Patient engagement at EMA

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Patient engagement:
Integral element of EMA activities

Patient Voice
Interaction with patients: a progressive journey...

- **1995**
  - EMA created

- **1996**
  - Dialogue with patients

- **2000**
  - Patients become Committee members

- **2003**
  - Working group with patients and consumers

- **2006**
  - Patient & Consumer Working Party (PCWP)

- **2005**
  - Framework of interaction with patients, consumers and their organisations

- **2014**
  - Public Engagement Department

- **2017**
  - Public Hearings
  - Involve young people

- **Ongoing**
  - Systematic patient input along medicine lifecycle
The patient voice along the medicine lifecycle

PRE-SUBMISSION
- Designation & Classification
- Scientific Advice
- Pediatric Investigation Plan

EVALUATION
- Marketing Authorisation Application

POST AUTHORISATION
- Post Marketing Procedures

Public Summaries of Opinion

Product information
Medicine overview

Safety Communications

COMP CAT
CHMP SAWP
PDCO

CHMP CAT
PRAC
COMP

Expert mtg

Expert mtg

Patient input

4 Classified as internal/staff & contractors by the European Medicines Agency
Different ways to participate:

- **Representing the patient community**
  - Members of EMA Management Board
  - Members of EMA Committees

- **Representing their own organisation**
  - Patients and Consumers Working Party (PCWP)
  - EMA consultations
  - Workshops

- **Patients as individual experts**
  - Scientific Advice procedures
  - Expert meetings
  - Committee consultations
  - Review of documents
Opportunities for young patients to contribute

- Scientific advice procedures (development plans) meeting or in writing
- Committee expert group meetings
- Committee direct consultations (f2f /questionnaire)
- Stakeholder meetings (medicine-related)
- Review of labelling, risk minimisation measures and safety communications (appropriate language / increase awareness)
- Public hearings
Vital elements

Flexible engagement methodologies

- Face to face
- In writing
- Committee meetings
- Surveys
- Patient preferences

Appropriate support and training

- Annual training day
- Info-sheets
- Videos
- Webpages
- One-to-one personalised support
- Training

One size does not fit all!
Patient networks

- **Any organisation** representing EU patients or consumers can express an interest to work with EMA
  (eligibility criteria & application form: EMA website)

- **Any individual** patient or carer can register to work with the EMA
  (application form on EMA website)
Requirements for involvement in EMA activities

- EMA has to ensure its experts (including staff and MB) do not have any financial or other interests that could affect their impartiality.

- Policy on handling of competing interests of scientific committee members and experts

All experts participating in EMA medicine related activities need to have:

- Up-to-date DoI, e-CV & Expert Nomination form (tick box option for patients)
- Valid for 1 year
- Includes confidentiality undertaking
- Published on the EMA website in the European experts list
DoI electronic form

SECTION 1: PERSONAL DETAILS

SECTION 2: PUBLIC DECLARATION OF INTERESTS

• 2.1 Employment
• 2.2 Consultancy
• 2.3 Strategic advisory role
• 2.4 Financial interests
• 2.5 Principal investigator
• 2.6 Investigator
• 2.7 Grant / Funding to organisation/institution
• 2.8 Close family member interest
• 2.9 Any other interests or facts

SECTION 3: CONFIDENTIALITY UNDERTAKING
Consultancy for a pharmaceutical company

Is ....

any activity where the expert provides *any kind* of advice (including training) to a pharmaceutical company regardless of what is being discussed or contractual arrangements or any form of remuneration.
Grant or other funding to an organisation/institution

Is ....

any funding received from a pharmaceutical company by an organisation/institution to which the expert belongs, or for which he/she performs any kind of activity, and which is used to support any activity of the expert whether or not it is related to research work.

Patients:

• Who are volunteers with their organisation do not have to include funding related to their organisation on their DOI, unless they are committee / working party member/alternate.

• who are employees of their organisation do have to include funding related to their organisation on their DOI under 2.7.
Involvement in EMA activities - examples

1. Alopecia; PDCO reached out to young people with experience of hair loss to understand their views about a potential treatment = 33 responses/15 countries

2. Hormonal contraceptive; PDCO asked young girls what they felt about different dosing options (how often to take the pill)

3. AADC deficiency (very rare); PDCO wanted to better understand needs and desired improvements versus the acceptable risks of a treatment

4. Haemophilia; a young boy joined a Scientific Advice meeting with his father and shared his views on dosing and change over of medicines.

5. ALS & Epidermolysis Bullosa COMP invited young patients to the plenary meeting to share their experiences in terms of the burden of the conditions
Why is patient engagement important?

• Engaging with patients:
  – Brings everyday aspects of living with a disease into scientific discussions
  – Helps bridge the gap between clinical trial data and real world data
  – Increases awareness and understanding: TRUST

• Engagement should be mutually beneficial - Learn together what format works best;
  – Be prepared – understand your role – provide relevant information

Everyone has a role to play to ensure engagement happens

Engaging with patients leads to more meaningful outcomes for everyone!
Questions?

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