



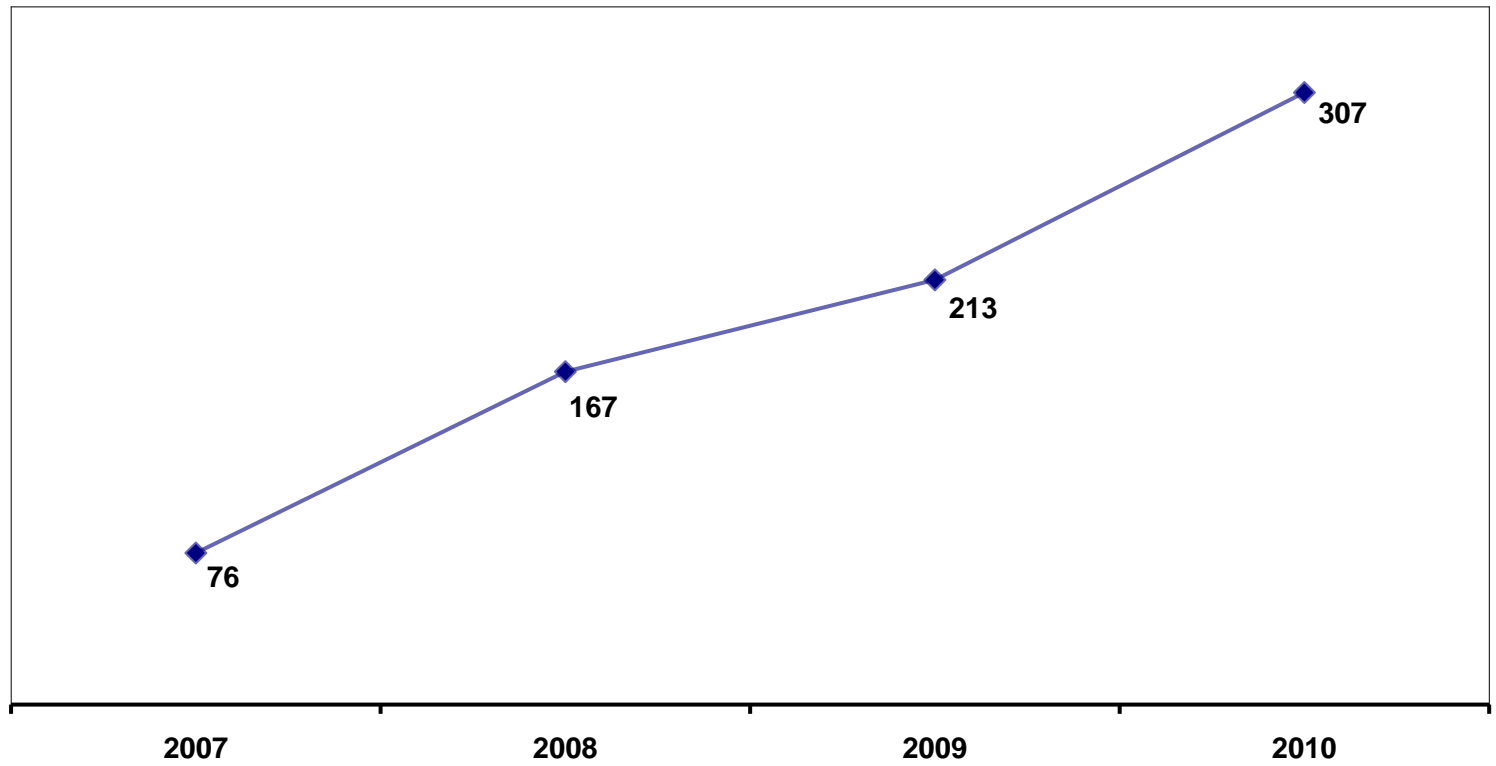
Recent developments and impressions of patient involvement in the EMA

By Lise Murphy, co-chair of the PCWP and a patient representative of EURORDIS and Christoph Thalheim, EMSP representative at PCWP

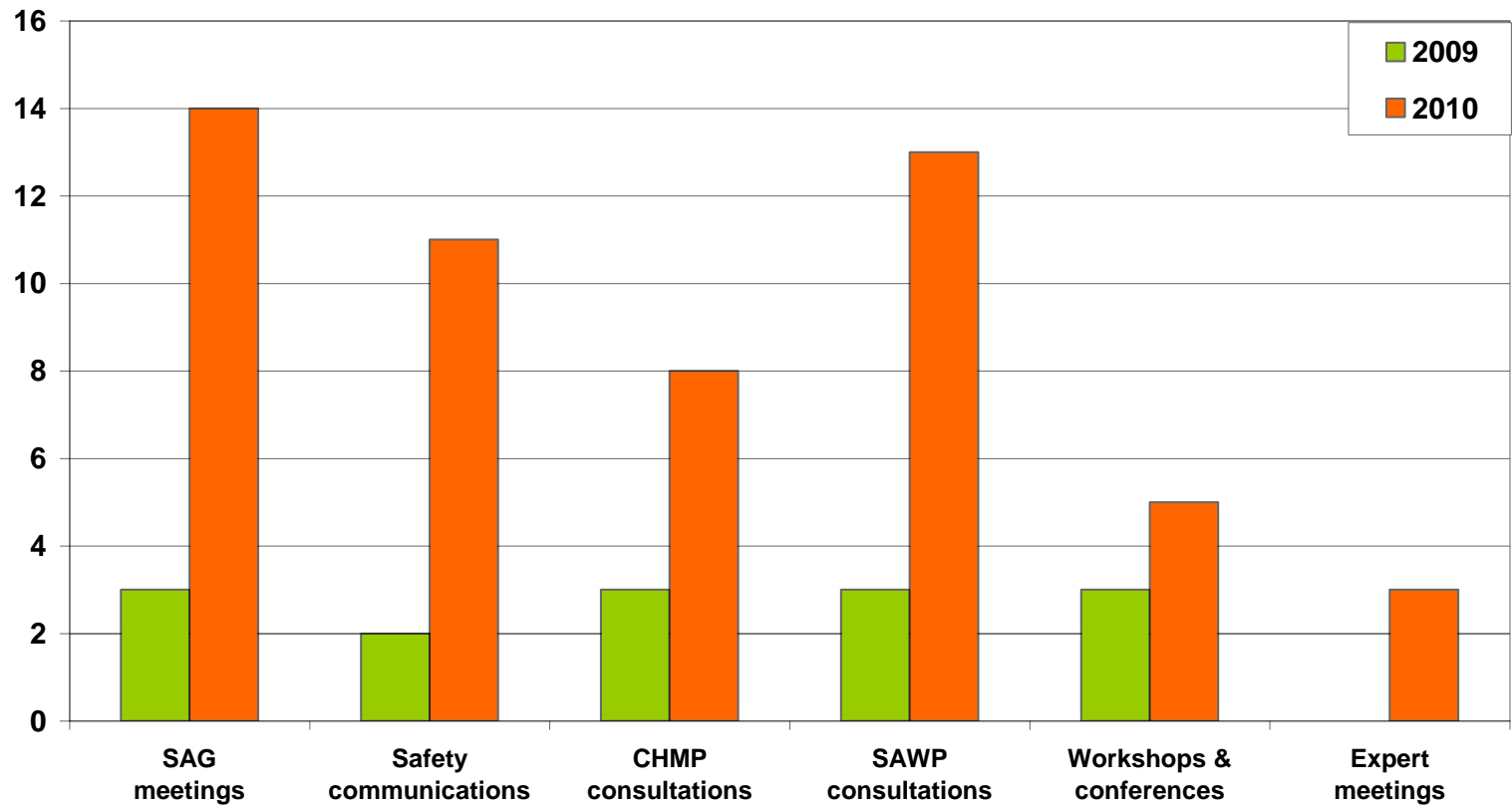
More Patients!



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



Comparison of involvement per activity 2009-2010





Where? Patients and consumers as members:

- Full members of:
 - Management Board (MB)
 - Committee for Orphan Medicinal Products (COMP)
 - Paediatric Committee (PDCO)
 - Committee for Advance Therapies (CAT)
 - Patients and Consumers Working Party (PCWP)
- Observers of:
 - Pharmacovigilance Working Party (PhVWP)
- (From July 2012 Pharmacovigilance Risk Assessment Committee PRAC)

ON WHAT?

Patient involvement in the Agency's activities so far:

- Review of product information:
 - EPAR summaries, package leaflets, safety information (Q&As)
- CHMP (Ad-hoc collaboration):
 - Input on assessment of products
 - Experts in scientific advice/protocol assistance
 - Input in guideline preparation
 - Participation in SAG meetings
- Regular participation in Agency's workshops and conferences
- Involvement in other initiatives such as ENCEPP, Eudravigilance, clinical trial related activities and EnprEMA



Quality -Patients as members

“Patients should not be solely used to substitute scientific experts in scientific fields but should remain critical and have a say : patients are attending because they have an added value and fill a gap that so called experts cannot fill. ...controlling that science works does not turn in closed circles but for the benefit of society.”

Daniel Brasseur, Chair of the PDCO

Quality - PCO in PhVWP

"Patients -

- *provide insight into new safety signals and risk assessments*
- *improve the quality of product information*
- *make a practical contribution to enhance the value of risk communication*
- *provide inside knowledge of how to ensure risk communications reach the appropriate target audiences*
- *input into strategic discussions on a wide range of topics from ADR reporting systems to drugs and driving"*

June Raine, Chair of the PhVWP



The Patients' and Consumers' Working Party – propelling change

- From workshop in 2002 to an expanded PCWP in 2010 consisting of:
- 12 patients' and 3 consumer org. (1 co-chair)
- 5 members from the human scientific committees (CHMP, COMP, PDCO, HMPC)
- the EMA Secretariat (1 co-chair)
- observers from HCP WG, EMA MB, CMD(h), EC
- 4 meetings per year (one joint with Healthcare Professionals Working Group, to be extended to two in 2012)


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



PCWP Members: 15/25 Eligible Organisations + representatives from Agency's Scientific Committees (CHMP, COMP, HMPC, PDCO and CAT)

Co-Chair: Isabelle Moulon (EMA)/ Lise Murphy(EURORDIS)

4 meetings per year (one joint with Healthcare professionals)



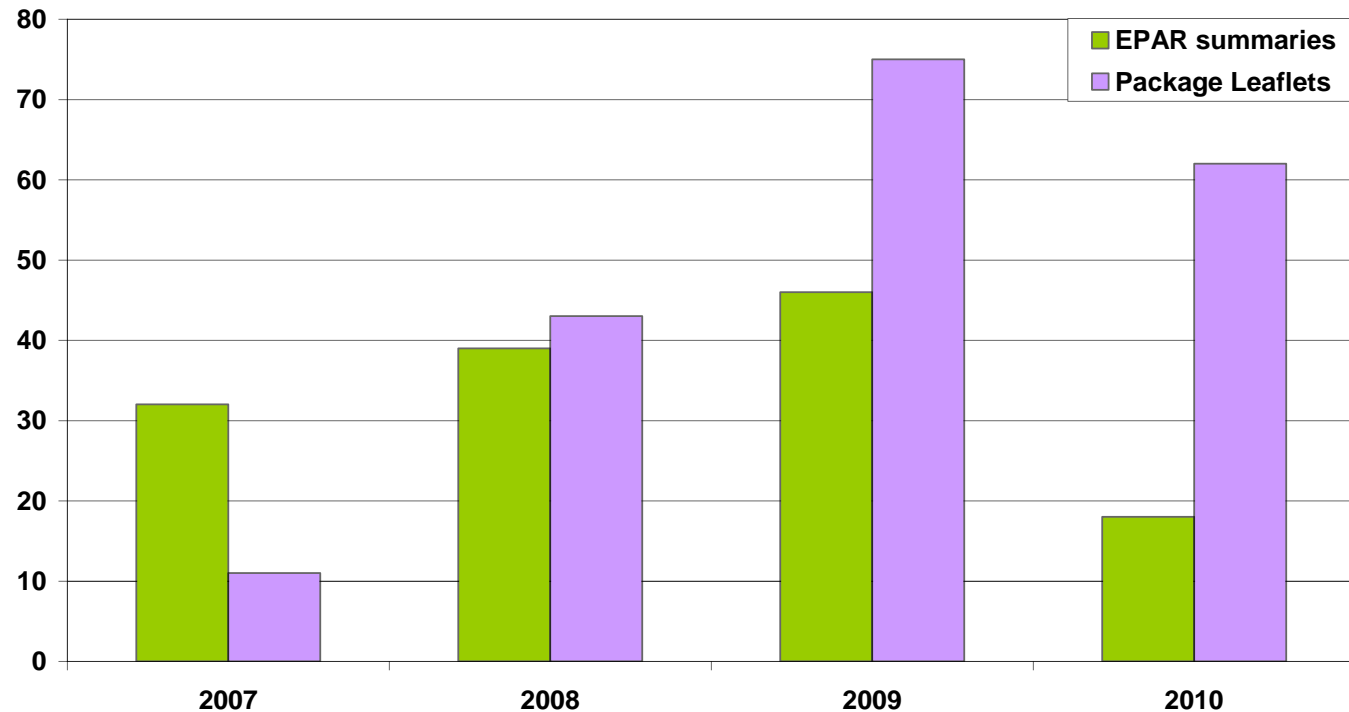
How? When? - The Mandate of the PCWP – facilitating involvement

- Transparency
- Information on medicines
- Pharmacovigilance
- Interaction with the scientific committees

PCWP to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients.

Reviewing EMA documents is one activity of many...

No. of package leaflets and EPAR summaries sent for review 2007-2010



Trends – EMA is developing more training for patients and consumers



Quality + Quantity – more opportunities for interaction with EMA officials and between patients involved





THREE PRACTICAL EXAMPLES from MS

- Tysabri
- Fampyra
- Transatlantic workshop on PML

Impressions - *Success so far...*

- *We have come a long way!*
- *Patients and consumer see the benefits of being involved and having a voice in regulatory matters!*
- *Impact of the patient involvement more evident – both in quantity and quality*
- *EMA-model of working with patients and consumer introduced to the HMA in April 2011 (ongoing surveys of PCO involvement in MS)*

... but many challenges ahead!

- *Patient network, also on a national level must expand as well – resources is an issue and*
- *Becomes worse due to the economic situation in Europe*
- *“EMA-literacy” and other training necessary since increasingly complex issues must be handled by patient and consumer representatives*
- *NCA's commitment?*



Thank you

(For more impressions please go to The fourth progress report on EMA website, available after approval of MB at EMA in mid-October

Look for: Partners and networks – key documents – progress reports



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Survey on involvement of Patient/Consumer Organisations in National Competent Authorities – Summary of results



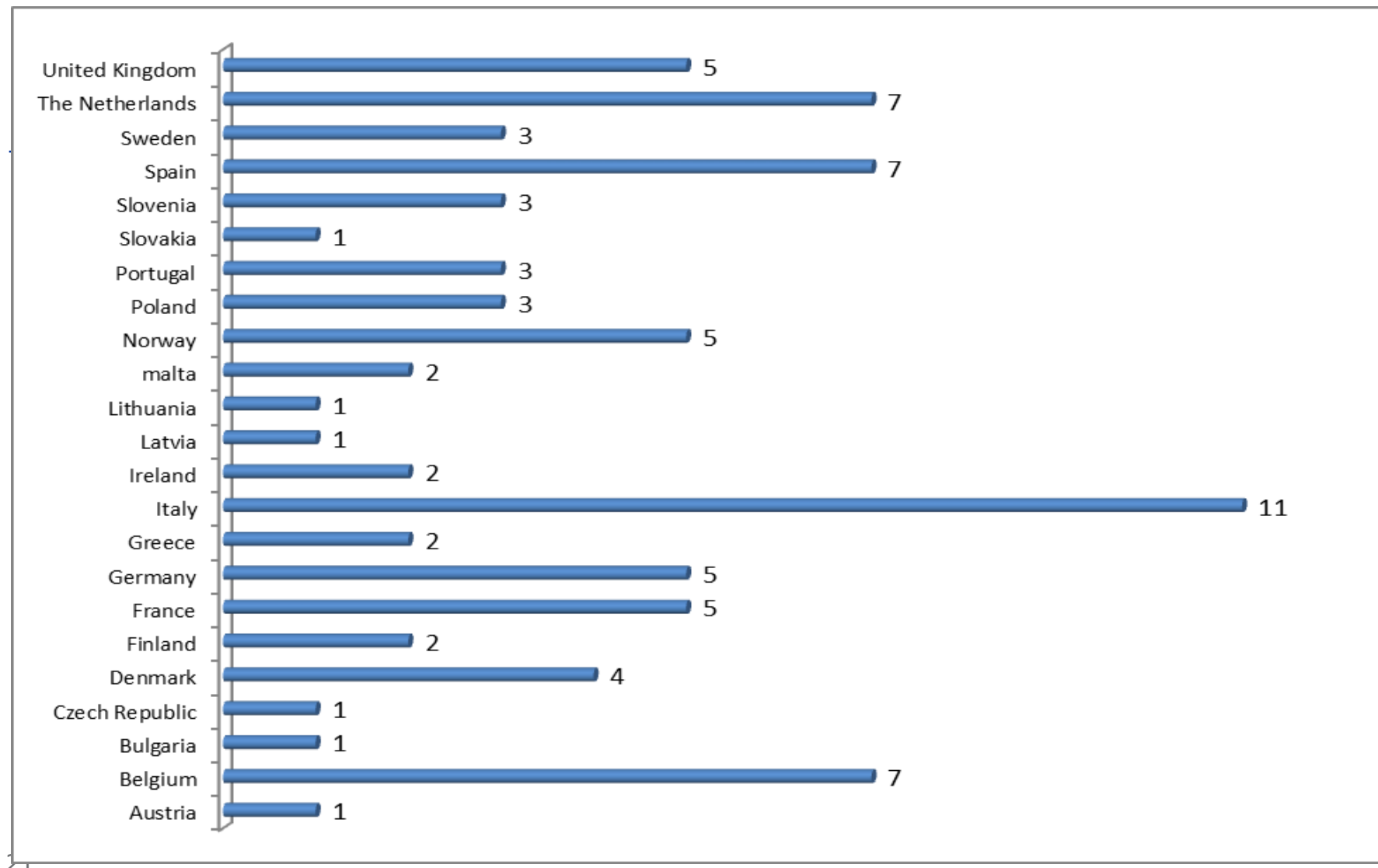


Background

- Based on survey on public and patient engagement by the HMA working group of communications professionals in 2011
- Aim was to obtain general feedback from PCOs on involvement with their national agencies
- Survey ran from 14 October until 25 November 2011
- 91 responses received from over 75 organisations in 24 EU countries (7 non-EU)

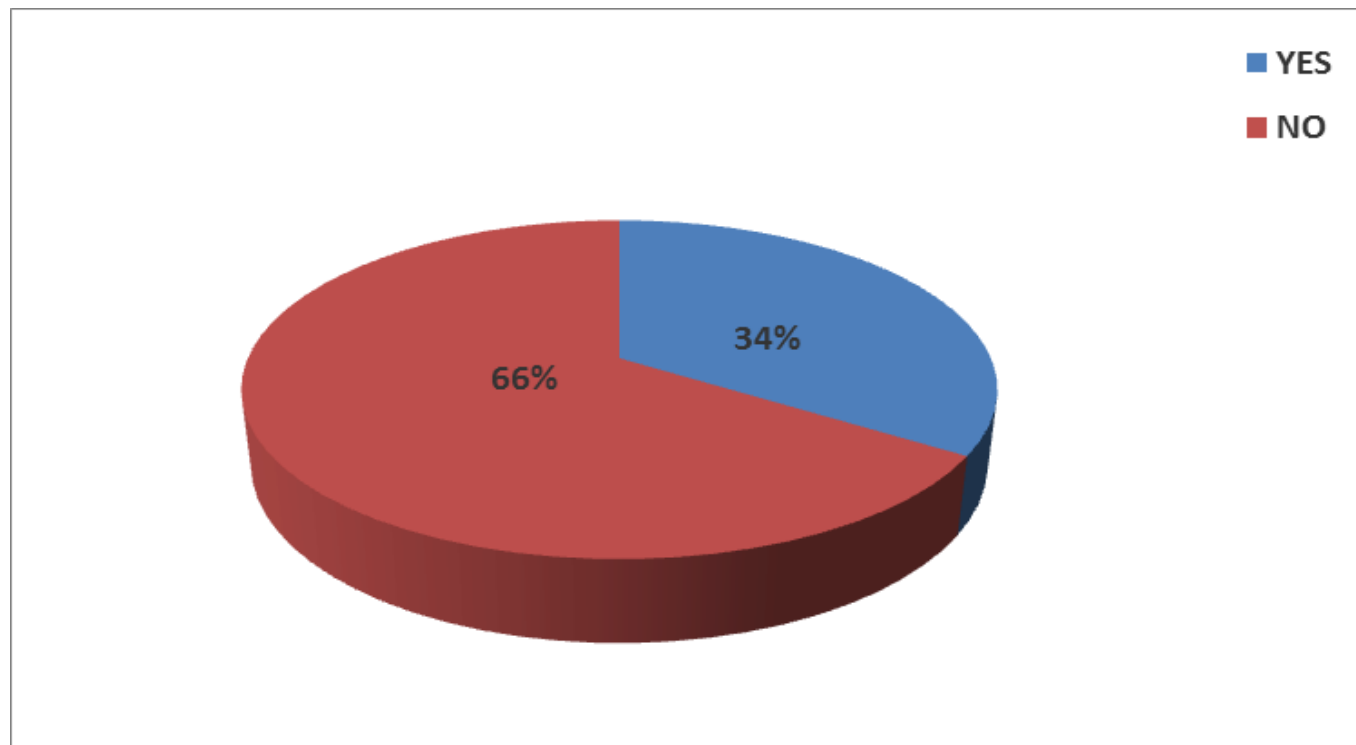


By country:





Are you involved with National Medicines Agencies?



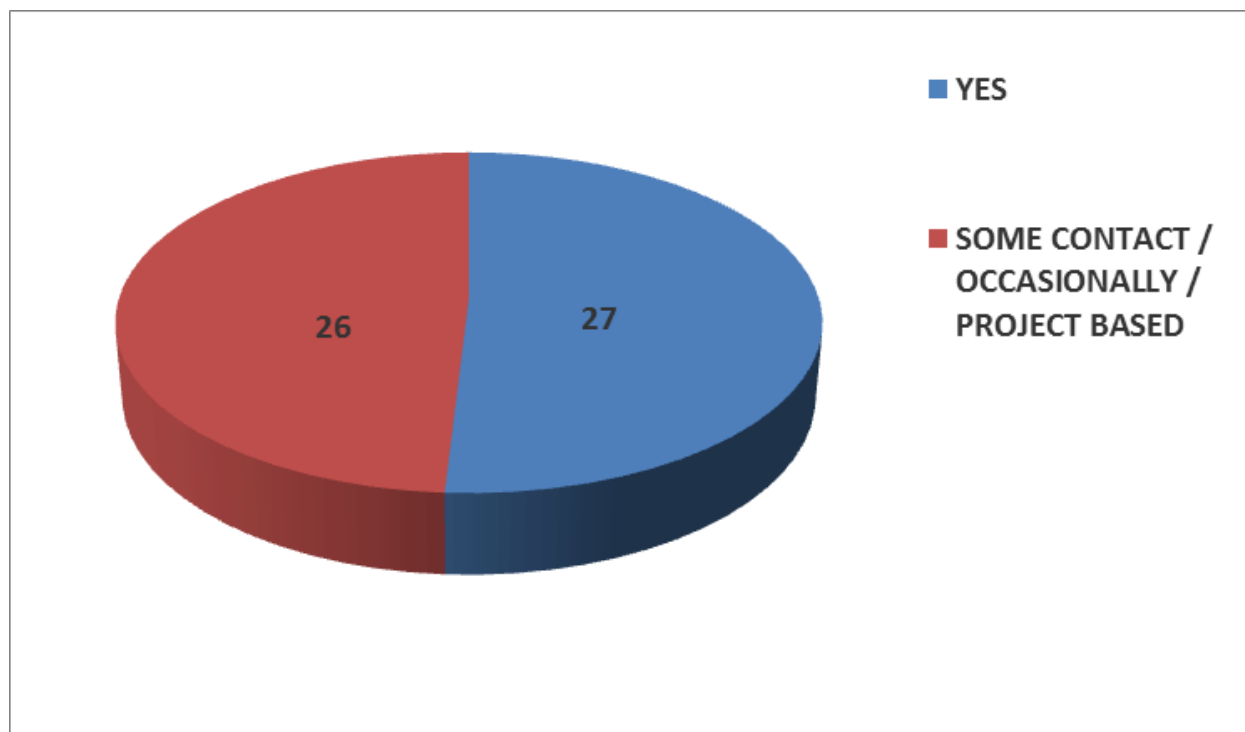


By Country:

Austria	NO	
Belgium	NO	YES
Bulgaria	NO	
Czech Republic		YES
Denmark	NO	YES
Finland	NO	YES
France	NO	YES
Germany	NO	YES
Greece	NO	
Italy	NO	YES
Ireland	NO	YES
Latvia	NO	
Lithuania	NO	
Malta	NO	
Netherlands	NO	YES
Norway	NO	YES
Poland	NO	
Portugal	NO	YES
Slovakia	NO	
Slovenia	NO	
Spain	NO	YES
Sweden	NO	
United Kingdom	NO	YES



If not, has there been any contact at all with your national agency?



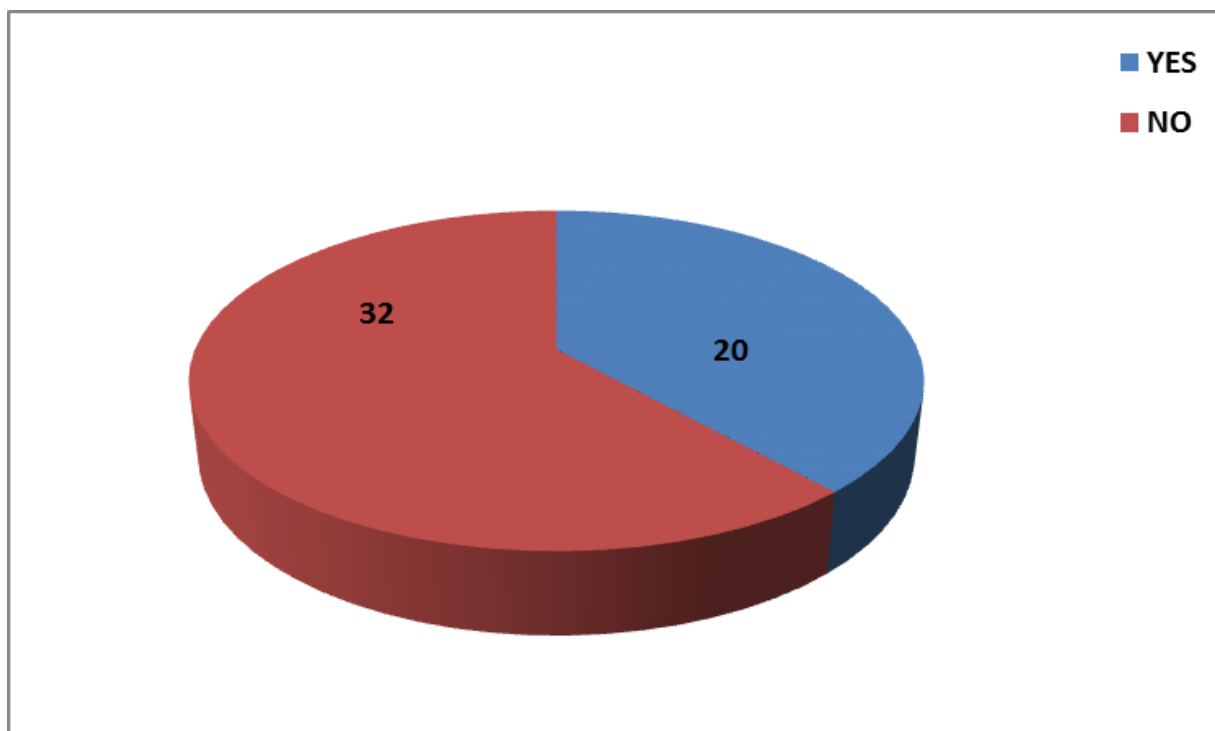


Comments:

- We were invited to discuss about upcoming medicine information strategy.
- We were asked to act as an independent expert.
- By correspondence on important issues.
- We had contact on several occasions, initiated by our organisation to discuss specific problems regarding access to medication. But there is no structural collaboration.
- We are only occasionally invited to conferences but we would like a more active role.
- There have been some contacts but we would more opportunities for interaction.
- We have no direct involvement.
- We sometimes write to them about things but there is no interaction.
- No contacts.
- We use the agency web site to search for information but we were never contacted. We would welcome more opportunities for interaction with the medicines agency.



Does the Agency(ies) have any criteria that individuals or PCOs must meet?



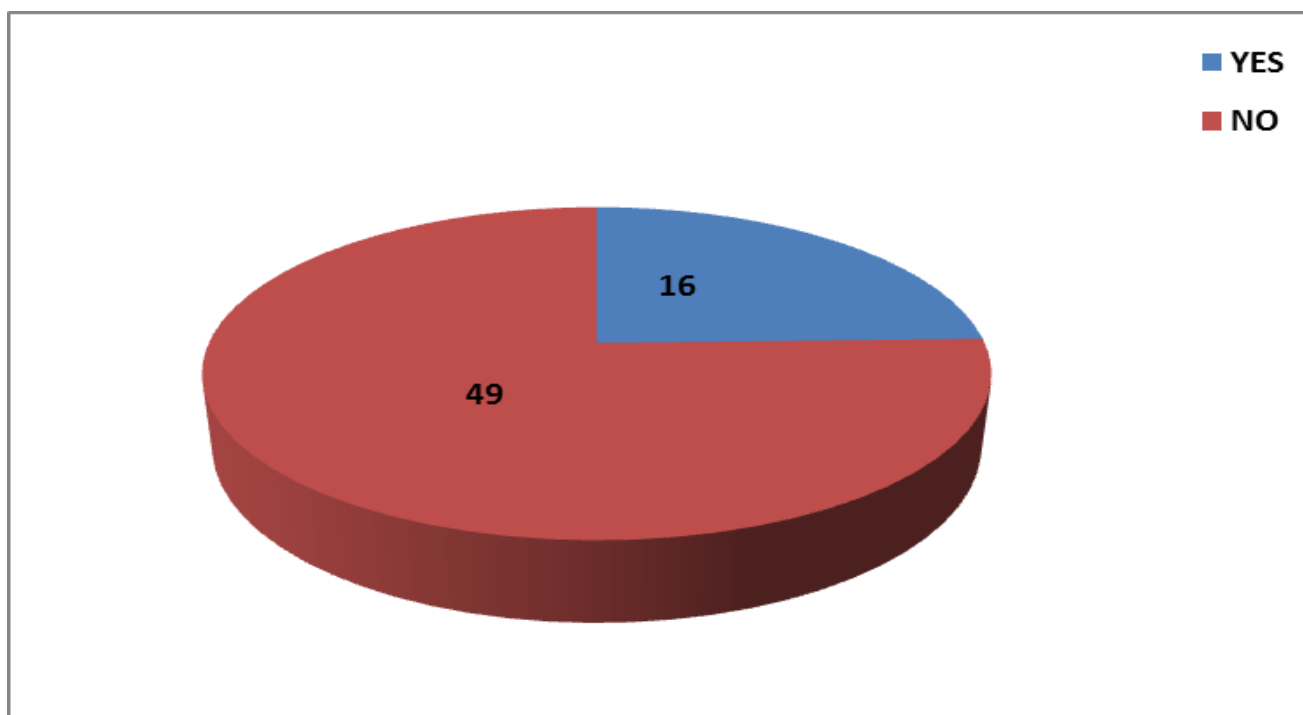


Comments:

- Declaration of conflict of interest for individual. Official recognition from the government for the organization.
- Organisation must be independent from pharmaceutical influence.
- We know there are discussions about defining criteria but so far there are not official criteria.
- Awareness and knowledge of specific disease.
- I don't think so; we were able to interact freely with them.
- The representative has to sign a declaration of interests.
- The patients and consumers associations elect a representative.
- To have the official agreement of the Ministry of Health.
- Confidentiality.



Is there a more permanent group of patients/consumers meeting at the Agency? (e.g. patient/consumer committee)



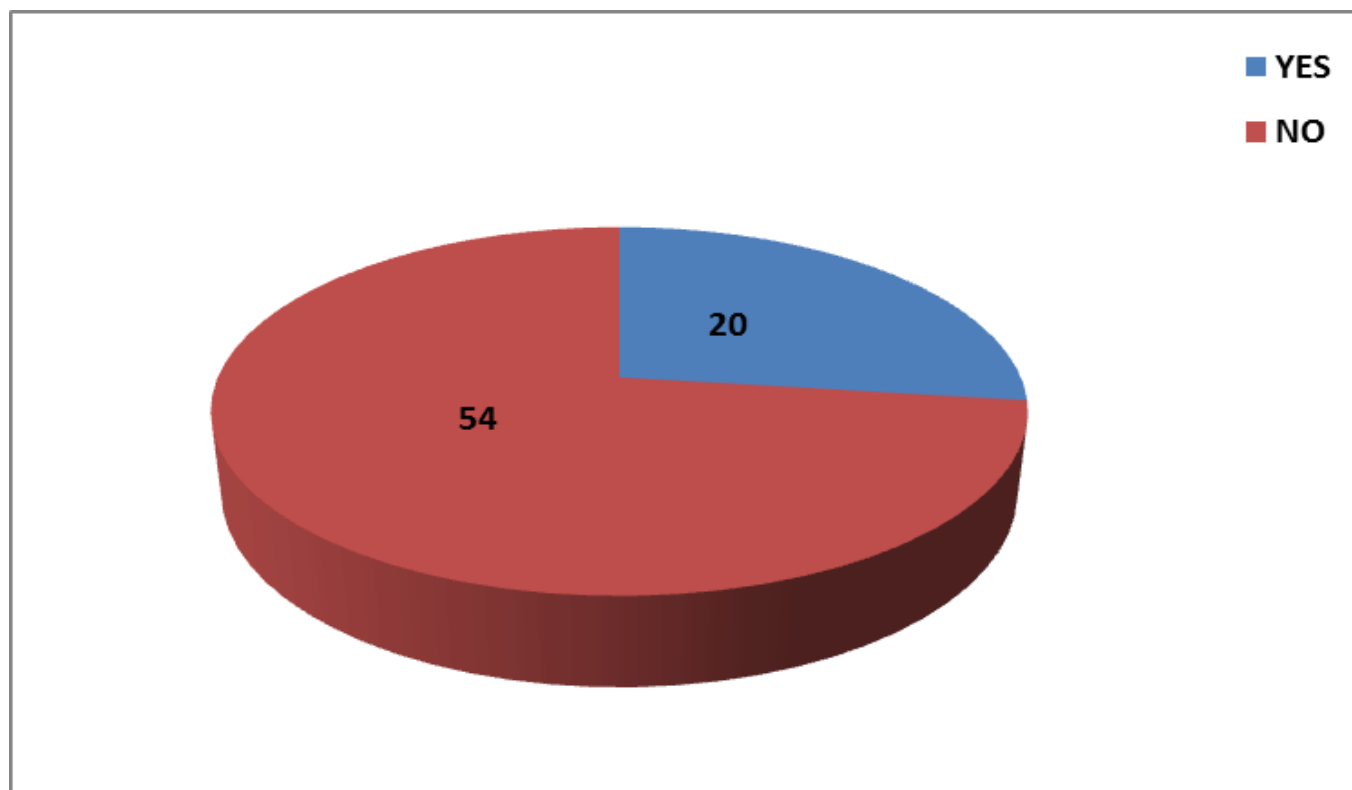


What kind of activities does your organisation perform with this Agency?

- Member of the consultative committee - members of platform with patients/consumers.
- Mailing, meetings about actual problems concerning registration, reimbursement.
- We attended a meeting concerning a new medicine information strategy.
- Member of the committee that assess ex post the advertising of health product.
- To be expert in several committees.
- Collaboration for the availability and pricing of drugs.
- Contacts in case of specific needs.
- Usually bilateral meeting to discuss specific issues, always upon our initiative and request.
- Providing advice from the patient's perspective on the reimbursement of drugs.
- Awareness campaigns, lectures and workshops for the public and general practitioners.
- Member of the Advisory board - joint initiative on direct reporting of side effects.



Are patients consulted on the design of patient communications such as public notices, leaflets and websites?





Do you feel that patient involvement has an impact on the discussions/decisions within the Agencies?

- As a consequence of a mutually respectful relationship the needs and views of the patients are not only listened to but the issues considered
- The involvement of our organisation was essential to obtain authorisation to self-administer
- Definitely, if we had not intervened we would never have received the drug during the emergency shortage
- Yes, the advice with respect to patient information has been followed up
- Yes, although we do not always agree
- Patient involvement improved transparency as well as prioritisation on medical problems
- Yes our involvement has led to many rare diseases being recognised
- Yes, we have an impact but this requires competence in the domain of the disease
- On the rare occasions we were able to negotiate with them, it impacted their decisions. The patients' perspective in the negotiations influenced their decisions



Continued...

- Not as much as we would like. But given that the national decisions follow the recommendations of the EMA where consumers interests are heard we see it as an indirect way to ensure that consumers interests are taken into account.
- Unfortunately not.
- Not at this moment.
- Apparently none as far as our experience goes.
- We do not participate in any decisions they take, so we do not feel involved.
- Unfortunately not enough.
- I don't think they recognize us as equal partners.
- Not so much, at least in our view.
- I don't feel so, the agency has an administrative rule and it's not easy to find solutions.
- Very low or nothing.



Continued...

- The lack of awareness of the Agency of the contributions patient organisations can bring.
- In our opinion the Agency lacks experience in dealing with patient organizations.
- Lack of consideration of the voice of the users of medicines.
- The hearing of patient organisations is not systematic.
- Patient organisations are often run by volunteers and agencies and common boards procedures are made for professional workers. Language and deadlines for contributions do not meet the requirements of voluntary working representatives.
- Lack of resources and Giving up the time is difficult.
- Lack of culture of stakeholder involvement and financial constraints.
- Political reasons and the Bureaucratic nature of the institution.
- Lack of culture of involving stakeholders and independent organizations representing patients. But we see a change due to the model used at European Level which is more open to stakeholders.



What would you see as a next step?

- We would have to find out if there is any interest to cooperate with patient organisations.
- First, it would be very useful to get to know each other (patient groups and Agencies), explore expectations, needs, ways where collaboration would be useful. I am convinced that the Agencies are not aware of the "added value" patient groups can bring to their work
- Full recognition as a PO.
- An "exploration" meeting, where both parties learn to know each other, learn about each other's initiatives, learn about the advantages of a possible collaboration.
- More openness and transparency for stakeholder involvement, stricter policy for conflict of interest for all those involved in the agency activities.
- Establishing closer cooperation between agencies and patient organizations.
- We want to have better discussions in the committees and we would like the meetings to be more than a one way provision of information from the agency to us.



Continued...

- The creation of a national patients or consumers party (like the EMA PCWP).
- We hope we will be involved on a more regular basis.
- That our Agency act in the same way as EMA and improve the cooperation with patient associations.
- It has always been very important to be neutral regarding sponsorship, so in that case, maintain a good collaboration with the industry, but get more sponsorship from other sources.
- We would of course like to have stronger influence on the medications that are selected for reimbursements.
- We would like to have more possibilities to interact and bring the consumer voice to the agency to make its work more patient-friendly.
- To increase patient involvement in the decision making processes.
- Further political steps to improve the impact and contribution of Patient Representation.



OUTCOME/ANALYSIS

General overview:

- Varying number of responses per country.
- 16% responses from consumer organisations.
- 34% responders indicated they were involved with their national NCA.
- 17.5% responders indicated there was a permanent group of PCOs.
- Some PCOs are involved with NCAs, whilst others, within the same country, are not.
- It is more often the PCOs who make contact with the NCAs.
- There are varying levels of criteria in place for PCOs.
- PCOs are involved in various activities: awareness campaigns, members of patient groups, meetings on registration, pricing and reimbursements, sharing of information...
- 22% of responders indicated they were involved in the review of communications.
- Most PCOs do not receive any remuneration, although some received travel expenses and support for literature (e.g. information leaflets).
- The majority of those that were involved felt that their input had an impact.



OUTCOME/ANALYSIS

Factors which hinder interaction:

- Bureaucracy of agencies and lack of experience in dealing with PCOs.
- NCA's lack of interest/willingness.
- NCAs lack of awareness of value of patient input.
- Lack of systematic involvement.
- Procedures (language and deadlines) not adapted for voluntary workers.
- Financial constraints for PCOs.
- Political challenges.



What are seen as potential next steps:

- Make contact with agencies; meet to explore expectations, needs and advantages of possible collaboration.
- Demonstrate to the agencies the added value that patient groups can bring.
- Create a network of POs; creation of groups like PCWP.
- Involvement on more regular basis and increased possibilities for interaction.
- More availability from NCAs to talk to PCOs.
- Further political steps to improve impact and contribution of POs, e.g. voting rights.
- Increased openness and transparency regarding stakeholder involvement.
- Stricter policy concerning conflicts of interest for those involved in Agency activities. PCOs to limit industry funding and use other sources.
- Full recognition of POs with funding for their input.



Summary

- According to the organisations who responded, there seems to be relatively low levels of involvement of PCOs within the national agencies (34%), although a higher number of organisations reported some contact.
- The responses within each country were notably inconsistent, i.e. some PCOs stated they had no interaction with their NCAs, whilst others, within the same country had regular involvement. There could be several explanations for this variability; the initiative on the part of the PCO, resource limitations, the size of the organisation, or perhaps the disease area.
- Some responders (mainly those not involved) reported a lack of experience and willingness from the NCAs towards a collaboration with PCOs and that there is the need for a better understanding of the potential value of PCO contributions to the NCAs work. However, some organisations reported a successful interaction with their NCAs and were of the impression that their input had an impact.
- With regards to the future, many PCOs would very much welcome the opportunity to meet with the NCAs, to discuss possibilities for interaction and to highlight potential benefits that patient contribution can bring. For those that already interact, they would hope to regularise and enhance their involvement, especially within the decision making process.



Overall Summary

- European level (EMA):
 - Regular patient involvement started 2007, but gained quantity and quality continuously
 - Today's involvement covers several Scientific Committees as regular member (Except CHMP) and a special Working Party for Patients and Consumer Organisations (PCWP)
 - Both EMA staff and patient representatives see this involvement as mutually beneficial
- National level (NCA / and probably HTA bodies as well)
 - Regular working relationship with patients exist for less than 50% of 91 responses received from over 75 organisations in 24 EU countries (7 non-EU)
- Lots of room for improvement