

1995-2015

Working together for safe and effective medicines



Timeline

20th Anniversary 2015 First stem-cell medicine recommended for approval 2012 2010 New pharmacovigilance legislation Directive 2010/84/EU Regulation (EU) No1235/2010 2009 First marketing authorisation for an advanced-therapy medicinal product Minor-use-minor-species / limited-market policy ChondroCelect 2007 First centrally authorised over-the-counter medicine approved in the EU First centrally authorised generic medicine First conditional approval 2001 Clinical Trial Directive First two orphan medicines authorised 2000 **Orphan Medicines** Regulation Regulation (EC) 141/2000 Patient representatives are full members of the Committee for Orphan Medicinal Products Launch of international harmonisation programme for pharmaceuticals First centrally authorised medicine for veterinary use **EMA**

established

EMA Anniversary

26 January 2015 marked the 20th anniversary of the establishment of the European Medicines Agency (EMA). Founded in 1995, the Agency has worked across the EU and globally to protect public health by assessing medicines to rigorous scientific standards and by providing partners and stakeholders with independent, science-based information on medicines.

Celebrating 20 years

EMA has a 20-year track record of ensuring efficacy and safety of medicines for humans and animals across Europe, and promoting research and innovation in medical science.

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.

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. This has encouraged the

exchange of knowledge, ideas and best practices between European experts striving for the highest standards in medicines regulation.

Bringing medicines to patients

EMA evaluates medicines and ensures that only medicines that have shown that they are safe and effective are authorised for use. In the past 20 years, the Agency has recommended the authorisation of a total of 975 human medicines and 188 veterinary medicines.

Involvement of patients and healthcare professionals

With the implementation of the legislation on orphan medicines (medicines for rare diseases) in 2000, EMA opened its doors to patients and healthcare professionals. Since then they have become involved in a wide range of the Agency's work.

Today, representatives of patients and healthcare professionals take part in most of EMA's scientific committees as full members, adding their unique perspective and experiences to the 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.

50 years of Pharmaceutical Legislation

2015 also marks 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.

EMA's achievements

The Agency's remit has expanded over time, in line with new EU legislation. Today, 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).

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.



Further information

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