EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Interaction with Stakeholders Communication at the Agency

Presented by: Juan Garcia Burgos
Head of Public Information and Stakeholder Networking - Medical Information

An agency of the European Union

Agency's principal activities

- involve representatives of patients, healthcare professionals and other stakeholders in its work, to facilitate dialogue on issues of common interest;
- publish impartial and comprehensible information about medicines and their use;

Interaction with stakeholders

- Patients' and consumers' organisations
- Healthcare professionals' organisations (and other scientific learned societies)
- Academia
- The media
- Pharmaceutical industry
- Healthcare technology assessment and reimbursement bodies

Interaction with patients'/consumers' organisations

- Long experience since the agency was created
- Unique model of interaction: **framework of interaction** and **selection criteria**
- patients and consumers are involved at different levels:
  - Full members of committees and Management Board
  - Contribution during preparation of the agency's communication material and product information
  - Regular participation to workshops and conferences
  - Specific working party within the agency

Selection criteria for involvement

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

EMEA Scientific Committees Working Party with Patients' and Consumers' Organisations (PCWP)

PCWP Members: 10/25 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)

The way forward

- Revision of the current framework of interaction is ongoing:
  - Define the role of patients/consumers in the agency's scientific committees
  - Develop clear criteria to identify in a consistent way when to involve patients in the assessment of benefit/risk
  - Foster involvement in the preparation and dissemination of EMEA information intended to the public (including safety communication)
  - Participation in the Pharmacovigilance working party
  - Provision of specific financial support

Interaction with healthcare professionals' (HCPs') organisations

- HCPs represented in Management Board and some scientific committees
- Framework of interaction under preparation
- Model developed with patients cannot be fully reproduced:
  - Difficult to define its added value (health professionals are already present in the Agency)
  - The plurality/heterogeneity of their expectations
- Still there is a recognised need for input from HCPs' organisations in many areas

Aims of the Agency's public communication

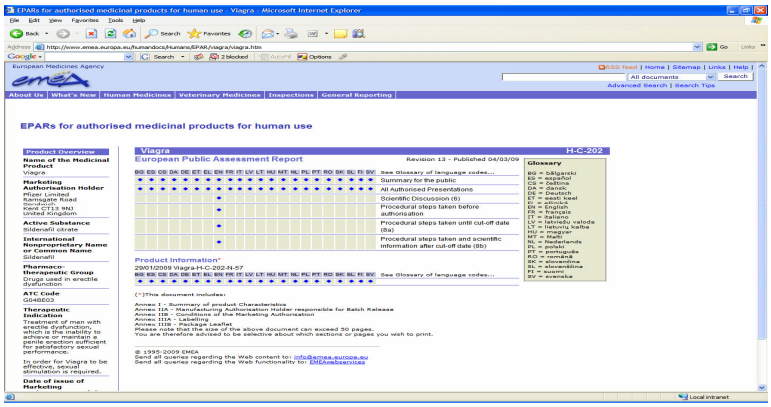
- Provide clear information about medicines and the opinions of the Agency
- Ensure that the information is accurate, properly balanced and consistent
- Ensure that the information is provided timely and that is easily accessible
- Whenever necessary, translate scientific and regulatory language into public-friendly language

Provision of information on medicines

For each medicine (centralised procedure) the Agency provides:

- EPAR (European Public Assessment Report):
  - Summary in lay language (Q&A document)
  - Assessment report
  - Statutory product information
- The principles of deletion of commercial confidential information apply

European Public Assessment Report (EPAR)



Other information

- Safety issues (patient-friendly documents – Questions & Answers)
- Withdrawals prior to CHMP opinion
- Negative opinions

} Q&A documents + Assessment report

- Press releases

Other ongoing initiatives

- EMEA website reconstruction (addressing stakeholders expectations in terms of information provision)
- Further transparency

Challenges ahead

- 23 EU languages
- Divergence in the information available across EU
- Public awareness of regulatory information
- The Agency to operate in the context of the EU regulatory system network, and to assist Member States in the provision of good-quality and timely information on medicines to patients and health professionals

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Thank you for your attention