EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

A forward look

PCWP 10th anniversary

14 June 2016
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Today's achievements (1/2)

- Over the past 2 decades: Continuously striving for authorising and maintaining on the market high-quality, safe and effective medicines, facilitated by:
  - The introduction of new legislation at various intervals
  - The adaptation of the EU regulatory system to changing demands

Today's achievements (2/2)

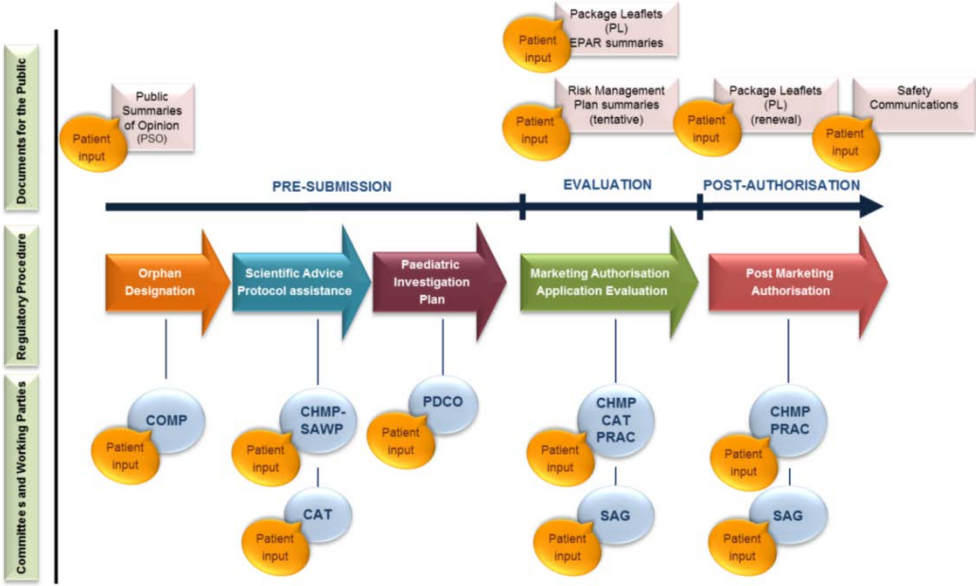
- However, 3 important paradigm shifts have gradually influenced the regulatory journey since 1996 (… and continue to do so):
  - The authorisation paradigm: from granting a marketing authorisation to timely access to medicines
  - The civil society involvement paradigm: from informing civil society, to involving and subsequently engaging with civil society
  - The transparency paradigm: from transparency on the outcome of the scientific review to transparency on the scientific data on which decisions have been taken

Lessons learned

- Lessons learned include the need to invest in the robustness of the decision-making by:
  - Ensuring the independence of the regulators' work
  - Improving the design of the regulatory review process
  - **Incorporating patients' preferences and values in the scientific review**
  - **Improving the transparency of the scientific review, including the rationale for the decisions taken**

Current achievements: Engagement of patients

Overview of patient involvement along the medicines lifecycle at EMA

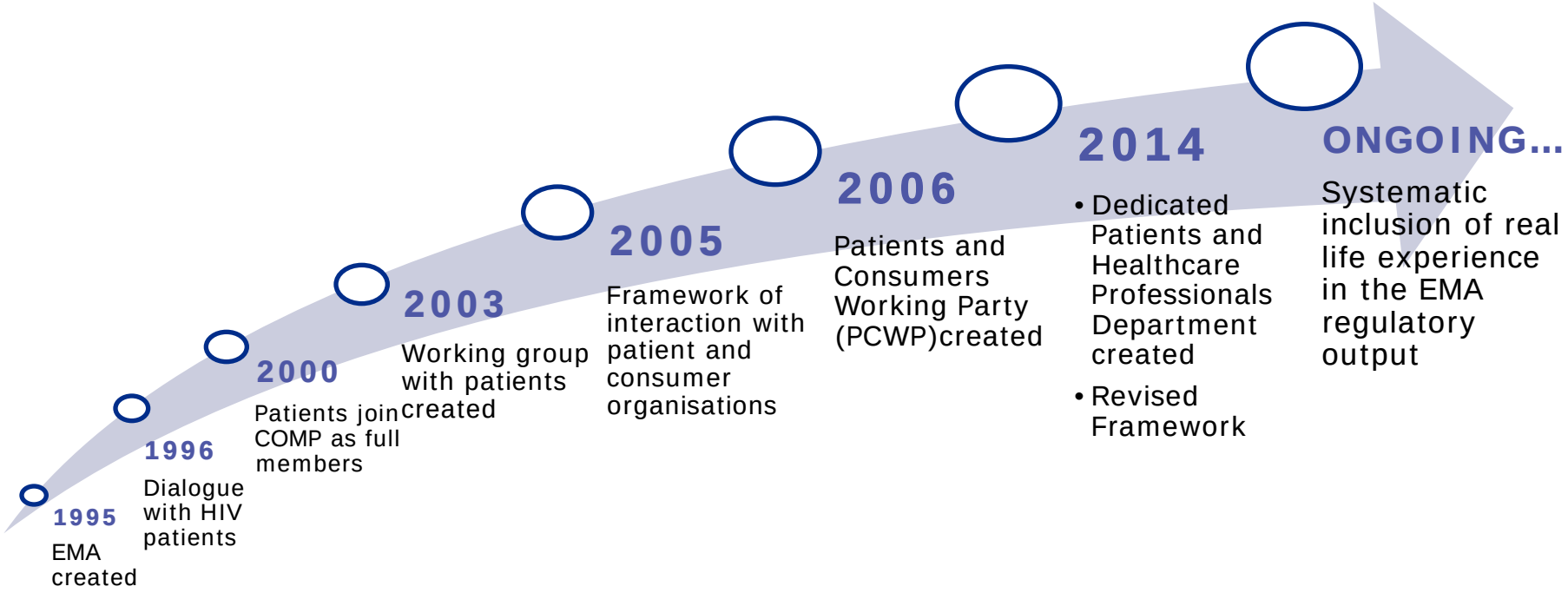


COMP: Committee for Orphan Medicinal Products
PDCO: Paediatric Committee
PRAC: Pharmacovigilance Risk Assessment Committee
CHMP: Committee for Medicinal Products for Human Use
SAWP: Scientific Advice Working Party
CAT: Committee for Advanced Therapies
SAG: Scientific Advisory Group
EPAR: European Public Assessment Report

Current achievements: Increased transparency

- New transparency measures implemented in accordance with the 2010 pharmacovigilance legislation (public hearings for safety related referrals to start as of September 2016)
- Additional transparency initiatives recently taken going beyond the legislative requirements:
  - Publication of agendas and minutes of all scientific committees
  - Development of EMA policy 0070: publication of clinical data for medicines for human use (publication of first clinical reports scheduled for September 2016)

Looking forward: Interaction with patients – the EMA journey



Looking forward: Interaction with patients – what's next? (1/2)

- EU Medicines Agency Network Strategy to 2020
  - Joint undertaken by EMA and the MSs
  - Provides a high-level vision for the next 5 years with a number of joint key strategic priorities where the highest benefit for human and animal health can be achieved
  - Is complemented by MAWPs (multi-annual work plans) for EMA, HMA, CMDh and v

Looking forward: Interaction with patients – what's next? (2/2)

- EMA MAWP[1]: Areas of interaction with patients include:
  - Strategic objective: Ensure timely access to new beneficial and safe medicines for patients
    - Capture and incorporate patients' values and preferences into the scientific review process, in particular the B/R evaluation
  - Strategic objective: Strengthen regulatory capability and transparency
    - Improve provision of information to patients and prescribers
  - Strategic objective: Strive for operational excellence
    - Share information on medicines within the network and with stakeholders
  - Strategic objective: Ensure effective communication of and within the network
    - Capture communication needs and expectations of patients and stakeholders
  - Strategic objective: Strengthen links with other authorities and with stakeholders
    - Involve patients, HCPs, academia more in order to further integrate clinical practice and real life experience of disease and its management along a medicine's lifecycle

[1]For adoption at the June 2016 MB meeting