EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 September 2012
EMA/507517/2012
Patient Health Protection

Fifth report on the interaction with patients' and consumers' organisations (2011)

7 Westferry Circus • Canary Wharf • London E14 4HB • United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8416
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

Table of contents

1. Executive summary

Introduction

This report provides a detailed overview of the various EMA activities where patients, consumers and their organisations have been involved during 2011. It also includes a comparison to preceding years and highlights future steps for interaction. A summary of the work carried out by the "EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations" (PCWP) is also included.

When the framework of interaction between the EMA and patient /consumer organisations was endorsed by the Agency's Management Board (MB) in 2005, it requested to be presented with an annual report each year in order to monitor the interaction.

The current report was presented to the PCWP during its meeting on 26 September and to the Management Board during its meeting on 4 October 2012.

Herewith attached is a link to our glossary of acronym definitions.

Interaction with patients' and consumers' organisations during 2011

The involvement of patient representatives throughout many aspects of the Agency's work is now well established and during 2011 an extensive collaboration was again achieved across a wide range of activities. The interaction with patient groups has proved to be extremely beneficial; they provide a crucial patient perspective to the scientific discussions on medicines and have helped to provide valuable insights. There is a need and expectation for public bodies to listen to the views and experiences of patients who are the ones most affected by the regulatory decisions and engaging with these stakeholders gives the Agency and the public more confidence and reassurance in its outcomes. However, the key to successful involvement is not only to consult patients, but to do so in the most appropriate manner to ensure the best use of their expertise and time.

During 2011, the patients and consumers work in the Agency has been enhanced in several areas; such as systematic patient participation in scientific advisory group (SAG) meetings, an increased review of EMA documents, especially safety communications (Q&As) and package leaflets, and participation in new activities related to the new pharmacovigilance legislation. This is in addition to existing regular interaction across many of the Agency's activities, which has remained consistent throughout the year (see below for full details).

Work has continued on the revision of the framework of interaction which will further develop the formal collaboration between the EMA and patient/consumer organisations. The revision will focus on; facilitating patient participation in benefit/risk deliberations, defining the role of patients involved in the scientific committees and delineating the training and support necessary to both facilitate and optimise patient involvement.

Progress on these enhancements to date includes the preparation of a document on the role of patients as members in the scientific committees which was adopted by all committees and published in December 2011. Additionally a 'training brainstorming' session was held in the margin of the PCWP meeting in February to gather information on the needs and expectations in terms of training for patients involved in EMA activities, with the ultimate aim to develop a training strategy during 2012.

Interest from patient/consumer organisations remains high and the number of organisations applying and becoming eligible to work with the Agency increased from 29 (end 2010) to 34 by the end of 2011.

The EMA has updated the Criteria to be fulfilled by patients' and consumers' organisations involved in EMA activities, adding clarity to several of the requisites. Additionally the process for evaluation and re-evaluation of organisations has been streamlined and in 2011 the Agency and the PCWP began reflecting on how to improve the way to handle possible conflicts of interest of organisations.

Next steps

The forward focus will be the revision of the "framework of interaction" between the EMA and PCOs, to incorporate:

- The role of patients within the scientific committees (document already published);
- An outline of their involvement in benefit/risk evaluations;
- A defined strategy for training and support.

PCO representatives will continue to be involved in many activities across the Agency, i.e. PCWP related activities, scientific advisory group meetings, committee consultations, the review of information for patients/general public, as participants in conferences and workshops and as patient representatives in the EMA MB, working parties and the different committees including the new pharmacovigilance risk assessment committee (PRAC).

The new pharmacovigilance legislation will serve to strengthen the interaction, for example through their participation in the development of new risk management plans and summaries for publication. Work on the implementation of this legislation has very much involved patients/consumers throughout the year and they will continue to be actively involved in the following years.

During 2012 the EMA and the PCWP will work on increasing transparency in its procedures for evaluation and re-evaluation of eligible organisations, and will also explore how to develop the way potential conflicts of organisations are handled when working with the Agency.

The management board will be presented with the next annual report on the interaction with patient and consumer organisations in 2013, together with the survey results and analysis on the level of satisfaction of patients and consumers in the EMA.

2. EMA activities involving patients and consumers during 2011

Patients are included as formal members in the Agency's Scientific Committees (COMP, PDCO, CAT) and since April 2010 have also been included as permanent representatives in the PhVWP (more details below). They will also be members of the new Pharmacovigilance Risk Assessment Committee (PRAC) in the future.

There has been an increased involvement of PCOs in benefit / risk evaluations, specifically through their involvement in the scientific advisory groups (SAGs) convened by the CHMP. In these meetings patients with the specific disease/condition under discussion have been able to demonstrate their ability to provide unique and valuable information which has ultimately contributed to the product-specific benefit-risk deliberations and the overall assessment data in terms of real life experiences and views.

Patients are systematically involved in the preparation of the Agency's safety communications; one of the main methods for conveying key messages to the public on the medicines evaluated by the Agency, as well as all package leaflets and EPAR summaries for new medicines. They review the readability of the information to ensure that it is clear and understandable for the target audience, and that it fulfils their needs in terms of information content.

PCOs continue to be involved in several on-going EU-wide initiatives, such as EudraCT (EU clinical trials register), Eudravigilance (public database), ENCEPP (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance) and more recently Enp-EMA (European Network of Paediatric Research).

The Agency has also consulted patients on key aspects related to the new pharmacovigilance legislation, through dedicated meetings with stakeholders as well as direct consultations; e.g. the public Eudravigilance website, proposals for RMP summaries, forms for direct patient reporting and the symbol and text to be included in the SmPC and package leaflet for medicinal products subject to additional monitoring (see tables below for full list of activities).

The Agency now has a well established 'network of experts' from patients/consumers organisations and through this network the EMA was able to reach many experts throughout diverse therapeutic areas. This network is an extremely valuable resource which has expanded due to the increasing number of organisations eligible to participate in EMA activities, and the wider areas represented. An up-to-date list of eligible organisations is published on the Agency website.

The value of the contributions brought to the Agency by 'lay experts' and the unique insights that they share is by now well acknowledged across the different areas and activities in which they are involved.

2.1 EMA Management Board (MB)

The MB consists of 35 Members, out of which there are two representatives of patients' organisations appointed by the Council along with Doctor organisations' representative and Veterinarian organisations' representative. The legal basis for these memberships is found in article 65 (1) of Regulation (EC) Nº 726/2004.

The Board adopts the Agency's budget, approves the annual work programme and is responsible for ensuring that the Agency works effectively and co-operates successfully with partner organisations across the EU and beyond.

The patient representatives on the MB are fully integrated into the work of the Board and actively participate in the discussions and the decisions taken, providing their views as users of medicines and representatives of civil society. There were 5 board meetings held at the EMA during 2011. One patient representative, Mike O'Donovan, is also a member of the Management Board Telematics Committee (MBTC). There were 7 meetings held by the MBTC in 2011.

Following the end of the civil society representatives' mandates in March 2012, both patients representatives continued to be invited to the Board meetings, and to the MBTC as relevant, throughout 2012. New patients representatives' nominations are expected to be received in the near future.

Mike O'Donovan also attended PCWP meetings as an observer to maintain 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. In addition, all the Committees may consult PCOs on specific issues as and 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:

In addition to patients being members of the COMP, 4 other patients' representatives were consulted as experts in procedures concerning orphan designations.

A COMP member attends the meetings of the PCWP to maintain a link between the two groups.

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 and alternates were nominated in August 2011 for a renewable term of three years.

Their tasks include, among others:

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

A PDCO member attends the meetings of the PCWP to maintain a link between the two groups.

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 last members were nominated at the end of 2008 for a renewable period of three years. New members will be selected and appointed in the near future.

Their tasks include, among others:

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

A CAT member attends the meetings of the PCWP to maintain a link between the two groups.

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 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. It is foreseen that PCO representatives with a specific interest/expertise in herbal medicines will contribute to the preparation of summaries of monographs which will be published in the near future.

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.

A CHMP member attends the meetings of the PCWP to maintain a link between the two groups.

During 2011 involvement of PCOs representatives in the work of the CHMP occurred as follows:

CHMP consultation with PCOs on products/issues under evaluation

The CHMP consulted with several organisations to obtain a patients/consumers viewpoint with reference to particular medicinal products under evaluation. The products were: Multaq (wording of safety information on the PL), Zerit (current use of product), Celecoxib (current use of product), Vpriv (availability of the medicine) and the review of the proposed patient communication by Baxter regarding dialysis solutions.

In each case, organisations are asked to respond in writing to a list of questions adopted by the Committee/working party. The information is then taken into account by the CHMP during the evaluation process towards their final opinions.

Third party intervention with CHMP

One patient organisation presented their concerns to the CHMP with regard to the product Fampyra and the re-examination of a negative opinion. These concerns were forwarded to the CHMP members for consideration. Patient representatives from this organisation also participated in the SAG meeting concerning this procedure.

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.

Following the occasional participation of patients in some SAG meetings early in 2010, the CHMP wanted to further explore the involvement of patient representatives in these meetings. It was therefore decided to run a pilot phase in which patients would systematically be invited to all SAG meetings during a period of one year and the outcome would decide the way forward. The pilot phase ran from October 2010 to October 2011 and questionnaires were sent out to both patient representatives and regulators to obtain feedback on their involvement.

The subsequent outcome report demonstrated that the inclusion of a patient viewpoint can enrich the SAGs output and the overall evaluation of the benefit and risk of the medicine with the unique real-life perspective from a patient who has experience of the disease/condition.

It was highlighted that the patient representative contribution to SAG meetings is, as would be expected with any expert, variable and depends on the type of questions addressed during the SAG (e.g. more on acceptability of risk), however there is an intrinsic value to their presence; only by having a patient present can his/her views be requested if, and when needed. Additionally involvement in SAG meetings is highly valued from the patients' perspective and is an activity which provides increased transparency in the assessment process.

Following the finalisation of the pilot phase, and agreement by the CHMP, patients will be invited to participate in all SAG meetings.

During 2011, a total of 22 patients participated as patient experts in 18 different SAG/expert meetings to provide their views on specific questions.

The areas covered were: multiple sclerosis (Gilenya & Movectro), anal cancer (HPV vaccine), HIV (concept paper), general cancer (dexrazoxane), lupus (benlysta), multiple sclerosis (fampridine), skeletal events related to cancer (denosumab), adrenal insufficiency (plenadren), pneumococcal vaccine (prevanaar), diabetes (actos), atrial fibrillation (multaq x 2), thyroid cancer (vandetanib), cystic fibrosis (bronchitol), uveitis (luveniq), lipoprotein lipase deficiency (glybera), migraine (sumatriptan) and an antifibrolytic (aprotinin).

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 from pharmaceutical companies for protocol assistance (for orphan drugs). These representatives gave their input during attendance at a SAWP plenary meeting or by submitting comments in writing.

Participation in the Pharmacovigilance Working Party (PhVWP)

During 2009 a pilot phase included two patients' representatives as observers in three consecutive PhVWP meetings. The subsequent analysis report, endorsed by the management board and the Heads of Medicines Agencies, proposed the permanent inclusion of patient/consumer representatives in the PhVWP.

Following a call for expression of interest and a selection procedure in 2010, the Agency nominated one patient representative and one alternate to join the PhVWP as observers with a yearly renewable membership. This participation officially began in May 2010; the representative being from the International Alliance of Patent organisations (IAPO) and the alternate from the European Myeloma Platform (EMP). This membership was subsequently renewed in 2011 with the same representative and the alternate this time from the European Consumers Organisation (BEUC).

There were also numerous consultations from the pharmacovigilance working party to the PCWP; namely regarding stevens-johnson syndrome and toxic epidermal necrolysis, anti-epileptic medicines and the risk of bone disorders, antipsychotics and use in pregnancy, carbamazepine related skin reactions and finally on the implementation of the Isotretinoin pregnancy prevention program.

2.2.6 Mutual Recognition & Decentralised Procedures - Human (CMDh)

During 2011 the CMDh consulted with PCOs to obtain feedback on a core package leaflet for Hormone Replacement Therapy products.

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

The PCWP continues to play a key role in the interaction between the EMA and PCOs.

The composition of the PCWP during 2011 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, the PhVWP and the EMA management board.

There were four plenary PCWP meetings during 2011, including one meeting with all 'eligible' organisations, 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 in November.

In consultation with PCWP, it was decided to increase the number of joint meetings with the HCP WG (soon to be HCPWP); therefore the work plan for 2012 includes 2 joint meetings.

In 2011 the PCWP Co-Chair patient representative initiated a 'mentorship' system whereby the 'older' PCWP organisations provide assistance to the more recent organisations. This system is a way for the established organisations to pass on their knowledge and experience, concerning the EMA and the role of the PCWP, in a relatively informal manner.

During the year the PCWP was consulted by the pharmacovigilance working party (PhVWP) in relation to five separate procedures (see below), and also by the CMDh (mutual recognition & decentralised procedures – human) concerning one procedure.

Through the PCWP, patients and consumers representatives are involved in other initiatives, for example 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 the European Network of Paediatric Research (Enpr-EMA).

2.4 Activities related to implementation of the new pharmacovigilance legislation

2.4.1 Stakeholder meetings

Three stakeholder forums took place during 2011 and included participants from industry, patient, consumer and healthcare professional representatives, representatives from national medicines regulatory authorities, the European Commission, and the Agency itself. The objective of these meetings is to raise awareness of the requirements of the new legislation and to provide a forum for the exchange of concerns and opinions.

The first meeting, held on 15 April 2011, was aimed at obtaining feedback from stakeholders mainly in relation to the Agency and Member States technical contribution to the draft European Commission implementing measures. Twelve patient representatives participated.

The second, on 17 June, and gave the opportunity for stakeholders to discuss with the Agency and Member States their expectations on other aspects of the implementation of the new legislation. Fifteen patient representatives participated.

The third meeting was held on 20 October and the objectives were to present an update on the implementation process, share the orientations related to the EMA and Member States planning and prioritisation for the implementation, and to obtain relevant feedback from a range of topics particularly relevant to stakeholders. Twenty patient representatives participated.

Several patient representatives gave presentations during these meetings, such as Eurordis on "Patient organisations use of Eudravigilance", BEUC on "direct patient reporting", IAPO on "experience as patient observer at the PhVWP", EATG and AGE on "what is expected from public hearings" and the co-chair of the PCWP on "the impact of pharmacovigilance on patients".

These meetings were well appreciated by PCOs and they have proven useful instruments for the Agency to obtain feedback on the implementation process.

Stakeholder meetings will continue to take place during 2012 and patient representatives will be invited to participate and to provide their input.

2.4.2 Additional monitoring of medicines & direct patient reporting - impact on the package leaflet

The new legislation defines that certain medicinal products will be included on a list for 'additional monitoring'. For these products, it is proposed to include a black symbol and an explanatory sentence in the summary of the product characteristics (SmPC) and in the package leaflet. Additionally a standardised sentence will also be included in the product information for all medicines, encouraging the reporting of suspected adverse reactions for these particular medicines.

During 2011 the Working Group on the Quality Review of Documents (QRD), within the Agency, worked on some draft proposals of the text to be implemented in the product information. The final proposals will be sent to the Pharmacovigilance Risk Assessment Committee (PRAC) after internal and external consultation. The black symbol will be chosen by the European Commission following a recommendation of the PRAC after the new committee is established in July 2012.

Draft proposals were presented at the PCWP meeting with all eligible organisations, held in November, for discussion and initial comments. Five PCOs were also involved in a written consultation on the design and selection of the symbol and proposed text during December. It is likely that they will also be further consulted on further versions during 2012 before the final options are presented to the PRAC.

2.4.3 Draft direct patient reporting form

The new legislation facilitates the reporting of suspected adverse reactions to medicinal products by both healthcare professionals and patients who will be able to report suspected side effects directly to their national medicines authorities.

As agreed during the panel discussion at the second stakeholder meeting (on the implementation of the pharmacovigilance legislation) the value of direct patient reporting has been demonstrated by analysing various research projects and pilots. Current evidence indicates the need to increase

awareness among patients of the opportunity they have to report adverse reactions directly. The role of patients' and healthcare professionals' organisations was highlighted here.

According to the legislation "the Agency shall, in collaboration with the Member States, develop standard web-based structured forms for the reporting of suspected adverse reactions by healthcare professionals and patients"; the EMA clarified that the core data will be harmonised, however as there are already several forms in use within some member states, there will be flexibility in the format used. The Agency prepared a draft standardised form which was reviewed by six patient organisations during October and November.

This project will continue during 2012 and PCOs will be kept updated and involved as appropriate.

2.4.4 Risk management plan summaries

The new legislation states that a Risk Management Plan (RMP) is required for all new medicines and that a summary of the RMP should be made public. In December 2011 following a call for expression of interest, several PCWP members expressed interest to participate in a workshop, whereby patients input is needed; namely in identifying key information to be included in the summary, exploring the most suitable format and identifying key principles for a process whereby PCOs can be involved in the preparation of the summaries. The workshop was held in March 2012.

The aim is to involve the perspective of patients and consumers on the development of this new type of document - which will include relevant information for the general public, and as such they will continue to be involved in the future discussion on this topic.

2.5 Activities related to clinical trials

2.5.1 Reflection paper on third country clinical trials

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").

The reflection paper aims to clarify the practical application of ethical standards in the context of EMA activities, to determine practical steps to be undertaken during the provision of advice in the drug development and marketing authorisation phases and to improve international cooperation in the regulation of the review and inspection of clinical trials.

The draft paper was released for public consultation during 2010 and an international workshop was also held including a wide range of stakeholders' associations; patients' representatives, ethics committees, national competent authorities, commercial and non-commercial sponsors' associations, CROs and researchers.

The working group met for the last time in February 2011 and the final reflection paper was published in April 2012.

2.5.2 Development of the EU clinical trials register

All clinical trials carried out within the EU since 2004 have to be registered in the EudraCT database. In March 2011 this information was made available for the first time to the public via the Clinical Trials

Register (in accordance with EU Regulation Nos. 726/2004 and 1901/2006). This register also includes worldwide trials involving children.

PCOs have been very involved in the development of the register; 10 representatives have been members of the EudraCT joint operational group since 2010. The group met three times during 2011 to focus on the new public interface to ensure it is 'user-friendly'. This included preparation of a guidance document for users and practical user-testing of the actual system prior to its launch.

In addition, links to the EMA eligible PCO websites have been included within the register for the benefit of patients looking for additional information on clinical trials within specific disease areas.

The Agency will continue to work with this group to improve the functioning of the register; by enhancing the quality and completeness of data and improving the search functionality. Plans for the future also include the publication of summaries of clinical trial results, which will require a major upgrade to the existing system.

2.6 Activities related to the provision of information to patients and the general public

The EMA publishes information about the 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 clear and understandable for patients/consumers and fulfils their needs in terms of information content.

Patients/consumers are regularly involved in the review of package leaflets (PLs), EPAR summaries, question and answer documents (Q&As), 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) and has been expanded to also include PLs for new medicines and Q&As 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 organised 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.

Experience acquired so far confirms the relevance of comments received – approximately 50% of comments are taken on board. The patients' and consumers' contribution increases the quality of the documents within the scope of this procedure.

Review of EPAR summaries

During 2011 PCOs representatives reviewed a total of 38 new EPAR summaries.

Review of package leaflets

During 2011 PCOs representatives reviewed a total of 71 package leaflets.

Review of EMA safety communications

During 2011 PCOs representatives reviewed a total of 24 Q&A documents.

Training on the 'review of EMA 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 2011. In addition to the usual training on the review of package leaflets, EPAR summaries and safety communications, this training also included an overview of the centralised procedure.

All eligible organisations and their nominated experts are invited to attend and in this case 25 "patient experts", attended the training session.

All experts who attend are provided with a CD ROM and a training manual containing all information needed to perform the review of these documents.

Human Medicines Highlights

Since several years now, the EMA publishes (and sends to subscribers) a 'human medicine highlights' (HMH) document each month, which is addressed primarily to patients, consumers and healthcare professionals organisations and provides a summary of key information relating to medicines published by the EMA during the previous month. PCOs collaborated in identifying the information in this communication tool and its further development. There are currently over 3000 subscribers to the HMH, increasing by an average of 200 per month.

2.7. Other activities

Involvement in EMA workshops, conferences, info sessions and expert meetings

- **Workshop on drug-related progressive multifocal leukoencephalopathy (PML)**

The EMA hosted this two-day transatlantic workshop, co-chaired by the FDA, on 25 and 26 July 2011, bringing together European and US stakeholders, including patients, healthcare professionals, academia, industry and regulators.

PML is usually a fatal condition, and its prevention or treatment would bring about significant benefits to patients. PML is a classic complication of HIV and an AIDS-defining illness. Drug-induced PML limits the therapy of multiple sclerosis and raises the question how PML inducing drugs can be used safely and effectively.

The aim of this workshop was to learn more about the disease for clinicians to be able to predict which patients are at higher risk of developing PML and to ensure that clinical decision-making and risk management are informed by the most up-to-date information. The workshop mapped on-going research, identified gaps and discussed research priorities. It also discussed how to foster funding and research partnerships and the best mechanisms to ensure efficient information sharing.

The patients' perspective on balancing risks and benefits was provided by a patient representative from the European Multiple Sclerosis Platform who explained how MS patients perceive the risk of PML in relation to the benefits they derive from MS therapy and how they are prepared to accept a much higher risk than regulators assume when treatment benefit is probable and they are adequately informed of the likelihood of the risks. He also reported that patients are changing from people accepting therapeutic decisions made for them by others into people who are well informed, engaged and who want to be in control of their own situation.

For further information see: PML workshop report.

- **Ophthalmology Workshop**

The EMA held its first workshop on medicines for eye disorders on 27 & 28 October 2011, assembling for the first time over 200 experts in eye diseases from Europe, Australia, Japan and the USA. The aim was to review regulatory and scientific challenges in developing medicines for eye disorders; new treatments are rapidly evolving, with the recent breakthrough of new medicines for wet age-related macular degeneration and on-going research into treatments for new eye diseases, such as retinitis pigmentosa.

The workshop participants, who included European regulators, the pharmaceutical industry, healthcare professionals and patient representatives, discussed methods for measuring visual function in clinical trials, developing stem cells and gene therapy, treatment for macular diseases and inflammation in the eye, repairing the corneal surface with stem cells and treatment for dry eyes. They also tackled the challenges associated with the development of treatments for children.

For further information see: Workshop on clinical development and scientific advice in ophthalmology.

- **HIV Prevention workshop**

This closed workshop was held on 8 July 2011 including academics, WHO representatives, African Institutional body and patient organisations. The discussion focused on the non-clinical and clinical development of medicinal products for HIV prevention including oral and topical pre-exposure prophylaxis (PrEP), following a public consultation of a concept paper on this topic. PrEP is recognized as a potentially valuable tool as part of an integrated approach for reducing an individual's risk of HIV acquisition and for combating the HIV epidemic.

Following the workshop and based on current knowledge and experience gained so far, a reflection paper was published providing recommendations for the pre-licensure non-clinical and clinical development of PrEP interventions. Critical aspects regarding the benefit that could be associated with the routine use of a PrEP intervention can only be assessed once a product is in routine use, therefore the Risk Management Plan will be important in the evaluation of future marketing authorisation applications in oral and topical PrEP.

The EMA/CHMP is following the scientific developments in this area and giving scientific advice as requested. Following consultations that culminated in this reflection paper the agency is prepared to evaluate future marketing authorisation applications for PrEP.

For further information see: HIV prevention

- **Enpr-EMA Workshop**

Every year, Enpr-EMA holds a workshop at the EMA; the third workshop was held on 10-11 March 2011 and served to introduce Enpr-EMA to a wider audience. 6 patient organisations participated in the workshop and 33 existing networks were represented by 41 participants.

The first day was dedicated to establishing and launching the co-ordinating group of Enpr-EMA, which includes a patient representative, and to discussing and defining priority tasks for this group.

The second day introduced the network to all stakeholders, particularly patient/parent organisations, clinical researchers and pharmaceutical industry staff responsible for paediatric studies.

The parent/patients' expectations and views were presented by a patient representative:

- Enpr-EMA must ensure that the quality standards required to become a member of Enpr-EMA, including public involvement, are implemented across all paediatric clinical trial centres in Europe.
- Parents should be involved in assessing benefit/risk.

- There is a need to increase awareness among ethics committees and politicians regarding paediatric research.

They summarised that patients should not only be involved as research subjects, but also as information providers, advisors, reviewers, co-researchers and a driving force and they should be involved before, during and after a CT.

Discussions on how patients can be involved in the networks and the trials focused on three topics; the added value of patient involvement, how to improve interaction/communication among all parties and consideration of resources.

For further information see: Enpr-EMA Workshop

- **EMA meeting with Thalidomide Patients' and victims' organisations**

This follow-up meeting held on 5 September 2011 provided an update on the activities and the use of Thalidomide Celgene in the post-marketing phase to those patients' and thalidomide victims' organisations that were previously consulted during its initial marketing authorisation evaluation in 2007.

The meeting included representatives from patients and victims of thalidomide, as well as members from the assessment team, representatives of national competent authorities and the EMA. The meeting covered the implementation of the risk management plan and the Pregnancy Prevention Programme (PPP) to date, as well as the periodic safety update reports (PSURs), revisions to the marketing authorisation and reports of events of interest, and the practical experience of some member states.

It was highlighted that since the product launch in the EU there have been no reported cases of pregnancy of a patient, indicating a successful implementation of the PPP.

Overall, the organisations welcomed the data presented and were reassured of the close monitoring of the medicinal product. The Chair informed the participants that the Agency will continue sharing the PSUR assessment reports of Thalidomide Celgene as well as any information of interest on the medicinal product and will consider the organisation of a future follow-up meeting after the 5-year renewal of the marketing authorisation (due April 2013).

For further information see: Thalidomide follow-up meeting

- **EMA meeting with the European Liver Patient Association**

Upon their request, the EMA organised a teleconference with four representatives from the European Liver Patient Association (ELPA), together with EMA staff, including the head of the Anti-infectives and Vaccines section at the EMA. The discussion centred on issues related to Hepatitis C and treatment options for HCV patients. The Agency advised that it would keep ELPA informed of any EMA involvement in developments in this area, as appropriate.

Involvement in other external workshops, conferences and info sessions

- **The 2nd Joint EMA/DIA ENCePP information day**

This info day, held at the EMA on 7 November 2011 included two patient representatives. Key topics related to the consolidation of ENCePP as the network for non-interventional research in the EU as well as other aspects of pharmacoepidemiology and pharmacovigilance of most current interest.

The principles contained in the ENCePP Code of Conduct were highlighted with focus on the provisions that have been revised taking into account experience gained so far. There was also a presentation on

how the ENCePP Guide on Methodological Standards in Pharmacoepidemiology will serve as an important learning tool and assuring high quality pharmacoepidemiological studies that benefit public health. Finally this event also provided the opportunity to obtain feedback from representatives from regulatory authorities, industries and academia on the role of ENCePP in post authorisation research.

For further information see: 2nd ENCePP infoday

- **A Eudravigilance/DIA information day**

This info day, held on 15 November, provided updates on the new pharmacovigilance legislation and the activities of the EudraVigilance Expert Working Group, including recent developments on the international standardization activities.

Topics included direct patient reporting of adverse drug reactions (ADRs), implementation of access to ADRs in Eudravigilance, Health Canada's perspective on topics addressed by the new legislation, the new CT3 guideline, as well as the use of the Important Medical Events List.

Ilaria Passarani (BEUC) gave a presentation on reporting ADRs and the perspective from a consumer organisation and Francois Houyez (Eurordis) presented the patient point of view on direct Patient ADR Reporting.

- **Joint TOPRA/EMA conference**

This two day conference was held on 24-25 November 2011 at the EMA and included; the EMA Road Map, CHMP work program, development of medicines in paediatrics and the elderly, practical work of the EMA, outcomes of the 3 year project on risk benefit decision making, Health Technology Assessment and the work of the Tapestry network, changes to the centralised procedure and community referrals and the impact of the Pharmacovigilance legislation for patients, industry and member states.

A representative from the European Aids Treatment Group (EATG) gave a presentation on the new pharmacovigilance legislation, including ADR reporting, access to ADR data, patient representation at PRAC, public hearings and patients' overall expectations.

For further information see: TOPRA/EMA conference

Involvement in access to Eudravigilance data

EudraVigilance is a web-based information system which provides data on suspected side-effects also known as suspected adverse reactions for medicines authorised in the EU. It was originally launched in December 2001 with no public access.

Since March 2012 EudraVigilance data is accessible to the public via the 'European database of suspected adverse drug reaction reports'; users can view the number of individual suspected side effect reports submitted for each centrally authorised medicine. (Reports for common drug substances used in nationally authorised medicines will be published during 2013).

A user-group, including 8 patient representatives has been in place since 2010 to assist in the implementation of the Eudravigilance access policy and the development of the public website giving access to Eudravigilance data.

The patient representatives have been very much involved in the preparation of a guidance document (interpretation of data) and also on the public interface specifically concerning user-friendliness, layout, navigation and relevance of information. Input from the group led to modifications and improvements to the system during the testing phase.

In addition Eudravigilance was presented and the test website demonstrated several times to the PCWP for discussion and feedback.

The group will continue to be involved in future phases and modifications of the website.

Involvement in EMA/EMCG study on disease outcome preferences

The EMA and the University of Groningen (UMCG) established a collaborative agreement to provide supportive research activities to the EMA Benefit-Risk Methodology Project. One agreed research project was the VALUE (VALues and Utilities in European patients) study which was a non-interventional, observational study designed to collect quantitative data on patient preferences for treatment outcomes.

This study ran during November and December 2011 and was conducted within the disease area of Multiple Sclerosis (MS) among patients within the United Kingdom (UK), who were contacted via the UK MS society.

The aims of the study were to evaluate the methodology of collecting preferences from a sample of MS patients for several proposed levels of treatment outcome and to construct measures of patients' benefit-risk trade-offs among the various potential outcomes. This study aimed to 1) evaluate the use of a multi-criteria decision analytic (MCDA) method to collect patient preferences; (2) provide quantitative data on value functions for disease outcomes within MS; (3) identify the most important attributes of a treatment from the patients' perspective; (4) evaluate the use of the preference data as weights in an MCDA treatment decision model.

The study was conducted during November and December 2011 and a total of 62 responses were received from the MS society members.

It is expected that the study analysis and report will be available sometime in 2012.

Involvement in Enpr-EMA

During the PCWP meeting in September 2011, the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) was introduced; it is a network of research networks, investigators and centres with recognised expertise in performing clinical studies in children.

Enpr-EMA aims to foster high-quality ethical research on quality, safety and efficacy of medicines to be used in children through networking and stakeholder collaboration with members from within and outside the EU.

Networks are recognised by the quality of paediatric research and a minimum set of recognition criteria has to be fulfilled in order to qualify as member of Enpr-EMA. One of these criteria is the involvement of patients, parents or PCOs in either, the protocol design, information package and/or the prioritisation of needs for clinical trials in children. A workshop was held in March 2011 (see page 14) to introduce the network to stakeholders and which patient representatives attended.

It was proposed that one PCWP member be the contact point and become a patient representative member in the Enpr-EMA coordinating group which meets three times per year. The group is responsible for the network's long- and short-term strategy. Its tasks include: facilitating access of the pharmaceutical industry to paediatric clinical study centres and experts; identifying new networks to include in Enpr-EMA and developing common educational tools for children and parents, to increase their willingness to take part in clinical trials.

Following the meeting Jose Drabwell from IPOPI was nominated and participated in the first face to face meeting of coordinating group on 20 June 2011.

Other possibilities for collaboration between Enpr-EMA and PCWP were also highlighted such as patient involvement in clinical trials; raising awareness, ethics committees, helping to identify research priorities, etc.

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. Plenary meetings were held in June and November and the steering group meeting in February.

The aims of this initiative are to bring together the available expertise and research experience 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. There are now over 100 partners registered in ENCePP including academic research and medical care centres, healthcare databases, electronic registries and existing networks. The details are public and accessible to all parties with an interest in post authorisation medicines research in the ENCePP Resources Database.

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 involved wherever possible.

Involvement in PROTECT (IMI)

Patient representatives are involved in the PROTECT consortium (Pharmacoepidemiological Research on Outcomes of Therapeutics), funded by the Innovative Medicines Initiative Joint Undertaking (IMI). The EMA coordinates the project, managing a multi-national consortium of public and private partners. It is a collaborative European project which aims to strengthen monitoring of the benefit-risk of medicines in Europe by looking at the limitations of current methods and developing innovative approaches. Examples of work packages are a framework for pharmacoepidemiological studies, signal detection, data collection from consumers and benefit-risk integration and representation.

Table 1. Activities involving patients/consumers at the European Medicines Agency during 2011

Management board/scientific committees
MB (members)
COMP (members) and individual expert contribution
PDCO (members and alternates)
CAT (members and alternates)
CHMP ad-hoc consultation on medicinal products under evaluation
Working parties
PCWP (members, alternates and observers)
PhVWP (observers) and individual consultations on products under evaluation
SAWP – participation as experts in the review of Protocol Assistance requests
Working groups
HCP WG (observers)
Working Group on Clinical Trials in Third Countries (members)
EudraCT Joint Operational Group (members)
Eudravigilance Users Group (members)
SAG/ad hoc expert group meetings
SAGs and ad-hoc expert group meetings – participation as patient experts
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
Training on the review of documents addressed to patients and the general public
Other activities / meetings
CMDh consultation
EMA meeting with liver patient association
Meeting with Thalidomide patients and victims organisations
Pharmacovigilance stakeholders information meetings
Input on proposed symbol and text for package leaflet of medicines under additional monitoring
Input on proposed direct patient reporting form
Workshops / info-days
HIV prevention workshop
EnprEMA workshop
EMA/FDA Progressive multifocal leukoencephalopathy workshop
TOPRA conference
Eudravigilance/DIA infoday
ENCePP/DIA infoday
Input on other EU-wide initiatives
European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
Pharmacoepidemiological Research on Outcomes of Therapeutics – (PROTECT – IMI)
European Network of Paediatric Research at the EMA (Enpr-EMA) – member of coordinating group

3. Organisations involved in EMA activities during 2011

There are currently 34 different patient/consumer organisations who work with the Agency across many different areas and who are included in the EMA list of '*eligible organisations'*.

Any organisation may apply to participate in the Agency's activities; however they must first become *eligible* by fulfilling the 'Criteria to be fulfilled by patients' and consumers' organisations involved in the European Medicines Agency activities'. These criteria are in place to ensure that the Agency works with organisations that are genuinely acting in the interests of European patients and consumers.

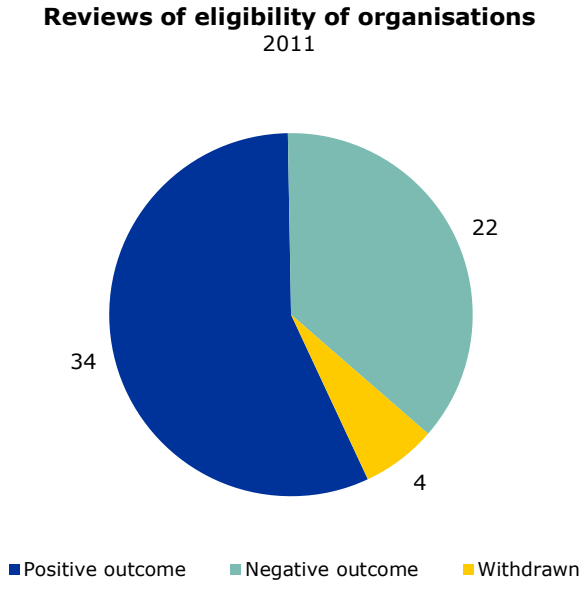
All the eligible organisations are not-for-profit and their work is focused at a European level. Some are general umbrella organisations whilst others have a particular emphasis within a specific area (such as rare diseases, HIV/AIDS, cancer etc.).

A list of these eligible organisations is published on the Agency website, including links to their websites and a summary of their mission and objectives.

Between 2006 and 2011 a total of 60 organisations have applied and been evaluated for eligibility; 34 had received a positive outcome, 22 received a negative outcome and 4 organisations withdrew their applications. The majority of the negative outcomes relate to limited EU representation, already being a member of another EU organisation or lack of patient/medicine focus. Organisations can apply or re-apply at any time.

The growing number of patient/consumer organisations who are able to be actively involved in EMA activities provides the Agency with access to the needs and concerns of patients across Europe.

During 2011, there were 5 new organisations that applied and became eligible.



There have been some cases when the agency has consulted an organisation not fulfilling all the criteria, however, as per the "rules of involvement of members of patients'/consumers' organisations in Committees' related activities" (EMA/483439/2008 rev.1), they were fully transparent with regard to activities and funding. They are listed in table 2b.

During 2011, a total of 46 patients'/consumers' organisations interacted with the Agency; table 2a shows those that are EMA eligible organisations and table 2b the other organisations that have been involved in EMA activities during 2011.

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

	NAME OF ORGANISATION
1	AGE Platform Europe (AGE)
2	Alzheimer Europe (AE)
3	Debra International
4	European AIDS Treatment Group (EATG)
5	European Cancer Patient Coalition (ECPC)
6	The European Consumers' Organisation (BEUC)
7	European Federation of Allergy and Airways Diseases Patients' Associations (EFA)
8	European Federation of Neurological Associations (EFNA)
9	European Gaucher Alliance (EGA)
10	European Genetic Alliances' Network (EGAN)
11	European Headache Alliance (EHA)
12	European Heart Network (EHN)
13	European Institute of Women's Health (EIWH)
14	European Liver Patient Association (ELPA)
15	European Multiple Sclerosis Platform (EMSP)
16	European Network of Fibromyalgia Associations (ENFA)
17	European Organisation for Rare Diseases (EURORDIS)
18	European Parkinson's Disease Association (EPDA)
19	European Patients' Forum (EPF)
20	European Public Health Alliance (EPHA)
21	European Prostate Cancer Coalition (EUomo)
22	Fabry International Network (FIN)
23	Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)
24	Health Action International (HAI)
25	Insulin Dependent Diabetes Trust (IDDT)
26	International Alliance of Patients' Organizations (IAPO)
27	International Bureau of Epilepsy (IBE)
28	The International Confederation of Childhood Cancer Parents Organisations (ICCCPO)
29	International Diabetes Federation European Region (IDF Europe)
30	International Patient Organisation for Primary Immunodeficiencies (IPOPI)
31	Myeloma Patients Europe (MPE)
32	Pain Alliance Europe (PAE)
33	Rett Syndrome Europe (RSE)
34	Thalassaemia International Federation (TIF)

Table 2b: Other organisations who interacted with the EMA during 2011 (e.g. participated in scientific advisory group meetings, scientific advice, workshops/conferences)

	NAME OF ORGANISATION
1	Multiple Sclerosis Society UK
2	EuropaDonna (European Breast Cancer Coalition)
3	Lupus UK
4	AMEND (Association for Multiple Endocrine Neoplasia Disorders)
5	Cystic Fibrosis Trust
6	Cystic fibrosis Europe
7	Kidney Alliance
8	Alstrom Syndrome UK
9	ENRAH (European Network for Research on Alternating Hemiplegia)
10	Deferno Trust (Progressive Multifocal Leukoencephalopathy)
11	HAE association (German patient organisation for C1 inhibitor deficiencies)
12	HAE AMSAO (French patient organisation for C1 inhibitor deficiencies)

4. Number of patients and consumers involved in EMA activities during 2011

During 2011, 423 patients/consumers have been involved in the activities of the Agency. In some cases the same patient/consumer participated in more than one activity.

The activities have been split into three categories; 1 – activities in which patients/consumers are members, alternates or observers, 2 – activities involving individual experts, and 3 – activities requiring organisations' representatives.

Table 3: Activities involving patients/consumers at the EMA during 2011

Membership of committees	Members / alternates
MB	2
COMP	3
PDCO	3 / 2
CAT	2 / 2
TOTAL	**14**

Membership of working parties	Members / alternates
PCWP	15 / 14
	Observers / alternates
PhVWP	1 / 1
HCP WG	2
TOTAL	**33**

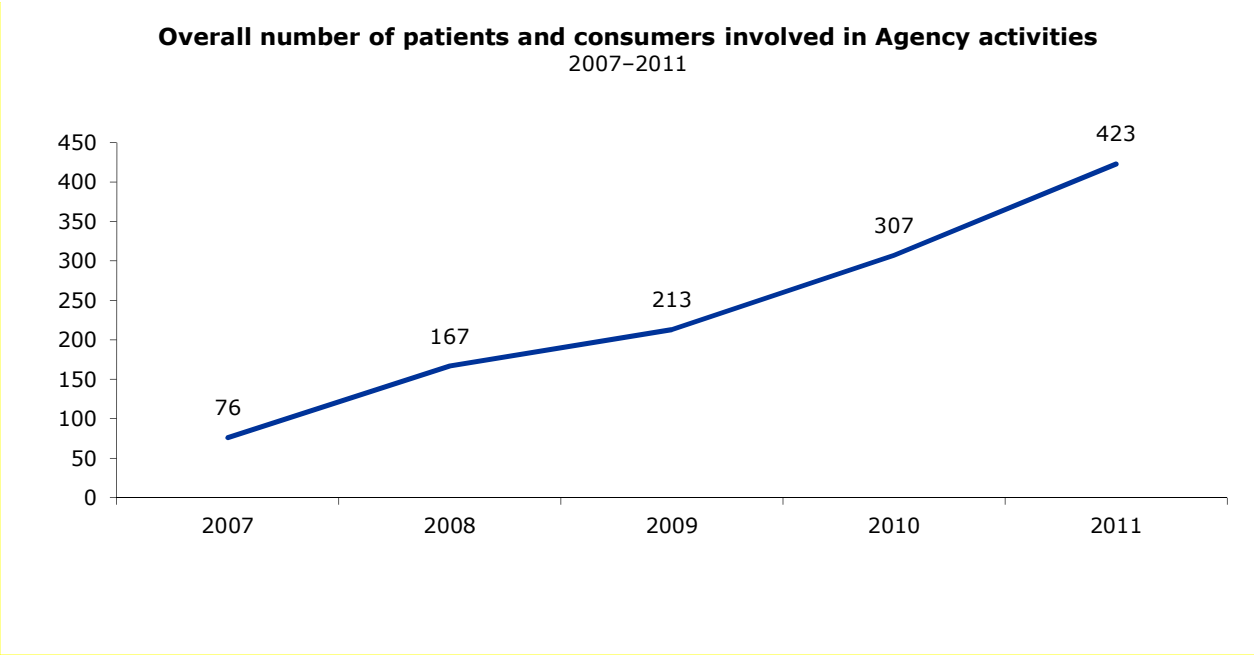
Activities involving individual experts	Experts
Participation in Scientific Advisory Group (SAG)/ad-hoc meetings	22
Participation in SAWP consultations	13
Participation in COMP consultations	4
Review of Q and A documents (safety communications)	27
Review of EPAR summaries	38
Review of package leaflets	71
Participation in EMA annual training session	25
TOTAL	**200**

Activities involving organisation representation	Representatives
Ad-hoc observers/experts attending PCWP meetings	14
CHMP consultations on products under evaluation	7
Organisation consultation with CHMP on products under evaluation	1
CMDh consultation on a core PL	6
PhVWP consultations on products under evaluation	14
Review of symbol & text for PL (new legislation)	5
Review of draft direct patient reporting form	6
User testing for EU clinical Trials register (Jan & Oct)	9
EMA/UMCG study on disease outcome preferences	1
Meeting with Thalidomide patients and victims organisations	12
Meeting with European Liver Association	4
HIV prevention workshop	2
EnprEMA workshop	6
Ophthalmology workshop	4
EMA/FDA PML workshop	6
Working Group on Clinical Trials in third countries meeting	2
EudraCT Joint Operational Group meetings	19
Eudravigilance Access Policy – Review of guidance and dashboard	5
ENCePP Steering Group meetings	1
Pharmacovigilance stakeholders information meetings	47
TOPRA conference	1
Eudravigilance/DIA infoday	2
ENCePP/DIA infoday	2
TOTAL	**176**

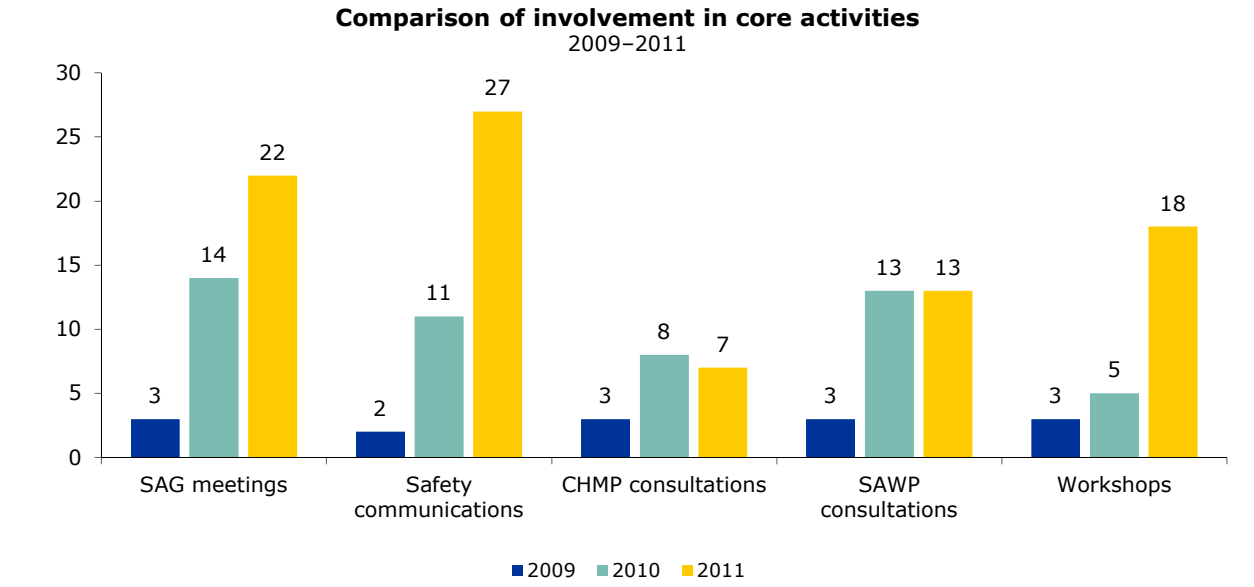
Total number of patients/consumers involved during 2011	**423**

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

The graphs below provide details of the numbers of patients/consumers who have been involved in the Agency's activities and compares them with previous years.



The figures show that, compared to previous years, the number of patients and consumers' participating in the different activities of the Agency has again increased during 2011.



- **Members:**

The number of members, alternates and observers within the EMA committees and working parties has remained predominately the same, as would be expected (one additional alternate).

- **Experts:**

200 experts were involved in Agency activities during 2011, compared to 175 in 2010, 108 in 2009, 87 in 2008 and 22 in 2007. This relates mainly to an increased involvement in:

- SAG/ad-hoc expert meetings (3 participants in 2009, 14 in 2010 and 22 in 2011);
- Review of package leaflets (33 in 2009, 41 in 2010 and 71 in 2011);
- Review of EPAR Summaries (36 in 2009, 14 in 2010 and 38 in 2011)
- Review of safety communications (2 in 2009, 11 in 2010 and 27 in 2011).

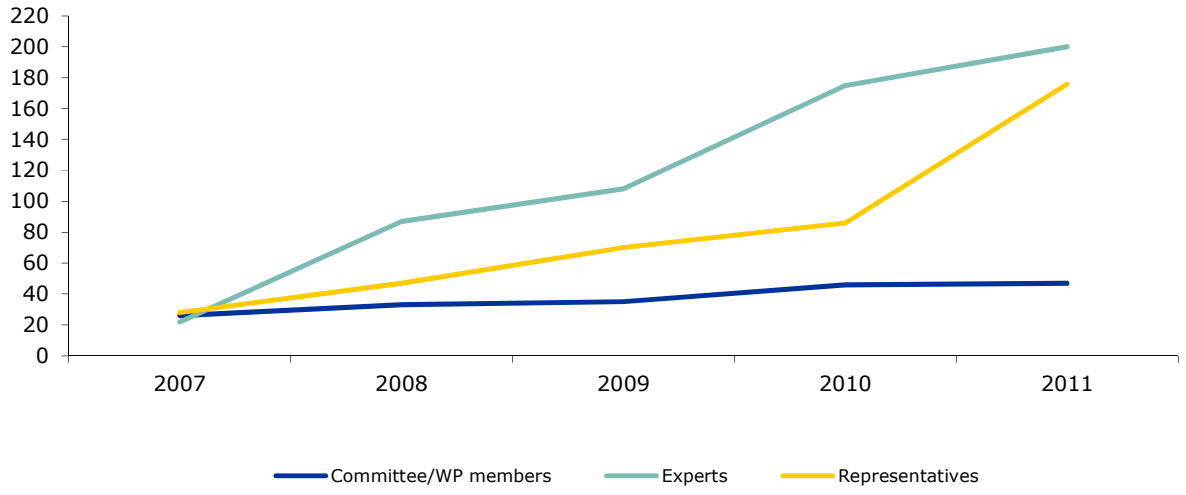
- **Representatives:**

46 different organisations interacted with the Agency during 2011, compared to 52 in 2010, 41 in 2009, 26 in 2008 and 24 in 2007.

There was a slightly lower number of organisations involved during 2011, however, the number of organisation representatives involved increased significantly, from 86 in 2010 to 176 in 2011. This indicates that patient involvement at the Agency now occurs mainly through the established eligible organisations and that many representatives are involved across several different EMA activities.

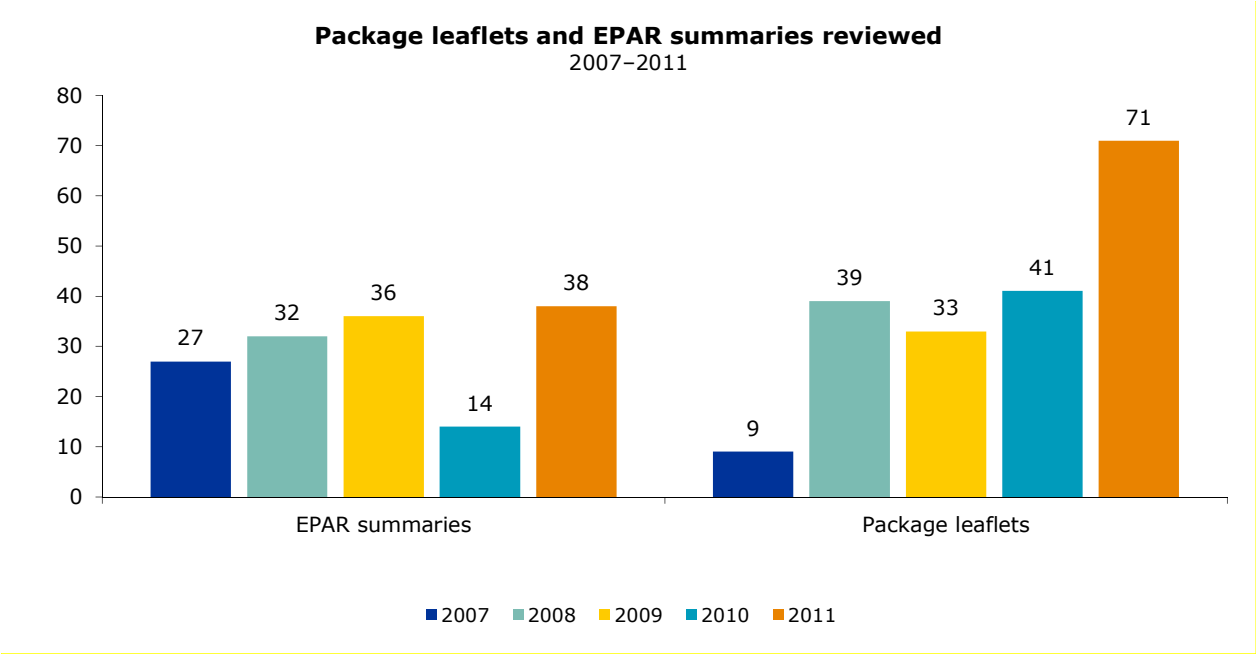
The increase in involvement of representatives can also be attributed to the new pharmacovigilance legislation stakeholder information sessions that the Agency has held, as well as systematic participation in EMA workshops and additional PhVWP consultations.

Comparison of involvement as committee/WP members, experts and representatives of organisations
2007–2011

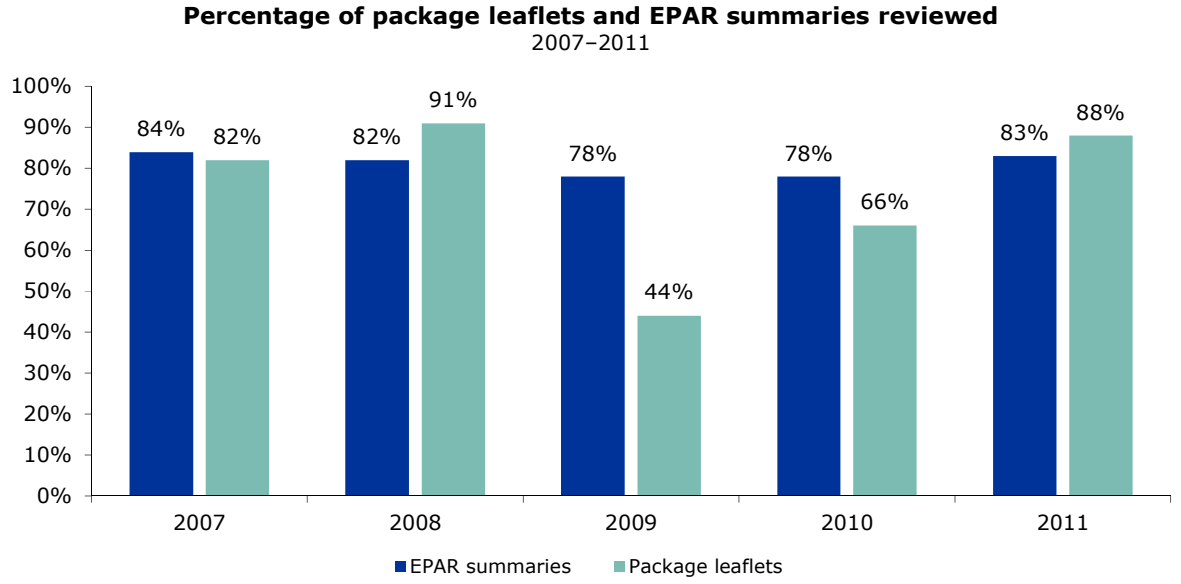


4.2 Document review procedure: comparative analysis of data between 2007 and 2011

The graph below shows the number of EPAR summaries and package leaflets sent for review in 2011, compared to the four previous years. There has been an increase in the number reviewed; especially package leaflets (mainly renewals).



The graph below shows the percentage of EPAR summaries and package leaflets reviewed (in relation to the number sent out), which demonstrates a high response rate.



5. Conclusions and next steps

During 2011 the number of patients and consumers who have been involved with the EMA has again increased; from 307 in 2010 to 423 in 2011 (77 in 2007). This growth relates mainly to an increased participation in SAG and ad-hoc expert group meetings, an increased review of safety communications and package leaflets and an increase in activities related to the implementation of new pharmacovigilance legislation, in addition to the usual continuing activities as described above. It is not expected that the numbers of patients/consumers involved will continue to increase in this way in the future; it is likely that a plateau will be reached in the next year or so.

The involvement of patients and consumers is now a recognised and integral part of the Agency's work and with the passing years since more formal interaction began, their involvement has not only expanded but has evolved and been refined to ensure it occurs in the most optimal manner possible.

This collaborative interaction allows patients to engage with the EMA on issues that affect them and to share their real-life experiences. In doing so, they provide meaningful feedback which ultimately contributes to the quality of the decision-making process by bringing to light the real-life implications of regulatory decisions. This is in line with the Agency roadmap to 2015 which emphasises that the decision-making process can be improved by taking account of patients/consumers experience.

Next steps

- The revision of the "Framework of interaction" between the EMA and PCOs will be finalised during 2012/2013, including the following:
  - A definition of the specific role of patients and consumers within the different scientific committees of the Agency (finalised).
  - A definition of how patients and consumers are involved in the benefit/risk assessment of medicinal products, highlighting criteria, areas of involvement and also how best to address the complexity of the benefit/risk data.
  - A training strategy which defines in detail the specific training that is provided to patients/consumers, depending on the activity in which they are involved.
- PCOs will continue to be involved across the Agency, providing their valuable input within many EMA activities, as well as being invited to take on new tasks that may arise, as and when needed.
- The implementation of the new pharmacovigilance legislation in July 2012 will lead to PCOs being further involved in regulatory activities; not only through the implementation of the legislation during 2012, but also with new activities, e.g. risk management plan summaries.
- The EMA, together with the PCWP, will ensure that there is complete transparency in its procedures for evaluating PCOs (publish procedures in 2012) and will also explore how to improve the way potential conflicts of interest of organisations are handled and will present proposals for action in 2012.
- The Agency will continue to look to increase the network of experts and eligible organisations in order to cover as many therapeutic areas as possible.
- The next progress report will be presented to the management board in 2013.