Clinical Trial Regulations

India and International

Module 5 Topic 1_2

European Medicines Agency (EMA)

- The EMA is a **decentralised agency** of the European Union (EU) responsible for the **scientific evaluation, supervision** and **safety monitoring** of medicines in the EU.

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Mission

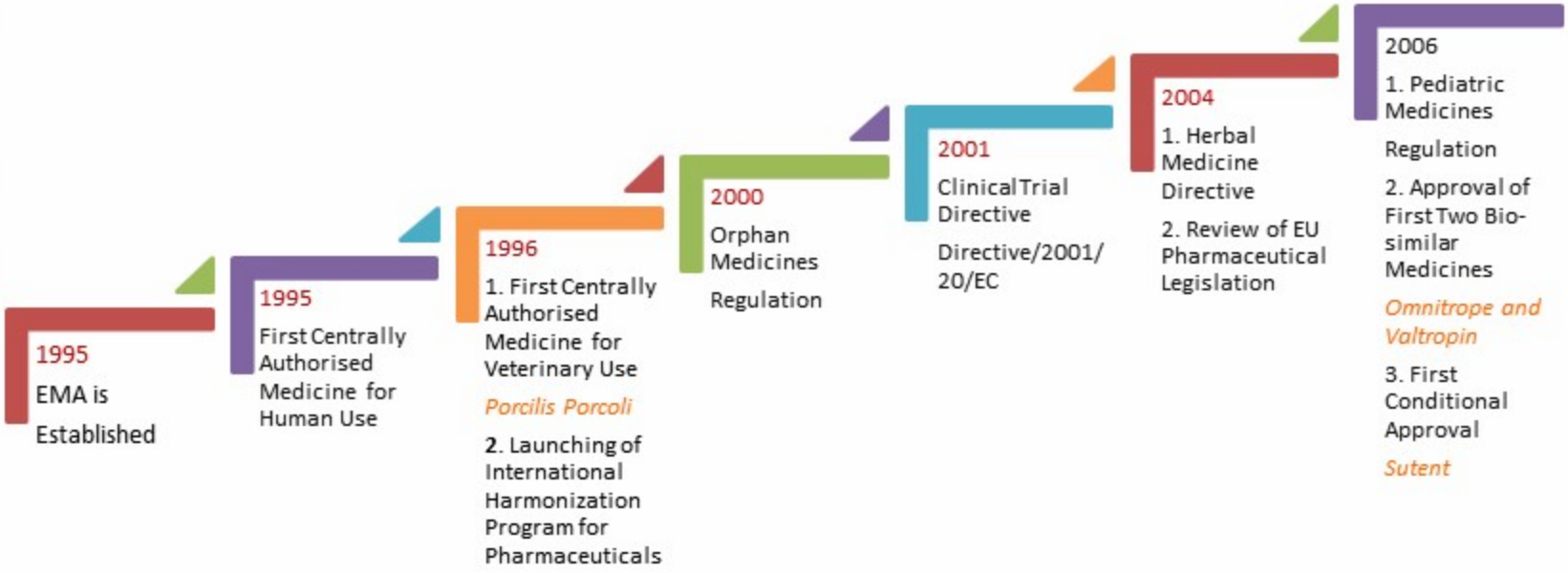
Protect human and animal health

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- ABC XΨΩ Provide reliable information on human and veterinary medicines in lay language

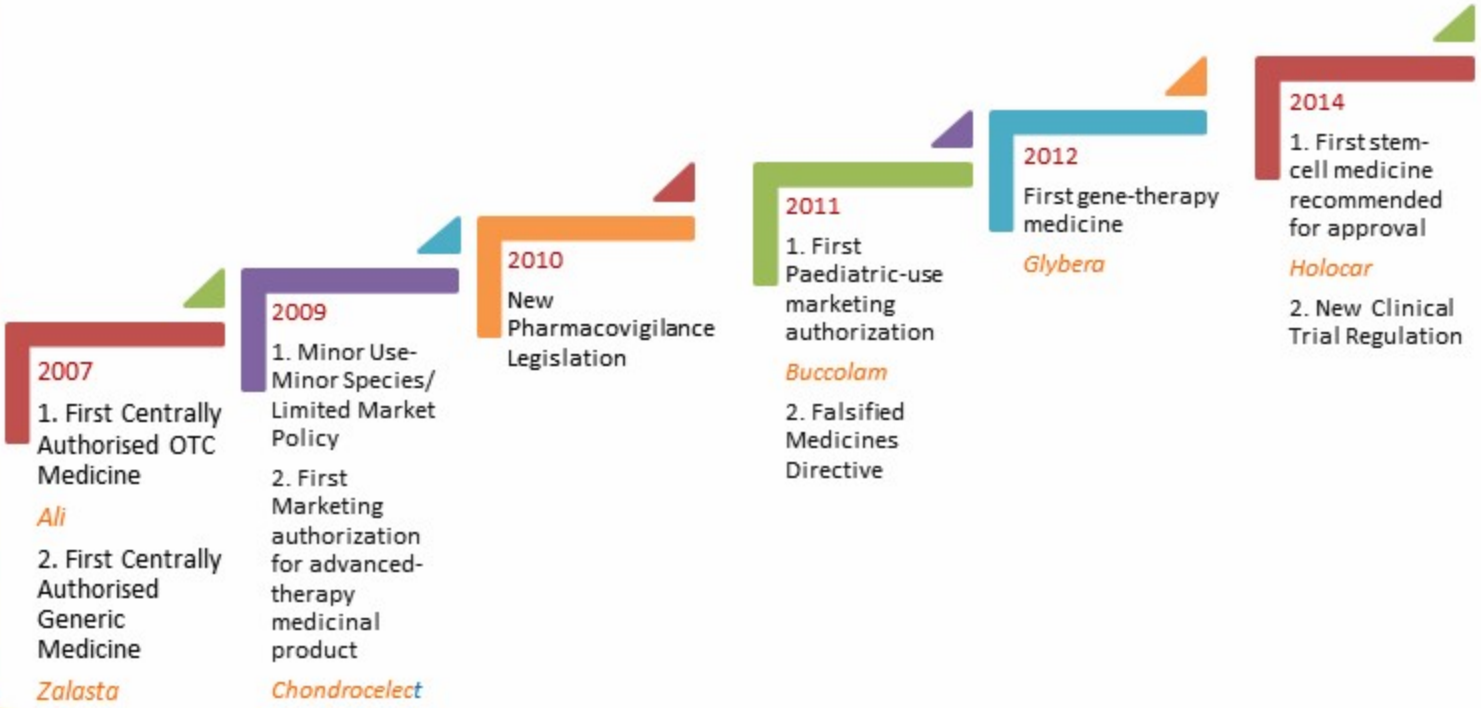
History of EMA

- European regulations in human medicines initiated in 1965 with introduction of the **first EU legislation** on human medicines
- On 26 January 1965 the Council Directive 65/65 on the approximation of the law relating to medicinal products was adopted
- Purpose of this adaptation was to safeguard public health
- EMA found and began operating in 1995

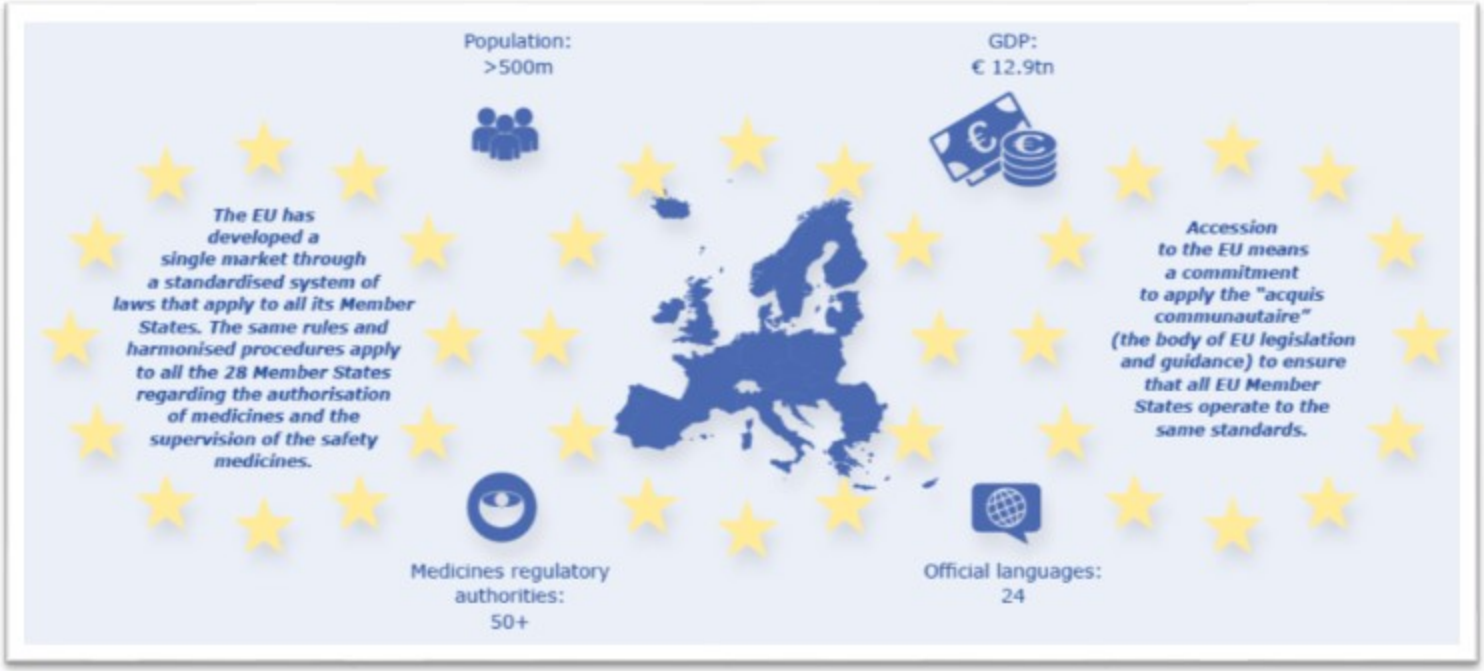
Milestones and achievements



Milestones and achievements



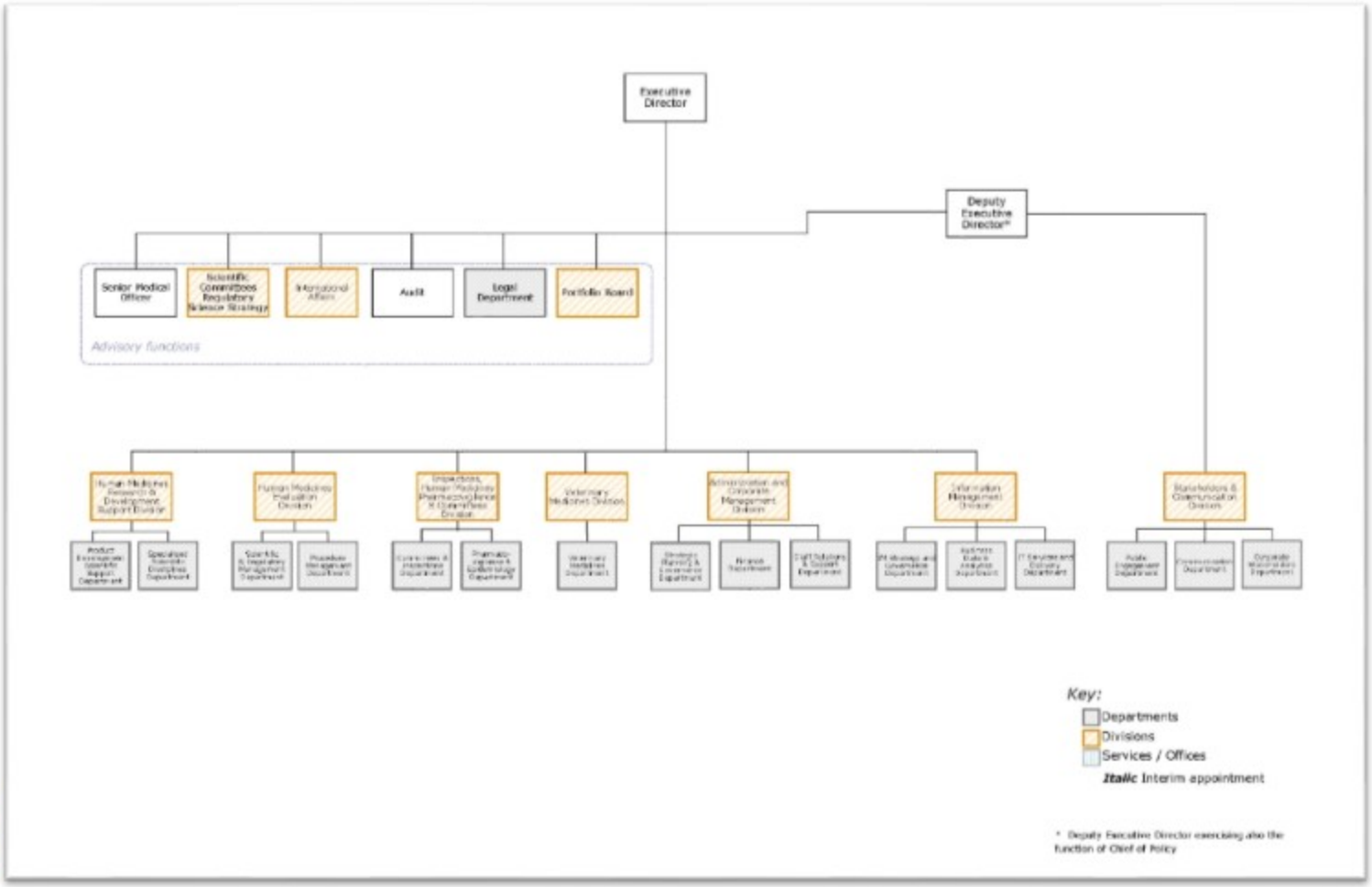
The European Union - key facts



Members of European Union

Total 31 members of European Union

Organisation chart



Structure of EMA

- EMA is governed by an **independent Management Board**. Its day-to-day operations are carried out by the EMA staff, based in London, overseen by EMA's Executive Director

- EMA is a **networking organisation** whose activities involve thousands of experts from across Europe. These experts carry out the work of EMA's scientific committees

Structure of EMA (contd)

Management Board

- The Management Board consists of **36 members**, appointed to act in the public interest, who do not represent any government, organisation or sector
- The Board sets the Agency's budget, approves the annual work programme and is responsible for ensuring that the Agency works effectively and co-operates successfully with partner organisations across the EU and beyond

Structure of EMA (contd)

- The members of the Management Board are appointed on the basis of their expertise in management and, if appropriate, experience in the field of human or veterinary medicines
- They are selected to guarantee the highest levels of specialist qualifications, a broad spectrum of relevant expertise and the broadest possible geographical spread within the EU

Structure of EMA (contd)

- **Management Board**
- The Management Board is made up of the following **36 members**:

One representative of each of the 28 EU Member States	**28**
Two representatives of the European Parliament	02
Two representatives of the European Commission	02
Two representatives of patients' organisations	02
One representative of doctors' organisations	01
One representative of veterinarians' organisations	01
In addition to the members, the Management Board also has one observer each from Iceland, Liechtenstein and Norway	03

36 Members

03 Observers

Structure of EMA (contd)

- **Executive Director**
  - The Agency's Executive Director is the legal representative of the Agency. He is responsible for all operational matters, staffing issues and drawing up the annual work programme.
- **Agency staff**
  - The Agency's staff support the Executive Director in carrying out his responsibilities, including administrative and procedural aspects of EU law related to the evaluation and safety-monitoring of medicines in the EU

Structure of EMA (contd)

Scientific Committees

- EMA has seven scientific committees
- These committee's evaluate medicines along their lifecycle from early stages of development, through marketing authorisation to safety monitoring once they are on the market
- In addition, the Agency has a number of working parties and related groups, which the committees can consult on scientific issues relating to their particular field of expertise

Structure of EMA (contd)

Scientific Committees

- These bodies are composed of European experts made available by national competent authorities of the EU Member States, which work closely with EMA in the European medicines regulatory network

Structure of EMA (contd)

Scientific Committees

- The European Medicines Agency (EMA) has seven scientific committees and a number of working parties and related groups which conduct the scientific work of **the Agency**.
- The committees are
  - Committee for Medicinal Products for Human Use (CHMP)
  - Pharmacovigilance Risk Assessment Committee (PRAC)
  - Committee for Medicinal Products for Veterinary Use (CVMP)
  - Committee for Orphan Medicinal Products (COMP)
  - Committee on Herbal Medicinal Products (HMPC)
  - Committee for Advanced Therapies (CAT)
  - Paediatric Committee (PDCO)

Structure of EMA (contd)

- The committee's evaluations of marketing-authorisation applications submitted through the centralised procedure provide the basis for the authorisation of medicines in Europe.
- The committees and working parties also contribute to the **development of medicines** and medicine regulation, by:
  - Providing scientific advice to companies researching and developing new medicines
  - Preparing scientific guidelines and regulatory guidance to help pharmaceutical companies prepare marketing authorisation applications
  - Contributing to the harmonisation of regulatory requirements n the EU and internationally

Committee for Medicinal Products for Human Use (CHMP)

- **Role of the CHMP**
- The CHMP plays a vital role in the authorisation of medicines in the European Union (EU).

Committee for Medicinal Products for Human Use (CHMP) (contd)

- In the **centralised procedure**, the CHMP is responsible for:
  - Conducting the initial assessment of EU-wide marketing authorisation applications;
  - Assessing modifications or extensions ('variations') to an existing marketing authorisation
  - Considering the recommendations of the the Agency's Pharmacovigilance Risk Assessment Committee on the safety of medicines on the market and when necessary, recommending to the European Commission changes to a medicine's marketing authorisation, or its suspension or withdrawal from the market.

Committee for Medicinal Products for Veterinary Use (CVMP)

- **Role of the CVMP**
- The CVMP plays a vital role in the authorisation of veterinary medicines in the EU. In the **centralised procedure**, the CVMP is responsible for:
  - Conducting the initial assessment of EU-wide marketing authorisation applications

Committee for Medicinal Products for Veterinary Use (CVMP) (contd)

- **Role of the CVMP**
  - Post-authorisation and maintenance activities, including the assessment of any modifications or extensions ('variations') to an existing marketing authorisation
  - Safety monitoring of veterinary medicines on the market and when necessary, recommending to the European Commission changes to a medicine's marketing authorisation, or its suspension or withdrawal from the market.

Pharmacovigilance Risk Assessment Committee (PRAC)

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

Committee for Orphan Medicinal Products (COMP)

Role of COMP

- The committee responsible for recommending orphan designation of medicines for rare diseases.
- 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

Committee on Herbal Medicinal Products (HMPC)

Role of HMPC

- The committee responsible for compiling and assessing scientific data on herbal substances, preparations and combinations, to support the harmonisation of the European market.

Committee on Herbal Medicinal Products (HMPC)(contd)

- To support EU Member States, the HMPC focuses on two main roles:
  - 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

Committee for Advanced Therapies (CAT)

Role of CAT

- The committee responsible for committee responsible for assessing the quality, safety and efficacy of advanced therapy medicinal products (ATMPs) and scientific developments in the field.
  - The committee's main responsibility is to prepare a draft opinion on each ATMP application submitted to EMA, before the Committee for Medicinal Products for Human Use (CHMP) adopts a final opinion on the marketing authorisation of the medicine concerned.

Committee for Advanced Therapies (CAT)

Role of CAT (Contd)

- At the request of EMA's Executive Director or the European Commission, the CAT can also draw up an opinion on any scientific matter relating to ATMPs.

Paediatric Committee (PDCO)

Role of PDCO

- The scientific committee responsible for activities on medicines for children and to support the development of such medicines in the EU by providing scientific expertise and defining paediatric needs.
  - The PDCO's main role is to assess the content of paediatric investigation plans (PIPs), which determine the studies that companies must carry out in children when developing a medicine. This includes assessing applications for a full or partial waiver and for deferrals.

Working parties and other groups

- The Agency has a number of working parties and related groups, which can be consulted by the Agency's scientific committees on scientific issues relating to their particular field of expertise.
- The groups are made up of members who have expertise in a particular scientific field, selected from the list of European experts maintained by the Agency.
- Members are given tasks associated with the scientific evaluation of marketing authorisation applications or drafting and revision of scientific guidance documents.

Regulations of EU in Authorisation of medicines

- All medicines must be authorised before they can be marketed and made available to patients
- In the EU, there are two main routes for authorising medicines:
  - Centralised authorisation procedure
    - Under the centralised authorisation procedure, pharmaceutical companies submit a **single marketing-authorisation application** to EMA
    - Today, **the great majority of new, innovative medicines** pass through the centralised authorisation procedure in order to be marketed in the EU
  - National authorisation procedures
    - Under the national authorisation procedure, pharmaceutical companies submit a **marketing-authorisation application** to specific member country of EU

Centralised authorisation procedure

- Under the centralised authorisation procedure, pharmaceutical companies submit a **single marketing-authorisation application** to EMA
- This allows the marketing-authorisation holder to market the medicine and make it available to patients and healthcare professionals throughout the EU on the basis of a single marketing authorisation

Centralised authorisation procedure

- MA's Committee for Medicinal products for Human Use (CHMP) or Committee for Medicinal products for Veterinary Use (CVMP) carry out a scientific assessment of the application and give a recommendation on whether the medicine should be marketed or not.
- Once granted by the European Commission the centralised marketing authorisation is **valid in all EU Member States** as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

Centralised authorisation procedure: Scope

Centralised procedure is compulsory for

- Containing a new active substance to treat: HIV/AIDS, cancer, diabetes, neurodegenerative diseases, auto-immune and other immune dysfunctions, viral diseases
- Medicines derived from biotechnology processes, such as genetic engineering
- Advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines
- Orphan medicines (medicines for rare diseases)
- Veterinary medicines for use as growth or yield enhancers

Centralised authorisation procedure: Scope (Contd)

Centralised procedure is not compulsory for

- Containing new active substances for indications other than those stated beside
- That are a significant therapeutic, scientific or technical innovation
- Whose authorisation would be in the interest of public or animal health at EU level

National authorisation procedures

- The majority of medicines available in the EU were authorised at national level, either because they were authorised before EMA's creation or they were not in the scope of the centralised procedure.
- Each EU Member State has its own national authorisation procedures.

National authorisation procedures

- If a company wishes to request marketing authorisation in several EU Member States for a medicine that is outside the scope of the centralised procedure, it may use one of the following routes:
  - **Mutual-recognition procedure** whereby a marketing authorisation granted in one Member State can be recognised in other EU countries
  - **Decentralised procedure** whereby a medicine that has not yet been authorised in the EU can be simultaneously authorised in several EU Member States

What EMA does not do?

- **EMA does not:**
  - Evaluate the initial marketing authorisation application of all medicines in the EU
  - Evaluate applications for the authorisation of clinical trials
  - Evaluate medical devices, food supplements and cosmetics
  - Carry out research or develop medicines
  - Take decisions or have information on the price or availability of medicines
  - Control the advertising of medicines
  - Control or have information on pharmaceutical patents
  - Develop treatment guidelines
  - Provide medical advice
  - Develop laws concerning medicines
  - Issue marketing authorisations

For further details please visit following urls

- http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/general/general_content_000155.jsp&mid=WC0b01ac0580036d63
- http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000311.jsp&mid=WC0b01ac058074c450
- http://www.ema.europa.eu/ema/index.jsp?curl=pages/home/Home_Page.jsp&mid=
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