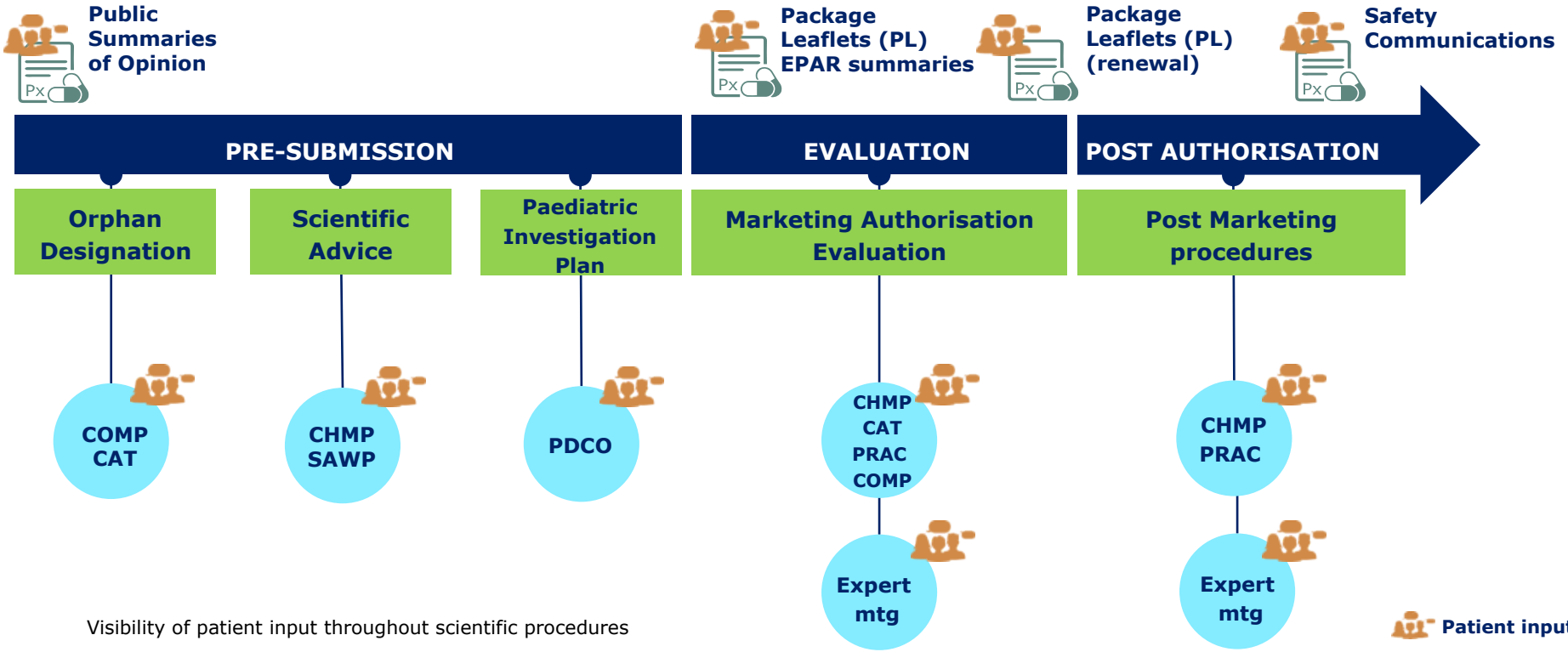
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Visibility of patient input throughout scientific procedures

PCWP plenary meeting

Presented by Maria Mavris on 25 September 2018
Public Engagement Department

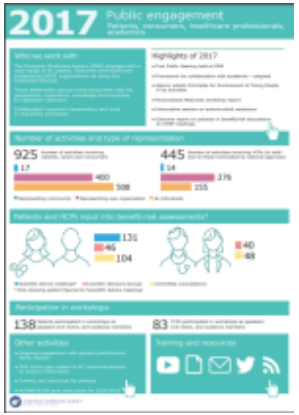
Patient involvement along the medicine lifecycle at EMA



Visibility of patient input throughout scientific procedures

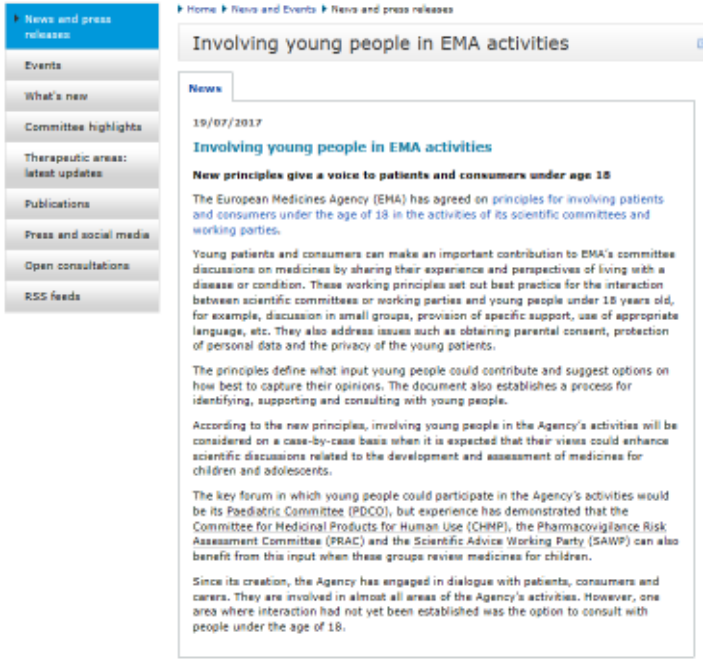
Annual reports (and highlights)

Started in 2007 as progress reports
Interactions
Then HCP
Now Public Engagement Report



Visibility of patient input throughout scientific procedures

Press releases



News and press releases
Events
What's new
Committee highlights
Therapeutic areas: latest updates
Publications
Press and social media
Open consultations
RSS feeds

Home ▸ News and Events ▸ News and press releases

Involving young people in EMA activities

News

19/07/2017

Involving young people in EMA activities

New principles give a voice to patients and consumers under age 18

The European Medicines Agency (EMA) has agreed on principles for involving patients and consumers under the age of 18 in the activities of its scientific committees and working parties.

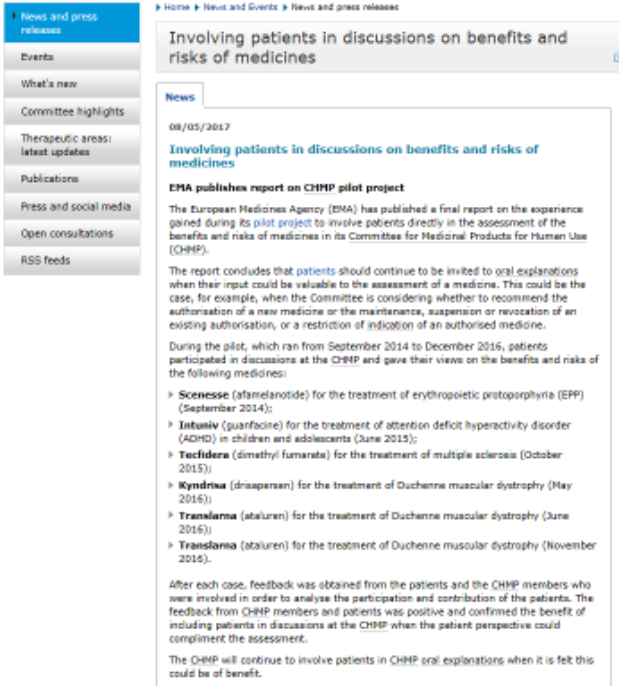
Young patients and consumers can make an important contribution to EMA's committee discussions on medicines by sharing their experience and perspectives of living with a disease or condition. These working principles set out best practice for the interaction between scientific committees or working parties and young people under 18 years old, for example, discussion in small groups, provision of specific support, use of appropriate language, etc. They also address issues such as obtaining parental consent, protection of personal data and the privacy of the young patients.

The principles define what input young people could contribute and suggest options on how best to capture their opinions. The document also establishes a process for identifying, supporting and consulting with young people.

According to the new principles, involving young people in the Agency's activities will be considered on a case-by-case basis when it is expected that their views could enhance scientific discussions related to the development and assessment of medicines for children and adolescents.

The key forum in which young people could participate in the Agency's activities would be its Paediatric Committee (PDCO), but experience has demonstrated that the Committee for Medicinal Products for Human Use (CHMP), the Pharmacovigilance Risk Assessment Committee (PRAC) and the Scientific Advice Working Party (SAWP) can also benefit from this input when these groups review medicines for children.

Since its creation, the Agency has engaged in dialogue with patients, consumers and carers. They are involved in almost all areas of the Agency's activities. However, one area where interaction had not yet been established was the option to consult with people under the age of 18.



News and press releases
Events
What's new
Committee highlights
Therapeutic areas: latest updates
Publications
Press and social media
Open consultations
RSS feeds

Home ▸ News and Events ▸ News and press releases

Involving patients in discussions on benefits and risks of medicines

News

08/05/2017

Involving patients in discussions on benefits and risks of medicines

EMA publishes report on CHMP pilot project

The European Medicines Agency (EMA) has published a final report on the experience gained during its pilot project to involve patients directly in the assessment of the benefits and risks of medicines in its Committee for Medicinal Products for Human Use (CHMP).

The report concludes that patients should continue to be invited to oral explanations when their input could be valuable to the assessment of a medicine. This could be the case, for example, when the Committee is considering whether to recommend the authorisation of a new medicine or the maintenance, suspension or revocation of an existing authorisation, or a restriction of indication of an authorised medicine.

During the pilot, which ran from September 2014 to December 2016, patients participated in discussions at the CHMP and gave their views on the benefits and risks of the following medicines:

- **Scenesse** (afamelanotide) for the treatment of erythropoietic protoporphyria (EPP) (September 2014);
- **Intuniv** (guanfacine) for the treatment of attention deficit hyperactivity disorder (ADHD) in children and adolescents (June 2015);
- **Tecfidera** (dimethyl fumarate) for the treatment of multiple sclerosis (October 2015);
- **Kyndrisa** (drisapersen) for the treatment of Duchenne muscular dystrophy (May 2016);
- **Translarna** (ataluren) for the treatment of Duchenne muscular dystrophy (June 2016);
- **Translarna** (ataluren) for the treatment of Duchenne muscular dystrophy (November 2016).

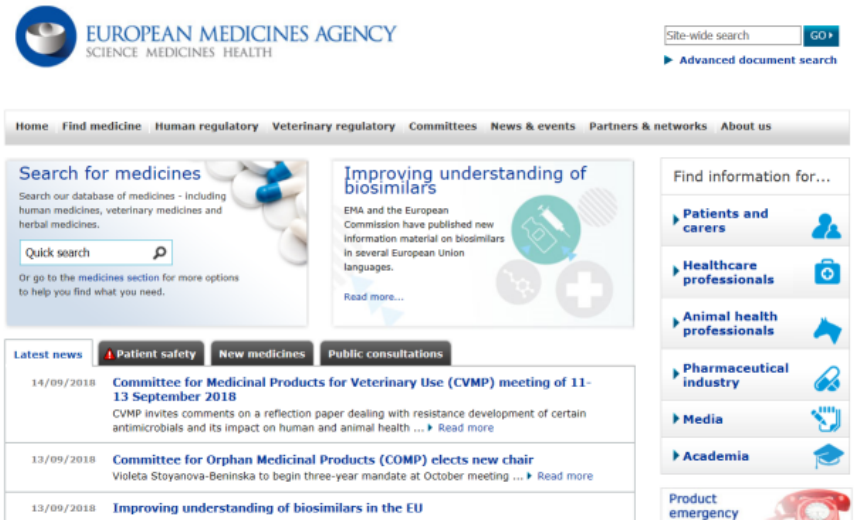
After each case, feedback was obtained from the patients and the CHMP members who were involved in order to analyse the participation and contribution of the patients. The feedback from CHMP members and patients was positive and confirmed the benefit of including patients in discussions at the CHMP when the patient perspective could compliment the assessment.

The CHMP will continue to involve patients in CHMP oral explanations when it is felt this could be of benefit.

Communication to the general public and the media

Visibility of patient input throughout scientific procedures

Webpage and landing pages



Visibility of patient input throughout scientific procedures

Social media

Visibility of patient input throughout scientific procedures

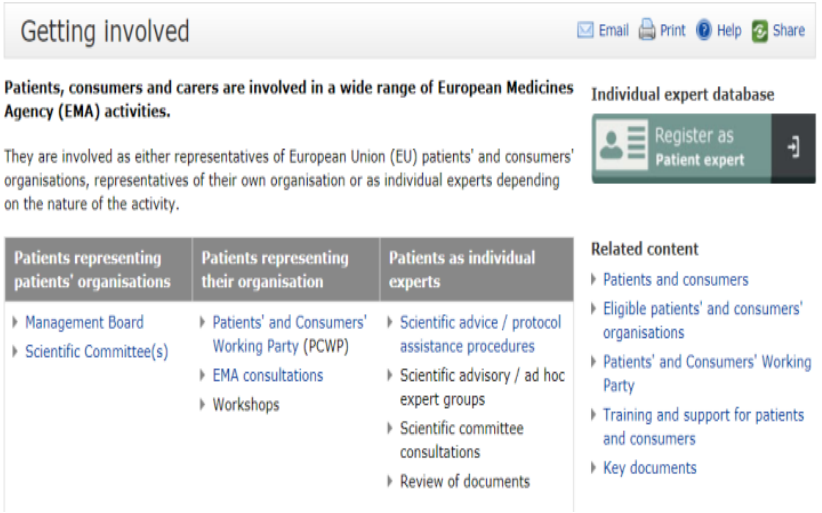
Training

Attendance at meetings and conferences

Targeted emailing

Stakeholder database

Visibility of patient input throughout scientific procedures



Getting involved

Email Print Help Share

Patients, consumers and carers are involved in a wide range of European Medicines Agency (EMA) activities.

They are involved as either representatives of European Union (EU) patients' and consumers' organisations, representatives of their own organisation or as individual experts depending on the nature of the activity.

Patients representing patients' organisations	Patients representing their organisation	Patients as individual experts
Management Board	Patients' and Consumers' Working Party (PCWP)	Scientific advice / protocol assistance procedures
Scientific Committee(s)	EMA consultations	Scientific advisory / ad hoc expert groups
	Workshops	Scientific committee consultations
		Review of documents

Individual expert database

Register as Patient expert

Related content

- Patients and consumers
- Eligible patients' and consumers' organisations
- Patients' and Consumers' Working Party
- Training and support for patients and consumers
- Key documents

- **432 individuals registered**
- **304 organisations registered**

Topic Group on visibility created

Acknowledge and promote visibility of patient input into the Agency's activities

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Annex 1

Recommendations from the PCWP topic group on acknowledging and promoting visibility of patients' input in the Agency's activities
Adopted on 26 November 2015

As part of its activities, the PCWP identified the need to raise awareness of the involvement of patients, consumers and their organisations in the work of the EMA and also to further acknowledge the value of their input.

The topic group was created to:

- Explore how to raise awareness and visibility of patients/consumers work at the EMA;
- Explore how to best acknowledge patient/consumer input in the context of the activities of scientific committees, working parties, scientific advisory groups and other expert groups;
- Make recommendations.

In order to get a better understanding of the current status and generate new ideas, the 2 co-leaders prepared a survey which was distributed to the 13 topic group members.

9 organisations answered. The questionnaire is attached in annex.

On the basis of the outcome of the questionnaire, the topic group agreed on the following recommendations:

Organisations acknowledge and promote recognition: Pre-requisites

- EMA to provide clear guidance on "confidentiality versus transparency" boundaries (organisations refrain to communicate on patients' involvement to avoid breach of confidentiality);
- EMA and organisations acknowledge that patients may refuse to be named (risk of stigma) and protection of private data has to be respected.

How to improve acknowledgement and promotion of patient input into EMA activities by EMA

- EMA to provide a certificate of attendance to meetings;

Visibility of patient input throughout scientific procedures

Annual Report: Follow up survey/working group?

Annual Report

- Review each section of the annual report
- Which information do you use?
- Which information is nice to know?
- Infographics of highlights

Year highlights

Areas of common interest

Patients and Consumers

Executive Summary

Next steps

Healthcare professionals

Conclusions

Academia

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**