



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# The European Medicines Agency: a model of patient/consumer interaction

## V International Conference on patient safety

---

Juan García Burgos  
Head of Public Information and Stakeholder Networking - Medical Information  
European Medicines Agency (EMA)





---

## Access to medicines in the EU: the role of the EMA

How patients and consumers contribute to the work of the EMA





---

# European Medicines Agency's role and responsibilities



## The role of the European Medicines Agency

---

A decentralised Agency of the European Commission, created in 1995.

The Agency provides the Member States and the European Institutions with scientific advice on the evaluation of the quality, safety and efficacy of medicines (Human and Vet).



## What does that mean

---

### The Agency is responsible for:

- The evaluation of marketing authorisation applications submitted by pharmaceutical companies, for certain types of products
- Coordination of pharmacovigilance at European level (supervision of the medicines on the market)
- Provision of scientific advice on the development of medicines
- Evaluation of applications for orphan designation in EU
- Evaluation of paediatric investigation plans (or waivers)
- Provision of good quality and independent information on medicines it evaluates to patients and health professionals



## The EMA is not responsible for:

---

- Controlling advertising
- Pricing and reimbursement
- Providing information on diseases (including therapeutic guidelines)



## Marketing Authorisation - Key Principles

---

- The EU is a Single Market for pharmaceuticals - approx. 0.5 billion people.
- In order to sell a medicinal product in the EU, a company needs a Marketing Authorisation
- There are a number of ways ( 'Procedures' ) for a company to obtain a marketing authorisation.
- The main scientific principle used in the evaluation of medicines is the benefit/risk balance, based mainly on quality, efficacy and safety aspects



# Marketing Authorisation Procedures PRE - 1995

**15 National Competent Authorities**

**15 Parallel National Reviews**

**15 Independent Marketing Authorisations**

- Poor resource utilisation
- Divergent scientific opinions
- Divergent patient / doctor information







# Marketing approval for medicines today - Two European Systems

**Centralised Procedure**  
**(via EMEA)**

**Mutual Recognition  
Decentralised  
Procedure**  
**(national licences)**

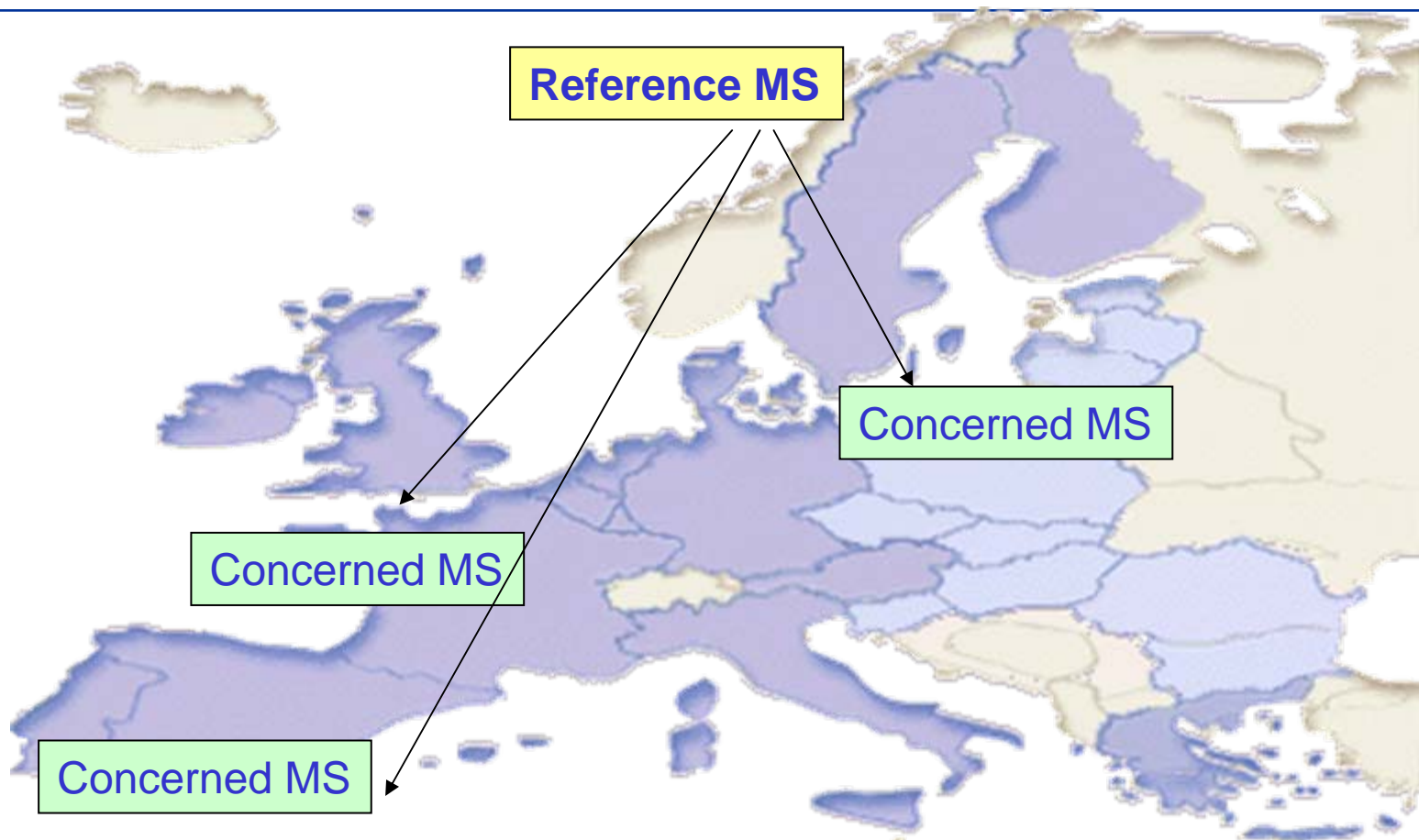
**Both Systems allow**



**Better Resource Utilisation**  
**Harmonised Scientific Opinions**  
**Harmonised Information to Doctors**  
**/ Patients**



# Mutual Recognition/Decentralised





# Centralised Procedure

## Creation of EMEA:

- to manage the centralised procedure
- to formulate scientific opinions



Sent to the European Commission :



**Commission Decision**

(Pan European Marketing Authorisation)





# Centralised Procedure

- 1 application
- 1 evaluation
- 1 authorisation for all EU
- 1 product information (SPC, Labelling, PL)
- All EU languages





## Which medicines are evaluated at the EMA?

- Rare diseases
- HIV, cancer, neurodegenerative disorders, diabetes
- auto-immune diseases, viral diseases
- All biotech products
- Gene therapy
- Monoclonal antibodies
- ± Other innovative products



## How does the Agency work? (1)

---

### Scientific Committees:

- Committee for Medicinal Products for Human Use (CHMP)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee for Orphan Medicinal Products (COMP)
- Committee for Herbal Medicinal Products (HMPC)
- Paediatric Committee (PDCO)
- Committee for Advance Therapies (CAT)

### Working parties:

- give support to the Committees



## How does the Agency work? (2)

---

### Agency's secretariat:

- gives technical, scientific and administrative support

### Experts:

- throughout the EU collaborates with Scientific Committees and Working Parties



# The European Medicines Agency network

A unique structure

•The Agency partners with:

- More than 40 national competent authorities
- 4000 EU Experts
- European Parliament
- European Commission



•Establishes relation with non-EU regulatory authorities, international health organisations, industry academia, and the general public





## Role of the Agency on antimicrobial resistance

---

Work with many partners across EU to monitor and evaluate risks to human and animal health related to antimicrobial resistance:

- Human health: Jointly with ECDC, EFSA, SCENIHR
- Animal health: CVMP (2006-2010 strategy)



---

# Agency's interaction with Patients' and Consumers' Organisations



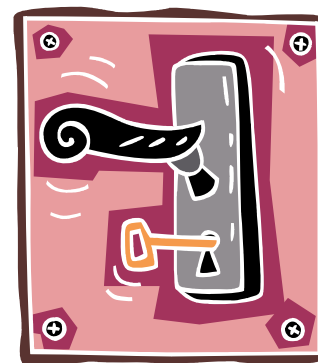
# Basis for interaction

---

Legal basis for interaction with consumers, patients and healthcare professionals

Agency's Road Map

Pharmaceutical Forum





# Interaction with patients'/consumers' organisations

---

- Long experience since the agency was created
- Unique model of interaction:
  - framework of interaction and,
  - selection criteria



# Framework of interaction

---

The framework comprises:

- The scope of the interaction
- The objectives to be achieved
- The working methodology
- The monitoring (including performance indicators)

Ultimate goal:

- Involve patients in the Agency's activities
- Better inform patients



## Framework of interaction

---

Principle of patient empowerment:

- Patient involvement/patient information/patient safety

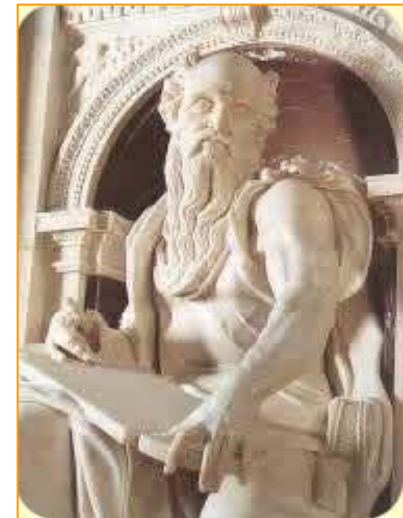
Role of patients/consumers' organisations as multipliers of the interaction (promoting patient safety)



# Selection criteria for involvement of patients' organisations

---

- Legitimacy
- Mission/objectives
- Activities
- Representativity
- Structure
- Accountability and Consultation Modalities
- Transparency





## Eligible organisations (1)

---

### **Permanent Call for interest to work with the EMEA:**

Launched in 2005 and "continuous"

List of eligible Patients' & Consumers' Organisations  
published on the Agency's website





# Eligible organisations (2)

## Working with patients and consumers

### Eligible organisations

The following patients' and consumers' organisations fulfil the criteria for eligibility and may be involved in the activities of the European Medicines Agency:

#### Name of organisation

Alzheimer Europe (AE) | [view summary information](#)

European AIDS Treatment Group (EATG) | [view summary information](#)

European Federation of Allergy and Airways Diseases Patients' Associations (EFA) | [view summary information](#)

European Cancer Patient Coalition (ECPC) | [view summary information](#)

European Federation of Neurological Associations (EFNA) | [view summary information](#)

European Genetic Alliances' Network (EGAN) | [view summary information](#)

European Heart Network (EHN) | [view summary information](#)

European Multiple Sclerosis Platform (EMSP) | [view summary information](#)

European Myeloma Platform (EMP) | [view summary information](#)

European Older People's Platform (AGE) | [view summary information](#)

European Organisation for Rare Diseases (EURORDIS) | [view summary information](#)

European Parkinson's Disease Association (EPDA) | [view summary information](#)

European Patients' Forum (EPF) | [view summary information](#)

European Public Health Alliance (EPHA) | [view summary information](#)

Global Alliance for Mental Illness Advocacy Networks (GAMIAN-Europe) | [view summary information](#)

Health Action International (HAI) | [view summary information](#)

Insulin Dependent Diabetes Trust (IDDT) | [view summary information](#)

International Alliance of Patients' Organizations (IAPO) | [view summary information](#)

International Diabetes Federation (IDF) | [view summary information](#)

International Patient Organisation for Primary Immunodeficiencies (IPOPI) | [view summary information](#)

Myeloma Euronet (ME) | [view summary information](#)

Rett Syndrome Europe (RSE) | [view summary information](#)

Thalassaemia International Federation (TIF) | [view summary information](#)

The European Consumers' Organisation (BEUC) | [view summary information](#)

The International Confederation of Childhood Cancer Parents Organisations (ICCCPO) | [view summary information](#)



## Patient involvement in the Agency's activities: so-far experience (1)

---

- Full members of:
  - Management Board
  - Committee for Orphan Medicinal Products (COMP)
  - Paediatric Committee (PDCO)
  - Committee for Advance Therapies (CAT)



## Patient involvement in the Agency's activities: so-far experience (2)

---

- Patients and Consumers Working Party (PCWP)
- Review of Product Information:
  - EPAR summaries, Package Leaflets, safety information–Q&As–)
- CHMP (Ad-hoc collaboration):
  - Input on assessment of products (e.g. thalidomide, tysabri, etc)
  - Experts in scientific advice/protocol assistance
  - Input in guideline preparation
  - Observers in Pharmacovigilance working party (pilot phase)
- Regular participation in Agency's workshops and conferences



## 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)

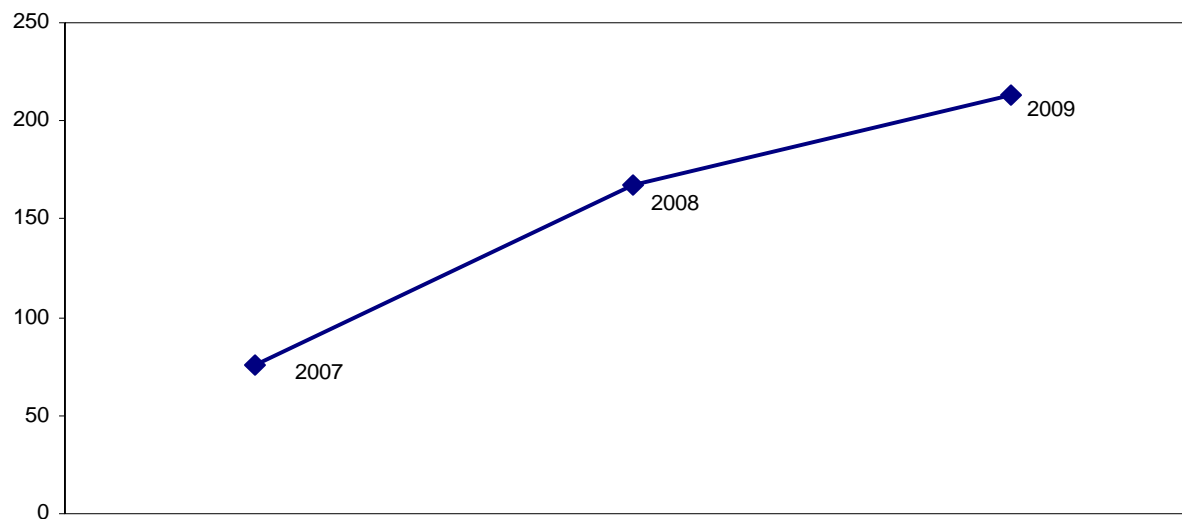
**Co-Chair:** Isabelle Moulon (EMA)/Nikos Dedes (EATG)

4 meetings per year (one joint with Healthcare professionals)



## Number of patients/consumers involved in EMA activities in recent years

---





---

# Outcome



## Which is the **added value** of involving patients in the scientific process?

---

- in general, patients bring real-life experience of the disease and its current therapeutic environment; as a consequence:
  - it enriches regulatory outcome by complementing it with the views of those directly affected by regulatory decisions,
  - it increases confidence and trust in the regulatory process
  - it incurs in higher level of transparency



## Issues to be considered

---

- Lack of resources in the organisations
- Need for training to understand the regulatory environment
- Need to define the roles of the patient in the different activities/scientific committees
- Difficulty to find suitable experts (e.g. language barrier)





# The way forward in involving patients in the work of the agency

---

- Revision of the current framework of interaction is ongoing:
  - Define the role of patients/consumers in the agency's scientific committees
  - Further involve patients in benefit/risk evaluation
  - Foster involvement in the preparation and dissemination of EMA information intended to the public (including safety communication)
  - Participation in the Pharmacovigilance working party
  - Provision of specific (financial) support



---

Thank you for your attention