EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cooperation between EMA and patients' and healthcare professionals' organisations

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EMA collaboration with patients and healthcare professionals

1996: . Building the foundation of the interaction between EMA and patients

→ Management Board warned of the danger of neglecting partnership with stakeholders, public, health professions and pharmaceutical industry.

"The Board will therefore keep a careful watch on these partnership and take them fully into account in shaping policies".

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→ EMA started dialogue with HIV patients on the value of surrogate markers in the approval of anti HIV drugs leading to the early approval of protease inhibitors.

2014: . Real life experience of patients is new routinely embedded in regulatory output

. Clinical practice is becoming an important element of the regulatory process

Interaction with patients/consumers' and healthcare professionals organisations

A unique model of interaction:

- Frameworks of interaction and
- Eligibility criteria

The frameworks rely on three critical elements

- A network of patients' consumers' and healthcare professionals' organisations;
- Interaction with the EU Regulatory Network in the field of communication (with particular emphasis on safety communication);
- Fora of exchange with the organisations established within the Agency:
  The EMA Patients' and Consumers' organisations Working Party (PCWP).
- The EMA Healthcare professionals' organisations Working Party (HCPWP)

Criteria to be fulfilled by organisations involved in EMA activities (eligibility criteria)

- **Legitimacy** (statutes registered in one of the Member States of the EU/EEA);
- **Mission / objectives** (clearly defined and should agree to have them published on the EMA website)
- **Activities** (specific interest in medicinal products, which should be documented, as part of its activities);
- **Representation** (representative throughout the EU/EEA);
- **Structure** (governing bodies which are elected by their members, who shall be patients or healthcare professionals respectively);
- **Accountability and Consultation Modalities** (statements and opinions of the organisation should reflect the views and opinions of its members and adequate consultation procedures with those members should be in place);
- **Transparency** (disclosure to EMA of all sources of funding; relationships with corporate sponsorship should be clear and transparent).

Network of patients and consumers
37 eligible organisations

Network of European healthcare professional organisations('eligible HCPOs')

- 28 eligible organisations by end of April 2014

EASD
ESMO
ESN EUROPEAN SPECIALIST NURSES ORGANISATIONS
E.A.P.
EACPT
EUROPEAN SOCIETY OF CARDIOLOGY
eahp european association of hospital pharmacists
ESO EUROPEAN STROKE ORGANISATION
CPME COMITÉ PERMANENT DES MÉDECINS EUROPÉENS STANDING COMMITTEE OF EUROPEAN DOCTORS
EAACI EUROPEAN ACADEMY OF ALLERGY AND CLINICAL IMMUNOLOGY
european forum for primary care
eular
European Society of Endocrinology the European hormone society
INTERNATIONAL LEAGUE AGAINST EPILEPSY Established 1909
PGEU GPUE
EHA
ESOP
EFNS EUROPEAN FEDERATION OF NEUROLOGICAL SOCIETIES
ECNP
ERBP
EUGMS European Union Geriatric Medicine Society
European Society of Radiology
UEMO UNION EUROPÉENNE DES MÉDECINS OMNIPRATICIENS/MÉDECINS DE FAMILLE EUROPEAN UNION OF GENERAL PRACTITIONERS/FAMILY PHYSICIANS
EACS
UNITED EUROPEAN GASTROENTEROLOGY ueg
eau European Association of Urology
EWGGD The European Working Group on Gaucher Disease

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Working with healthcare professionals

An agency of the European Union

Patients and healthcare professionals in EMA governance

Patients and healthcare professionals are members of the Management Board:

- 2 patients' representatives
- 2 healthcare professionals' representatives:
  - 1 for the human medicines
  - 1 for the veterinary medicines

Involvement as Members of scientific committees 1/2

Patients and healthcare professionals as Members of scientific committees:

- Committee for Orphan Medicinal Product (COMP) – (patients only)
- Paediatric Committee (PDCO)
- Committee for Advanced Therapies (CAT)
- Pharmacovigilance and Risk Assessment (PRAC)

The Committee for Medicinal Products for Human Use (CHMP) has no member representing patients.

Involvement in other EMA activities

Patients and healthcare professionals as representatives of their organisation

- Members of **PCWP and HCPWP**
- Consultation on **guidelines**
- Consultation on **policies**
- Involvement in several on-going **EU-wide initiatives**, *e.g.*:
  - **EudraCT** (EU clinical trials register), **Eudravigilance** (adverse reaction data), **ENCEPP** (European Network of Centres for Pharmacoepidemiology and Pharmacovigilance), and **Enpr-EMA** (European Network of Paediatric Research)
- Participate in Agency **conferences** and **workshops**

Involvement in product-related activities 2/2

Patients and healthcare professionals as experts:

- Participate in Scientific Advice/Protocol Assistance during product development
- Participate in Scientific Advisory Groups (SAG) meetings during the evaluation phase
- Review communication material and information on medicines, particularly safety communication and other agency documents intended to the public

Pre-requisite to participation

- Process and structure in place
  - → Declaration of interest – confidentiality undertaking
  - → Personalised support
  - → Role of patients' organisations
- Identify situations where they bring added value (e.g. benefit-risk evaluation)

Challenges

- Identify when regulators should get views from individual versus patient community
- Develop means to identify and manage differences of view between patients and between patients and other stakeholders
- Ensure that patients' and healthcare professionals' views come from independent sources
- Look at training/support to maximise input
- Research how to collect and use the wealth of information available from patients and physicians in post-marketing phase
- Identify and address all legal, regulatory, financial issues that could give rise to procedural barriers to patients' and healthcare professionals' involvement

Conclusion

European Medicines Agency engagement with patients/consumers and healthcare professionals is key in addressing public health challenges.