EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Registries: Recommendations from the registries workshop

10th Industry Stakeholder Platform - Operation of EU Pharmacovigilance Legislation
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Problem statement

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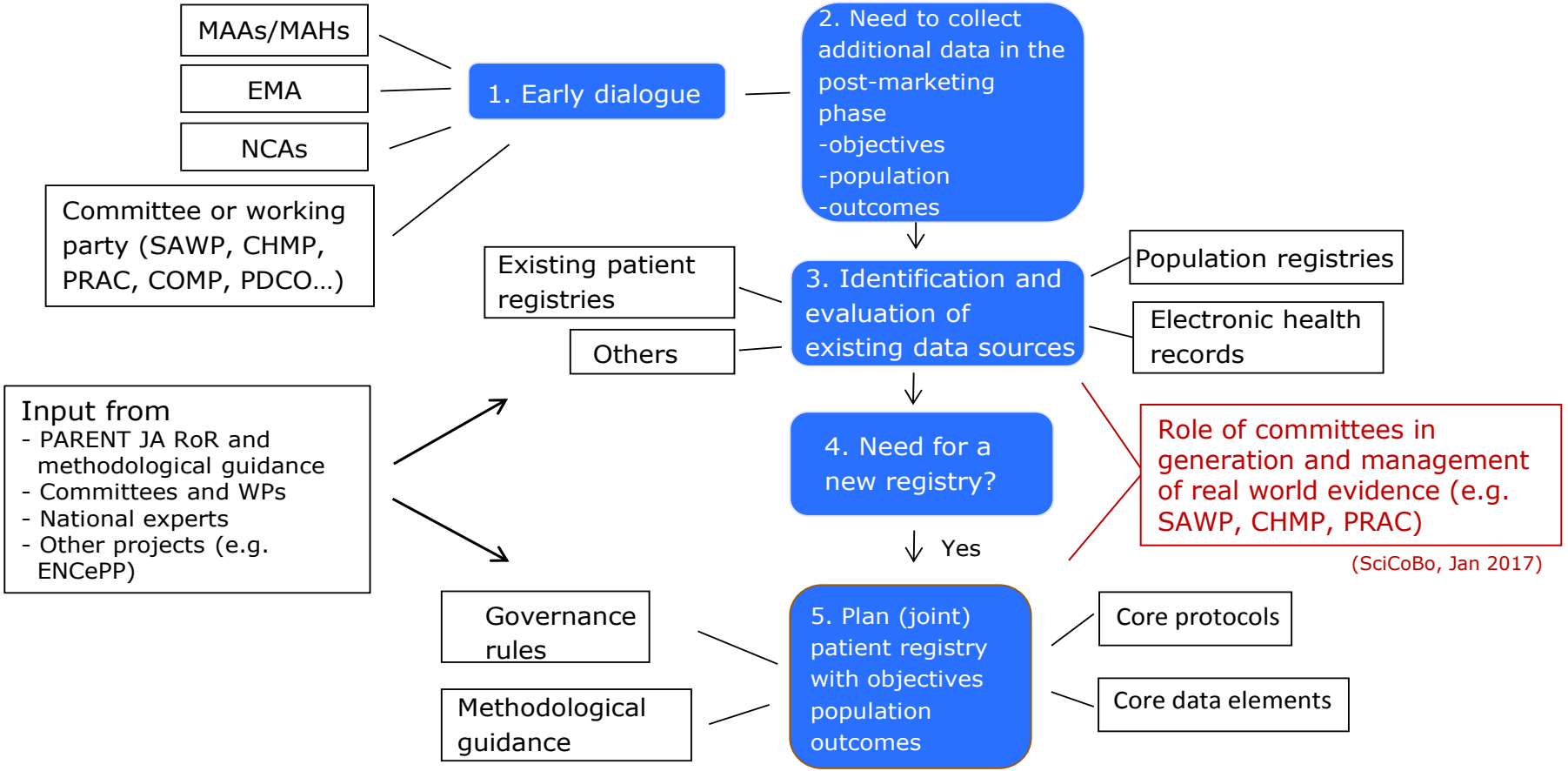
- Registries are requested to MAHs in the context of risk management plans and as regulatory requirements, e.g. for advanced therapies, medicinal products for paediatric use and orphan products.
- The current approach to registries is sometimes suboptimal in scientific and resource terms:
  - existing disease registries are not fully exploited, which may lead to duplication of efforts and inefficiencies
  - lack of common protocols, scientific methods and data structures
  - lack of data sharing and transparency
  - lack of sustainability
- Difficulty to assess the validity of results from individual registries
- On-going national and EU initiatives on registries not well coordinated.

EMA Initiative on Patient Registries

- Cross-Committee Task Force on Patient Registries, Q4 2014
  - EMA Strategy on patient registries
- Pilot phase initiated Q4 2015
- Registries Workshop, 28th October 2016

Proposed approach



Pilot phase

17 expressions of interest or requests for information

- 8 from pharmaceutical companies: 4 for products with MAA (2 authorised by December 2016), 2 products in development, 1 regulatory question and 1 on general aspects of interactions with existing registries
- 9 from registry holders.

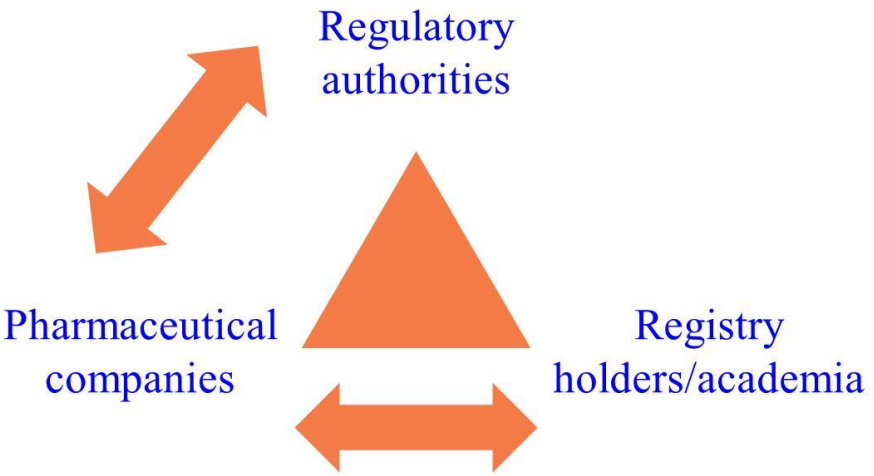
Topics of discussions:

- with pharmaceutical companies: relevance and feasibility of using existing disease registries to answer regulatory questions, issues regarding collaboration with existing registries, such as data quality and data sharing, and data elements to be included in new registries ;
- with registry holders: regulatory requirements on data elements, data quality and processes (e.g. reporting of adverse drug reactions), options for ensuring sustainability of the registry.

Observations and recommendations arising on 5 topics:

1. Benefits of patient registries for regulators, HTA and payers, industry, public health authorities, clinicians and researchers, patients

2. Benefits and challenges of collaborations between:
   - registries,
   - regulators and registry holders
   - registry holders and industry
   - involvement of HTA and payers
   - involvement of patients.



3. Technical aspects: data platform, core data elements, data quality and completeness, data analysis

4. Governance: general aspects, data ownership, data sharing, data pooling and analysis, informed consent, reporting of ADRs, timelines.

5. Sustainability

Conclusions and next steps - DRAFT

The following activities will be initiated by the EMA:

- To facilitate sharing and dissemination of information on disease registries to support collaborations (e.g. through ENCePP network, ENCePP resource database)
- To explore different options to interact directly with registry holders in specific situations, e.g. through Scientific Advice, Qualification process, the Innovation Task Force, or specific meetings with registry holders per treatment areas.
- To build on other initiatives (such as the ADVANCE good practice guide) and recommend principles and standards to apply to interactions between stakeholders on governance aspects.
- To evaluate the need for additional methodological and technical guidance in addition to that already available, e.g. through survey of registry holders.

Conclusions & next steps - DRAFT

The following activities will be initiated by the EMA (2):

- To identify mechanisms to increase role of committees (e.g. CHMP, SAWP, PRAC) for the generation of data from registries
- In collaboration with patients' associations, to investigate relevant patient-reported outcomes that could be collected by registries.
- To explore measures that could contribute to registry sustainability aside from those being already undertaken by individual registry holders/groups.

Thank you !