European Patients' Forum Spring Conference

"Empowerment, Information, Sustainability"

The Regulatory Perspective: What Role Should the EMEA Perform With Regard to the Provision of Information on Medicines?

Noël Wathion, EMEA

Brussels

20 March 2007

Interaction with Patients: EMEA Objectives

To empower patients and to promote a true partnership between patients and healthcare professionals by:

- Providing information better adapted to the patients' needs
- Developing appropriate communication tools
- Increasing the awareness of patients in relation to the use of medicines
- Promoting a rational use of medicines

Interaction with Patients: Availability of Networks

The achievement of the EMEA objectives will rely mainly on:

- Network of excellence between all EU Regulatory Authorities in the field of medical information
- Network of patients and consumers which will build on the work carried out by the former EMEA/CHMP Working Group with Patients' and Consumers' Organisations

Interaction with Patients: EMEA Focus

The EMEA will primarily focus on 2 aspects:

- Patients' participation in the EMEA activities
- Provision of information to patients

EMEA Provision of Information: A Continuous Process Improvement Exercise

- Since its establishment the EMEA has
  - Taken numerous initiatives to increase its transparency of operation
  - On an ongoing basis introduced improvements in relation to the information provided to its stakeholders, and in particular patients
- Either this was done on the Agency's own initiative (as part of the Transparency Measures agreed by the Management Board, or as a follow-up to the recommendations from the EMEA/CHMP Working Group with Patients' and Consumers' Organisations) or as a consequence of the introduction of new Community legislation

EMEA Provision of Information: Current Achievements (1/2)

The following is already available on the EMEA website:

- EPARs and EPAR Summaries in a language understandable by the public
- Summaries of Opinion: key information on the product prior to the granting of the marketing authorisation or on orphan drug designation
- Assessment Reports on applications withdrawn prior to the Opinion of the Agency's Scientific Committee

EMEA Provision of Information: Current Achievements (2/2)

The following is already available on the EMEA website (cont'd):

- More patient friendly information on safety issues
- EudraPharm database, which will contain, once fully populated, information on all medicines authorised in the EU:
  - Product information
  - Information on treatment of children
  - Information on clinical trials

EMEA Provision of Information: Future Plans

- Further populating EudraPharm (stepwise approach) and introducing additional functionalities (in accordance with the EU IT Master Plan)
- Providing access to the EudraVigilance database
- Developing a longer term EMEA vision on the provision of information to the Agency's stakeholders, including patients

Patients' Involvement in the Provision of Information by the EMEA (1/2)

- Objective: improvement of the quality of the information provided by the EMEA
- Measures put in place:
  - Review of the EPAR summaries
  - Review of the package leaflet at the time of the renewal of the marketing authorisation

Patients' Involvement in the Provision of Information by the EMEA (2/2)

- Who:
  - Experts designated by the Patients' or Consumers' Organisations fulfilling the criteria for involvement in EMEA activities
  - EMEA will check declarations of interest and confidentiality undertakings
- When: patients' involvement in reviewing product information at the EMEA will start in April 2007

Conclusions

- Several high-level initiatives have been taken at EU level in relation to information to patients and patient safety, hence emphasising that this constitutes a priority at EU level
- Within the EU Regulatory System networking model the EMEA will continue to develop and strengthen its interaction with patients and consumers to better inform patients and the general public and to promote a better use of medicines