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Stakeholders and Communication Division

Annual report on EMA's interaction with patients, consumers, healthcare professionals and their organisations (2013)

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5550
Send a question via our website www.ema.europa.eu/contact

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Executive Summary

Introduction

The current report outlines the Agency's interaction with patients, consumers, healthcare professionals and their representative organisations during 2013. It provides a comprehensive overview of the involvement of these stakeholders within a single document in a structured manner and reinforces the robustness of the Agency's model of interaction.

The report is organised into three main sections; section 1 looks at areas of common interest where shared approaches and joint participation have occurred; sections 2 and 3 provide details of specific interactions with patients and consumers and with healthcare professionals, respectively.

If the Agency's interaction with patients, consumers and healthcare professionals throughout 2013 could be summarised in one word, it would be 'consolidation'. The year has seen a number of key developments leading to the streamlining of interaction with these groups, namely the Agency's new department dedicated to the interaction with patients and healthcare professionals. This new department under the Stakeholders and Communication Division will strive to improve the quality of work with these stakeholders, in a very open and communicative manner.

This was also the year where the former HealthCare Professionals' Working Group (HCPWG) became the official Healthcare Professionals' Working Party (HCPWP) which provided additional alignment with the existing Patients and Consumers' Working Party (PCWP). New mandates have been endorsed for both working parties for the period 2013-2016 with particular emphasis on their collaboration on topics of common interest. An excellent example of a mutually beneficial was the joint contribution on the preparation and deliverance of a coordinated message to the public to promote awareness on the additional monitoring of medicines within the new Pharmacovigilance legislation.

The network of eligible patients, consumers and healthcare professionals' organisations has expanded to a total of 62 organisations covering a wider range of therapeutic areas and clinical practice backgrounds (9 more than in the previous year).

In addition, a number of important workshops took place where participation of patients and healthcare professionals' representatives increased significantly (61 additional participants compared to the previous year). Of particular relevance was the '*Workshop on the patient's voice in the evaluation of medicines'* where the different ways of involving patients in benefit / risk assessments, from the early stages of medicines' development through to its authorisation and beyond, were discussed.

The systematic review of safety communications merits particular attention as it has been fully implemented in 2013 with the support of a wide range of patients living with different diseases, and healthcare professionals ranging specialities and clinical backgrounds, thus contributing to additional clarity of the messages prepared for the public by the Agency.

In conclusion, 2013 has been a successful year of interaction with patients, consumers and healthcare professionals demonstrating the Agency's continuous commitment to bringing the views of those directly impacted by its decisions into the regulatory discussions.

Challenges ahead

Recognising that patients are the end users of medicines, the EMA will continue to seek their effective involvement in benefit-risk discussions in order to consider their values and preferences appropriately when making regulatory decisions.

The input of patients and healthcare professionals is also expected to play an increasing role in improving the way benefits and risks are communicated in the product information.

In addition, medicines are licensed on the basis of findings from clinical studies, and pre-licensing studies can only provide estimates of benefits and risks. It is therefore important to bring real-life experience post-marketing. To this end, the EMA is working on further developing collaboration with healthcare professionals and in particular general practitioners in order to learn about any differences in benefits and risks in clinical practice and narrow the gap between efficacy and effectiveness.

As we move forward with the finalisation of the revision of framework of interaction with patients and consumers and the full implementation of the framework of interaction with healthcare professionals, we will be analysing our current practices to identify areas where there may be room for improvement in order to promote a realistic and sustainable involvement of these stakeholders and continuing to increase transparency and visibility.

The endorsement in 2014 of specific guidance on the evaluation of financial information from patients', consumers' and healthcare professionals' organisations and its implementation thereafter is expected to bring additional transparency and clarity in the way the EMA assesses organisations for 'eligibility'. 'Eligibility criteria' allow the Agency to identify the most appropriate organisations that act in the interests of European patients, consumers and healthcare professionals.

In addition, exploratory work will be carried out to assess ways to further recognise the increasing number of individual experts involved in EMA activities.

Finally, as cross-Agency systems to monitor interaction and participation of patients and healthcare professionals are further implemented, reporting will progressively focus not only on quantitative elements but also on the qualitative input and impact of such interaction.

The current report was circulated to the joint PCWP/HCPWP during September and was presented to the Management Board during its meeting on 2 October 2014.

SECTION 1

1. Common areas of interest and collaboration

1.1. Introduction

Building on the positive experience from 2012, joint meetings between the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) were also organized in 2013. As further described in this section, the meetings provided a unique platform for information and dialogue on a wide range of topics of common interest.

Likewise, participation in specific EMA workshops, teleconferences and advisory groups was organised throughout 2013 which not only provided an opportunity to raise awareness on the Agency's activities and current thinking around specific topics related to EMA policies and or scientific guidelines under development or revision, but also allowed the Agency to gather input from relevant representative organisations on issues that can directly or indirectly impact patients, consumers and healthcare professionals.

1.2. PCWP and HCPWP joint meetings

During 2013, three PCWP and HCPWP joint meetings were organized. Several topics were presented and discussed ranging from updates on EU legislation to different EMA core activities, policies and projects.

An update on the implementation of the falsified medicines Directive adopted in 2011 and in force since January 2013 was provided. This new legislation aimed to prevent falsified medicines entering the legal supply chain and reaching patients. The main consideration made by the participants was that the foreseen awareness campaign needed not only to focus on the logo to be placed on the websites of legally operating online pharmacies and on what it means, but also to clarify what is expected from consumers/citizens; as well as explaining how legally operating sites would be supervised.

Specific discussions related with the on-going implementation of the pharmacovigilance legislation also took place, covering topics such as the urgent union procedure which is triggered when a member state or the European Commission considers that urgent action on a medicine is necessary due to a safety issue, and allows stakeholders who are not holders of a marketing authorisation to submit data for evaluation in the course of a PRAC assessment.

The draft rules of procedure on the organisation and conduct of public hearings were also presented, with a group of volunteers identified among PCWP and HCPWP members to join a virtual group for more in-depth discussion.

Together with the EMA, a drafting group of PCWP/HCPWP members, developed a European guidance on direct patient reporting. The aim was to produce a simple and practical document in lay language useful to patients and healthcare professionals across Europe on what patient direct reporting is and how to report side effects. This was then circulated and agreed among representatives of all member states agencies.

In terms of direct involvement in EMA activities discussions covered the EMA policy on conflicts of interest (as further described under 1.4) as well as the draft document "evaluation of financial information from patients'/consumers' and healthcare professionals' organisations for assessment of EMA 'eligibility' and subsequent involvement in product-related evaluations". The purpose of this document is to explain how financial information obtained from organisations is used to decide whether that organisation can be considered "eligible" to work with the Agency on a regular basis. It also

outlined the framework to identify and handle potential conflicts of interest when an organisation may be involved in product-related evaluations or discussions.

The EMA initiative to involve children and young people in the work of the paediatric committee (PDCO) was presented to the PCWP/HCPWP and they contributed to the preparatory work. The EMA also presented this topic during a European Patients Forum seminar "Europe meets young patients", in the margin of a EC funded project (EMPATHY). PCWP/HCPWP will continue to contribute wherever applicable to future developments in this area.

The work of the Agency in providing scientific advice to pharmaceutical companies and how patients are involved in this particular activity was also presented. This prompted a request from nurses and pharmacists to be involved in scientific advice whenever relevant and appropriate.

In the future patients will be involved within scientific advice procedures held together with health technology assessment (HTA) bodies.

The area of communication and information led to several important discussions aimed at raising awareness of EMA processes and identifying areas where these could be further improved whilst maximising the dissemination power of the network of European organisations. This included the Agency's communications on the outcome of safety-related referrals. The importance of receiving safety communications in a timely manner and adapted to national circumstances as much as possible was underlined.

Another main discussion concerned the need to improve the way regulators communicate on risk to build trust in the regulatory system. More transparency is generally welcome but there is a need to assess the impact of bringing certain information into the public domain. Information needs to be conveyed in a balanced manner to users of medicines (patients and healthcare professionals) - more transparency does not necessarily mean better communication. The discussion culminated with a concrete suggestion to organise a workshop on benefit-risk communication in 2014.

Regarding the dissemination of new information on medicines, the example of Insulin degludec was used to illustrate the important role of the network of EU organisations representing patients and healthcare professionals in encouraging national diabetes patient associations and learned societies to prepare their members for the introduction of a new higher strength insulin.

Concerning the EMA Online Roadmap 2012-2017, the Agency worked on 'User personas' to assess potential user needs for an EU medicines web portal and PCWP/HCPWP members were invited to validate these user personas.

In the area of clinical trials, feedback from the EMA workshop organised in November 2012 to discuss the proactive release of data from clinical trials was presented.

The involvement of patients', consumers' and healthcare professionals' organisations in the development of the EU Clinical Trials Register (through their participation in the EMA EudraCT joint operational group) was also reported. During 2013, 16 patient representatives and 4 healthcare professional representatives participated in the meetings of this group. The year's work focused mainly on the upgrade of the European Clinical Trials Database (EudraCT). A new version, EudraCT V9, was launched in October 2013, marking the initial step of a process through which summary clinical trial results will be made publicly available through the EU Clinical Trials Register.

The joint meetings also served as a unique platform to update and engage patients and healthcare professionals' organisations in specific projects where the Agency is involved (e.g. IMI-PROTECT).

The PCWP and HCPWP work programmes for 2014 were also presented and discussed prior to adoption by the EMA's human scientific committees. These include implementation and monitoring of the frameworks of interaction.

The new structure of the Agency and the core EU telematics governance were presented.

Further to the different topics outlined above, three additional subjects received particular attention throughout the year and are covered in separate points hereafter: additional monitoring of medicines; shortages in the supply of medicines; and involvement in development and evaluation of medicines.

1.3. Promoting better understating and awareness of EMA activities

The Agency has a clear policy to inform stakeholders of the key information it produces. This includes EMA safety communications as well as concept papers and draft guidelines open for public consultation. To do this, the EMA targets relevant EU organisations included in its internal stakeholders' database and during 2013, over 45 communications and 80 concepts papers/guidelines were disseminated. The network of EU organisations representing patients and healthcare professionals plays a key role in syndicating this information and promoting further outreach of EMA produced information.

In addition the Agency publishes the *Human Medicines Highlights* (HMH); a monthly newsletter addressed primarily to organisations representing patients, consumers and healthcare professionals. It provides a summary of key information relating to medicines for human use published during the previous month by the EMA. Information is selected based on recommendations from consulted patients, consumers and healthcare professionals. Throughout 2013, eleven issues were published and disseminated to more than 4,500 subscribers.

Also in 2013, the Agency produced a new EMA brochure focusing on how it works with healthcare professionals; and updated the EMA brochure on working with patients and consumers.

Finally, and in order to promote further awareness on how the Agency is involving patients and healthcare professionals in its activities, the Agency participated in specific meetings and conferences organised by patients', consumers' and healthcare professionals' organisations in 2013 (namely: IAPO; EGAN; PGEU; UEG; ECSF).

The examples of specific interaction and collaboration aimed at increasing awareness about additional monitoring of medicines and the Agency's activities in the field of prevention and management of shortages in the supply of medicines are further detailed below.

1.3.1. Awareness campaign: additional monitoring of medicines

During 2013, following the implementation of the Pharmacovigilance legislation, specific communication on additional monitoring of medicines was implemented. This led to the introduction of a list of medicines under additional monitoring and the "black symbol" introduced to products' packaging with an explanatory text in the Product Information of these medicines. Patients, consumers and healthcare professionals provided valuable comments and ideas on how to support the communication campaign such as the creation of an explanatory video.

A survey aimed at collecting feedback from stakeholders regarding the overall communication campaign uptake, the communication channels used, the working processes and the quality of the EMA materials was carried out in October 2013. Patients, consumers and healthcare professionals' overall feedback were very positive. They highlighted that very short documents are needed for healthcare professionals and the issue of limited resources, lack of time and prioritisation and that information

takes time to reach entire networks through various channels. They also mentioned the importance of providing materials in a way that can easily be built into individual communication plans.

1.3.2. Shortages in the supply of medicines

As a response to concerns raised by several patient, consumer and healthcare professional organisations early in 2013 regarding the increasing number of supply shortages in Europe, and in the context of the EMA initiative to improve management of medicine shortages cause by manufacturing and quality issues, this topic was extensively debated between the HCPWP and the PCWP. This collaboration paved the way for a position paper endorsed by several organisations on the general problem of shortages of medicinal products as well as very concrete contributions to the EMA workshop on 'product shortages due to manufacturing and quality problems: Developing a proactive approach to prevention' organised on 14 October (for further information on the workshop, please refer to the following webpage: Shortages).

Considering the underlying multifactorial and complex causes of shortages, the workshop provided a platform to clarify the remit of the Agency's role and responsibilities. The experience and perspectives from healthcare professionals and patients provided real examples of the difficulties and extent of the problem. Speakers pointed to the importance of early interaction and discussions with healthcare providers and patient organisations and the need for all partners involved in the evaluation, supply and use of medicines to work together to advance solutions.

Also in the context of the EMA initiative to improve management of medicine shortages, communication aspects on shortages and recalls of medicines were discussed. A proposal to communicate on shortages via a public catalogue using agreed criteria was well received and the involvement of relevant patient, consumer and healthcare professional organisations in the communication process was welcome.

1.4. Involvement in the development and evaluation of medicines

1.4.1. Patient involvement in the evaluation of medicines

Representatives from patients', consumers' and healthcare professionals' organisations, together with the European Federation of Pharmaceutical Industries and Associations (EFPIA), and the Agency's scientific committees representatives, met during the '*Workshop on the patient's voice in the evaluation of medicines'* on 26 September, to discuss the different ways of involving patients in benefit / risk assessments, from the early stages of development of a medical product, through to its authorisation and beyond.

For further information on this workshop, please refer to the following webpage: Patient's voice.

The workshop concluded that giving patients a voice in the development and evaluation of medicines is acknowledged as being of fundamental importance by the major stakeholders in the process. Much has already been done, and the challenge is now to build on the extensive work to date, broadening patient understanding of medicines development and regulation, and the concept of benefit-risk that lies at the heart of it, so that patients can contribute their insights and understanding in the most effective way.

1.4.2. EMA/HTA-bodies workshop on parallel scientific advice in drug development

On 26 November, the European Medicines Agency (EMA) hosted a workshop on 'parallel scientific advice in drug development' to look at the need for, and the current use of, parallel scientific advice from regulatory and health technology assessment (HTA) bodies during the medicines development process.

The workshop brought together over 280 representatives from the European Commission, European regulators, HTA bodies from 12 European Union Member States, the European Network for Health Technology Assessment (EUnetHTA), the pharmaceutical industry, payers, patients, healthcare professionals and academics, as well as representatives from the Agency's Committees and Scientific Advice Working Party.

For further information on this workshop, please refer the following webpage: EMA / HTA-body workshop.

Yann Le Cam, from the European Organisation for Rare Diseases (EURORDIS), clearly evoked the patient goal - to achieve the quickest access to as many safe, efficient and affordable medicines with a real therapeutic added value, for all disease patients in the European Union. This common goal can only be delivered by all relevant interested parties working together each addressing their respective elements in a coordinated fashion**.** He appealed for more dialogue between regulators and HTAs, including very early discussions, a more integrated HTA view and greater patient involvement.

1.5. Contribution to EMA transparency initiatives

Targeted participation in specific EMA workshops, teleconferences and advisory groups was also organised throughout 2013 and is described below.

On several occasions, patient and healthcare professional organisations' representatives were invited as speakers and their contributions have greatly enriched the discussions bringing the external world reality into the frame of the regulatory and scientific debate, as detailed in this section.

1.5.1. EMA policy on conflicts of interests

As part of the consultation exercise supporting the revision of the Agency's policy in 2014, several patients, consumers and healthcare professionals' representatives contributed to the dedicated stakeholders' workshop of 6 September (for further details on this workshop, please refer to the following webpage: Conflicts-of-interests policy) and discussed further the topic in the context of the PCWP/HCVWPWP joint meetings.

1.5.2. EMA policy on the proactive publication of clinical trial-data

Several patients', consumers' and healthcare professionals' representatives joined the advisory groups created to support the development of the Agency's policy on proactive publication of clinical-trial data. The groups met between January and April 2013 to discuss and advise on the following areas: protecting patient confidentiality; clinical-trial-data formats; rules of engagement; good analysis practice; and legal aspects.

For further information on the work of the advisory groups, please refer to the following webpage: Publication and access to clinical-trial data.

In June 2013, the Agency released the draft policy for a three-month public consultation and significant input was also received from healthcare professionals and patient organisations.

1.6. Focused input on EMA pharmacovigilance-related initiatives

1.6.1. Workshop on medication errors

The European Union regulatory workshop on medication errors was held on 28 February and 1 March and was aimed at raising awareness among stakeholders involved in the reporting, evaluation and prevention of this important public-health issue of the new legal provisions at EU level in order to facilitate their implementation. For full details, please refer to the following webpage: Medication errors.

During this workshop, patients and healthcare professionals' representatives gave valuable comments on two main sessions: regulatory tools for managing the risk of medication errors and implementation of preventive measures.

Among the speakers, Mr Tony West, from the European Association of Hospital Pharmacists, emphasized the necessity of educating healthcare professionals and patients in order to minimise risks by using a case study from his hospital where a medication error led to death. The primary focus of the presentation was the role of healthcare professionals and how future changes within the EU may help minimise the risk of future incidents (revision of package information leaflets, risk-management plans, the mandate of the PRAC and the cross-border healthcare directive).

Regarding the implementation of preventive measures, Dr Angeles Alonso, speaking on behalf of the European Society of Cardiology, analysed, thanks to valuable feed-back from her practical clinical experience in an acute care setting, how medication errors occur. She reinforced the importance of effective communication between healthcare professionals and patients.

On the patients' side, Mr François Houÿez (European Organisation for Rare Diseases) discussed strategies patients can use to minimise medication errors. He provided several recommendations, introducing sophisticated tools that can help to prevent medication errors and suggested that their efficacy and convenience should be further explored. He also highlighted the need to improve package design and labelling.

1.6.2. Workshop on patient support programmes and market research programmes

This workshop, organised on 6 June, aimed at gathering a better understanding of the diversity of patient-support programmes (PSPs) and market-research programmes (MRPs) and the type of safety information that is collected in those programmes.

For further details on the workshop, please refer to the following webpage: PSPs and MRPs.

Mr David Haerry (European AIDS Treatment Group) emphasised the experiences of patients when participating in PSPs or MRPs with the intention of understanding their opinions and expectations. Reflections from the patient side showed that PSPs and MRPs can be of interest for patients, especially if they concern new medicinal products. He highlighted the fact that PSPs can allow patients to share their concerns or challenges with marketing authorisation holders regarding their treatment or disease.

Ms Suzete Costa (Pharmaceutical Group of the European Union) focused on the possible role of pharmacists participating in PSPs or MRPs, in building a bridge between clinical trial development and post-marketing phase in terms of safety knowledge of medicinal products, and in strengthening their

risk benefit profile. She explained how pharmacies can participate in programmes such as adherence or compliance programmes, patient access programmes (for reimbursement by MAHs), or market research studies, which allow for the collection of safety information at individual patient level.

1.6.3. Pharmacovigilance stakeholders' forum

On 27 September the seventh stakeholders' forum took place to provide an update on key changes and aspects implemented since November 2012. The forum was also an opportunity to share positive and negative experiences on the implementation of the pharmacovigilance legislation across all stakeholders.

For further information on the seventh stakeholders' forum, please refer to the following webpage: Seventh forum.

Several topics were addressed such as:

- Additional monitoring

In order to achieve clarity and proportionate public reaction, representatives from Patients' organisations suggested to be consulted by National Competent Authorities (NCAs) while preparing their communication material, in relation to additional monitoring in particular.

- Adverse Drug Reaction (ADR) reporting

It was proposed to further explore possible tools to stimulate patient reporting (e.g. EMA ADR website). EMA and other Patients' organisation noted the usefulness of EURORDIS web-portal which makes reference to all patient reporting tools across the EU.

Healthcare professionals' representatives pointed to difficulties associated with reporting adverse drug reactions experienced by older patients and to the need for closer monitoring of this age group. Clinical trials in the oldest age groups with different endpoints are urgently needed, and cannot be replaced by post-authorisation safety studies.

Healthcare professionals' representatives also remarked the need to continuously support better access to safety data and promote the efficient use of technological advances in order to enhance reporting rates.

- Decision–making and Committees coordination

Patients' representatives highlighted that the overall decision-making process appears unclear to patients and recommended that the role of the media in terms of engagement, training and education is carefully considered.

- Communication

Patients' representatives in particular emphasised the need to be proactively involved in the development and review of educational material.

1.7. Input provided on EMA scientific guidelines

1.7.1. Workshop on clinical investigation of medicines for multiple sclerosis

During the workshop on 'the clinical investigation of new medicines for the treatment of multiple sclerosis' on 17 October, stakeholders had the opportunity to come together and discuss the key scientific issues in the field of the considerable interest created by the on-going revision of the current 'Guideline on clinical investigation of medicinal products for the treatment of multiple sclerosis'.

The main goal of the workshop was to make sure that in the revision of the multiple-sclerosis guideline, the European Medicines Agency can take the most up-to-date, state-of-the-art scientific developments in multiple sclerosis into consideration, as well as the positions of experts in the field on the main topics in the guideline.

Representatives from the European Multiple Sclerosis Platform, the Multiple Sclerosis Society UK and the European Federation of Neurological Societies contributed to the discussions.

For further information on this workshop, please refer to the following webpage: Multiple sclerosis.

1.7.2. Workshop on biosimilars

The aim of the workshop on biosimilars of 31 October was to bring together regulators and stakeholders to discuss the three draft revised guidelines, including comments received so far during the public consultation: the draft guideline on similar biological medicinal products, the draft guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: non-clinical and clinical issues, and the draft guideline on similar biological medicinal products containing biotechnology-derived proteins as active substance: quality issues.

Representatives from the European League Against Rheumatism, the International Patient Organisation for Patients with Primary Immunodeficiencies, the European AIDS Treatment Group and the International Alliance of Patients' Organizations contributed to the discussions.

For further information on the biosimilars workshop, please refer to the following webpage: Biosimilars.

1.8. Other workshops and conferences

1.8.1. Antimicrobial resistance event

The European Medicines Agency (EMA), in collaboration with its EU and international partners, is involved in a number of initiatives attempting to limit the development of antimicrobial resistance.

The event 'Best use of medicines legislation to bring new antibiotics to patients and combat the resistance problem' of 8 November brought together various EU and international stakeholders and decision-making factors and aimed at facilitating the discussion around the optimal ways in which the existing EU pharmaceutical legislation could be used to foster the development and approval of new antibiotics and to address antimicrobial resistance.

The workshop was divided into three sections, covering the approval process of new antibacterials, the existing tools to encourage the appropriate use of antibacterials and the aspects related to research and development and new antibiotics.

Bringing the healthcare professional's perspective, Mr John Chave (PGEU), remarked that the appropriate use of antibacterials might be one of the tools which could be used to reduce the speed at which antimicrobial resistance develops. He stressed that the appropriate use of antibacterials was the responsibility of all actors in the health care sector and that healthcare professionals would need to do their part in preventing illegal dispensing and reducing imprudent prescribing. Some evidence shows that public awareness campaigns alone are much less effective that multifaceted approaches which include health professionals. He highlighted the importance of enforcing current legislation rather than looking into new regulation.

For further information on this event, please refer to the following webpage: Antimicrobial resistance.

1.8.2. ADVANCE project kick-off workshop

The objective of ADVANCE IMI project is to 'Develop a framework for vaccine benefit-risk monitoring in Europe'. On 13 November 2013, EMA organised the Kick-off meeting of work package 1, aimed at developing and testing a best practice guidance for the initiation, conduct and reporting of studies on the benefits and risks of vaccines in Europe.

During this workshop, Lina Buzermaniene from the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), representing patients, highlighted the importance of being fully transparent when communicating about academically-led studies sponsored by industry which generate scepticism among patients and raise criticism. This is mainly due to the lack of transparency, such as the unavailability of the protocols to the public, or the use of scientific jargon which is challenging to understand.

However, it is important to consider the impact of vaccinations on people's quality of life and show the benefits outweigh the risks.

Hildrun Sundseth, from the European Institute of Women's Health, pointed several important facts regarding vaccination, for example that vaccination coverage and trust in the general population is low and recent outbreaks of measles and whooping cough in some regions in the EU are a warning signal; that communication about infectious diseases is usually done at the time of an outbreak when prevention is too late. She emphasized that emotional reactions to vaccine-related risks have to be counteracted with an evidence-based benefit/risk analysis and that a proof-of-concept study about the effectiveness of influenza vaccines would have the widest impact for the general public (focus on pregnant women and older people).

In the discussion, it was mentioned that patients' representatives could be involved in the steering committee or standing committee of specific studies to allow them to better understand the study and evaluate the trustworthiness of the results.

Additional input to the workshop was also received in writing from the European Union Geriatric Medicine Society and the Standing Committee of European Doctors. Essentially, healthcare professionals remarked their role in vaccine uptake and communication on safety and effectiveness. They emphasised the importance of high quality, up-to-date, evidence-based information as a vital component in increasing vaccine uptake. Promotion of and support for research on vaccinations should be embedded in a fully transparent framework of cooperation which avoids duplication and guarantees non-biased research. A special concern was raised regarding old, frail persons (mean age 85 years) who are a group in greater need of vaccines and show a low response rate to vaccines available to date.

SECTION 2

2. Interaction with patients and consumers

2.1. Introduction

Since several years now, patients have been formally and systematically involved within many different areas of the Agency's work and as such have become valuable contributors to an increasingly transparent and more rounded assessment of medicines at the EMA. Some activities relate to the involvement of individual patients providing input on medicine specific benefit/risk deliberations whereas other activities involve patient/consumer organisations as a whole. This distinction becomes more evident within the details later in the report.

During 2013 a mutually-beneficial collaboration was achieved which increased slightly compared to previous years; from 525 patients and consumers involved during 2012 to 551 during 2013. As foreseen, the volume of involvement is now starting to reach a plateau; the focus is not on increasing numbers but rather on ensuring that involvement occurs in the most optimal and beneficial manner for all parties concerned.

There has been a consistent participation within the benefit/risk evaluation of medicines through the Scientific Advisory Groups, CHMP consultations and Scientific Advice/Protocol Assistance procedures where patients can bring value in relation to their real life experience of the disease and treatment. Next year we will look at further enhancing their involvement directly within CHMP procedures.

The systematic review of material prepared for the public (package leaflets, EPAR summaries, and safety communications) continues with an average rate of 40%-50% of comments from patients/consumers incurring a change to the text under review.

Involvement within conferences and workshops has considerably increased as the Agency endeavours to ensure that patient representatives are given opportunities to participate as often as possible.

The PCWP continues to be a dynamic platform for exchange between the Agency and patients' and consumers' organisations, on a wide-range of topics of common interest which has been further enhanced with increased collaborations with the members of the HCPWP. In June 2013, David Haerry (EATG) was elected as co-chair of this working party for its new three-year mandate (2013-2016). The membership of the working party was expanded to include a total of 19 organisations.

The EMA also continues to ensure that the patients, carers and consumers who are invited to participate in EMA activities receive appropriate and tailored training to ensure that they are fully prepared to participate and know what is expected of them as patient representatives. To this end, there is a specific training strategy in place which incorporates the different methods and materials available depending on the activity, including a dedicated webpage. In addition to personalised training, the Agency holds an annual training day to which all the eligible patient organisations and their members are invited to participate. This training session held in 2013 comprised over 65 participants, who subsequently confirmed that they found the training very useful.

2.2. Next steps

The "framework of interaction" between the EMA and patients' and consumers' organisations is being revised, to ensure that it can adequately encompass and address the increasing scope of involvement.

Patients' and consumers' will continue to be involved in the various activities across the Agency, as detailed within this report, with involvement in benefit/risk evaluations being enhanced where possible, for example future involvement within adaptive licensing procedures.

The Agency will also be looking at expanding its network of individual patients to ensure sufficient numbers throughout additional therapeutic areas allowing access to the most appropriate patients when needed.

The EMA together with the PCWP will continue looking at its procedures for evaluating the appropriateness of eligible organisations; especially how to assess and handle potential conflicts of organisations when they work with the Agency.

2.3. Key areas of patient involvement during 2013

2.3.1. Input provided on medicines development

Patient involvement in scientific advice / protocol assistance procedures

Patients are involved in protocol assistance (PA) procedures for orphan medicines since 2005 and scientific advice (SA) for all other medicines since 2013.

During 2013, 28 patients were involved in one of these procedures, either in writing and/or in a discussion meeting with the company.

Highlighted below are some concrete examples of very positive and tangible input received from patients within SA/PA procedures;

During a SA procedure related to a potential treatment for melanoma, the patients' contribution during the meeting had a positive impact on the outcome of the advice particularly in relation to the rationale for the product development, the target population and the selection of endpoints in the trial, as well as the pharmacovigilance strategy.

Another example relates to the involvement in a SA procedure related to a medicine intended for the treatment of HIV-1 infection. The patient highlighted that patients see the development of long acting parenteral formulations in a favourable way. He commented on the need for dose ranging studies with long acting formulations and recommended including a higher induction dose. These contributions were included in the final advice.

During another SA procedure meeting for the potential treatment of osteoarthritis the patient emphasised that hand osteoarthritis is very debilitating in day to day life and should be taken into account in the development plan; this input contributed to the final advice.

In addition, patients participated within a SA procedure which looked at potential biomarkers; in this case within the autistic spectrum. These patients contributed information in relation to their knowledge of the day-to-day "real life" experience of autism spectrum disorder, some ethical considerations, as well as requirements for collection of further information regarding biomarkers and clinical outcomes measures in ASD; their input was included in the final reports.

2.3.2. Input provided within benefit/risk evaluations

Patient involvement in Scientific Advisory Group (SAG) / ad-hoc expert group meetings

The EMA endeavours to find patients or carers to participate in all SAG and ad-hoc expert meetings convened by the CHMP or the PRAC; they participated in over 80% of all such meetings held during 2013. During the meetings patients contribute to the discussions on the benefits and risks of certain medicines by providing their unique perspectives gained from living with the disease and its treatment options. Interestingly it has been found that their opinions are sometimes different from those assumed by the assessors.

These discussions can be related to new medicine applications or re-examinations of previous negative outcomes or to referral procedures. During 2013, 33 patients/carers participated within these meetings over a wide range of therapeutic areas, such as hypertension, obesity, HIV, prostate, breast and colorectal cancer, multiple sclerosis, rheumatoid arthritis, hypercholesterolaemia, acne, hepatitis C, asthma, combined hormonal contraceptives, hepatic veno-occlusive disease, migraine, osteoporosis, tuberculosis, duchenne muscular dystrophy and heart failure.

Some particular examples demonstrating the success of these interactions are highlighted here-under:

A SAG meeting was convened in relation to the evaluation of a proposed medicine to treat Duchenne muscular dystrophy which is a rare genetic neuromuscular condition which causes progressive muscle weakness and eventual death in young boys. For this meeting the EMA invited 6 parents/patients to participate and they were able to provide vital information and views from their experiences of the day to day aspects of living and dealing with this debilitating disease. They emphasized that even at a late stage of the disease any small effects allowing longer independent use of arms and hands, or preserving the ability to feed and drink from a cup on their own, would represent a significant and important effect for them. This input was very valuable and contributed to the overall data evaluated by the CHMP to reach its final recommendation, which was a conditional approval.

During an ad-hoc expert group convened by the PRAC in relation to a referral procedure reviewing the benefits of Diane 35 (cyproterone acetate 2 mg / ethinylestradiol 35 micrograms), the patient was able to provide very useful input on the educational material proposed to ensure that the risks of thromboembolism are presented in the best manner to minimise the risk.

During an ad-hoc expert group meeting of an Article 31 referral procedure related to some combined hormonal contraceptives, the patient representative's comments were very much appreciated, taken on board for the overall evaluation and included within the minutes of the meeting. For example the perceived effects of a particular combined hormonal contraceptive on skin or weight was highlighted as well as the fact that patients may request a particular brand that they may feel has a particularly beneficial effect on a particular symptom which may have the beneficial effect of improving the compliance in those patients. Also those representatives of the users (women) should be involved in the drafting of national guidelines and educational material for prescribers and patients.

Subsequently, later within this referral procedure, and in order to receive wider input, the PRAC requested a written consultation with patients on the best way to present the risks in the SmPC and the Package Leaflet for these products. Four options on graphical representation of VTE risk; text, table, bar graph and paling palate were proposed, as well as questions on how to put the size of the risk into perspective (e.g. compared to risk when pregnant). The consulted patients felt that whereas a bar chart was preferable for the SmPC, a simple table with incidence rates was better for the PL; regarding the use of pregnancy as a comparator, feedback suggested that HCPs find the comparison helpful, but women found this confusing and inclusion of risk during pregnancy or specifying incidence rates was not favoured.

Patient involvement in the Pharmacovigilance Risk Assessment Committee

Although the EMA had already involved patients in the process of safety assessment, the formation of the PRAC allowed the patient role to be formalised, with a patient representative and alternate sitting as full members of the this Committee. As a result, patients are now fully involved with the difficult assessments of benefit-risk that sit at the heart of the regulatory process.

Experience to date has shown that patients also play an important role in contributing to decisions on the wording and timing of risk communications which play a fundamental role in ensuring medicines safety. Furthermore, as a communication channel between the Committee and patients' organisations

and wider civil society, they can play an invaluable part in explaining the concepts of benefit-risk evaluations

Patient contribution to research

The EMA has also engaged in research activities to explore methods for eliciting patient preferences for use in benefit-risk assessment. This work is being carried out in collaboration with several academic institutions under the support of the IMI-PROTECT project and the EMA assisted by contacting relevant patient organisation who participated in the study.

In addition, during 2013 the Agency received 13 submissions by patients/consumers (either single individuals or organisations) in the context of public requests for information related to specific safety referrals.

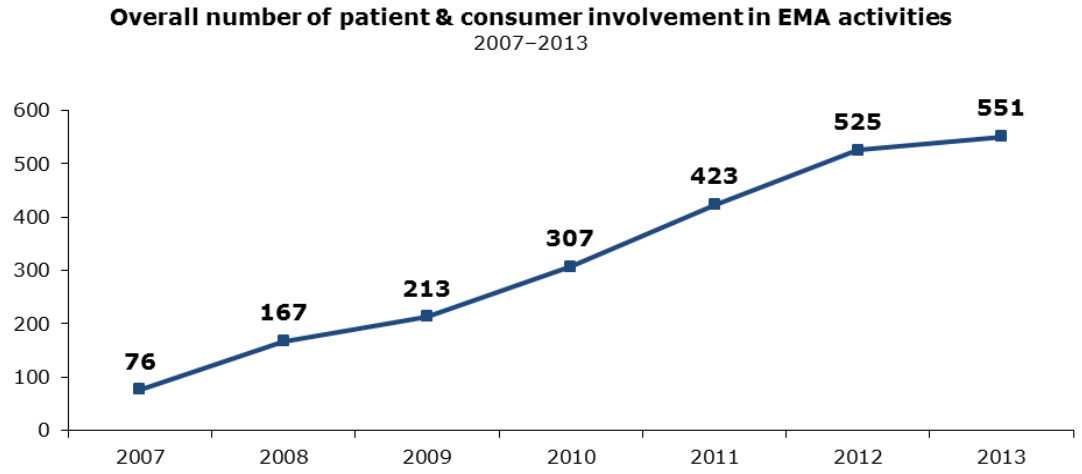
2.3.3. Input provided on EMA communications and information to patients

During 2013 patients and consumers continued to be very involved in the review of information prepared for the public; they reviewed a total of 110 package leaflets, 48 EPAR summaries and 39 safety communications. The review of this material by patients has a significant impact as many of their comments lead to changes in the proposed text (approx. 50%).

In addition to the above mentioned regular reviews there are also ad-hoc requests for review of communication material prepared during the evaluation phase, such as;

During a PRAC evaluation of Tredaptive, Trevaclyn and Pelzont (nicotinic acid/laropiprant) and the subsequent recommendation to suspend them due to a lack of efficacy and concerns of adverse events; patients were asked to provide feedback / comments on the content and readability of the proposed DHPC and Q&A documents. The overall feedback received from the patients/consumers was that these communications adequately explained why the product no longer had an added therapeutic value and that on the basis of recent evidence no longer fulfilled the criteria to stay on the market and be used by patients. They also confirmed that although widely used they did not feel that the suspension would generate alarm or problems and that it is important to raise awareness among the general public that the safety profile of medicines, especially of relatively new ones, can change on the basis of new evidence generated by the daily use that could not be captured in clinical trials.

2.4. Activities involving patients and consumers during 2013



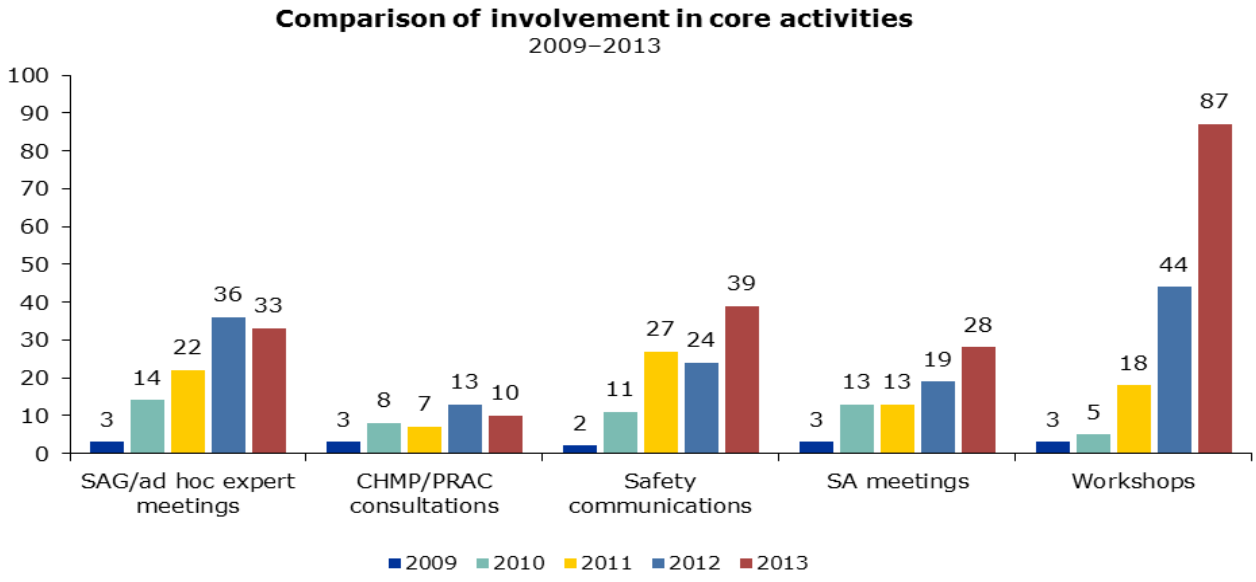
The different types of interaction which have occurred are summarised below:

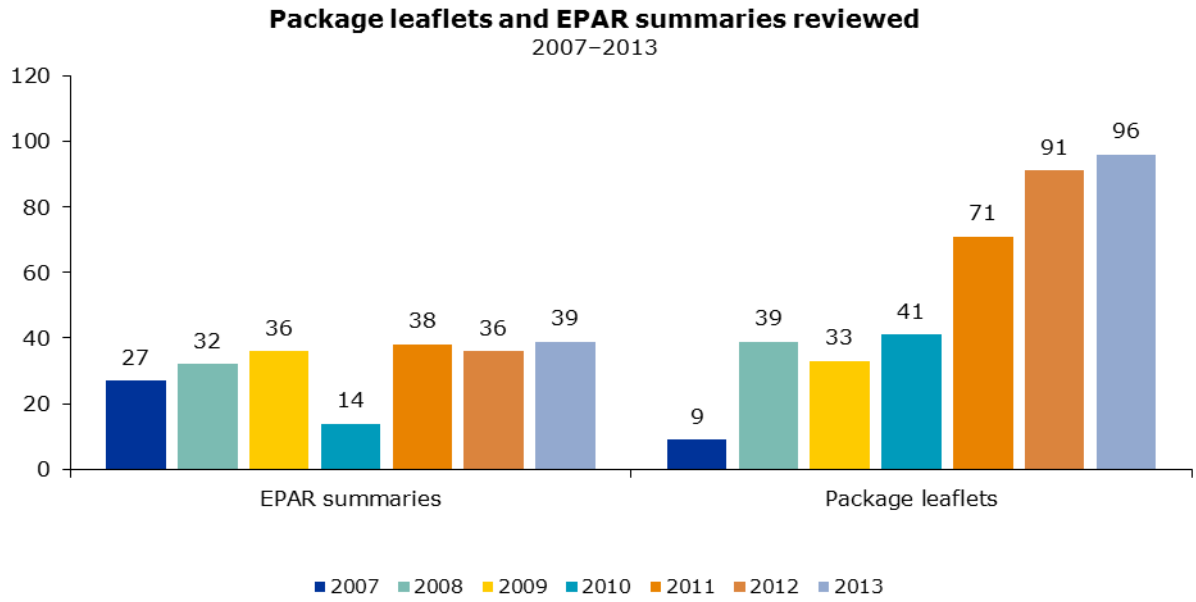
Table 1: Activities involving patients and consumers at the EMA during 2013

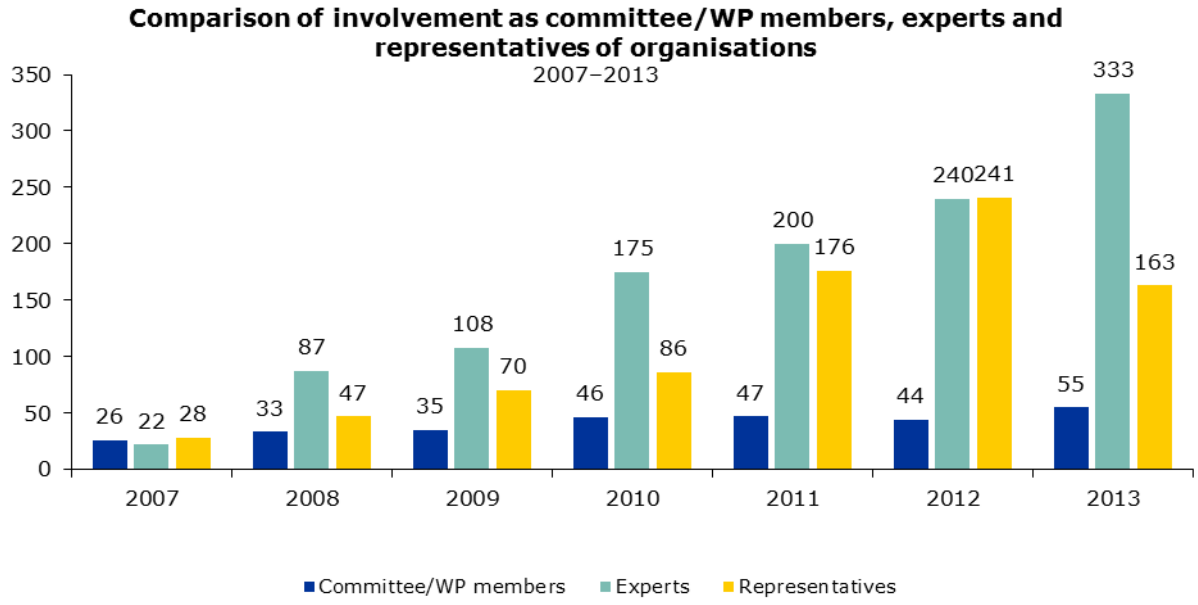
Membership of committees/MB	**Members / alternates or observers**
Management Board (MB)	2
Committee for Orphan Medicinal Products (COMP)	2
Paediatric Committee (PDCO)	3 / 3
Committee for Advanced Therapies (CAT)	2 / 2
Pharmacovigilance and Risk Assessment Committee (PRAC)	1 / 1
TOTAL	**16**
Membership of working parties	**Members / alternates or observers**
Patients' and Consumers' Working Party (PCWP)	19 / 18
HealthCare Professionals Working Party (HCPWP)	2
TOTAL	**39**
Activities involving individual experts	**Experts**
• Participation in Scientific Advisory Group (SAG)/ad-hoc meetings	33
• Participation in Scientific Advice / protocol assistance procedures	28
• COMP consultation x 2	3
• PRAC consultation x 2	8
• Review of safety communications	39
• Review of EPAR summaries	48
• Review of package leaflets	110
• Review of shortage catalogue	1
• Participation in EMA annual training session	63

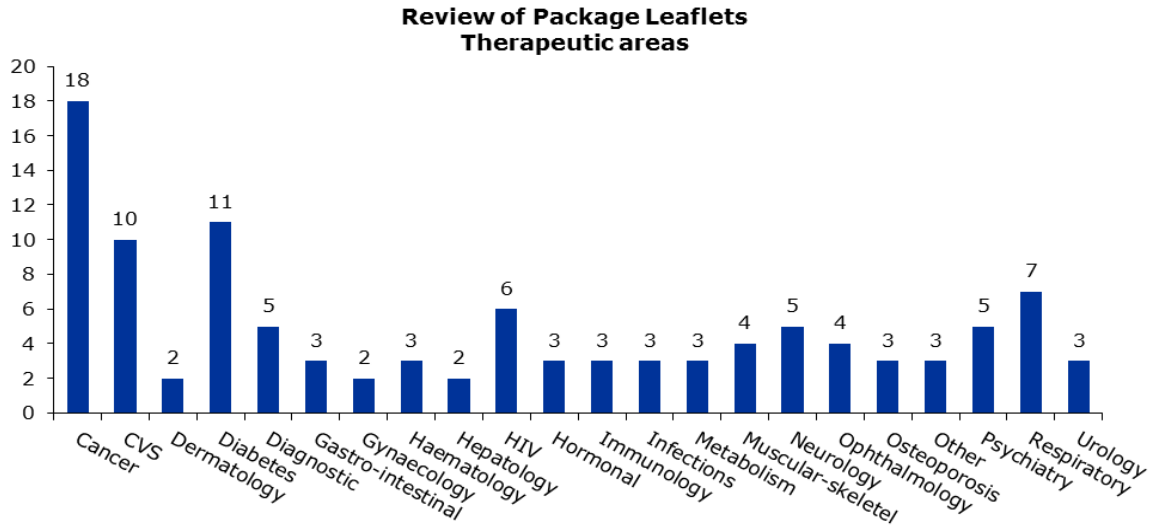
Membership of committees/MB	Members / alternates or observers
TOTAL	**333**

Activities involving organisation representation	Representatives
• Ad-hoc observers/experts attending PCWP meetings	17
• Committee for Human Medicinal Products (CHMP) consultation	2
• TC on conflicts of interest policy	12
• Workshop on medication errors	9
• Briefing teleconference for stakeholders forum	2
• Pharmacovigilance stakeholders forum	11
• Clinical Trial advisory groups	13
• EudraCT Joint Operational Group meetings x 3	16
• Workshop on patient support programmes and market research programmes	5
• Workshop on Conflicts of Interest Policy	8
• Workshop on shortages of medicines	8
• Workshop on Patient Voice in benefit-risk assessment	21
• Workshop on the clinical investigation of new medicines for the treatment of multiple sclerosis	6
• Workshop on biosimilars	3
• Antimicrobial Resistance event	6
• ADVANCE project kick-off workshop	7
• EMA / HTA-body workshop on parallel scientific advice in drug development	14?
• EMA/TOPRA conference	1
• Enpr-EMA coordination group meetings	1
• ENCePP steering group meetings	1
TOTAL	**163**
TOTAL number of patients/consumers involvement during 2013	**551**


Comparison of involvement in core activities
2009–2013
100
90
80
70
60
50
40
30
20
10
0
3
14
22
36
33
3
8
7
13
10
2
11
27
24
39
3
13
13
19
28
3
5
18
44
87
SAG/ad hoc expert meetings
CHMP/PRAC consultations
Safety communications
SA meetings
Workshops
2009
2010
2011
2012
2013


Package leaflets and EPAR summaries reviewed
2007–2013
120
100
80
60
40
20
0
27
32
36
14
38
36
39
9
39
33
41
71
91
96
EPAR summaries
Package leaflets
2007
2008
2009
2010
2011
2012
2013





2.5. Organisations involved in EMA activities during 2013

By the end of 2013 there were 36 patients' and consumers' organisations included on the EMA list of "eligible organisations".

This included three new organisations:

- European Foundation for the Care of Newborn Infants (EFCNI)
- European Haemophilia Consortium (EHC)
- Spinal Muscular Atrophy Europe (SMAE)

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. 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.

Occasionally the agency consults organisations not fulfilling all the criteria; due to the need to consult on a specific area, however this is in line with the "rules of involvement of members of patients' and consumers' organisations in Committees' related activities" (EMA/483439/2008 rev.1). They are listed in table 2.

During 2013, a total of 45 patients and consumers organisations interacted with the Agency and are listed in the tables below:

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

	EMA eligible organisations
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 Foundation for the Care of Newborn Infants (EFCNI)
9	European Federation of Neurological Associations (EFNA)
10	European Gaucher Alliance (EGA)
11	European Headache Alliance (EHA)
12	European Heart Network (EHN)
13	European Haemophilia Consortium (EHC)
14	European Institute of Women's Health (EIWH)
15	European Liver Patient Association (ELPA)
16	European Multiple Sclerosis Platform (EMSP)
17	European Network of Fibromyalgia Associations (ENFA)
18	European Organisation for Rare Diseases (EURORDIS)
19	European Parkinson's Disease Association (EPDA)
20	European Patients' Forum (EPF)
21	European Prostate Cancer Coalition (EUomo)
22	European Public Health Alliance (EPHA)
23	Fabry International Network (FIN)
24	Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe)
25	Health Action International (HAI)
26	Insulin Dependent Diabetes Trust (IDDT)
27	International Alliance of Patients' Organizations (IAPO)
28	International Bureau of Epilepsy (IBE)
29	The International Confederation of Childhood Cancer Parents Organisations (ICCCPO)
30	International Diabetes Federation European Region (IDF Europe)
31	International Patient Organisation for Primary Immunodeficiencies (IPOPI)

	EMA eligible organisations
32	Myeloma Patients Europe (MPE)
33	Pain Alliance Europe (PAE)
34	European Genetic Alliances' Network (EGAN)
35	Spinal Muscular Atrophy Europe (SAME)
36	Thalassaemia International Federation (TIF)

Other organisations who interacted with the EMA during 2013 (e.g. participated in scientific advisory group meetings, scientific advice, workshops/conferences)

	Other or ganisations
1	Adexo
2	Bowel Cancer UK
3	EUROPA DONNA
4	Hepatitis C Trust
5	British Heart Foundation
6	Rett Syndrome Europe
7	Parkinson’s UK
8	Danish Consumer Council
9	Society of Mucopolysaccharide Diseases

SECTION 3

3. Interaction with healthcare professional organisations

3.1. Introduction

Recognising the importance of bridging the regulatory and real-life clinical practice worlds and in order to promote a more structured contact between the Agency and healthcare professionals a specific framework of interaction (EMA/688885/2010)[1] was endorsed by the Agency's Management Board in December 2011. The framework gives particular attention to healthcare professional organisations, as these are relevant intermediaries able to facilitate relations with the wider community of healthcare professionals. The main goals of the framework are to support the Agency in order to access the best possible independent expertise in any matter related to medicines; contribute to a more efficient and targeted communication to healthcare professionals; and to enhance healthcare professionals' organisations' (HCPOs) understanding of the role of the EU medicines Regulatory Network.

This framework is being progressively implemented and the very first steps were taken in 2012 with over 20 European organisations covering different areas of practice and expertise joining the so called network of 'eligible HCPOs'. The year of 2013 saw further progress with milestones such as the establishment of the Agency Human Scientific Committees' Working Party with Healthcare Professionals Organisations (HCPWP) and the further expansion and operation of the network of eligible organisations. We are confident to have established solid grounds that will contribute to a sustainable and meaningful level of interaction in the coming years.

The spirit of the framework for interaction with healthcare professionals is to support and reinforce knowledge already existing within the European Regulatory Network with additional valuable input from day-to-day clinical practice whilst enhancing communication and outreach to those impacted by EU decisions. It recognises healthcare professional organisations' as key facilitators to channel inputs from and outputs to the wider community of healthcare professionals.

The present report provides an indicative baseline of the level of interaction achieved so far.

3.2. Next steps

We will continue to further develop collaboration with healthcare professionals and in particular general practitioners in order to learn about any differences in benefits and risks in clinical practice and narrow the gap between efficacy and effectiveness.

As we move forward with the further implementation of the framework in the years to come, we will be analysing our current practices to identify areas where there may be room for improvement in order to promote a realistic and sustainable involvement of healthcare professionals in EMA activities while continuing to increase its transparency and visibility.

In addition, exploratory work will need to be carried out to assess ways to further recognise individual experts involved in EMA activities.

Finally, as cross-Agency systems to monitor interaction and participation of healthcare professionals are put in place, reporting will progressively focus on the qualitative input and impact of such interaction.

[1] http://www.ema.europa.eu/docs/en_GB/document_library/Other/2011/12/WC500119625.pdf

3.3. Input provided on use of medicines in real clinical practice, for the purposes of benefit/risk decision-making

The Agency's Committee for Human Medicinal Products (CHMP) and Pharmacovigilance Risk Assessment Committee (PRAC) are supported by scientific advisory groups (SAGs) and ad hoc expert groups to provide advice in connection with the evaluation of specific types of medicines or treatments. They consist of European experts selected according to the particular expertise required on the basis of nominations from the committees or the Agency. Through the network of European healthcare professional organisations, the Agency called upon 49 individual experts to participate in SAG/Ad –hoc expert group meetings and bring additional expertise in specific domains during 2013.

Many therapeutic areas were covered including highly specialised input on Duchene's muscular dystrophy; severe primary insulin-like-growth-factor-1 deficiency; transfusion-dependent anaemia due to low- or intermediate-1-risk myelodysplastic syndromes; multidrug-resistant tuberculosis; sepsis; and cognitive impairment no dementia.

In the context of the Agency's scientific advice to support the qualification of innovative development methods for a specific intended use for research and development into pharmaceuticals, the network of European healthcare professional organisations was also valuable to identify individual experts. Specialised nephrologists supported the work of two Qualification Teams for biomarkers to be used in polycystic kidney disease and drug-induced kidney injury, providing reassurance that the discussions had external validity by taking into account clinical practice.

During the evaluation procedure of a medicinal product, whereby aspects related with product information and risk minimisations measures are being assessed, the Agency may also consult with healthcare professionals to obtain their input. In 2013, two product-specific written consultations associated with potential medication errors were conducted where expertise in psychiatry and oncology was sought after (including physicians, nurses and pharmacists with particular expertise in medication errors). These experts advised on aspects related with expression of dosage strength in the product name and labelling and on how to minimise potential risks of mix ups between the medicine being evaluated and another already authorised medicine.

In addition, it is relevant to highlight that throughout 2013, the Agency received 116 submissions by healthcare professionals (from single individuals and from organisations) in the context of safety referrals. This contributed to identifying and gaining a better understanding of real-life clinical practice issues related with the medicines under assessment.

3.4. Input provided on information on medicines and EMA communications targeted to healthcare professionals

Early in 2013, the EMA launched a public webpage which provides information on the preparation and review of a summary of product characteristics (SmPC) and this was presented to healthcare professional organisations' representatives. Although the webpage is intended to enable companies to make sure that the information in SmPCs is of high quality when they submit them to the Agency as part of applications for new marketing authorisations or updates to existing marketing authorisations, it was considered as a good resource to also raise awareness of the information provided in SmPCs among healthcare professionals.

Throughout 2013, healthcare professionals were asked to provide their views on particular aspects related to the application of EMA guidance on product information. This included two written consultations related with the Summary of Product Characteristics (SmPC) guideline: one seeking input on the use of decimals in the expression of strength of medicinal products and another one exploring

the need to make a reference to the SmPC of another product when two or more medicines are indicated in combination. These consultations provided a variety of input from different organisations whereby harmonised positions were difficult to extract due to different practices and realities across Europe. However the views expressed provided additional elements that complemented the discussions at the level of the CHMP/CVMP Quality Working Party (QWP), Quality Review of Documents Working Group (QRD) and the SmPC Advisory Group.

Views on the proposals for improvement of the labelling of pandemic vaccines following lessons learnt from the influenza pandemic in 2009 were also discussed with healthcare professionals. There was general agreement that the proposals and recommendations point in the right direction to ensure safe use of vaccines in the event of the pandemic; however it was also acknowledge that their practical implementation must be balanced against the need to have the vaccines available as soon as possible once a pandemic is declared.

In terms of communication, the Agency has a clear policy to inform stakeholders of key safety information the Agency produces. EMA public information on 'start of safety referrals' as well as 'summary of recommendations' are written specifically with the intention to target patients and healthcare professionals, and the Agency's policy is to disseminate these communications at the time of their publication to the key EU organisations in the field. In order to promote clarity of the messages prepared, the Agency also seeks specific input from relevant reviewers in the target groups during the drafting process. The same applies to direct healthcare professionals' communications (DHPCs).

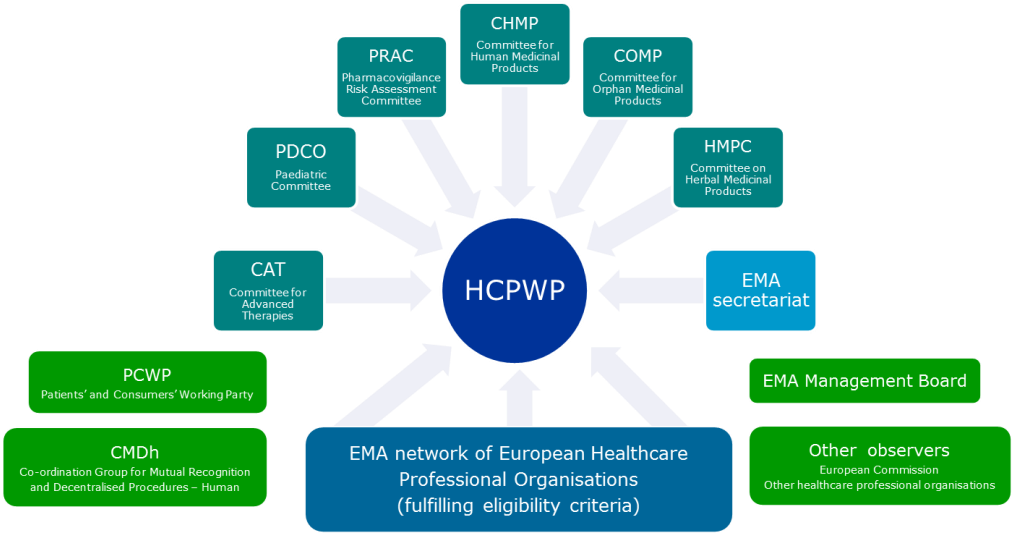
In 2013, a total of 20 experts ranging different specialities and clinical backgrounds were involved in the review of 27 safety communications and 19 DHPCs. Most of the feedback received was positive with pertinent suggestions used to reinforce the clarity of the messages to be conveyed.

A concrete example where healthcare professionals contributed to shaping the messages to be included in various communication documents streaming from a referral procedure is that of the EMA review of certain combined hormonal contraceptives (CHCs) authorised in the European Union. This review was initiated following concerns over the increased risk of venous thromboembolism (VTE) associated with their use and also looked at the risk of arterial thromboembolism (ATE).

Since cases of VTE and ATE continue to be reported by women with contraindications and risk factors for thromboembolic risk, the set of recommendations resulting from the review focused, among other aspects, on the need to prepare a package of communication and educational materials intended to increase awareness of the risk of thromboembolism, highlight the importance of the contraindications and risk factors and promote better awareness of signs and symptoms. In this context, the Agency discussed and agreed core messages to be included in a direct healthcare professional communication (DHPC), a questions-and-answers document for women, a checklist for prescribers and an information card for women. Public communications on the outcome of the review were also discussed. Throughout these different stages, the Agency involved individual gynaecologists and general practitioners.

It is important to mention here that every year the Agency receives a number of individual queries from healthcare professionals. In 2013, the Agency responded to 242 queries from healthcare professionals and registered an increasing number of non-English users. Queries were mainly triggered by referrals and orphan medicines.

3.5. Establishment of the EMA Human Scientific Committees' Working Party with Healthcare Professionals Organisations (HCPWP)



The HCPWP was formally established in June 2013 to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to healthcare professionals in relation to medicinal products and monitor the progress of interaction between the Agency and healthcare professionals.

In its composition, the working party includes links to the six EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC) as well as the following healthcare professionals' organisations:

- Standing Committee of European Doctors (CPME)
- European Association for Clinical Pharmacology and Therapeutics (EACPT)
- European AIDS Clinical Society (EACS)
- European Association of Hospital Pharmacists (EAHP)
- European Association of Urology (EAU)
- The European Academy of Paediatrics (EAP)
- European Association for the Study of Diabetes (EASD)
- European Federation of Internal Medicine (EFIM)
- European Federation of Neurological Societies (EFNS)
- European Society of Cardiology (ESC)
- European Society of Endocrinology (ESE)
- European Society for Medical Oncology (ESMO)
- European Society of Radiology (ESR)
- European Specialist Nurses Organisations (ESNO)

- European Union Geriatric Medicine Society (EUGMS)
- European League Against Rheumatism (EULAR)
- Pharmaceutical Group of the European Union (PGEU)
- United European Gastroenterology (UEG)

The above composition is set out for the period June 2013- June 2016.

In the first HCPWP meeting in June 2013, Gonzalo Calvo, chair of the European Association for Clinical Pharmacology and Therapeutics (EACPT), was elected as co-chair of the HCPWP. He is a consultant in clinical pharmacology in Barcelona and has extensive experience both in medicines regulation, including nearly ten years as member of the Agency's Committee for Medicinal Products for Human Use (CHMP), and in learned societies.

The working party is also co-chaired by Isabelle Moulon, Head of Patients and Healthcare Professionals Department in the Stakeholders and Communications Division, appointed on behalf of the EMA.

3.6. Activities involving healthcare professionals during 2013

The Agency works with a network of almost 5000 European experts nominated by the different national competent authorities throughout the EU/EEA. The vast majority are trained healthcare professionals with an in-depth knowledge of all aspects related to medicines' scientific evaluation and regulation.

The aim of the current report is to highlight the additional input from clinical practitioners that have been identified via representative organisations as experts in their fields of practice and/or nominated to represent their organisations in specific activities where the input of their organisations has been requested. It is important to underline that these are in addition to the already existing network of experts nominated by the national competent authorities and which are not reflected in this report.

The figures also include those healthcare professionals that have been appointed by the EU Institutions as members (and alternates) of the Agency's scientific committees and the Agency's Management Board.

During 2013, different types of interaction have occurred and are summarised as follows:

Table 1: Activities involving healthcare professionals at the EMA during 2013

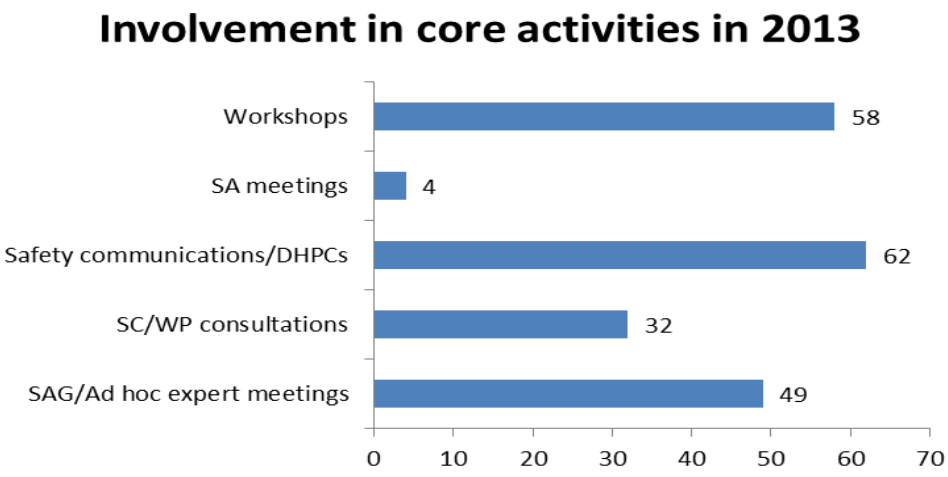
Membership of committees/MB	Members / alternates or observers
MB	2
PDCO	3 / 2
CAT	2 / 2
PRAC	1 / 1
TOTAL	13

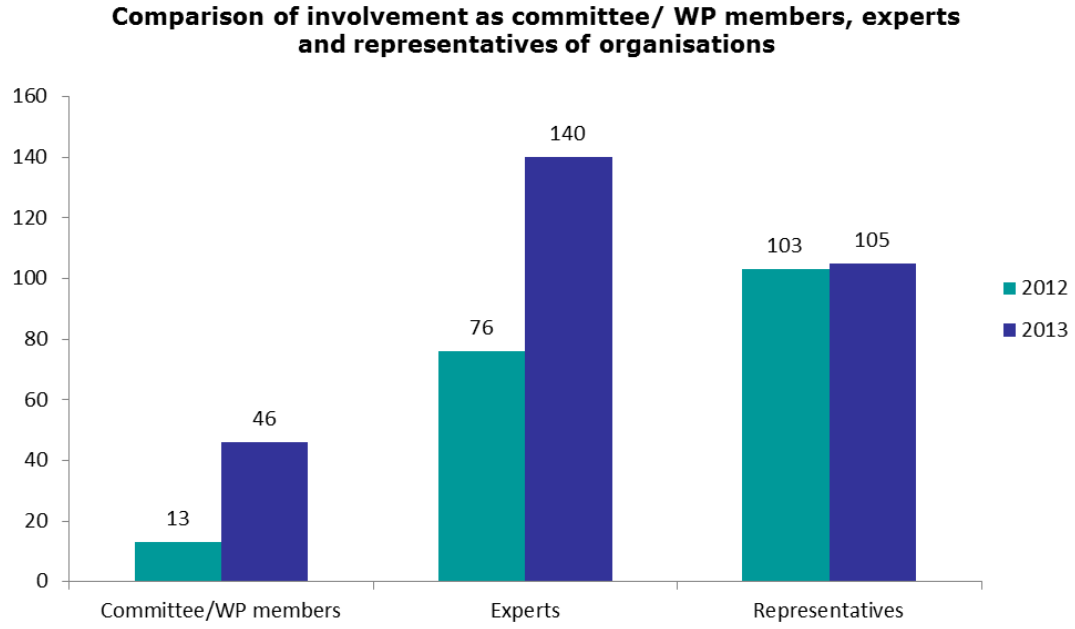
Membership of working parties	Members / alternates or observers
HCPWP	18 / 14
PCWP	1
TOTAL	33

Activities involving individual experts	Experts[2]
• Participation in Scientific Advisory Group (SAG)/ad-hoc meetings	49
• Participation in SA meetings	4
• Consultation on minimisation of potential risk of medication errors	15
• Review of safety communications	35
• Product information related consultations	8
• Review of DHPCs	27
• Review of shortage catalogue	1
• Participation in Enpr-EMA WG4 on dialogue with ethics committees	1
TOTAL	140

Activities involving organisation representation	Representatives[2]
• Ad-hoc observers/experts attending HCPWP meetings	3
• SmPC Advisory Group consultation	6
• Additional monitoring campaign	14
• QRD/QWP consultation	9
• Submissions related with the review of EMA guidelines and harmonisation of product information	1
• Comments to concept papers and draft guidelines	5
• Meetings with the Executive Director	4
• Workshop on medication errors	6
• Pharmacovigilance stakeholders forum	4
• Clinical Trial advisory groups	13
• EudraCT Joint Operational Group meetings	4
• Workshop on patient support programmes and market research programmes	1
• Workshop on Conflicts of Interest Policy	4
• Workshop on shortages of medicines	5
• Workshop on Patient Voice in benefit-risk assessment	13
• Workshop on the clinical investigation of new medicines for the treatment of multiple sclerosis	1
• Workshop on biosimilars	2
• Antimicrobial resistance event	3
• ADVANCE project kick-off workshop (contributions in writing)	2
• EMA / HTA-body workshop on parallel scientific advice in drug development	4
• EMA annual training session	1
TOTAL	105
TOTAL cases of interaction with healthcare professionals in 2013	291

[2] A single expert/representative may be involved more than once.





3.7. Organisations involved in EMA activities during 2013

By the end of 2013 there were 26 healthcare professionals' organisations included in the EMA list of "*eligible organisations"*.

Any organisation may apply to participate in the Agency's activities; they are encouraged to first become *eligible* by complying with the 'Criteria to be fulfilled by healthcare professionals' organisations involved in European Medicines Agency activities'. These criteria are in place to ensure that the Agency works with organisations that are genuinely representing healthcare professionals and acting in the interests of public health. 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 diabetes, oncology, neurology, etc.).

A list of these eligible organisations (table 2) is published on the Agency's website, including links to their websites and a summary of their mission and objectives.

Table 2: Eligible healthcare professionals' organisations working with the EMA

	NAME OF ORGANISATION
1	European Academy of Paediatrics (EAP)
2	European AIDS Clinical Society (EACS)
3	European Association for Clinical Pharmacology and Therapeutics (EACPT)
4	European Association for the Study of Diabetes (EASD)
5	European Association of Hospital Pharmacists (EAHP)
6	European Association of Urology (EAU)
7	European College of Neuropsychopharmacology (ECNP)
8	European Federation of Internal Medicine (EFIM)
9	European Federation of Neurological Societies (EFNS)
10	European Forum for Primary Care (EFPC)
11	European Hematology Association (EHA)
12	European League Against Rheumatism (EULAR)
13	European Renal Best Practice (ERBP)
14	European Society for Medical Oncology (ESMO)
15	European Society of Cardiology (ESC)
16	European Society of Endocrinology (ESE)
17	European Society of Oncology Pharmacy (ESOP)
18	European Specialists Nurses Organisations (ESNO)
19	European Stroke Organisation (ESO)
20	European Society of Radiology (ESR)
21	European Union Geriatric Medicine Society (EUGMS)
22	European Working Group on Gaucher Disease (EWGGD)
23	International League Against Epilepsy (ILAE)
24	Pharmaceutical Group of the European Union (PGEU)
25	Standing Committee of European Doctors (CPME)
26	United European Gastroenterology (UEG)

During 2013, the list of eligible organisations was expanded to include primary care professionals (including general practitioners) as well as organisations of specialists in nephrology, neuropsychopharmacology, oncology pharmacy, epilepsy and Gaucher disease.

As the list of eligible organisations continues to expand in order to cover as much as possible different areas of practice and medical disciplines, the Agency occasionally needs to approach organisations which have not yet undergone the voluntary process of applying for eligibility. This is in line with the "rules of involvement of members of patients'/consumers' and healthcare professionals' organisations in Committees' related activities" (EMA/483439/2008 rev.1).

In table 3 we list the organisations that have also supported the Agency in identifying experts in particular areas of expertise not yet covered by the network of European healthcare professional organisations.

Table 3: Other organisations that interacted with the EMA in 2013

	NAME OF ORGANISATION
1	European Association for the Study of Obesity (EASO)
2	European Union of General Practitioners (UEMO)
3	European Society of Clinical Microbiology and Infectious Diseases (ESCMID)
4	European Society of Gynaecology (ESG)
5	European Psychiatric Association (EPA)
6	European Society of Vascular Surgery (ESVS)
7	European Respiratory Society (ERS)
8	European Association for the Study of the Liver (EASL)
9	European Union of Medical Specialists (UEMS)
10	International Headache Society (IHS)
11	Federation of Veterinarians of Europe (FVE)[3]
12	Association of Veterinary Consultants (AVC)[3]

During 2013, a total of 38 healthcare professionals' organisations interacted with the Agency.

[3] These organisations were contacted in the context of a QRD/QWP consultation on use of decimals in the expression of strength of a medicinal product (human and veterinarian)