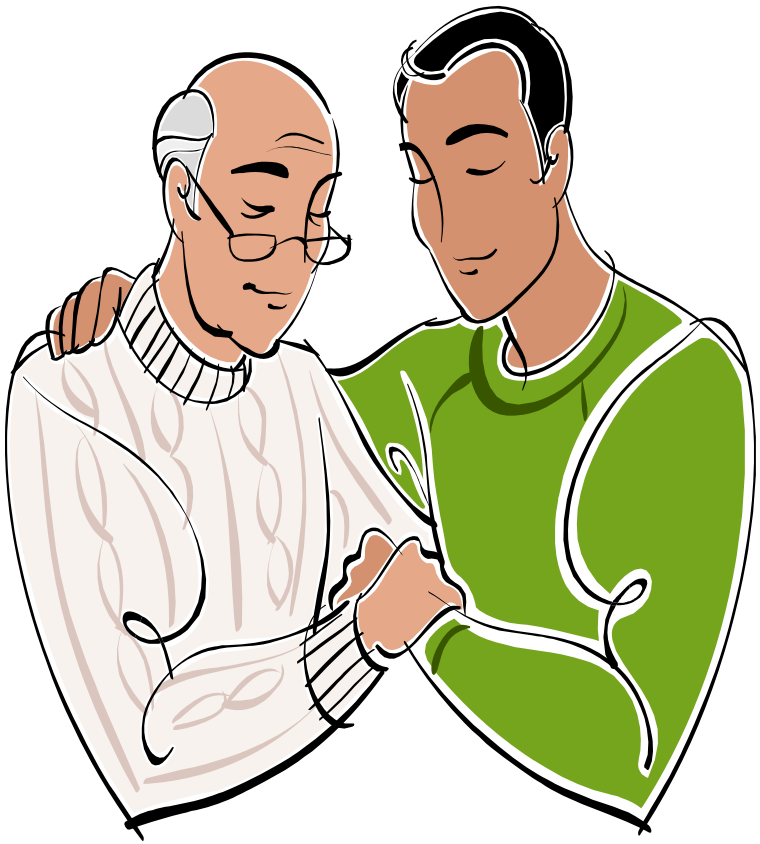
10 year celebrations
COMP

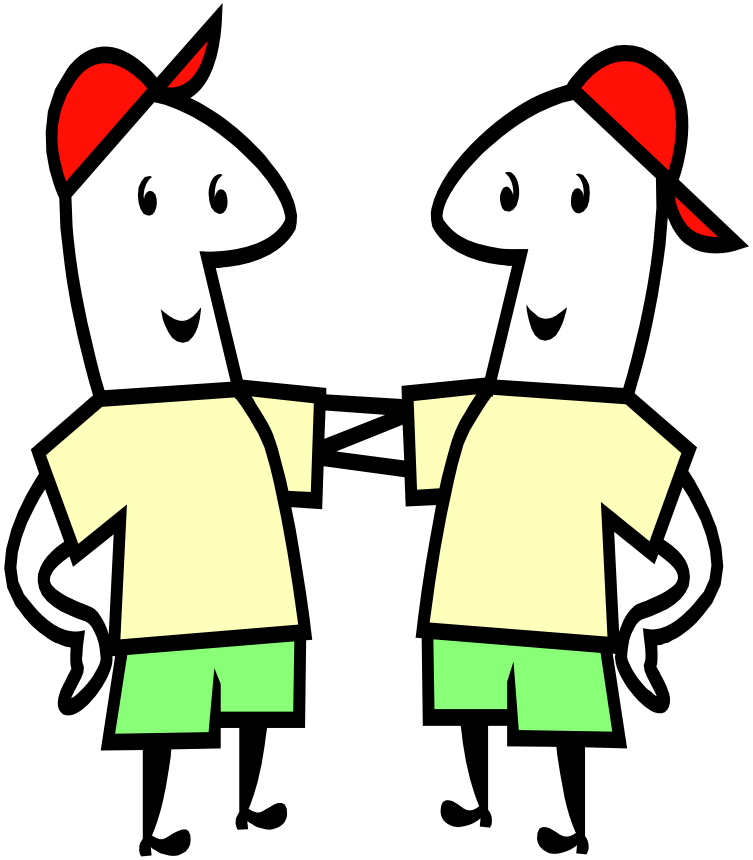
Collaboration between COMP and CHMP

Patrick Salmon.... a delegate

EMA 5th May, 2010

Collaboration between the CHMP and COMP





CHMP-COMP

CHMP-COMP

What’s COMP?

What does it do?

CHMP Role

CHMP prepares the Agency's opinions on all questions concerning medicinal products for human use:

- the initial assessment of medicinal products
- several post-authorisation and maintenance activities, including
  - modifications or extensions (‘variations’) to the existing marketing authorisation

- In the ‘mutual-recognition’ and ‘decentralised’ procedures, the CHMP arbitrates in cases where there is a disagreement between Member States concerning the marketing authorisation of a particular medicinal product (‘arbitration procedure’).

- The CHMP also acts in referral cases, initiated when there are concerns relating to the protection of public health or where other Community interests are at stake (‘Community referral procedure’).

CHMP Responsibilities at time of Marketing Authorisation

Assessments (in accordance with EU legislation), based on purely scientific criteria (QSE):

- Quality,
- Safety and
- Efficacy requirements.

- Positive risk-benefit balance

Committee for Medicinal Products for Human use (Gate keeper function)

- Interrogative
- Adversarial
- If in doubt, negative
- Precautionary principle applies
- Quality

  Safety

  Efficacy

Committee Orphan Medicines

COMP

31 members and chairman

3 representatives from patient groups

Responsible for:

- Orphan designation
- advising on general EU policies and
- international co-operation

Committee on Orphan Medicinal Products (Gate opener)

- OD application may be submitted at any stage of development
- If unsuccessful re-application is user friendly
- Occasionally can encourage dreams

Application

Indication at COMP

Based on data available at the time of application for designation

Indication at CHMP

Based on assessment of data provided for quality, safety, and efficacy in a specific population

Assessment

Hypothesis **COMP**

Evidence **CHMP**

Authorisation Orphan Medicines

- Designation shall be removed if it is established prior to MA that designation criteria are no longer met
- Re-evaluation by COMP to ensure that the basis for original designation is unchanged
- COMP required to review significant benefit criterion prior to granting of MA
- Assess whether or not assumptions of benefit are supported by available data provided by the applicant

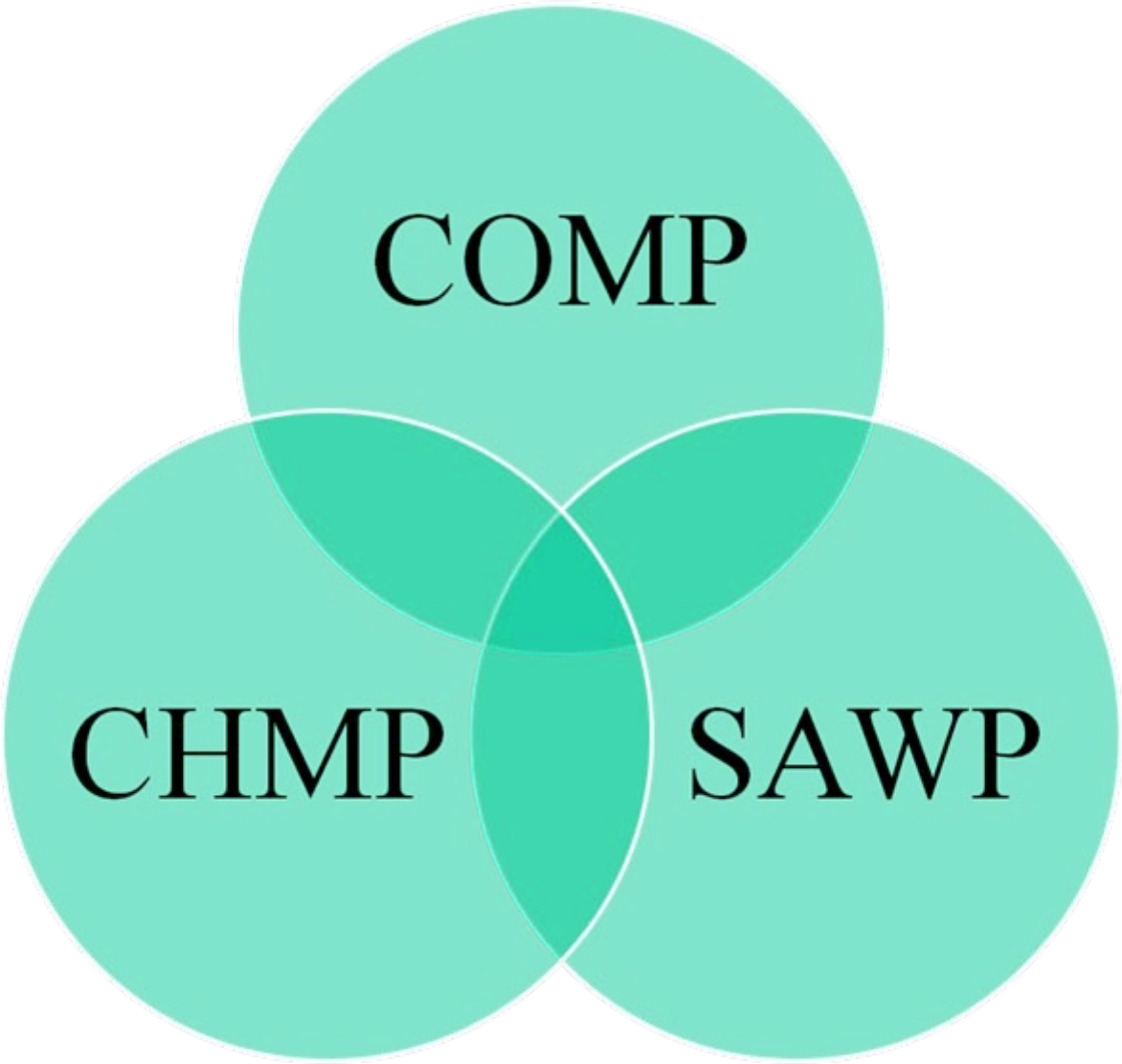
Collaboration

- Separate and distinct roles
- Assess medicine at different times

- Joint role for scientific advice
- CHMP needs to be aware of “significant benefit” and requirements for maintaining designation
- COMP needs to understand CHMP assessment

Collaboration

- CHMP represented at COMP
- COMP represented at SAWP
- Joint meetings between COMP and CHMP


COMP
CHMP
SAWP

Thank you for your attention