Working with the European and National Medicines Agencies - knowledge and tools

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Disclaimer: Opinions expressed in this presentation are entirely my own.

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Why, what and how?

- Why do we want to be involved?
- What is the part to be played by a patient representative at an medicinal agency do?
- How can we establish involvement?

Why are we happy to be here?

Why are we happy to be at EMA?

We bring the patient's perspective into the discussions at EMA

We can help to ensure that information on medicines is clear and understandable.

We can also direct members to this information.

We can ensure that there is transparency.

We can be part of benefit/risk assessments

We can influence discussions on ethical issues.

We can increase our knowledge of regulatory affairs.

We can…

(EMA= The European Medicines Agency)

Patients and consumers as members:

- Full members of:
  - Management Board (MB)
  - Committee for Orphan Medicinal Products (COMP)
  - Paediatric Committee (PDCO)
  - Committee for Advance Therapies (CAT)
  - (From July 2012 Pharmacovigilance Risk Assessment Committee PRAC)
  - Observers of:
    Pharmacovigilance Working Party PhVWP

- Patients and Consumers Working Party (PCWP)

COMP- the Committee of Orphan Medicinal Products - 2000

- COMP is reviewing applications from people or companies seeking 'orphan medicinal product designation'.
- This designation is for medicines to be developed for the diagnosis, prevention or treatment of **rare diseases.**
- Three patient representatives (two from Eurordis)

Patients and consumers involvement so far:

- Scientific advice (protocol assistance)
- Input on assessment of products
- Reviewing product information
- Training
- Workshops and seminars
- Involvement in other initatives such as ENCEPP, Eudravigilance, clinical trial related activities and EnprEMA

The Mandate of the PCWP – facilitating involvement

- Transparency
- Information on medicines
- Pharmacovigilance
- Interaction with the scientific committees

PCWP to provide recommendations to the EMA and its Human Scientific Committees on all matters of direct or indirect interest to patients.

The Patients' and Consumers' Working Party – propelling change

- From workshop in 2002 to an expanded PCWP in 2010 consisting of:
- 12 patients' and 3 consumer org. (1 co-chair)
- 5 members from the human scientific committees (CHMP, COMP, PDCO,HMPC)
- the EMA Secretariat (1 co-chair)
- observers from HCP WG, EMA MB, CMD(h), EC
- 4 meetings per year 1/+1 (two joint with Healthcare Professionals Working Group, from 2012)

Members of the PCWP – therapeutic areas and general PCO

- Orphan medicines – EURORDIS
- Medicines for aids –EATG
- Cancer – ECPC
- Neurological disease – EFNA
- Diabetes – IDF
- Immune dysfunctions – IPOPI
- General CO- BEUC, EPHA
- General PO- EPF, IAPO
- Enlargement 2010- EHN, HAI, AGE, EMSP, EFA,

Training of patients to review product information

The EMA-model of working with patients

- Eligibility and framework is already there
- Presented to the Heads of Medical Agencies in spring 2011
- Surveys to National Medical Agencies and Patient Organisations about patient involvement Oct./Nov. 2011
- 91 responses from 75 org. in 24 EU countries

What do the national agencies do?

- Used to do all the tasks which EMA performs.
- Now still responsible for nationally authorised medicines.
- Pharmacovigilance
- Information in national language
- Co-operating with EMA in all activities

Nationally speaking…

The new Pharmacovigilance legislation means an obligation for the member states to enable patients to report adverse reaction

- More interested and trained patients mean more opportunities for advocating, influencing decisions and legislation within the regulatory framework – also on European level.

Do you feel that patient involvement has an impact on the discussions/decisions within the Agencies? (from survey)

- As a consequence of a mutually respectful relationship the needs and views of the patients are not only listened to but the issues considered
- The involvement of our organisation was essential to obtain authorisation to self-administer
- Definitely, if we had not intervened we would never have received the drug during the emergency shortage
- Yes, the advice with respect to patient information has been followed up
- Yes, although we do not always agree

So why would we want to interact with the national medicinal agencies?

- For the same reasons that we interact with EMA.
- And also because there is the national perspective involving language, culture, special issues.
- We need to inform and support our members locally.

Three step approach NCAs

Letter

- introduction
- aim

Agenda

- Starting point
- Next steps

Framework

- involvement
- eligibility

Eligibility criteria - 1

- Definition of a patient organisation in EU
- Statutes (rules), registered
- Mission/Objectives (goals to go on EMA:s web-site)
- Activities (be interested in medicines)
- Representativity
- Structure
  - A governing body elected by members
  - Members=patients, carers or representing these

Eligibility criteria - 2

- Accountability and Consultation Modalities
  - Whose opinions?
  - flow of information to and from members?
  - Transparency
    - Activities on website
    - Funding on website
    - Conflict of interest
    - Member associations

- (So far, 61 PCOs have applied for eligibility:34 positive, 22 negative, 8 suspended/withdrawn.)

Thank you

(For more impressions please go to The fourth report on the progress of interaction with patients and consumer organisations

ema.europe.eu go to

Partners and networks –patients and consumers- key documents – annual progress reports