EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

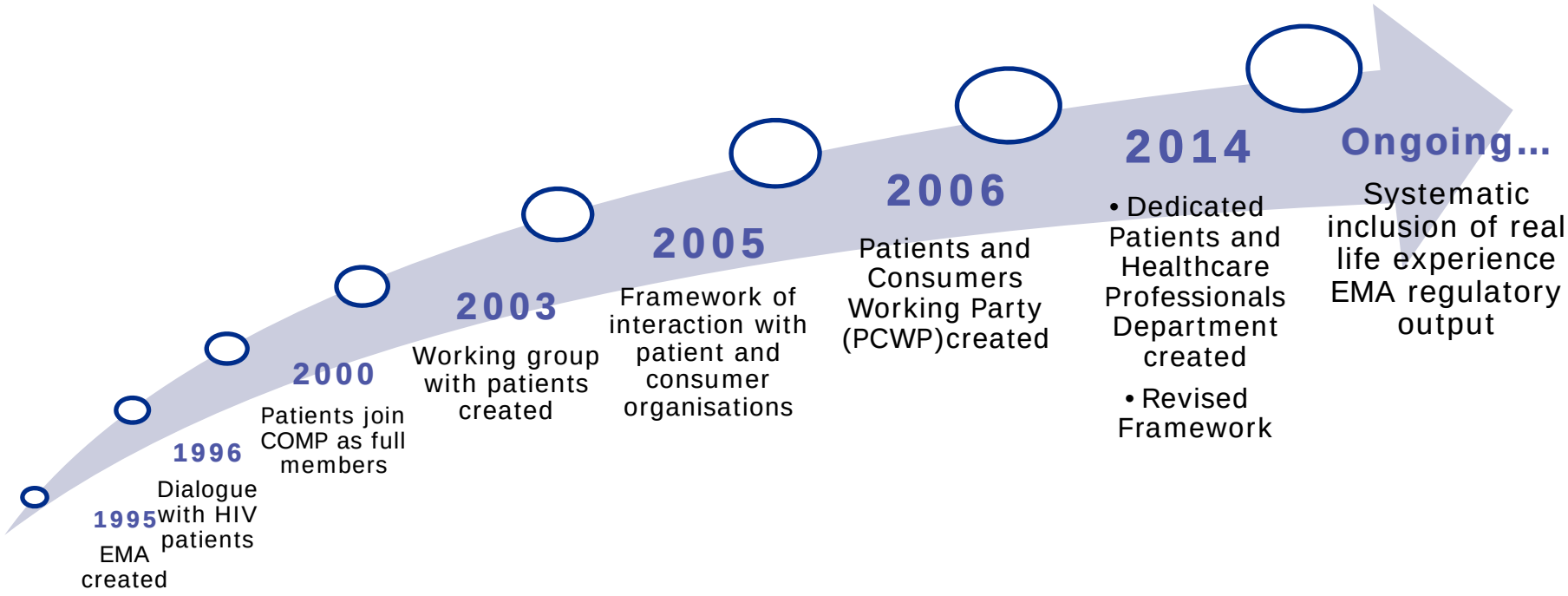
Paving the way for EUPATI Fellows into regulatory authority committees

EUPATI final conference, Brussels, 14 December 2016

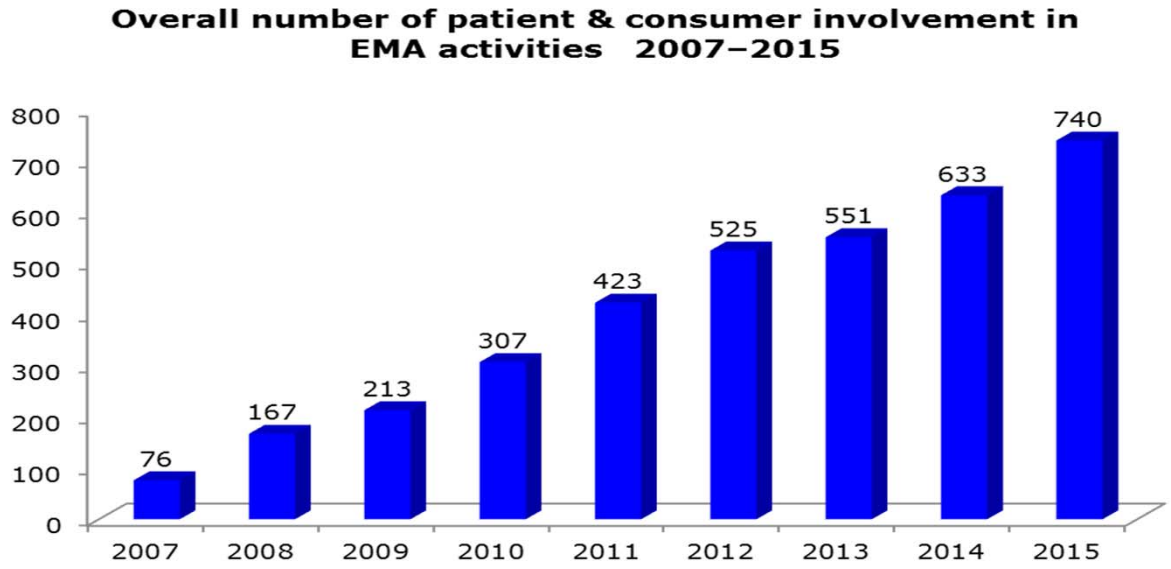
Presented by Isabelle Moulon
Head of Public Engagement Department

EUROPEAN MEDICINES AGENCY

Collaboration with patients: the EMA journey…



Evolution of patients' involvement at EMA



Categories of patient participation: from advice to decision-making

Patients representing *patients'* organisations	• Management Board • EMA Scientific Committee(s)
Patients representing *their* organisations	• Patients' and Consumers' Working Party (PCWP) • EMA consultations • Workshops
Patients as *individual* experts	• Scientific Advice / Protocol Assistance Procedures • Scientific Advisory / *ad hoc* expert Groups • Scientific committee consultations • Review of documents

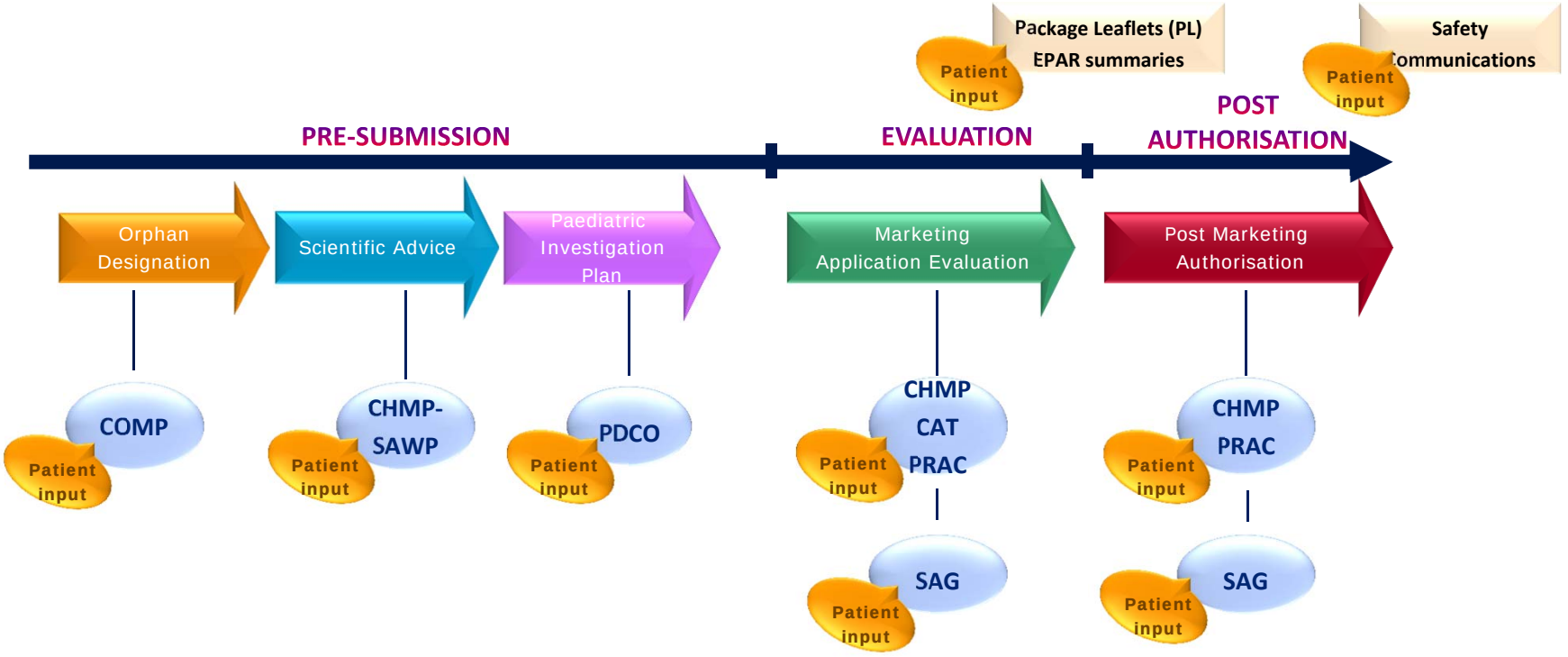
Working methodology

1. A network of European patients and consumers' organisations
2. A forum of exchange: EMA Working Party with Patients and Consumers' organisations
3. A pool of patients acting as experts in their disease and its management
4. Interaction with the EU Regulatory Network
5. Capacity-building focusing on training and raising awareness about EU regulatory system

Taking into account time, budget and availability constraints

EUROPEAN MEDICINES AGENCY

Opportunities for involvement throughout medicines lifecycle



EMA framework of interaction with patients
PARTICIPATION – CONSULTATION – INFORMATION

Facilitate participation in benefit/risk evaluation and related activities throughout the life cycle of medicines to capture values and preferences and obtain information on the use of medicines from early development through evaluation and post-marketing surveillance.

Examples: Patients/carers affected by rare diseases invited to discuss benefit/risk evaluation with the scientific committee CHMP

- Scenesse (afamelanotide) to treat patients with erythropoietic protoporphyria, rare intolerance to light in September 2014
- Translarna (ataluren) to treat Duchenne muscular dystrophy in November 2016

Example: written consultation

Humalog / Liprolog: concerns regarding introduction of a new high insulin strength and how to ensure its safe and correct use

→ Consultation with patients to obtain input on how best to minimise potential risk of medication errors

- Input received prompted the committee to request further changes to the labelling (differentiations of strengths)
- The company subsequently amended the labelling and other measures in the risk minimisation plan

Example: face to face consultation

PRAC review of Valproate: review of new information on risk of long-term developmental problems in children whose mothers took Valproate

→ Patient meeting included epilepsy, bipolar disorder and migraine patient organisations and organisations representing the patients, families and carers affected by valproate

- Very constructive exchange of information; patients shared their personal experiences and provided input on how best to raise awareness for all concerned;
- In turn allowed PRAC to explain the assessment process

→ Followed by written consultation on educational and communication material to raise awareness & understanding of risks

- Input used by the PRAC in its final recommendations

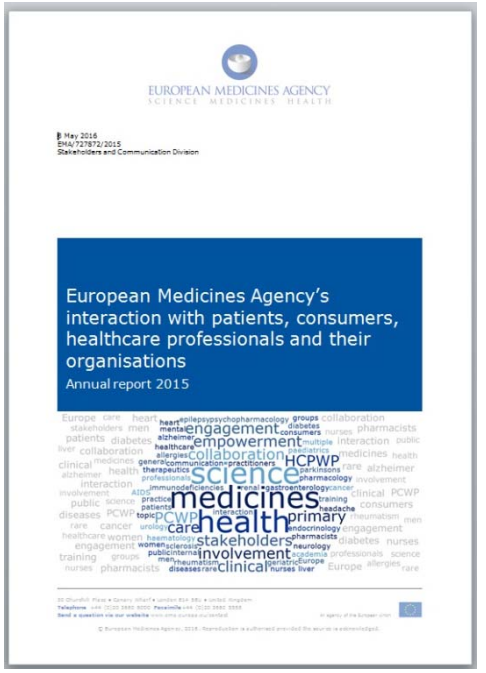
How do you get involved?

- Through the Network of eligible organisations fulfilling the following criteria:
  - Legitimacy
  - Mission/activities
  - Representation
  - Structure
  - Accountability
  - Transparency
- Pool of experts has been established:
  Call for expression of interest published on EMA website

Monitoring

- Yearly report on interaction presented to the EMA Management Board
- Satisfaction survey every two years

The work and opportunities for improvement will be included in the Agency annual work programme and/or PCWP annual work plan, as appropriate.

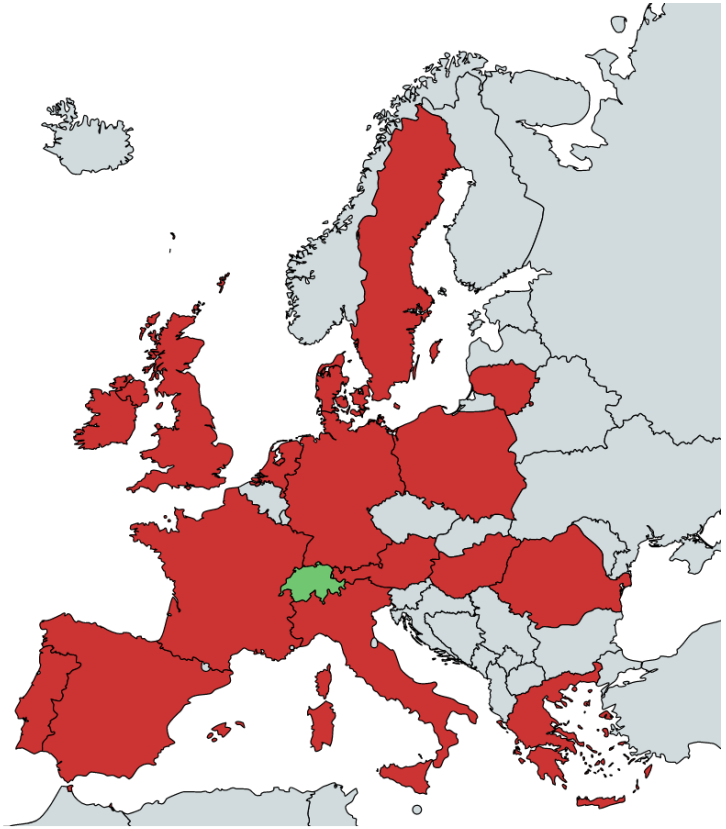


National Competent Authorities and patient involvement

Austria
Czech Republic
Denmark
France
Germany
Greece
Hungary
Ireland
Italy
Lithuania
Netherlands
Poland
Portugal
Romania
Spain
Sweden
UK

Liechtenstein
Switzerland

Based on information from Ingrid Klingmann and EMA including PCWP survey in 2014



Take home messages for EUPATI fellows

- Register in the EMA pool of experts: form
- Liaise with your national medicines agencies
- And…

Ayant plustost envie d'en reussir habil'homme, qu'homme sçavant, je voudrois aussi qu'on fust soigneux de luy choisir un conducteur, qui eust **plustost la teste bien faicte, que bien pleine**

Michel de Montaigne

Since I would rather make of him an able man than a learned man, I would also urge that care be taken to choose a guide with a well-made rather than a well-filled head

EUROPEAN MEDICINES AGENCY

Thank you for your attention

Further information

Isabelle.moulon@ema.europa.eu

http://www.ema.europa.eu/ema/

Patients and consumers page:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/general/general_content_000317.jsp&mid=WC0b01ac058003500c

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

Follow us on **@EMA_News**