EMEA Activities:
Access to Information on Medicinal Products

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To contribute to protection and promotion of public and animal health by:

- Mobilising scientific resources from throughout the European Union to provide high quality evaluation of novel medicinal products, providing advice on R & D programmes and ensuring useful information to users and health professionals.
- Developing efficient procedures to allow timely access by users to innovative medicines through a single European marketing authorisation.
- Reinforcing the safety of medicines for humans and animals, in particular through a pharmacovigilance network and limiting the risks of residues in food-producing animals.
The Interested Parties

- Patients and Patient Groups
- Health Professionals
- Regulatory Authorities
- Industry
- Other
EMEA Current Policy

- No public disclosure prior to the Opinion stage
- At CPMP Opinion: summary of opinion in consultation with the company (both for + and - opinions)
- In case of press release by the company after a CPMP opinion, conformity with the opinion and SmPC/PIL must be ensured
- At Commission Decision: EPAR, including SmPC and PIL
Patient Information

- EU Guidelines on
  - Patient information leaflets (PILs) and labelling: *Guideline on the packaging information of medicinal products for human use authorised by the Community*
  - Readability of patient information: *Guideline on the readability of the label and package leaflet of medicinal product for human use*

- PILs and Labelling published on the EMEA website

- Quality review of product information procedure
  - System in place involving EMEA, member States and industry
  - Currently being streamlined
  - Monitoring system
EMEA is determined to improve official drug information available to all parties

- Web site launched September 1995
- Authorised medicines
- European Public Assessment Report (EPAR)
- Pharmacovigilance/product safety information

- 1.3 million ‘hits’ in 1996
- 5.7 million ‘hits’ in October 2001
The assessment report without commercially confidential information

Modular EPAR structure = EMEA opinion, assessment report, SPC, patient leaflet and labelling (regularly updated)

Availability in the official EU languages

Provides public audit trail of EMEA scientific evaluation (since 1995)
Abstract
Authorised presentations
Product Information Leaflet
Labelling
Summary of Product Characteristics
Scientific discussion
Steps taken for the assessment of the product
Steps taken after granting the Marketing Authorisation

All readers
Patients
Pharmacists/patients
Health professionals
Scientific community Health professionals
Anyone interested
Anyone interested

available in all 11 languages
available in English

EMEA
EU IT Strategy

Objectives:
- Support operation of procedures, related to marketing and surveillance of medicinal products
- **Enhance transparency of the system and provide effective tools to disseminate information**
- Increase efficiency in using available resources

Projects
- EudraNet
- EudraVigilance
- EuroPHARM Database
- E-Submissions
EU IT Strategy

- EuroPHARM Database
  - Medicinal Products database
    - Core information
    - Gradually cover all products
EU IT Strategy

- EudraVigilance
  - Pharmacovigilance database
    - Support pharmacovigilance obligations
    - Ensure availability of information on ADRs
    - Allow share of information at the same time between authorities
Review of Pharmaceutical Legislation

- Earlier patient access to medicines for important public health needs
  - Fast track registration procedure
  - Conditional authorisation
  - Compassionate use programmes
- Reinforce transparency and information on medicines
Reinforced pharmacovigilance and inspection activities
  - Develop appropriate information to the public

Provision of information to patients on certain diseases
  - Adopt applicable principles
  - Validate information
  - Monitor information
  - Role of industry, member States and EMEA