EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Involvement of Healthcare Professionals' Organisations in EMA activities in 2011

Presented by: Ivana Silva
Medical Information Sector/ Public Information and Stakeholder Networking

Area of information on medicines

- **Revised template for the package leaflet** (PL) was presented to the HCP WG following the consultation in 2010
- **Public consultation on pack design and labelling for centrally authorised non-prescription human medicinal products** (targeted dissemination to 52 organisations, of which 29 HCPOs; comments received from 17 entities, of which 3 were HCPOs - 1 was in the targeted dissemination)
- The involvement of HCPs in the **review of product labelling** was discussed with the HCP WG and the Agency is preparing a procedure to identify in advance which specific cases would most benefit from HCPs' input and how they are to be involved

Area of information on medicines

- A **proposal to publish DHPCs** on the EMA website was presented to the HCP WG
- **eHealth** and aspects related with electronic product information were introduced as a topic for information and discussion in 2 two meetings (March and June)
- Comments were requested prior to public consultation on the draft guideline on the warning on transmissible agents in SmPCs and packages leaflets for plasma-derived medicinal products (in order to discuss with QRD)
- There was a good cooperation with the relevant organisations to **streamline communication** with their constituencies on aspects **related with shortages and recalls** (e.g. shortage of Apidra cartridges; precautionary recall of Advagraf)

Actions for 2012

- Promote **awareness and understanding of the SmPC** (through participation in the SmPC Advisory group).
- Get input during the preparation of **relevant safety information**.
- Dissemination of key safety information.
- Involvement in the update of the **pandemic communication strategy**.

Area of Pharmacovigilance and Risk Management

- Three **Stakeholders Forum on the PhV legislation** were organised (1st April and 2nd June – 4 HCPOs attending (of which 2 were speakers); 3rd October – 3 HCPOs attending)
- **Product-specific consultations** related with:
  - communication practice on a safety issue (use of gadolinium-containing contrast agents for magnetic resonance and risk of Nephrogenic Systemic Fibrosis)
  - implementation of a risk minimisation activity (Pregnancy Prevention Programme) in clinical practice (isotretinoin)
- Initial ideas for the **web-based reporting of ADRs** presented at the HCP WG (October) and input requested

Actions for 2012

- Continue to contribute to the Agency's **preparation for the implementation of the legislation**

- Explore the potential contribution of the HCP WG to assess the **effectiveness of risk minimisation measures** in clinical practice (using existing examples).

- Continue to explore healthcare professionals' contribution to the **preparation and awareness of DHPC**.

- Contribute to the further implementation of the **EudraVigilance access policy**

Area of transparency and dissemination

- Comments to the **EudraVigilance dashboards/ feedback questionnaire** (3 HCPOs provided input, through the 'EV users group')
- **Draft guidance for the interpretation of ADRs data** available for HCPs/General public in EudraVigilance to be circulated to the 'EV Users Group' for review and comments (4Q 2011)
- Participation in the **user acceptability tests of the EU Clinical Trials Register** (4 HCPs involved)
- Enlargement of HCPs representation in the **EudraCT JOG** (3 representatives)
- Continued **observer role in ENCePP** (identification of three HCPs representatives: 1 member and two alternates)
- Call for expression of interest to participate in the **EMA/DIA Infodays** on ENCePP and on EudraVigilance
- Call for participation on the **Agency website online survey**

Area of transparency and dissemination

- Dissemination of the following strategic documents:
  - EMA Road MAP to 2015
  - EMA geriatric medicines strategy
  - Implementing the European Medicines Agency's Road map to 2015: The Agency's contribution to Science, Medicines, Health "From Vision to Reality

- Dissemination of information on other relevant activities:
  - Launch of the EU Clinical Trials Register
  - European Commission's call for expression of interest to represent healthcare professionals and patient organisations in the EMA Management Board, CAT and PRAC
  - Publication of the European Commission’s legislative proposals on information to patients

Actions for 2012

- Support to the further implementation of the new **Agency's transparency policy**.

- Support to the development of the **EudraCT** database and the **EU Clinical Trials Register** (through participation in EudraCT JOG).

- Raising **public awareness of EMA activities**.

- Continue to provide feedback on the functionality and user-friendliness of the **EMA website** (HCPs dedicated section).

Involvement in Agency SC related activities

- **Participation in SAGs** (by 27.10.2011):
  - 23 SAGs/ Ad hoc expert group meetings for which HCPOs were contacted (able to provide experts for 15 SAGs; attending experts in 12 SAGs)
  - 13 organisations contacted (some more than once; 3 non-HCP WG)
  - 43 experts identified (15 attended meetings; 6 had CoI; 21 unavailable; 1 already identified)
- **Involvement in guideline development**:
  - Expert Group meeting on the concept paper to develop the HIV guideline (expert identified by EACS)
  - Workshop on monoclonal antibodies (participation of the International Psoriasis Council, following input received during the public consultation in Nov 2010 on the draft guideline on biosimilar medicines containing monoclonal antibodies)
  - By 24.10.2011: 59 documents disseminated (16 concept papers; 11 draft guidelines; 7 reflection papers; 21 herbal monographs; 4 other public consultations)

Involvement in Agency SC related activities

- **Product-specific consultations** related with:
  - changes in the pharmaceutical form (re. expression of strength) with a potential for medication errors (topotecan)
  - obtaining information on the current use of the medicine in clinical practice and the therapeutic environment, for the purpose of benefit/risk decision-making (stavudine; celecoxib)
  - obtaining information on the availability of a medicine in clinical practice, in the context of the evaluation of a new marketing authorisation application (velaglucerase alfa)

Actions for 2012

- Facilitate that healthcare professionals' organisations can contribute as an additional source for identifying the most adequate **independent experts** (e.g. SAGs participation).

- Identify those situations where healthcare professionals' organisations can provide **relevant information from real clinical practice**, which can be used during benefit/risk evaluation.

Organisational Matters

- **New policy on conflict of interest**
  - New policy presented to HCP WG in March
  - 17 e-DoIs out of 26
- **Framework for interaction between the Agency and healthcare professionals**
  - The full document was presented, following extensive discussion throughout 2010, and adopted by the HCP WG in March 2011
  - Endorsement by the Management Board is foreseen in December 2011

Actions for 2012

- Contribute to establish an **evaluation process of healthcare professionals' organisations**.
- Prepare the **HCP WP Mandate and Rules of Procedure**.
- Develop a template to support the **systematic monitoring of the interaction**.
- Develop **performance indicators** to assess further aspects on the progress of the interaction (e.g. communication).
- Prepare an **annual report** on the progress of the interaction to be presented to the Management Board.

Interaction with patients and consumers

- Joint meeting organised in June

  Actions for 2012: Organise two joint HCP WG-PCWP meetings; Ensure adequate coordination on issues of common interest.

Other areas of participation

- EMA workshop on drug-related progressive multifocal leukoencephalopathy (July) – 3 experts identified by 1 HCPO
- EMA workshop on regulatory ophthalmology (October) – 4 experts identified by 3 HCPOs (2 non-HCP WG)

  Areas identified for 2012: geriatric medicines, implementation of new legislation in the area of falsified medicines, EnprEMA, ENCePP, online public registry of EMA's stakeholders

Meetings scheduled for 2012

- **28 February** 2012 PCWP/HCPWG Joint meeting
- 27 or 29 February HCPWG Plenary meeting (to be confirmed)
- **8 May** 2012 HCPWG Plenary meeting
- 24 September HCPWG Plenary meeting (to be confirmed)
- **25 September** 2012 PCWP/HCPWG Joint meeting