EU Collaborative Framework for Patient Registries

Strategy on Patient Registries

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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

1. Early dialogue

2. Need to collect additional data in the post-marketing phase
   - objectives
   - population
   - outcomes

3. Identification and evaluation of existing data sources
   - Population registries
   - Electronic health records

4. Need for a new registry?
   - No
     5a. Amendment or addition to existing registries
   - Yes
     5b. Plan (joint) patient registry with objectives population outcomes

Input from
- PARENT JA RoA and methodological guidance
- Committees and WPs
- National experts
- Other initiatives (e.g. ENCePP)

Committee or working party (SAWP, CHMP, PRAC, COMP, PDCO...)

MAAs/MAHs
- EMA
- NCAs

Governance rules
Methodological guidance
Core protocols
Core data elements
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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