EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The European Medicines Agency: An example of patient engagement

EUPATI Patients-Regulator-Industry workshop, Berlin, 20 July 2016

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An agency of the European Union

Patient engagement

- Members – representatives – experts
- Few facts on the evaluation of the declaration of interests

Can we identify key success factors?

→ Framework of interaction between the EMA and patients and consumers and their organisations

→ Eligibility criteria

→ The network of eligible organisations

→ EMA Patients' and Consumers' Working Party

→ Training strategy

Different levels of engagement

Three categories of patient participation:

1. Member, alternate or observer
2. Individual patient expert
3. Representative of an organisation

Patients members of EMA governance and scientific committees

Full members of:

- **Management Board**
- Committee for **Orphan Medicinal Products** (COMP) since 2000
- **Paediatric** Committee (PDCO) since 2007
- Committee for **Advanced Therapies** (CAT) since 2009
- **Pharmacovigilance and Risk Assessment** Committee (PRAC) since 2012

No patients members of the Committee for Human Medicinal Products (CHMP): pilot on involvement of patients in benefit/risk evaluation is on-going.

Patients as representatives/experts

Representatives	Experts
Consulted on issues of general interest (e.g. Policies, guidelines, clinical trial register)	Consulted on issues related to evaluation of medicines
Present the position of the organisation they represent	Provide their own experience/ expertise on the disease and its management
Involved in non-confidential discussions	Sign a confidentiality undertaking
Transparent on the funding of the organisations	Fill in declaration of interest
	Follow same rules as other (scientific) experts

Objectives of the policy on handling of declaration of interest

- Main objective of the policy is to ensure that the scientific committees' members and **experts** participating in the Agency's activities have no **interests** in the **pharmaceutical industry** *that could affect their impartiality*, as per the requirements of EU legislation (*Article 63(2) of Regulation (EC) No 726/2004)*.

- This has to be balanced with the need to secure the best expertise.

Two categories of interests are defined

Direct interests in pharmaceutical industry are:

- Employment with a company
- Consultancy to a company
- Strategic advisory role for a company
- Financial interests

Indirect interests in pharmaceutical industry are:

- Principal investigator
- Investigator
- Grant or other funding to an organisation/institution

Definitions cannot address all the scenarios which may exist; additional guidance included in “Procedural guidance on inclusion of declared interests in the EMA’s electronic DOI form (EMA/627294/2014, Rev. 1).

Direct interests	Indirect interests
Employment at a company (currently or within the last 3 years)	Principal investigator (currently or within the last 3 years)
Consultancy for a company (currently or within the last 3 years)	Investigator (currently or within the last 3years)
Strategic advisory role for a company (currently or within the last 3 years)	Institution/organisation **currently** receives grant/funding with direct **benefit** to the expert
Current financial interests (personal shares, fees, honoraria, patents, … Not reasonable expenses for conference)	Close family member **currently** has interest in a company (employment, consultancy, strategic advisory role, financial)

Status	Length of involvement (in years)	Committee / WP member	Committee / WP Expert	SAG member / Expert
Employee (depends on whether executive role, lead role or cross company role)	Current	**No involvement**	**No involvement**	**No involvement**
	0 to 3	Restrictions	Restrictions	Restrictions
	>3	Restrictions	Restrictions	Restrictions
Consultancy/ Strategic Advisory Role (depends on whether cross product / general or individual product)	Current	**No involvement**	**No involvement**	Restrictions
	0 to 3	Restrictions	Restrictions	Restrictions
Financial Interest	Current	**No involvement**	**No involvement**	**No involvement**
	0 to 3	**Full involvement**	**Full involvement**	**Full involvement**
Principal Investigator / Investigator	Current	Restrictions	Restrictions	Restrictions
	0 to 3	Restrictions	Restrictions	**Full involvement**
Grant / funding to organisation / institution	Current	Restrictions	**Full involvement**	**Full involvement**
	0 to 3	**Full involvement**	**Full involvement**	**Full involvement**
Close family member	Current	Restrictions	**Full involvement**	**Full involvement**
	0 to 3	**Full involvement**	**Full involvement**	**Full involvement**

Can we identify key success factors?

EMA framework of interaction with patients

PARTICIPATION – CONSULTATION – INFORMATION

Rationale	• Support the interaction
Scope	• With whom does the Agency wants to interact
Objectives	• Should aim at mutual benefit and easy to translate into concrete deliverables
Working methodology rules	• Clear with strict rules
Implementation & monitoring	• Action plan • Performance indicators • Reporting to EMA Management Board

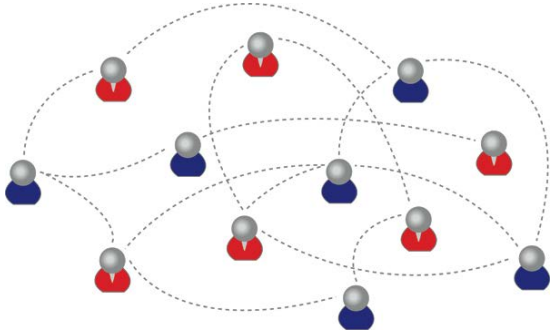
Criteria for involvement of organisations

- **Legitimacy**, with statutes registered in the European Union (EU)
- Clear **mission** and **objectives** with an interest in medicines
- **Activities**: interest in medicines
- European patient or consumer **representation**
- Adequate **structure** and consultation modalities
- **Accountability**
- **Transparency:** all sources of funding are public, code of conduct with sponsors available

Network of European patients' and consumers' organisations

Eligible organisations: patients/consumers

Network of European patients' and consumers' organisations



What is the role of the Network?

- Identify experts
- Provide a variety of positions on non-product related issues
- Available for targeted consultation
- Disseminate information
- Collaborate on various topics (outside of EMA involvement)

EMA Patients and Consumers Working Party (PCWP)

The PCWP plays a key role in the interaction between the EMA and patient organisations. Platform for dialogue and exchange on relevant issues concerning medicines; mandated to help monitor the interaction and identify gaps and priorities in the overall interaction;

- 20 members representing Patients and Consumer Organisations;
- 6 members from the EMA Scientific Committees;
- 1 member from the EMA secretariat;
- Observers from the Management Board.

Four meetings held annually; one plenary, one with all ‘eligible’ organisations, two joint with the Healthcare Professionals’ Working Party (HCPWP) and a one-day training session.

Training and support

Patients should have adequate knowledge on the Agency's work, as well as their role as an expert or representative

EMA training:

- Written information: training manual, rules of involvement, medicine specific information, leaflet, etc
- Patients training webpage, patient specific webpages, glossary
- Video clip on specific meetings where patients are participating
- In-house training: annual training day
- Individual training/support tailored to each patient/activity

Other sources of training:

- EUPATI
- Training organised by eligible patients organisations , *e.g.*:
  - → EURORDIS summer school
  - → European patient ambassador programme (ELF)
  - → EATG training programme

Thank you for your attention

Further information

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