Registries: legal framework

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Health and Consumers

1."Registry": a multi-faceted concept

- Disease registries typically aim at collecting information about a disease and the available treatments.
  - They are outside the scope of the medicines rules but their information could be considered in the context of MAA or pharmacovigilance.
- Product registries typically aim at collecting information about the safety/efficacy profile of a medicinal product.
  - They can be imposed as a post-marketing obligation in a marketing authorisation.

This presentation only covers product registries imposed to the MAH under the terms of the marketing authorisation.

2. What is the legal status of "product registries"?

- Product registries are not specifically mentioned in Directive 2001/83 or Regulation 536/2014.
- Is the compilation of data about the efficacy/safety of a medicinal product in accordance with SmPC to be consider as:
  - "non-interventional study"?
  - "low –intervention clinical trial"?
  - none of the above?

3. "Non-interventional" studies

- A "non-interventional" study is a clinical study other than a clinical trial.
- 'Clinical study' means any investigation in relation to humans intended to:

  (a) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;

  (b) to identify any adverse reactions to one or more medicinal products; or

  (c) to study the absorption, distribution, metabolism and excretion of one or more medicinal products;

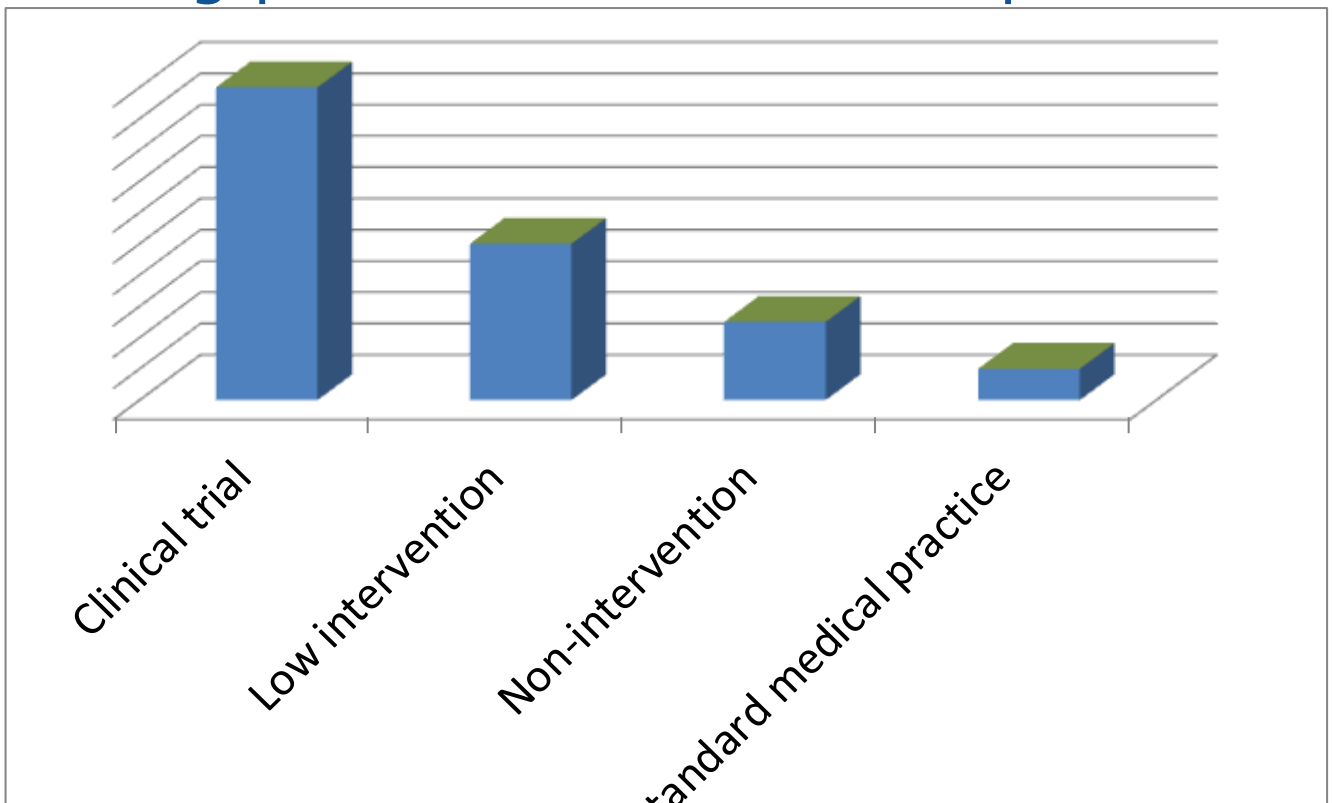
  with the objective of ascertaining the safety and/or efficacy of those medicinal products;

4. "Low-intervention" clinical trial

- Two sets of criteria in the definition of "low-intervention CT":
  1) It must be a **clinical trial:**
     (a) the assignment of the subject to a particular therapeutic strategy is decided in advance and does not fall within normal clinical practice of the Member State concerned;
     (b) the decision to prescribe the investigational medicinal products is taken together with the decision to include the subject in the clinical study; or
     (c) diagnostic or monitoring procedures in addition to normal clinical practice are applied to the subjects.
  2) It must fulfil **all of the following conditions**:
     (a) medicinal product is authorised;
     (b) medicinal product used in accordance with SmPC (or evidence-based and supported by published scientific evidence); and
     (c) the additional diagnostic or monitoring procedures do not pose more than minimal additional risk or burden to the safety of the subjects compared to normal clinical practice in any Member State concerned;

5."non-intervent." or "low intervent."?

- The distinguishing factor lies in the additional monitoring procedures that are required:



6. The consequences

- Registries as low-intervention clinical trials:
  - Prior authorisation by the CA's.
    - What happens in case of discrepancies between CT's authorities and conditions laid down in the marketing authorisation?
  - Specific reporting channels.
- Registries as non-interventional studies:
  - Not subject to clinical trials rules.
  - Can CA's launch an inspection if necessary? How to ensure reliability of data?
- Registries falling under national regulation:
  - What happens in case of discrepancies with conditions laid down in the marketing authorisation?
  - Reliability of data may vary according to national practices.

Thank you for your attention!