Real World Evidence at Swissmedic

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Background

- Pharmaceutical environment undergoing **rapid change**
- Increasing technical capabilities for **data collection**
- Real World Data (RWD)/Real World Evidence (RWE) already a **reality** for regulators
- **Challenges** with RWD/RWE
- International efforts towards **harmonization**

→ **Swissmedic Position Paper** on RWE as published 1 July 2022

Definition of RWD and RWE

Real World Data

Swissmedic considers all data as RWD, which are collected outside a clinical trial conducted as per ICH GCP*.

Data Sources

Among others: registries, observational studies, electronic health care records, medical claims, billing data, patient generated data (e.g. through mobile devices)

Real World Evidence

Real world evidence is defined as the information derived from analysis of RWD.

* International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP)

Legal Framework

- Currently **no legal basis** for the inclusion of RWE in the authorization process for therapeutic products.
- Clinical trials need to be conducted according to the rules of **good clinical practice** (ICH GCP).
- **Numerous challenges** regarding data handling
  - detectability and traceability
  - discrimination
  - manipulation
  - liability
  - privacy/data security
  - consent
  - …

Regulatory Considerations

- **Gold standard**: Clinical trials conducted according to ICH GCP
- Swissmedic **accepts RWE** as supportive evidence **in addition** to clinical trial data conducted according to ICH GCP.
- *New marketing authorisation* applications **solely based on RWE** are **currently not acceptable.**
- In general, *indication extensions* **solely based on RWE** are **currently not acceptable.**
  → for exceptions, clarification in pre-submission meeting
- In the *post-marketing surveillance* setting, Swissmedic *accepts RWE* for the implementation of or changes to **risk minimization** measures.

Key Aspects

- Medical context
- Data sources/quality
- Prespecified Methodology

To reach appropriate **evidence level**

Next steps

- Continuous **development** of regulatory and scientific expertise
- International **harmonization**
  → Active participation of Swissmedic in national and international workshops
- Communication to national and international **stakeholders**

Conclusions

- Swissmedic **accepts applications** containing RWE
- RWE considered as **supportive evidence** for marketing authorisation applications
- **Data sources and quality** of crucial importance
- **Legal framework** to be established
- **Pre-submission meeting** recommended
- Seeking **harmonization** with **international regulatory authorities**

Further Informationen

Swissmedic position paper on the use of real-world evidence:

https://www.swissmedic.ch/swissmedic/en/home/news/mitteilungen/positionspapier-verwendung-real-world-evidence.html