



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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The European Medicines Agency: A well-established Agency of the EU protecting human and animal health for all EU citizens

1. Who we are

The European Medicines Agency (EMA) is a decentralised agency of the European Union (EU), created in 1995. Its creation followed the decision by the EU Heads of State and Government on 29 October 1993, choosing London as the location for EMA's premises. Annex 1 provides key facts and figures on the Agency.

2. What we do

The mission of EMA is to protect human and animal health in the EU and to ensure access to medicines that are safe, effective and of good quality. It is the sole EU body responsible for the scientific assessment with respect to the authorisation, maintenance and supervision of medicines in the following therapeutic areas: treatment of cancer, diabetes, neuro-degenerative dysfunctions, viral diseases and rare human diseases ("orphan" medicines). Also medicines derived from biotechnology processes (such as genetic engineering), as well as advanced-therapy medicines (such as gene-therapy, somatic cell-therapy or tissue-engineered medicines) must be submitted for assessment to EMA on behalf of the EU. To achieve this, EMA provides a single route for the evaluation of innovative medicines in the EU, hereby avoiding the duplication of the evaluation in each of the 28 Member States. This allows making available to all EU citizens highly needed medicines within the shortest possible timeframe whilst guaranteeing a robust scientific assessment process.

In addition, EMA monitors the safety of all medicines authorised in the EU throughout their lifecycle and provides for regulatory action (such as restricting a medicine's use, or withdrawing a medicine from the EU market) within the shortest possible timeframe where public or animal health is endangered. Information to patients and healthcare professionals is made available in all EU languages at the same time, ensuring that consistent information on medicines is provided to all EU citizens.

EMA is also involved in other public health activities such as stimulating research and innovation in the pharmaceutical sector. It facilitates medicines development by giving scientific advice and guidance to developers of medicines, including on the development of medicines for children and for rare diseases. EMA coordinates, on behalf of the EU, inspections to verify compliance with the principles of good manufacturing, good clinical, good pharmacovigilance and good laboratory practices.

The EMA is responsible for providing information-technology (IT) services to implement European pharmaceutical policy and legislation. These services are provided to the EU regulatory network (comprising national competent authorities (medicines regulatory authorities in Member States), the European Commission and EMA). In this context EMA delivers, maintains and provides IT systems and infrastructure to Member States.

It hosts on behalf of the EU a number of databases important for public health such as EudraVigilance, the largest database in the world on adverse reactions reported for all medicines authorised in the EU. In addition EMA plays a key role in tackling public health threats such as antimicrobial resistance, and public health emergencies such as the 2014 outbreak of the Ebola virus disease. Over the past years EMA has also become a recognised pioneer in terms of transparency and openness of operation, and in terms of interaction with patients.

3. How we work

Since its creation in 1995 the environment in which EMA operates has undergone major changes. As a result of the Agency's achievements over the past two decades – widely recognised by its stakeholders and partners, including at international level – EMA's responsibilities have continuously increased, resulting not only in a well-established and mature agency, but also an agency that covers a very wide range of activities in the regulation of human and veterinary medicines, and, therefore, plays a key role in the protection of human and animal health in the EU. New legislation is being implemented or underway to further widen EMA's role, for instance in the field of clinical trials.

EMA provides for a single scientific assessment resulting in a scientific recommendation for the European Commission (EC) which subsequently translates this scientific recommendation into a single marketing authorisation decision valid for the whole EU. To achieve its tasks EMA brings together the best scientific expertise on medicines from across the whole of the EU. This translates into 7 scientific committees¹ which evaluate medicines along their lifecycle from early stages of development, through marketing authorisation to safety monitoring once they are on the market. These scientific committees are supported by 34 working parties and scientific advisory groups, and can draw from a network of some 3700 scientific experts made available by the Member States to the Agency.

A robust scientific assessment process is pivotal in order to make safe, effective and good quality medicines available to patients, with the necessary guarantees ensuring the independence of EMA's work embedded in the way it operates. The main features of EMA's scientific review process are illustrated in Annex 2, demonstrating the robustness of the framework put in place, whilst also giving a flavour of the complexity of the proceedings at EMA. The authorisation, maintenance and supervision of medicines performed by EMA on behalf of the EU is a multifaceted process with numerous challenges to be addressed.

¹ CHMP: Committee for Medicinal Products for Human Use
CVMP: Committee for Medicinal Products for Veterinary Use
PDCO: Paediatric Committee
COMP: Committee for Orphan Medicinal Products
CAT: Committee for Advanced Therapies
PRAC: Pharmacovigilance Risk Assessment Committee
HMPC: Committee on Herbal Medicinal Products

The success of EMA is based on the EU regulatory system for medicines. At the heart of it is a network of around 50 medicines regulatory authorities from the European Economic Area Member States, the European Commission and EMA. This network is what makes the EU regulatory system unique. The diversity of the experts from across Europe involved in the regulation of medicines in the EU encourages the exchange of knowledge, ideas and best practices between scientists striving for the highest standards for medicines regulation.

FACTS AND FIGURES

Facts

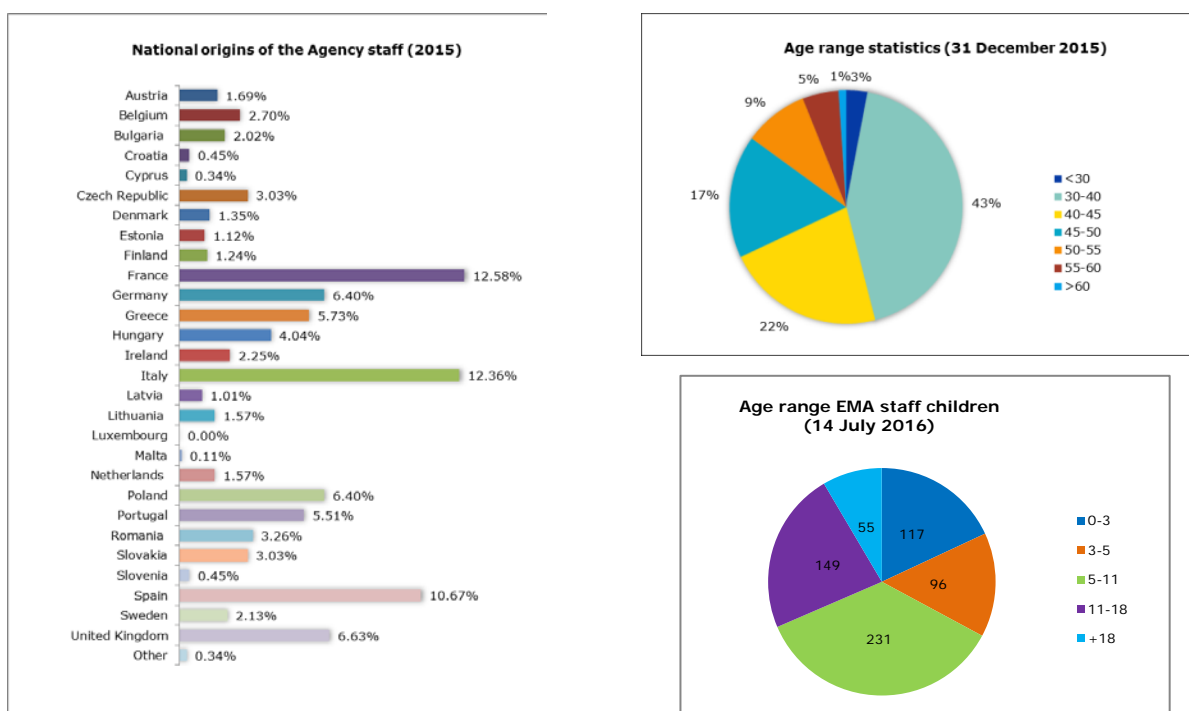
- EMA was created in 1995.
- EMA protects human and animal health in 28 Member States, serving a market of over 500 million EU citizens.
- The medicines EMA recommends for marketing authorisation account for 27% of global pharmaceutical sales.
- EMA brings together the best scientific expertise on medicines from across the whole of the EU.
- The EU model on regulation of medicines with EMA as a central hub has become a formula that other regions in the world look to as an example of collaboration.
- On a global scale EMA works closely with other medicines regulators in the world (FDA (US), PMDA (Japan), Health Canada, TGA (Australia), ...) and international organisations such as WHO.

2015 Figures

- More than 1,000 marketing authorisations issued since 1995.
- Revenue of € 304.119 million.
- Payment to the Member States for expertise provided amounted to € 108 million.
- EMA building surface area: 26,450 m²
- 564 meetings and 4,273 teleconference (audio, video- and web-conference) meetings.
- 36,000 visitors (scientific experts, patients, healthcare professionals, industry, ...), spending 65,000 days at the Agency.
- 6,630 travel transactions.
- 15,068 hotel nights booked by EMA + 15,000 booked separately by visitors. Peak hotel room capacity needed of 350 rooms per day.

EMA staff information

- 890 staff members (623 women and 267 men), coming from the EU Member States.



EMA scientific review process for the assessment of a new, non-orphan, non-ATMP (advanced therapy medicinal product) medicine

