EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Cancer medicines as pathfinder

Presented by F. Pignatti

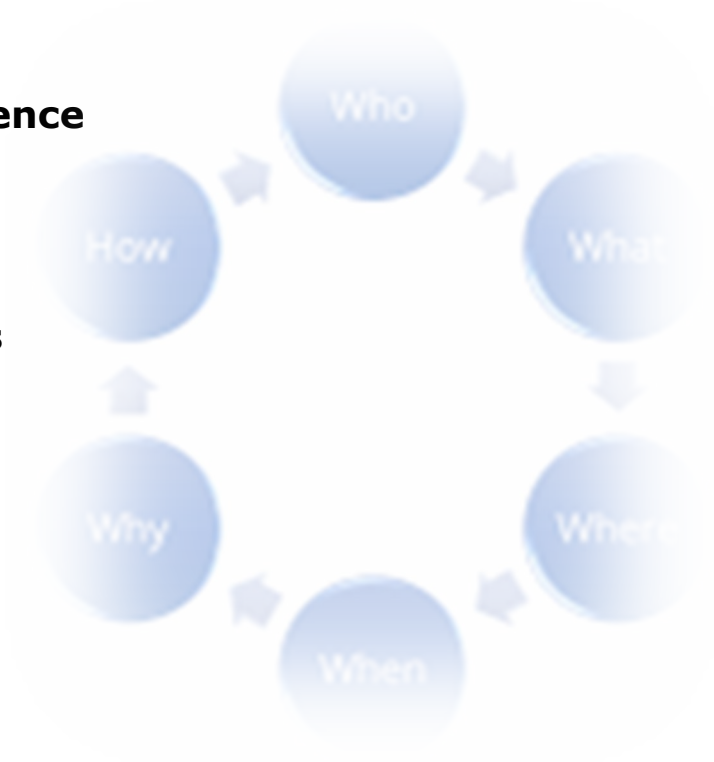
EMA PCWP and HCPWP joint meeting - 27 February 2024

Cancer medicines as pathfinder

- **Extraordinary pace of innovation** and **development** to address **high unmet medical need**
  - **Evidence generation more complex** and **decisions more challenging**
- How to further **maximise efficiency and excellence** in addressing the needs and expectations? In oncology and beyond

The ambition

- **Maximising efficiency and maintaining excellence**
  - A regulatory system that could become **faster**, **more selective**, and **innovative**
- Address the **complexity of approval and access decisions**
  - Limited data (conditional approval; real-world data; pragmatic trials)
- **Increase capacity** (volume, future-proofing) and support scientific **quality in the assessment**



Maximising efficiency and maintaining excellence

Topic	Action
CHMP oncology **preparatory** meeting	Assessment timetables – efficiency gains through preparation **Accelerated assessment** opportunities; Early rapporteur appointment for key products (PRIME, other breakthroughs)
Support to assessment teams	**European Specialised Expert Communities** **Regulatory curriculum**
International collaboration	**Expand cluster activities to whole lifecycle**; observer status in project ORBIS

Address the complexity of approval and access decisions

Topic	Possible action
Early access	Analysis of experience with **conditional marketing authorisation** and decision making **Uncertainties** and commitments **Communication to patients and doctors** • Assessment templates • Patient preferences on benefits, risks, and uncertainties
Evidentiary standards	**Strength of evidence and uncertainties**; sources of evidence external controls, RWD; Collaboration with HTA/payers on **oncology endpoints** and basis for approval

Increase capacity and support scientific quality in the assessment

Topic	Action
Stakeholder and interested parties input	**Cancer Medicines Forum** • Develop framework for systematic approach to recommendations and commitments about post-marketing benefit-risk **optimisation** studies; generalisability; repurposing. Collaboration with **leading learned societies** (ESMO and EHA) **Patients and advocates**: Develop oncology specific activities Roundtable with **industry** (oncology R&D and regulatory)

Summary

Cancer medicines as pathfinder

- Ambitious program of initiatives to address efficiency and complexity while ensuring high quality of the assessment
  - Can we maximise efficiency and maintain excellence in addressing the needs?
- An opportunity to develop impactful initiatives and collaborations
  - Impact may go beyond oncology
- Re-engineer and develop new processes over the coming years