EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA presentation on proposals to optimise treatment within current procedures

Cancer Medicines Forum meeting 29th June 2023

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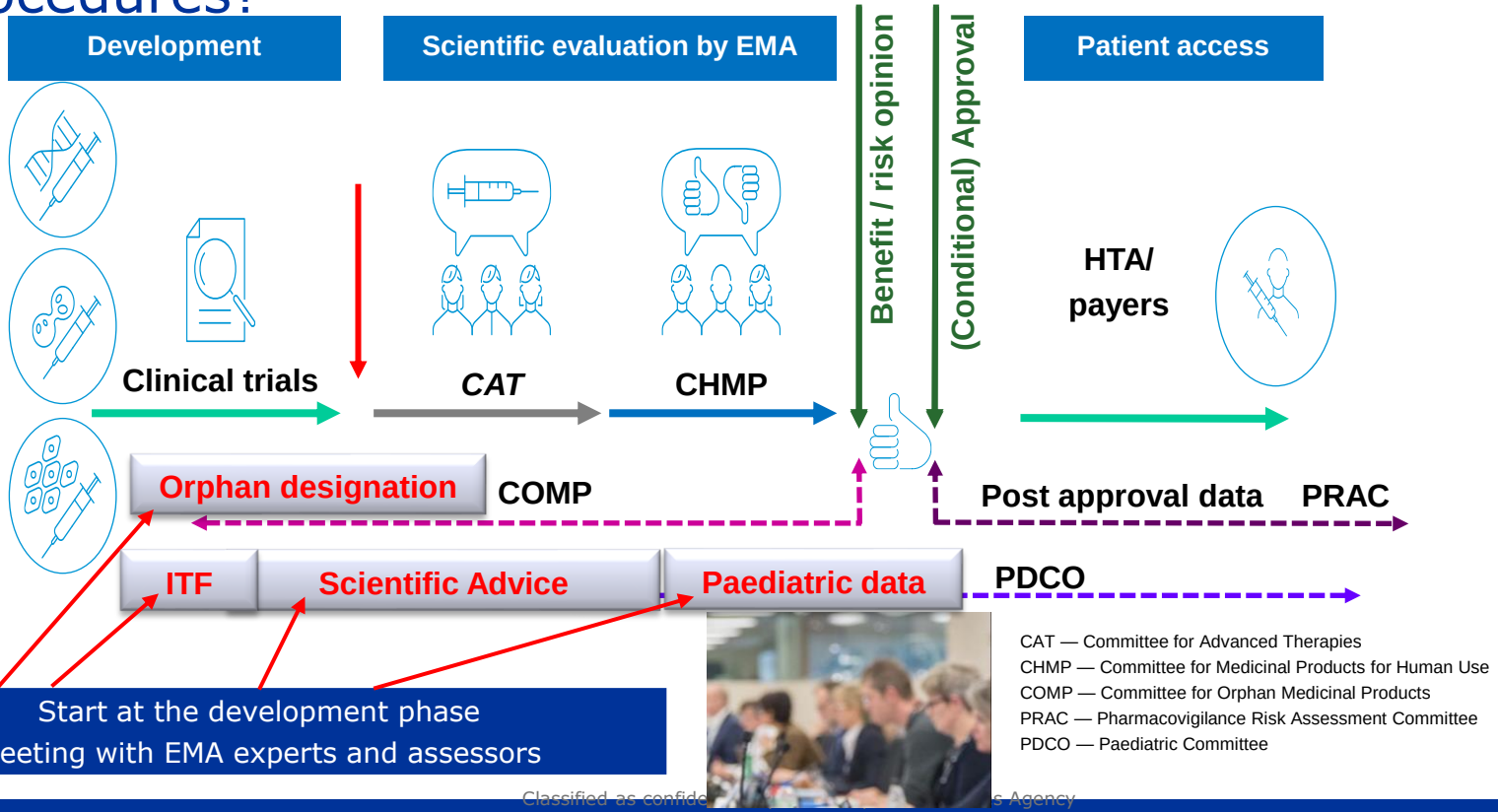
The views expressed in this presentation are the personal views of the speaker and may not be understood or quoted as being made on behalf of or reflecting the position of the EMA committees or working parties

How to integrate treatment optimisation in existing EMA procedures?



CAT — Committee for Advanced Therapies
CHMP — Committee for Medicinal Products for Human Use
COMP — Committee for Orphan Medicinal Products
PRAC — Pharmacovigilance Risk Assessment Committee
PDCO — Paediatric Committee

How to integrate treatment optimisation in existing EMA procedures?

In Scientific Advice/Protocol Assistance

- Prompt applicant to ask specific questions around treatment optimisation (e.g. dose)?

Project Optimus and Pragmatica by FDA

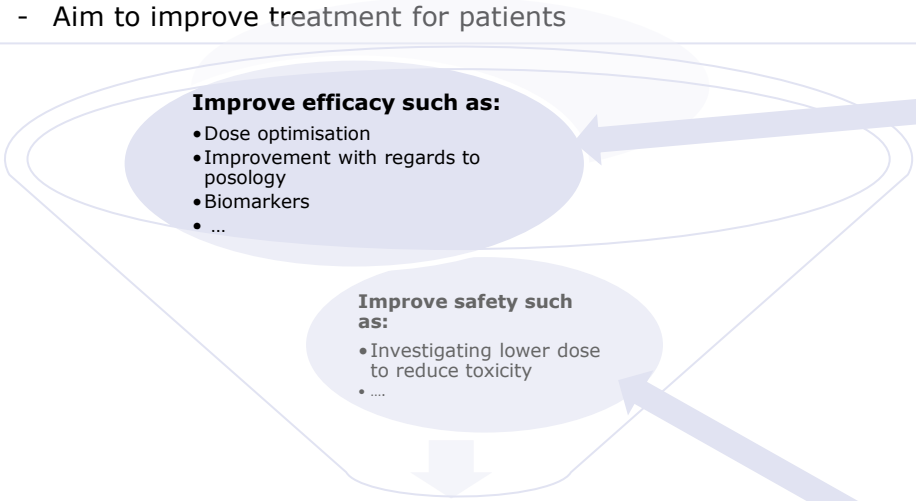
- Some questions might only arise during evaluation of the MAA
- CHMP identifies these gaps which could be:
  - Either addressed as imposed post-authorisation studies
  - Or clearly described in the European Public Assessment Reports

As part of Marketing Authorisation Application

European Public Assessment Report

Highlighting gaps in order to improve the efficacy and safety profile of the medicine:

- Generally aspects <u>not precluding a MA</u>
- Gaps identified endorsed by EMA as area for further research
- Aim to improve treatment for patients



5.1. Therapeutic Context

5.1.1. Disease or condition

5.1.2. Available therapies and unmet medical need

5.1.3. Main clinical studies

5.2. Favourable effects

COMMENTS

- Avoid interpretation and value judgements (e.g., it was convincingly shown that overall survival was greatly improved for treatment X).
- This section should be consistent with the favourable effects described in 5.6. Effects Table and with the SmPC section 5.1. No new results should be introduced here that have not been described in detail in the previous sections
- This section does not need to be updated during the procedure unless new key results are submitted

For more guidance on definitions of favourable effects, how to select "key" effects, and examples, see the *D80 assessment report Overview template/guidance+D120 LOQ*.

5.3. Uncertainties and limitations about favourable effects

5.4. Unfavourable effects

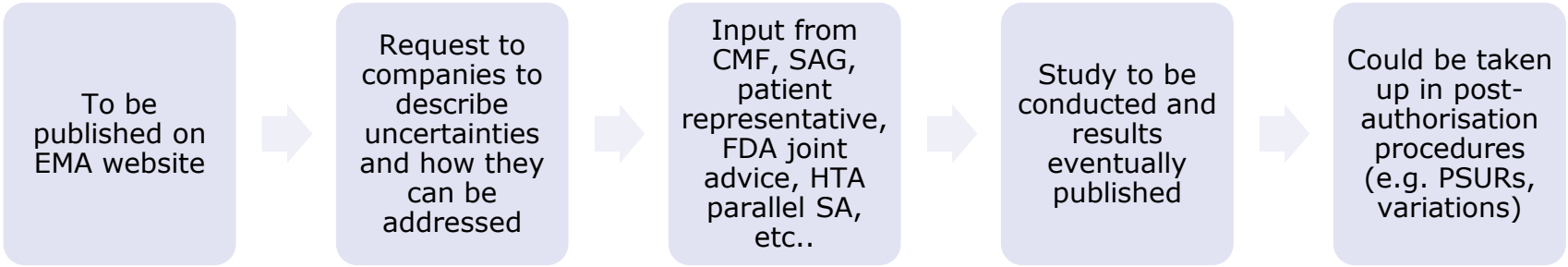
COMMENTS

- Avoid interpretation and value judgements (e.g., low-grade toxicity for treatment X was significant);
- Try to avoid long lists of individual side-effects. If meaningful, try to group them (e.g., in terms of their consequences such as life-threatening reactions or by System Organ Classes).
- This section should be consistent with the unfavourable effects described in 5.6. Effects Table, the important identified risks described in section 3.4 Risk Management Plan, and the SmPC Section 4.8. No new results should be introduced here that have not been described in detail in the previous sections (typically under Clinical Aspects).
- This section does not need to be updated during the procedure unless new key results are submitted

For more guidance on how to describe unfavourable effects, see the *D80 assessment report - Overview & D120 LOQ template with guidance* .

5.5. Uncertainties and limitations about unfavourable effects

Research priorities



Next steps

Discussions around proposal

Thank you for your attention

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