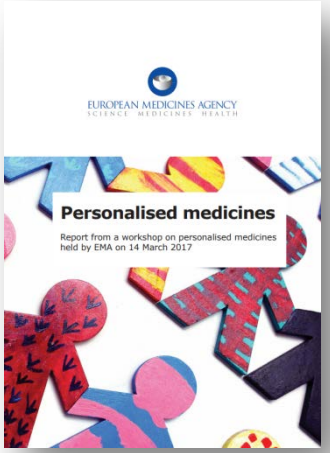
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Highlights of 2017

Presented by Maria Mavris on 22 November 2017
Public Engagement department

An agency of the European Union

PCWP and HCPWP joint meeting – workshop



Personalised Medicine

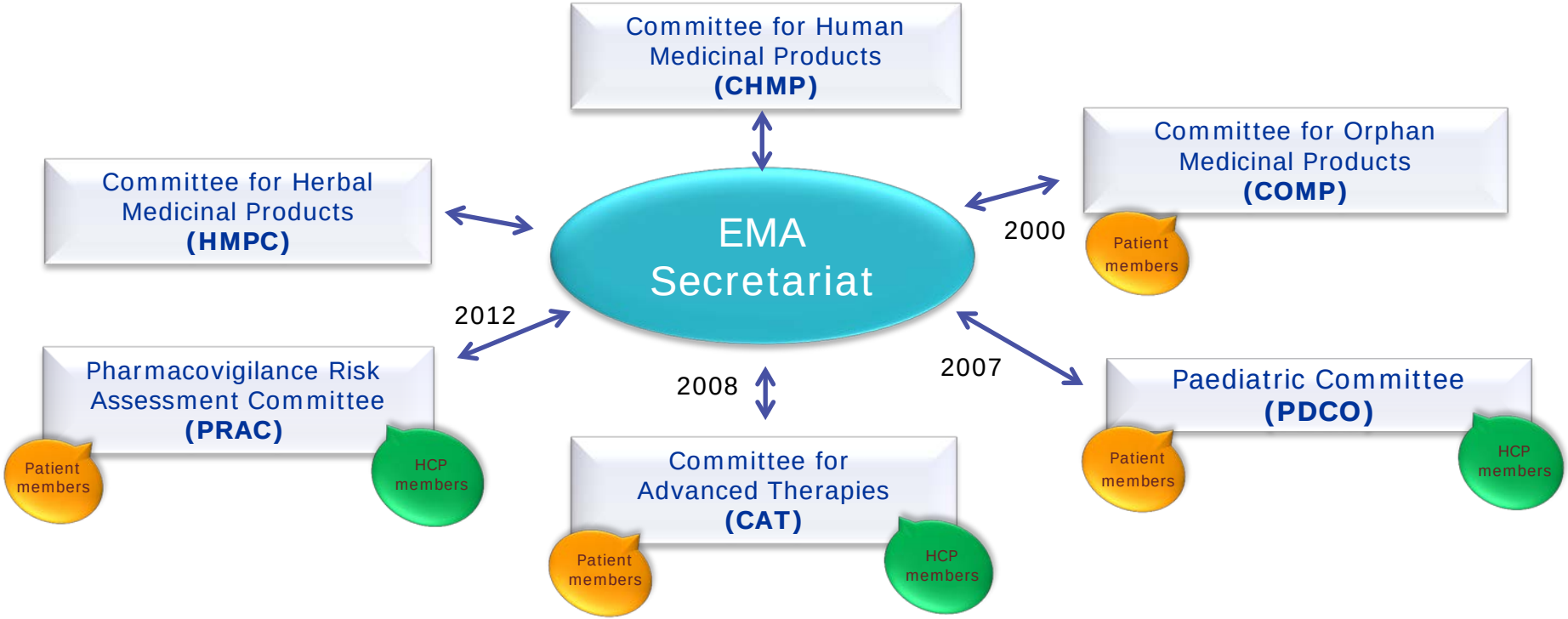
1. Understand how the European and global landscapes are shaping policy developments;
2. Illustrate how the activities of the European Regulatory Medicines Network contribute to personalised medicine, within the existing legislation and regulatory tools;
3. Discuss how clinical practice and public participation can support personalised medicine in the context of EU regulatory activities;
4. Identify areas requiring attention from EU regulators, patients, healthcare professionals and civil society at large.

PCWP and HCPWP joint meeting – information session

Antimicrobial resistance

1. Raise awareness of the work of EU Institutions, member states and WHO in the fight against AMR.
2. Enhance understanding of how EMA and ECDC can support the European and global-level fight against AMR.
3. Discuss how to coordinate efforts on awareness and empowerment by patients, consumers and healthcare professionals.

Support to patients and healthcare professionals in EMA committees



Meeting with patients and healthcare professional members

Committee members:

- COMP, CAT, PDCO and PRAC represented

EMA staff:

- Public Engagement department
- Committees and Inspections department

Ongoing actions include:

- Induction and training
- Increased support for committee activities
- Better definition of role of committee members

Involvement of young people

All Committees
(CXMP)

Young people

Principles document adopted by management board

- Contribution to scientific discussions
- Experience of living with a condition
- Fills gap that other experts can not fill
- Increase understanding and trust in healthcare

Training day 2017

- Four young people invited to training day
  - Real examples of patient involvement
  - Material not yet adapted for age
- Follow up on content and mechanisms for capturing preferences for their input

Patients in benefit-risk discussions at CHMP meetings

Committee for Human Medicinal Products **(CHMP)**

CHMP oral explanations

- Pilot ran from September 2014 to December 2016
- Questionnaires sent after each case to the patients, CHMP members and EMA staff
- Proposal to continue to invite patients to oral explanations on a case-by-case basis
- CHMP members agreed unanimously that inclusion of patient viewpoint enriches overall evaluation of the benefit and risk of the medicine.

Patient involvement with Herbal Committee

Committee for Herbal Medicinal Products **(HMPC)**

Herbal committee observers

- Pool of patients/consumers interested in involvement with herbal medicines
- Systematic review of herbal summaries
  - 24 reviews performed in 2017
- Pilot of patient representatives as observers in Herbal committee meetings
- Next steps to be discussed with the Committee, i.e. regular interactions

Academics and researchers and the EMA

The **framework objectives** are:

- Raise awareness of the work of the European medicines regulatory network
- Promote and further develop the regulatory support to academic research
- Support timely and effective evidence generation, regulatory advice and guidance
- Work in collaboration with the regulatory network in developing regulatory science

Engagement with general practitioners/family doctors

- Meeting held in 2016 with three organisations
- Discussion on:
  - Impact of regulatory actions on general practice
  - Type of input at primary care level that is valuable and feasible for regulatory decision-making process

Outcomes:

- Creation of a virtual expert group
- Development of a joint position statement outlining areas of collaboration and recommendations.

Update of product information – Commission report – next steps


EUROPEAN COMMISSION

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

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Documents:

- Summary of Product Characteristics (SmPC)
- Package Leaflet (PL)

Commission report – 22 March 2017

Recommendations identified to improve and better meet needs of patients and healthcare professionals

Stakeholder meetings (isotretinoin and valproate)

- Safety issues identified
- Multi-stakeholder meeting held at EMA
  - Including patients, carers and healthcare professionals
- Issues discussed
- Recommendations proposed

Public hearing

First public hearing held on 26th September

Valproate and related substances

Total of 65 attendees:

- 28 patients and patient representatives
- 19 healthcare professionals and academics
- 11 pharmaceutical industry representatives
- 7 media representatives

EMA website:

- Summary report published
- Written interventions published
- Recording available

EMA annual training day

- 21st November 2017
- Largest number of participants to date
- For the first time, included:
  - Healthcare professionals
  - Young people
  - Academics
- Hands-on break-out sessions facilitated by EMA staff on:
  - Scientific advice
  - Scientific advisory groups
  - Document review

Any questions?

Further information

[Insert relevant information sources or contact details as applicable.]

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