



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU Collaborative Framework for Patient Registries

Strategy on Patient Registries



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An agency of the European Union





Problem Statement

Registries may be requested in the context of risk management plans

Current regulatory approach to registries suboptimal in scientific and resource terms:

- lack of common protocols, scientific methods and data structures
- lack of data sharing and transparency
- lack of sustainability

On-going national and EU initiatives on registries not well coordinated



Definition of Patient Registry

An organised system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition or exposure



Cross-Committee Task Force on Patient Registries

Cross-Committee Task Force established

- Develop strategy paper
- Proposal for Pilot phase to test alternative regulatory approaches

Objectives of Strategy on Patient Registries

Primary objective:

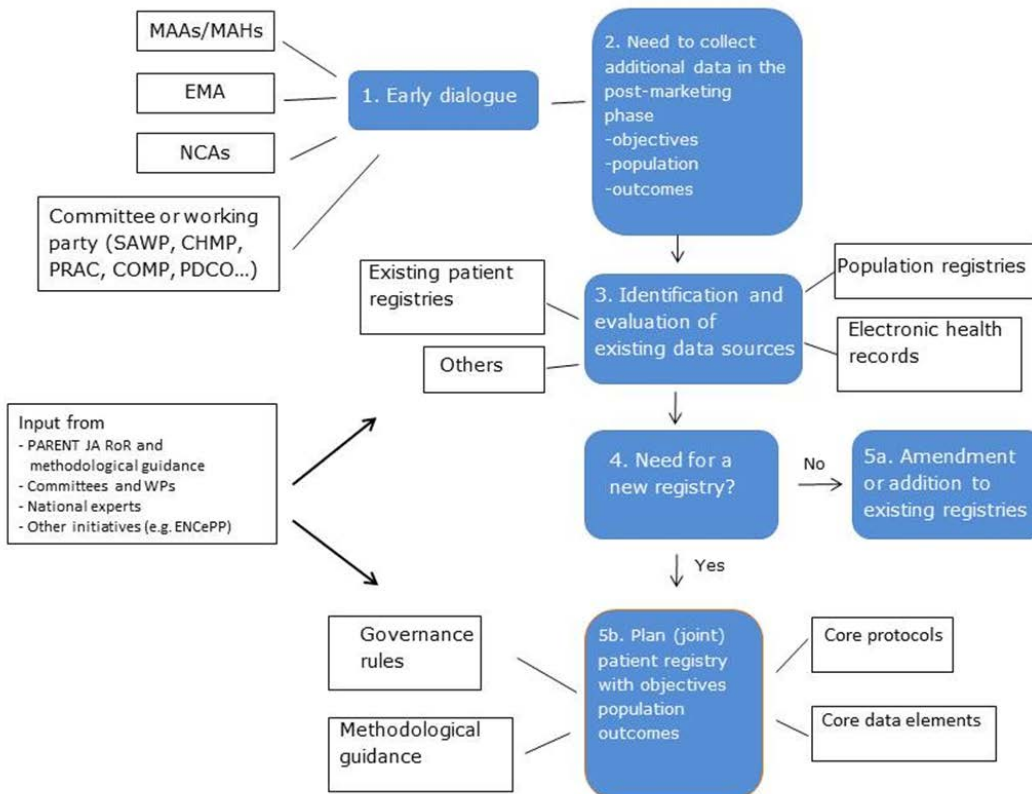
- Develop and test EU collaborative framework for patient registries that would facilitate collection and analysis of high quality data to inform regulatory decisions;

Long term objective:

- Test the feasibility of integrating registries in the adaptive licensing pilot, the one-stop shop strategy and the joint discussions between regulators and HTA bodies/payers.



Regulatory Approach





Aim of pilot phase

To test different methodological elements of the strategy on registries that may facilitate use of existing registries (or development of a new registry) to help MAAs/MAHs meet regulators' needs for additional data in the post-marketing phase



Current status and future steps

- Cross-Committee Task Force is established;
- Design of pilot phase will be finalised in coming months;
- Selection of products for pilot phase;
- Start pilot phase end of 2015



Thank you for your attention

Further information

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