

EMEA (EUROPIAN MEDICINES AGENCY)

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INTRODUCTION

- ❖ The EMEA began its activities in 1995, when the European system for authorizing medicinal products was introduced.
- ❖ European Medicines Agency (EMA) is a decentralized body of the European Union, headquarters in London.
- ❖ Its main responsibility is the protection and promotion of public and animal health, through the evaluation and supervision of medicines for human and veterinary use.

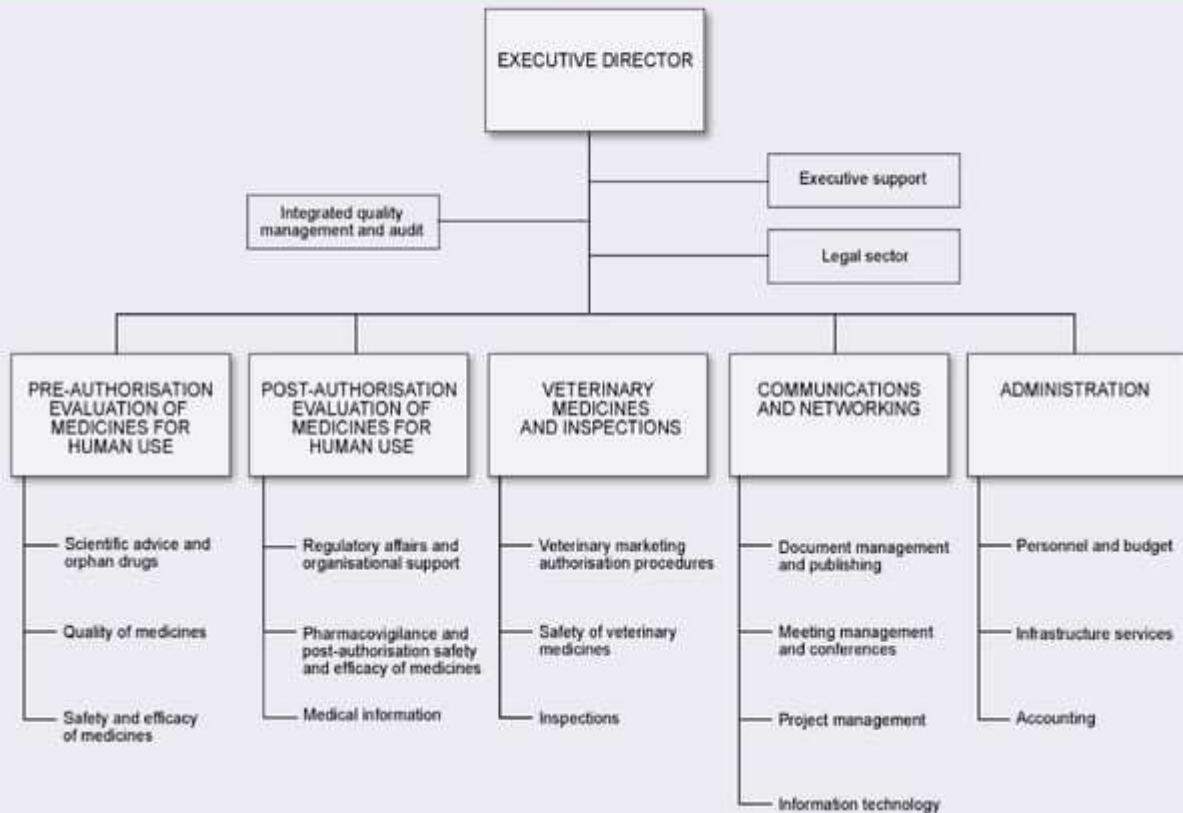
Conti...

- ❖ The EMEA primarily involved in the centralized procedure.
- ❖ Where the centralized procedure is used, companies submit one single marketing authorization application to the EMEA.
- ❖ A single evaluation is carried out through the Committee for Medicinal Products for Human Use (CHMP) or Committee for Medicinal Products for Veterinary Use (CVMP).

Conti...

- ❖ In 2001, the Committee on Orphan Medicinal Products (COMP) was established, charged with reviewing designation applications from persons or companies who intend to develop medicines for rare diseases (so-called 'orphan drugs').
- ❖ The Committee on Herbal Medicinal Products (HMPC) was established in 2004 and provides scientific opinions on traditional herbal medicines.
- ❖ The main responsibility of the Pediatric Committee (PDCO) is to assess the content of pediatric investigation plans and adopt opinions on them in accordance with Regulation

EMEA organisation



EMEA Mission Statement

- ◆ Developing efficient and transparent procedures to allow rapid access by users to safe and effective innovative medicines and to generic and non-prescription medicines through a single European marketing authorization
- ◆ Controlling the safety of medicines for humans and animals,
 - ◆ in particular through a pharmacovigilance network
 - ◆ the establishment of safe limits for residues in food-producing animals

- ❖ Facilitating innovation and stimulating research
- ❖ Mobilizing and coordinating scientific resources from throughout the EU
 - ❖ to provide high-quality evaluation of medicinal products,
 - ❖ to advise on research and development programmes

EMEA committee management board

:: CHMP

:: CVMP

:: COMP

:: HMPC

:: PDCO

:: CAT

:: PRAC

Management Board

- ▶ A Chairman
- ▶ Two members of
 - European parliament
 - European commission
- ▶ Two representatives of
 - Patients' organizations
 - Doctors' organizations
 - Veterinarians' organizations
- ▶ One representative of each member country
- ▶ One representative of observer countries

25 Member countries

- | | |
|--------------------|-------------------|
| 1. Austria | 2. Belgium |
| 3. Cyprus | 4. Czech Republic |
| 5. Denmark | 6. Estonia |
| 7. Finland | 8. France |
| 9. Germany | 10. Greece |
| 11. Hungary | 12. Ireland |
| 13. Italy | 14. Latvia |
| 15. Lithuania | 16. Luxembourg |
| 17. Malta | 18. Netherlands |
| 19. Poland | 20. Portugal |
| 21. Slovakia | 22. Slovenia |
| 23. Spain | 24. Sweden |
| 25. United Kingdom | |

Role and responsibilities

- ❖ Responsible for several post-authorization and maintenance activities
- ❖ Assessments conducted by the CHMP are based on purely scientific criteria and determine whether or not the products concerned meet the necessary quality, safety and efficacy requirements.
- ❖ These processes ensure that medicinal products have a positive risk-benefit balance in favour of patients/users of these products once they reach the marketplace.

Conti.....

- ❖ The CHMP plays an important role in this EU-wide 'pharmacovigilance' activity by closely monitoring reports of adverse drug reaction reports, making recommendations regarding changes to a product's marketing authorization or the product's suspension/withdrawal from the market.
- ❖ Can issue an 'urgent safety restriction' (USR)
- ❖ The CHMP publishes a European Public Assessment Report (EPAR) for every centrally authorized product that is granted a marketing authorization

The EMEA's integrated quality-management system ensures effective planning, operation and control of the CHMP's processes and records.

Other important activities of the CHMP

- ▶ providing **scientific advice** to companies researching and developing new medicines;
- ▶ preparing **scientific guidelines** and regulatory guidance to help pharmaceutical companies prepare marketing authorisation applications for human medicines;
- ▶ cooperate with **international partners** on the harmonisation of regulatory requirements.

Role and responsibilities

- ✦ Establishment of MRLs: the 'maximum residue limits' of veterinary medicinal products permissible in food produced by or from animals for human consumption, including dairy products, meat, honey etc.
- ✦ These limits must be established for all pharmacologically active substances contained in a medicinal product before the product can be granted a marketing authorization.

COMP

The Committee for Orphan Medicinal Products (COMP) is the European Medicines Agency's (EMA) committee responsible for recommending orphan designation of medicines for rare diseases.

Role for COMP :

- ❖ The COMP is evaluating applications for orphan designation.
- ❖ This designation is for medicines to be developed for the diagnosis, prevention or treatment of rare diseases that are life-threatening or very serious. In the European Union (EU), a disease is defined as rare if it affects fewer than 5 in 10,000 people across the EU. The European Commission decides whether to grant an orphan designation for the medicine based on the COMP's opinion.

- ❖ An orphan designation allows a pharmaceutical company to benefit from incentives from the EU, such as reduced fees and protection from competition once the medicine is placed on the market.

- ❖ The COMP also advises and assists the European Commission on matters related to orphan medicines, including:
 - ▶ developing and establishing an EU-wide policy;
 - ▶ drawing up detailed guidelines;
 - ▶ liaising internationally.

The Committee on Herbal Medicinal Products (HMPC) is the European Medicines Agency's (EMA) committee responsible for compiling and assessing scientific data on herbal substances, preparations and combinations, to support the harmonisation of the European market.

Role and responsibilities

- ❖ The HMPC's activities aim at assisting the harmonization of procedures and provisions concerning herbal medicinal products laid down in EU Member States, and further integrating herbal medicinal products in the European regulatory framework.
- ❖ The HMPC provides EU Member States and European institutions its scientific opinion on questions relating to herbal medicinal products.

- ▶ To support EU Member States, the HMPC focuses on two main tasks:
 - ▶ establishing EU monographs covering the therapeutic uses and safe conditions of well-established and/or traditional use for herbal substances and preparations;
 - ▶ drafting an EU list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products.
- ▶ The HMPC and its working parties and other groups also:
 - ▶ prepare scientific guidelines and regulatory guidance to help companies prepare marketing authorisation and registration applications for herbal medicines;

- ▶ coordinate with other scientific committees at the Agency on the regulation and safe use of herbal medicines;
- ▶ provide scientific and regulatory support to companies researching and developing herbal medicines;
- ▶ provide advice and training to herbal assessors of national competent authorities

The Paediatric Committee (PDCO) is the European Medicines Agency's (EMA) scientific committee responsible for activities on medicines for children and to support the development of such medicines in the European Union by providing scientific expertise and defining paediatric needs.

Role of PDCO :

Pediatric Committee (PDCO) main role is to assess the content of pediatric investigation plans and adopt opinions on them in accordance with Regulation

committee's other roles include:

- ▶ assessing data generated in accordance with agreed PIPs;
- ▶ adopting opinions on the quality, safety or efficacy of a medicine for use in the paediatric population, at the request of the Committee for Medicinal Products for Human Use (CHMP)
- ▶ advising the Agency and the European Commission on how to communicate the arrangements available for conducting research into paediatric medicines.
- ▶ advising Member States on the content and format of data to be collected through surveys on the uses of medicines in children

CAT

The Committee for Advanced Therapies (CAT) is the European Medicines Agency's (EMA) committee responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and following scientific developments in the field.

Role of the CAT

- ▶ participates in certifying quality and non-clinical data for small and medium-sized enterprises developing ATMPs;
- ▶ participates in providing scientific recommendations on the classification of ATMPs;
- ▶ supports the work programmes of the CHMP working parties.

PRAC

The Pharmacovigilance Risk Assessment Committee (PRAC) is the European Medicines Agency's (EMA) committee responsible for assessing and monitoring the safety of human medicines.

Role of the PRAC

- ▶ The PRAC is responsible for assessing all aspects of **risk management** of human medicines, including:

- ▶ the detection, assessment, minimisation and communication of the risk of adverse reactions, while taking the therapeutic effect of the medicine into account;
- ▶ design and evaluation of post-authorisation safety studies;
- ▶ pharmacovigilance audit.

Inspections - Activities of the Sector

- ❖ Coordination of the verification of compliance with the principles of Good Manufacturing Practice (GMP), Good Clinical Practice (GCP) and Good Laboratory Practice (GLP)
- ❖ Co-coordinating any inspection requested by the CHMP or CVMP
- ❖ Pharmacovigilance
- ❖ Vaccine Antigen Master File (VAMF) and Plasma Master File (PMF) certification.

- ❖ Sampling and Testing Programmed.
- ❖ Communication and action by Member States in response to suspected Quality Defects
- ❖ Responsibility for issuing Certificates of Medicinal Products in accordance with WHO requirements

While most scientific activities of the Agency are divided between medicinal products for human and for veterinary use, the tasks of the Inspections Sector are typically common to both types of products.

Inspections

EMA Certificates of Medicinal Products

- ❖ The EMA certification scheme is based on World Health Organization (WHO) recommendations
- ❖ EMA Certificates are issued by EMA, on behalf of the European Commission, to confirm the Marketing Authorization status of products
- ❖ EMA issues certificates within 10 working days following receipt

Inspections

Good Clinical Practice - Human Medicinal Products

- ❖ Good Clinical Practice (GCP) is an international ethical and scientific quality standard for designing, recording and reporting trials that involve the participation of human subjects.
- ❖ Compliance with this standard provides public assurance that
 - ❖ the rights, safety and well being of trial subjects are protected,
 - ❖ the clinical trial data are credible.

Conti...

- ❖ Clinical trials included in any marketing authorization application in the EU are required to be conducted in accordance with GCP
- ❖ The sector is involved in the preparation of new and revised guidance on GCP topics, co-ordination of advice on the interpretation of EU GCP requirements and related technical issues, and on the development of community-wide procedures relating to GCP inspections.
- ❖ Europe has adopted the ICH-GCP in July 1996

Inspections

Good Laboratory Practice

- ◆ The principles of Good Laboratory Practice (GLP) define a set of rules and criteria for a quality system concerned with the organizational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, reported and archived.
- ◆ The Procedure describes the co-ordination of GLP inspections of the non-clinical safety, toxicological and pharmacological studies proposed in human and veterinary applications for marketing authorizations under the centralized system.

Inspections

Product Defects and Recalls_

- ❖ In order to protect public health and animal health, it may become necessary to implement urgent measures such as the recall of one or more defective batches of a medicinal product during its marketing period.
- ❖ Competent Authorities should ensure that information concerning the recall of medicinal products is notified rapidly to other Member States, if the nature of the defect presents a serious risk to public health.
- ❖ This information is communicated using the Rapid Alert Procedure

Inspections

Sampling and Testing of Centrally Authorized Products

- ✦ The EMEA implements every year a sampling and testing programme, aimed at supervising the quality of the Centrally Authorized Products (CAPs) available on the European market.
- ✦ Annual reports on the outcome of the sampling and testing programme have been published starting with products submitted for testing in 2003.

EMA Implementation of the New EU Pharmaceutical Legislation

These new provisions provide tools to speed up patients' and healthcare professionals' access to medicinal products in the Community.

They also introduce measures for better safety monitoring of medicinal products for human and veterinary use

EMEA Implementation of the New EU Pharmaceutical Legislation

New name for the EMEA

- ❖ As a consequence of the revised EU pharmaceutical legislation, the name of the EMEA changed from the 'European Agency for the Evaluation of Medicinal Products' to the 'European Medicines Agency'.
- ❖ The acronym 'EMEA', however, remains unchanged.

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REFERENCE

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