EMA – European Medicines Agency

Your Objectives:

By the end of this lesson, you have understood the function and importance of the EMA and how it plays a crucial role in the pharmaceutical industry.

Formerly called the "European Agency for the Evaluation of Medicinal Products" (EMEA), the European Medicines Agency (hereafter EMA) is a decentralised agency of the European Union (EU) that ensures the scientific evaluation, monitoring, safety review, and approval, of both human (but also veterinary) **medicinal products*** in (EU).

In addition to the above, the EMA is responsible for coordinating the 30 EU member states (27 EU states + 3 only EEA states) as per the maintenance and promotion of public health, using the scientific resources from the National Competent Authorities (NCA) and European Economic Area (EEA)**.

On the basis of its scientific assessment, the European Commission issues a positive or negative decision regarding the marketing authorization applications made by pharmaceutical manufacturers in a centralised procedure.

Medicinal products which have already been authorised in the EU are also continuously monitored for their safety (pharmacovigilance), by defining safety standards in coordination with EudraVigilance (a European registry for drug safety notifications). Reports by national authorities on drug side-effects are summarised and evaluated there.

The EMA works closely with international bodies such as the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), as well as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), in order to achieve a global harmonization of drug approval conditions.

* **Medicinal product:** A substance or combination of substances that is intended to treat, prevent or diagnose a disease, or to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action.

**** The **EEA** serves to extend the EU's internal market to countries in the European Free Trade Area (EFTA).

Useful toolbox (and glossary) for pharmaceutical terms: https://toolbox.eupati.eu/