History of EMA

Founded in 1995, the European Medicines Agency (EMA) has worked across the European Union (EU) and globally to protect public and animal health by assessing medicines to rigorous scientific standards and by providing partners and stakeholders with independent, science-based information on medicines.

EMA has a 20-year track record of **ensuring efficacy and safety** of human and veterinary medicines across Europe, and promoting research and innovation in the development of medicines.

In its first two decades, the Agency recommended the authorisation of a total of 975 human and 188 veterinary medicines.

EMA's success is based on cooperation within the European medicines regulatory network – a unique partnership between the European Commission, the medicines regulatory authorities in the European Economic Area countries, and EMA. Working together has encouraged the exchange of knowledge, ideas and best practices, in order to ensure the highest standards in medicines regulation.

Today, seven EMA scientific committees and more than 30 working parties provide scientific expertise for the regulation of medicines by drawing on a pool of several thousand European scientific experts from the network.

Milestones and achievements

EMA was set up in 1995 to **harmonise** the work of existing national medicine regulatory bodies.

The Agency's remit has expanded over time, in line with new EU legislation. On top of its remit to evaluate human and veterinary medicines, EMA is also responsible for products developed in the specialised areas of **medicines for rare diseases** (since 2000), **herbal medicines** (since 2004), **medicines for children** (since 2006) and **advanced-therapy medicines** (since 2007). Acquiring these responsibilities resulted in new scientific committees which provide the expertise in these areas.

With the establishment of the Committee for Orphan Medicinal Products in 2000, EMA opened its doors to **patients and healthcare professionals**. Today, their representatives take part in most of EMA's scientific committees as full members, adding their unique perspective and experiences to discussions. They play an increasingly important role in the assessment of the risks and benefits of medicines. In 2014, patients discussed the benefit-risk evaluation of a medicine within the Committee for Medicinal Products for Human Use (CHMP) for the first time.

With the creation of the Pharmacovigilance and Risk Assessment Committee (PRAC) in 2012, EMA started to play an even more important role in **monitoring the safety of medicines** across Europe.

As of January 2015, EMA has been implementing its landmark policy on publishing the clinical data that underpin European decision-making on medicines. This will provide an unprecedented level of **transparency** for patients, healthcare professionals, academia and industry.

20th anniversary of EMA

2015 marked the 20th anniversary of EMA. The Agency produced a 20th anniversary book, which captures the important progress in regulatory science and changes in medicines regulation in the first 20 years, and describes EMA's role in addressing these drivers for change.

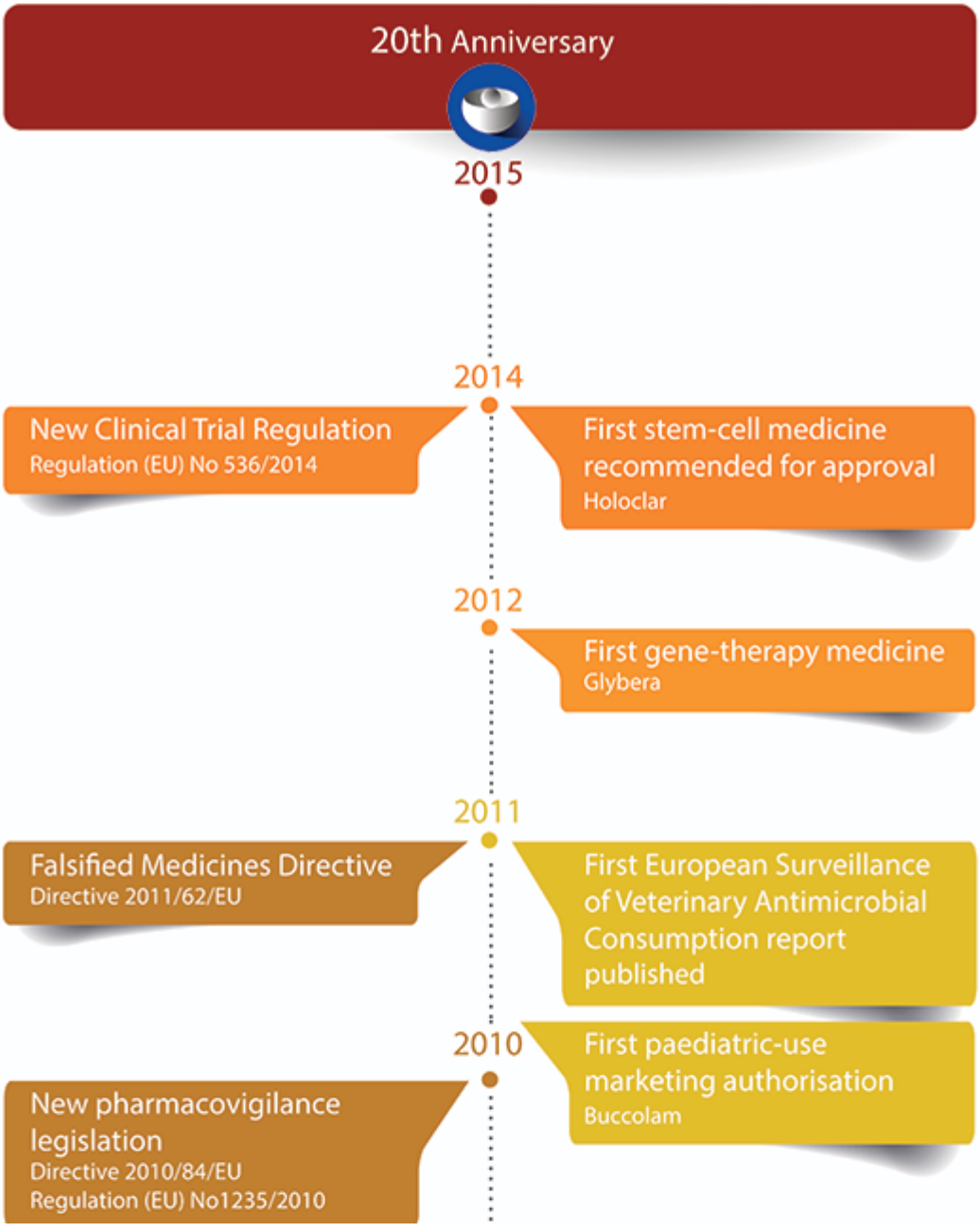
The Agency also held a scientific conference on the theme of 'Science, Medicines, Health: Patients at the heart of future innovation'. For more information and the video recording, see 20th anniversary scientific conference highlights.

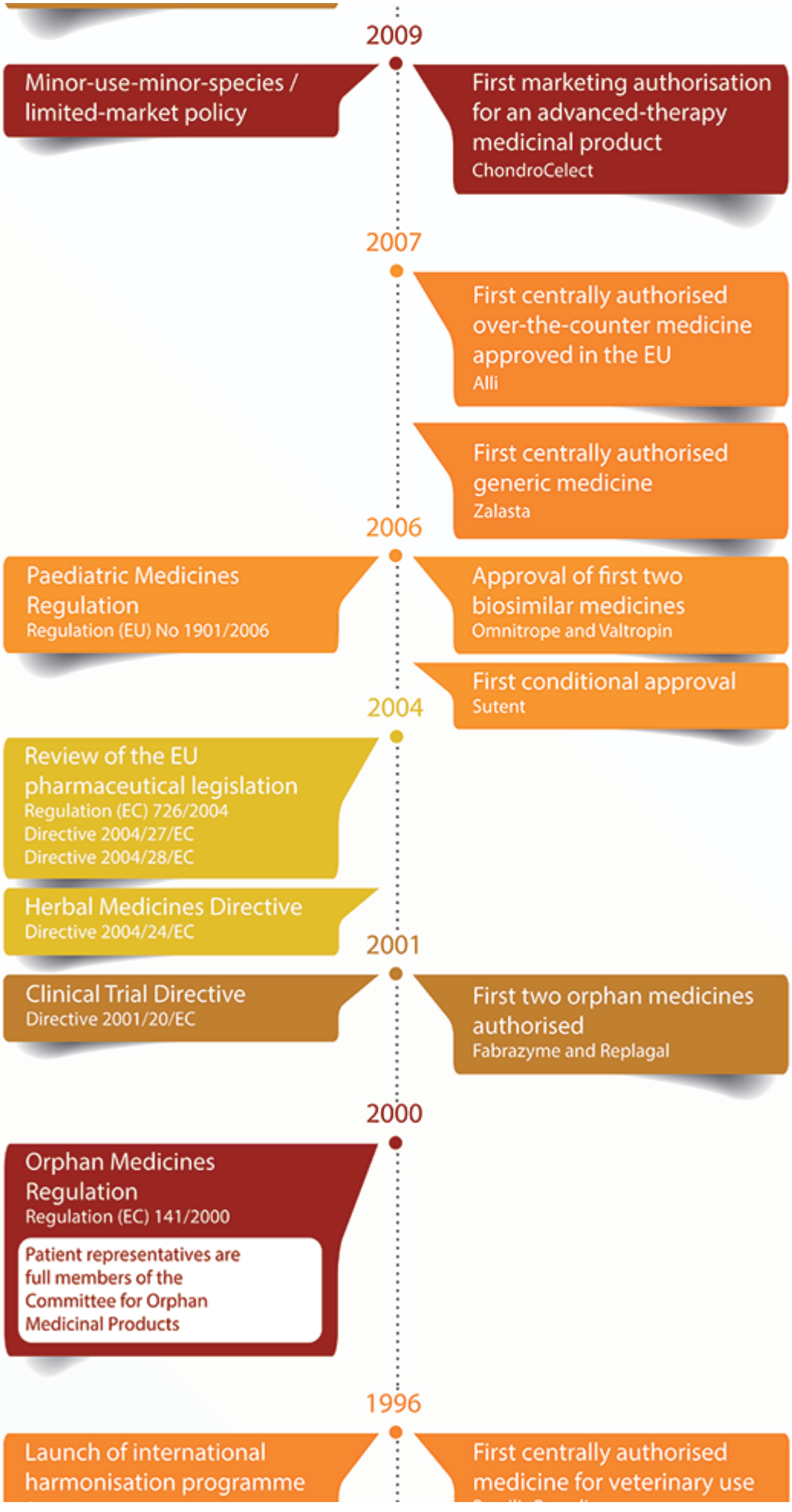
50 years of pharmaceutical legislation

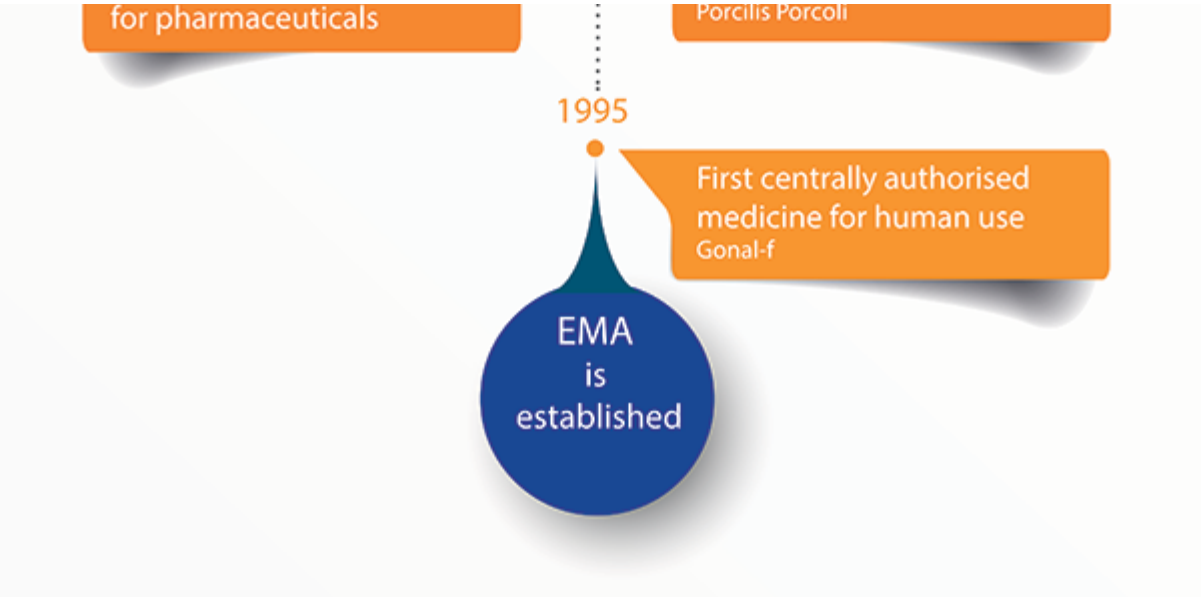
2015 also marked the 50th anniversary of the introduction of the **first EU legislation** on human medicines. On 26 January 1965 the Council Directive 65/65 on the approximation of the law relating to medicinal products was adopted.

To mark the anniversary, the European Commission held a conference entitled '50 Years of EU Pharma legislation: Achievements and future perspectives' reviewing the role of EU pharmaceutical legislation in protecting public health, and in promoting advances in science, innovation and health. For more information, see 50 years of pharmaceutical regulation in Europe.

EMA's first 20 years




2009
Minor-use-minor-species / limited-market policy
First marketing authorisation for an advanced-therapy medicinal product
ChondroCelect
2007
First centrally authorised over-the-counter medicine approved in the EU
Alli
First centrally authorised generic medicine
Zalasta
2006
Paediatric Medicines Regulation
Regulation (EU) No 1901/2006
Approval of first two biosimilar medicines
Omnitrope and Valtropin
First conditional approval
Sutent
2004
Review of the EU pharmaceutical legislation
Regulation (EC) 726/2004
Directive 2004/27/EC
Directive 2004/28/EC
Herbal Medicines Directive
Directive 2004/24/EC
2001
Clinical Trial Directive
Directive 2001/20/EC
First two orphan medicines authorised
Fabrazyme and Replagal
2000
Orphan Medicines Regulation
Regulation (EC) 141/2000
Patient representatives are full members of the Committee for Orphan Medicinal Products
1996
Launch of international harmonisation programme
First centrally authorised medicine for veterinary use



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