EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

1995 – 2015
20 years of European Medicines Agency

Presented by Marie-Agnes Heine on 4 March 2015 at the PCWP/HCPWP joint meeting
Head of Communication Department

What to expect?

- How it all started
- Key milestones of patient involvement
- Celebrating 20 years of EMA
- 20th anniversary events in 2015

How it all started: Pharmaceutical legislation

26 January 1965 - adoption of Council Directive 65/65 an the approximation of the law relating to medicinal products

First piece of EU pharmaceutical legislation introduced some founding principles valid until today.

EU pharmaceutical sector

- Employs 1.8% of total manufacturing workforce.
- Main R&D employer (over 110,000 people).
- EU world's biggest trader in medicinal and pharmaceutical products in 2013 (159.9 bn EUR).
- Most importantly **450 million patients**.

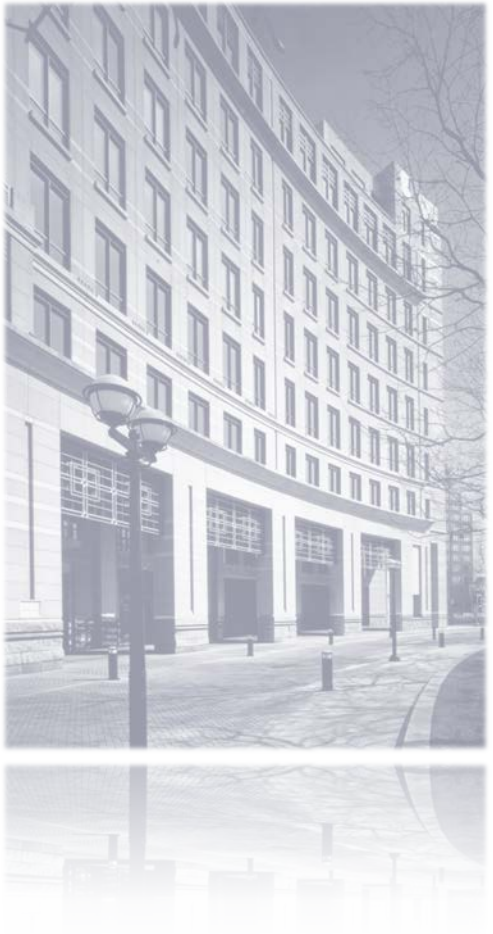
50th anniversary of EU pharmaceutical legislation

- Conference organised by EC – 28 September 2015
- The EU has one of the safest and most advanced systems for monitoring the safety of medicines.
- Medicines authorised in the EU are of high quality and undergo a detailed assessment of benefits and risk before placed on the market.
- The safety of medicines is continuously monitored also after the authorisation.

1995 – 2015
20 years of European Medicines Agency

Agency founded on 26 January 1995

- Protection of public health by assessing medicines
- Providing partners with independent, science-based information on medicines
- Ensuring safety, efficacy and high quality of medicines
- Promoting research and innovation
- Cooperation with EU regulatory network



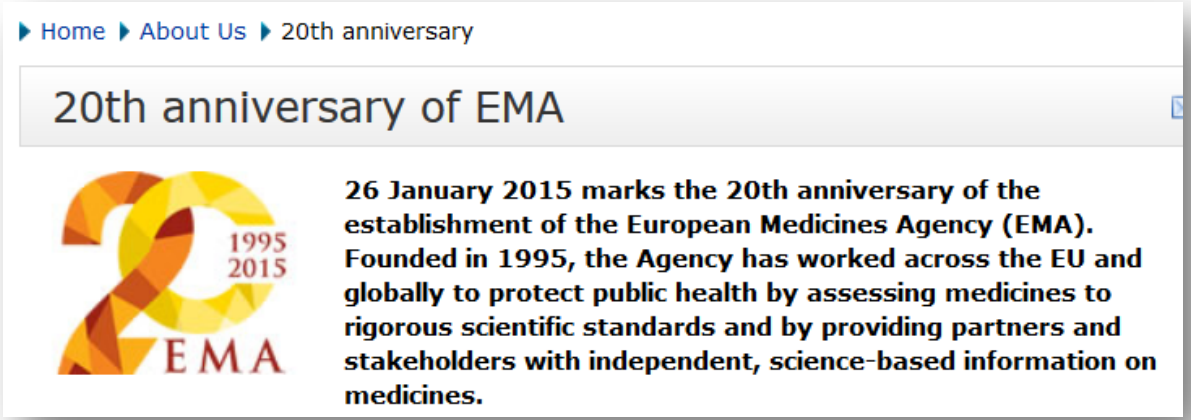
1995 – 2015
20 years of European Medicines Agency

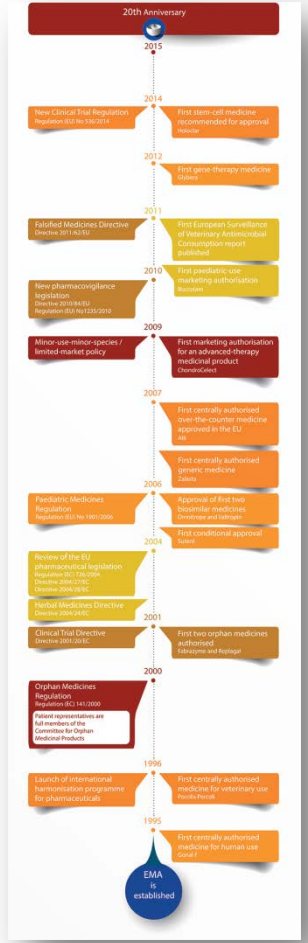
Today:

- 7 scientific committees
- Over 30 working parties
- Several thousands of European scientific experts
- 975 human medicines and 188 veterinary medicines recommended for approval

Overview of activities over the 20 years

Dedicated webpage





Key milestones of patients involvement

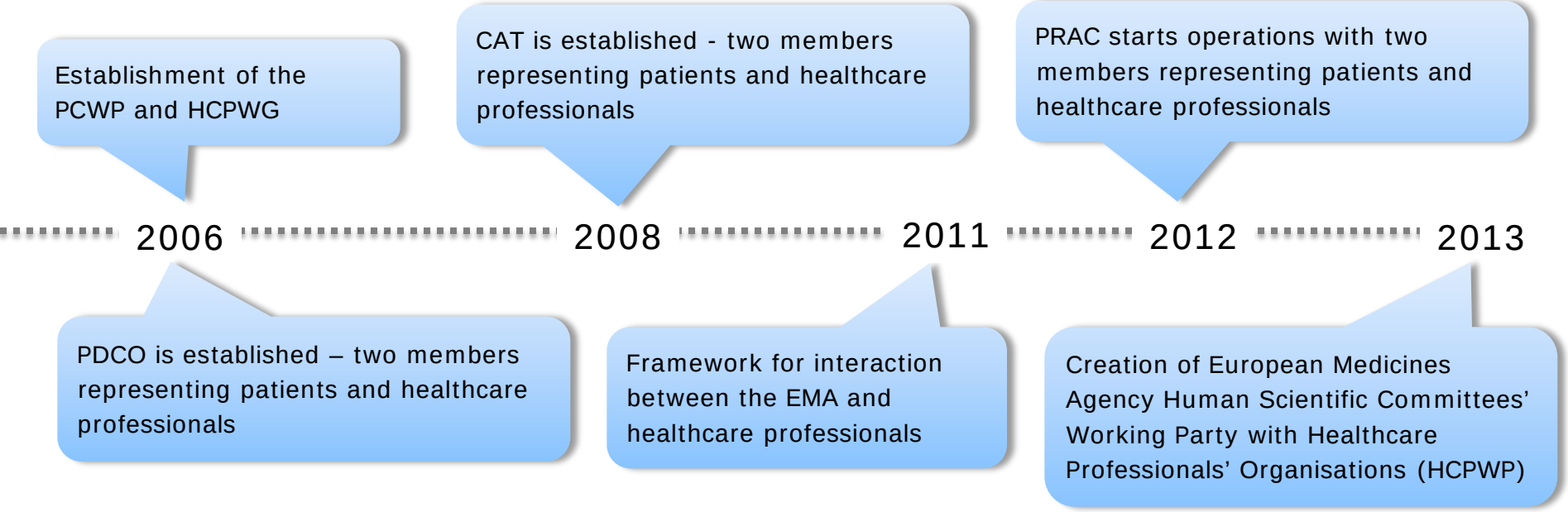
1995 – Establishment of EMA

2001 – COMP – the first scientific Committee to include patient representatives as full members

2002 – Creation of EMEA/CPMP Working Group with Patients' organisations

2005 – Framework of EMA interaction with patients' and consumers' organisations

2005 – Representatives of patients', healthcare professionals' and veterinarians' organisations join EMA Management Board


Establishment of the PCWP and HCPWG
CAT is established - two members representing patients and healthcare professionals
PRAC starts operations with two members representing patients and healthcare professionals
2006
2008
2011
2012
2013
PDCO is established – two members representing patients and healthcare professionals
Framework for interaction between the EMA and healthcare professionals
Creation of European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)

Staff celebrations

- On 26 January 2015
  - Former directors and staff members present
  - Ribbon cutting and choir
  - General Assembly with speeches, evening celebration
- Monthly events for staff, committee and working party members throughout the year

Scientific conference: Patients at the heart of future innovation

Main theme: looking at the future challenges, how to support innovation to increase public health.

290 participants attending

Speech by Margaret Hamburg, Commissioner, US FDA.

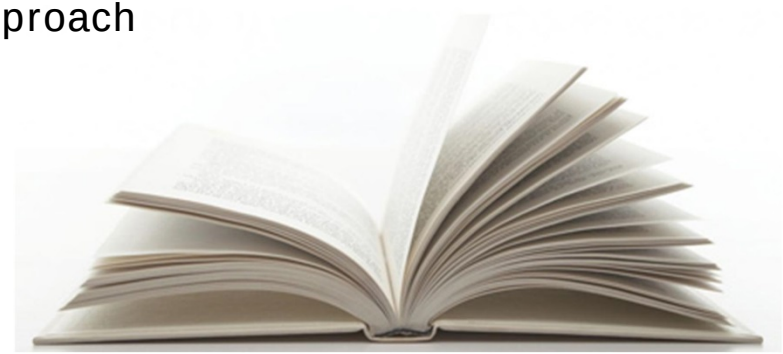
Keynote addresses by

- Elias Zerhouni, President, Global R&D, SanofiSir
- Mark Walport, Chief Scientific Adviser to Her Majesty's Government

20th anniversary book

Contents:

- Progress in science and developing new medicines
- Unmet health needs and health threats
- Robust decision-making facilitating access to treatment
- From marketing authorisation-only to life span approach
- Access to data and empowering patients



Internal anniversary monthly events (selection)

panel debate
roundtable
lunchtime talk
lecture
video
workshop

Feb. Ensuring quality in Low and Middle Income Countries

Mar. - Falsified and substandard medicines

Apr. - Innovation in veterinary medicines in global food security

May - Rare diseases – innovation provides hope to patients

Jun. - Pathfinder – innovative medicines for patients

- How to make data talk - lecture

Internal anniversary monthly events (continued)

panel debate
roundtable
lunchtime talk
lecture
video
workshop

Jul. - Making medicines safer: implementation of PhV legislation

Sep. - Health literacy: getting health information across

Oct. - Tailoring medicines for children

Nov. - Antimicrobial resistance – a challenge in human and veterinary practice

Dec. - Patients as driving force: 10 years Patients and Consumer WP

Thank you for your attention

Further information

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