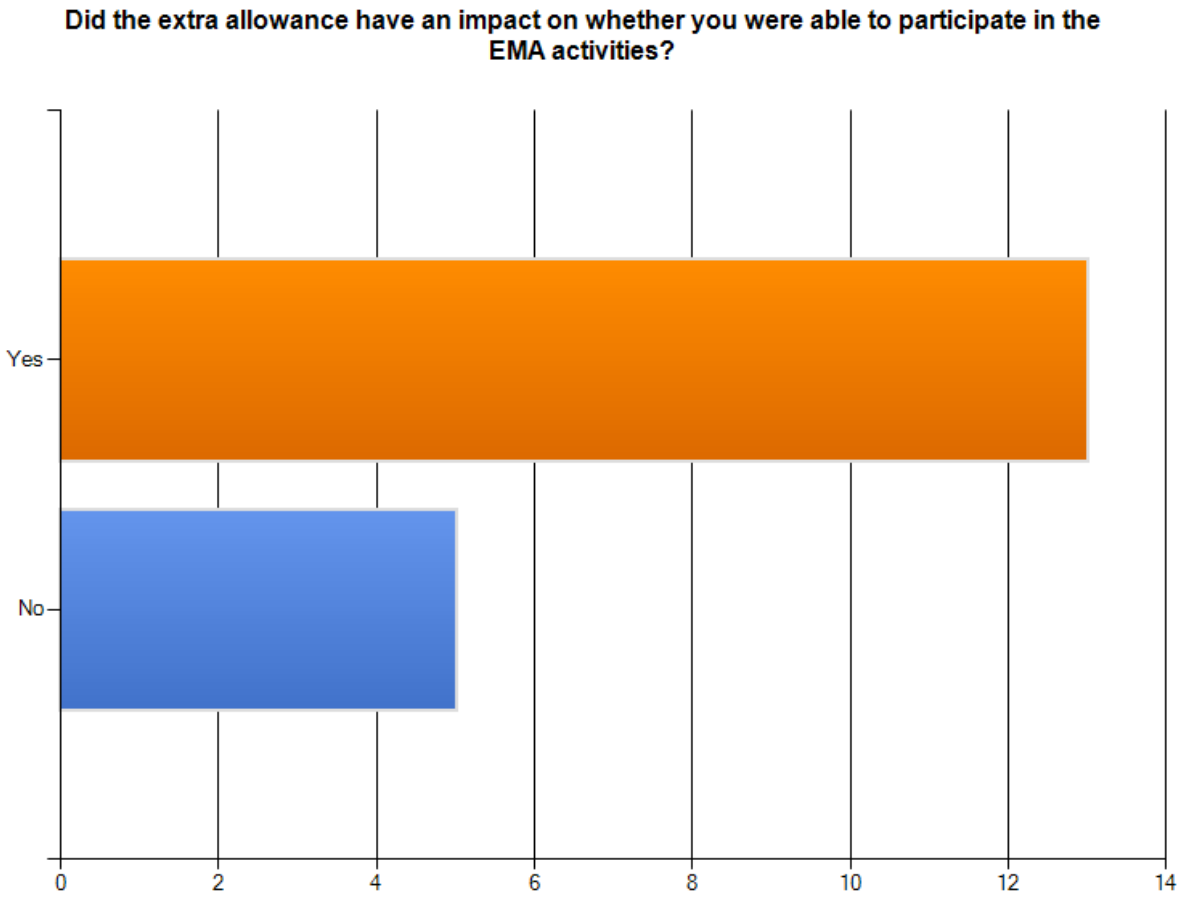


Summary of comments received

Not so many patients/consumers who requested financial support during 2010.

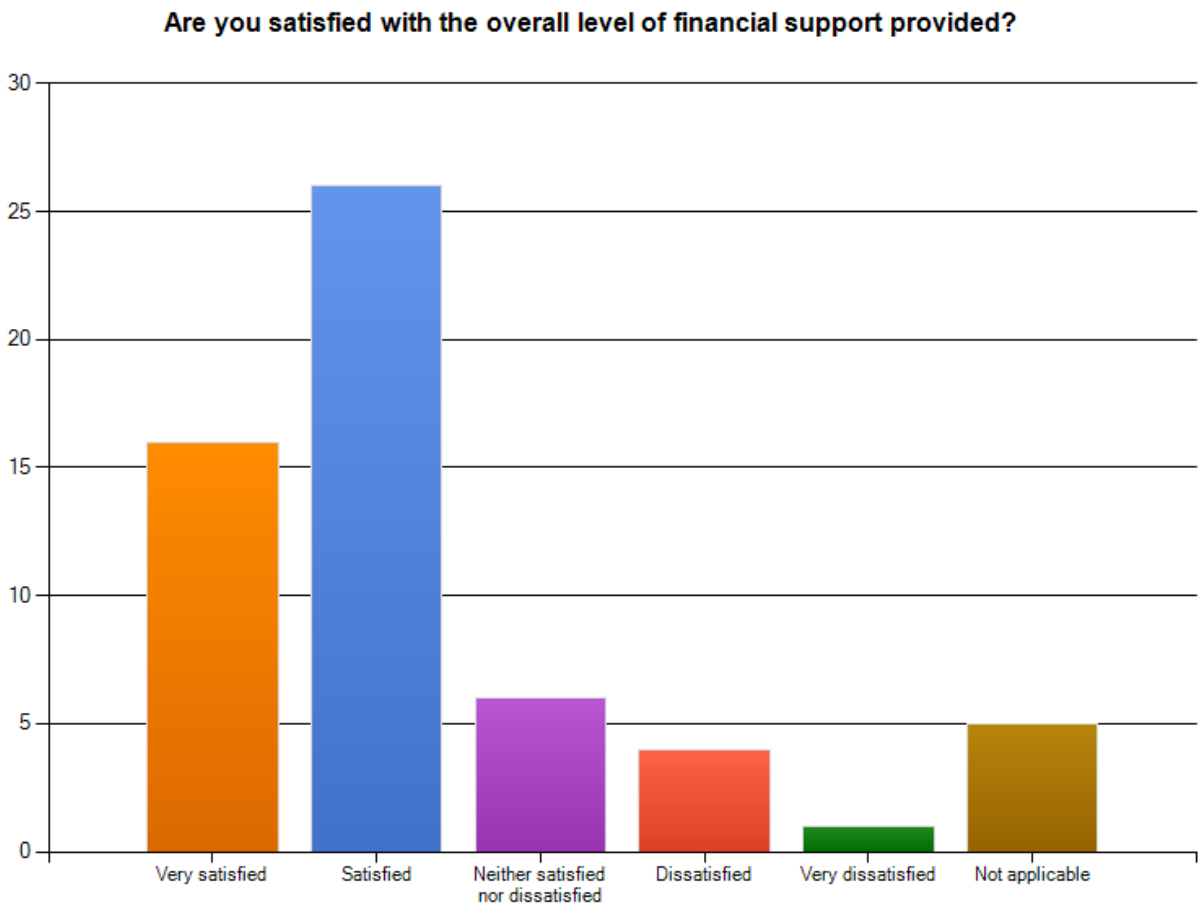
Areas for improvement have been suggested as follows:

Remind all organisations about the financial provisions in place and the related criteria.



Summary of comments received

Many PCOs felt that receiving an extra financial assistance did have an impact on their participation in EMA activities. Some comments included : “I am happy with the extra allowance for there are so many additional costs when you are traveling”, “It showed a willingness to understand the conditions of the patient reps”, “I am self employed- this payment made by EMA made it possible for me to attend and not worry about my loss of income”, “A definite plus”, “The allowance helps to cope with the loss of salary (not completely)”, “Makes a difference to organisations with very few staff “.



Summary of comments received

Overall it was highlighted that as patients' representatives undertake a lot of work as volunteers - this payment was very welcome. Most responders were happy with the overall level of financial support; however it was pointed out that for example, reviews of PLs are carried out during leisure time and that additionally the financial support applies only for the time spent in meetings, not for the time invested in their preparation. The lack of compensation discourages professionally active patient representatives to take on more responsibilities and work.

It was also mentioned that the overall financial support to patient representatives, particularly to volunteers, is not enough to compensate for their loss of revenue/days off and makes it often very difficult to identify volunteers in the various scientific committees.

Areas for improvement have been suggested as follows:

- Evaluate if the current criteria used to select those patients eligible for support are suitable.

Notwithstanding that any possibilities for further financial support are linked to the budgetary situation.

Overall conclusions on 2010 performance indicators (PI) questionnaire

The results and analyses of the performance indicators questionnaire demonstrate that overall general satisfaction remains high from PCOs who have been involved in EMA activities during 2010.

The review process continues to be a success, from both PCOs and EMA perspectives and satisfaction with regards to the level of feedback obtained, has increased which shows that measures put in place have been effective.

Financial support included since 2009 is very well received and perceived as an EMA understanding of the value of patient contributions, however not everyone is benefitting from this, in particular those not attending meetings (e.g. experts involved in the review procedure and in CHMP written consultations).

Many of the comments received in the questionnaire can be linked to specific actions proposed towards further improvement. These actions are largely included within the proposals for the revision of the framework of interaction and/or are highlighted in the 'next steps' above (pages 25/26).

General comments from PCOs

At the end of the questionnaire there was an area for general comments on the overall interaction between PCOs and the Agency. Some of these comments are included below:

“Over the past few years there has been genuine progress in actively involving PCOs and widening their roles, this will always take time given the complexities of EMA's role, plus the need to ensure PCOs are adequately trained to take part in EMA's affairs. There is a continuing need to regularly remind all EU patients organisations of the opportunities for involvement and where possible to encourage the national competent authorities to mirror the EMA approach when involving patient/consumer organisations”

“Go on this way and let the PCWP come with proposals to make the involvement even more meaningful. The single fact that EMA has at the moment the best performance with regard to PCO involvement is a reason for satisfaction, but also a motivation to stay on top”

“It is about partnerships and collaborative work!”

“The two events I have attended we were made to feel very welcome - that is so important and our views were sought on various issues”

“Time is an issue and short deadlines are not good for us”

“I feel the EMA could do more to assist in the education and engagement of patients - to allow patients with appropriate credentials to gain sufficient knowledge to represent patient views at higher and more influential levels”

“Maybe for some functions, more patient alternates should be foreseen. Patients unfortunately are confronted with health problems, meaning that they sometimes "drop out" because of their health“

“The interaction between the EMA and patients and consumers is at an early stage; there is a long way to go on either side”

“Much more consumer consultation is required before products are discontinued”

“I believe EMA really wants to involve patients but because of complex procedures and limited time and meeting schedules it's very hard to really present a patient's perspective in the whole process”.

“All people involved were very open and ready to help but still it was hard to figure out what the precise process would involve and how and when we could intervene and express our point of view”

“The idea to involve relevant organisations and patients-consumers is very important and I hope I will have more opportunity to attend similar trainings in the future, and learn more about your excellent work “