



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PDCO/CHMP interaction

4th Industry stakeholder platform on research and development support

Presented by Chrissi Pallidis
November 2018

An agency of the European Union





Overview

- initiative started February 2017 organised by E and D divisions
- facilitated by CHMP and PDCO plenary meetings taking place on the same week
- aims:
 - To improve communication and understanding between committees
 - To optimise use of expertise available
 - To provide input in PIPs and MAs



Overview

- up to November 2018 15 topics discussed
- topics proposed by PDCO and/or CHMP members: may be related to
 - a particular application or
 - a more general issue i.e. paediatric development programmes in schizophrenia, haemophilia, MS



Overview

-tailored to the need of interaction:

- Entire plenaries
- Subgroup of interested parties
- Breakout sessions in the margins of the meetings

-outcome of discussions: input in PIPs and MAs

-no regulatory decisions made

Survey of experience Feb 2017 – March 2018

Participants in the survey: PDCO and CHMP members, EMA product leads, EMA Paediatric coordinators



To provide an overview of
one year interaction
between **CHMP and PDCO**



To analyse the **utility** of
these **interactions**



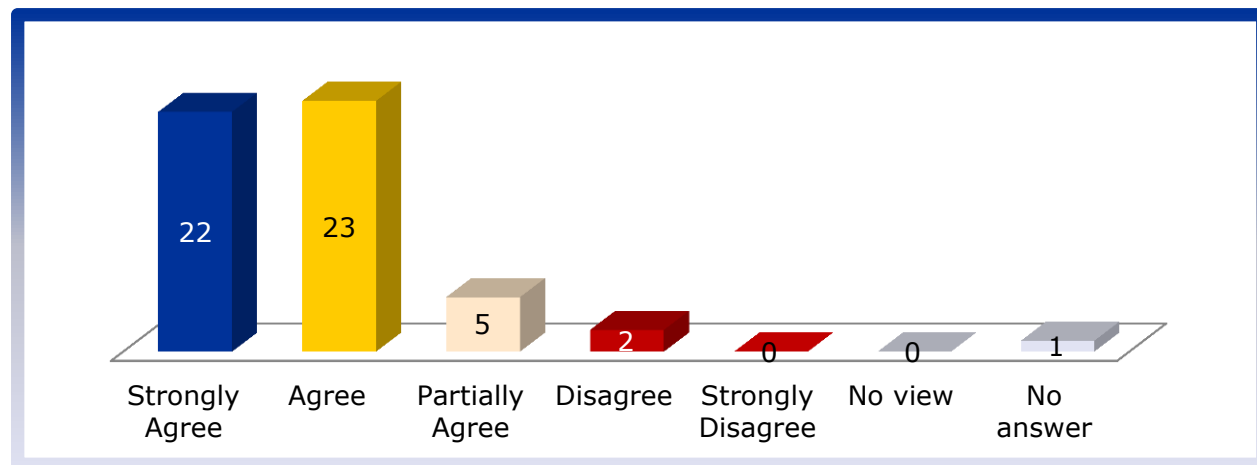
To identify areas of
improvement



Survey responses

Overall participation – 53 answers

The PDCO/CHMP interaction over the last year, particularly with regards to the organised joint sessions can be considered useful. **Do you agree?**





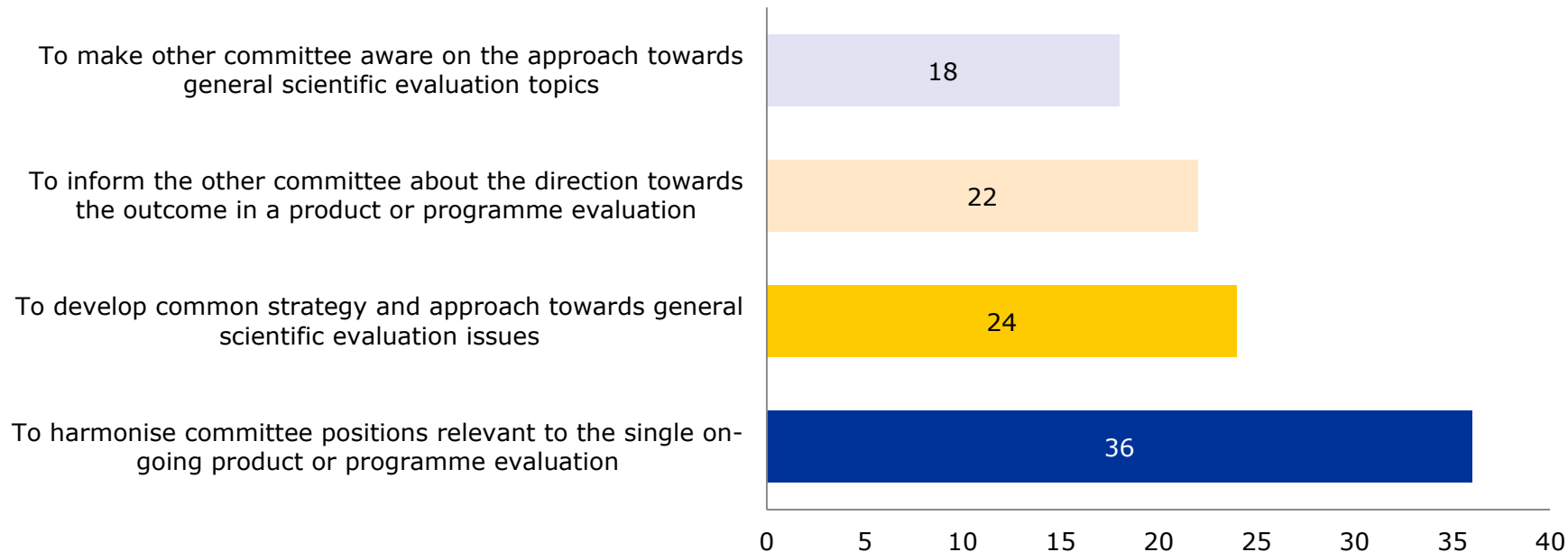
Additional questions:

Do you agree with the following statement?

- The topic(s) was (were) **relevant** for PDCO/CHMP interaction
- The main issue(s) for the interaction was (were) **adequately addressed**
- The members of both committees were well **informed and engaged** in the interaction
- A **clear outcome** was expressed at the conclusion of the interaction
- The session had a significant **impact** on the outcome of either committee procedure

- **The main purpose of the interaction(s)**
- **Suggestions for improvement**

The most appropriate scope of the interactions for the future would be*



**people were allowed to give more than one answer*



Main conclusions

- Overall satisfaction with the organisation and outcome (relevance, impact)
- Both procedure/product specific and general topics to be addressed
- Variability of future interactions depending on topic
- Selection and advanced communication of the topics (dedicated group)