Contextualizing Value-Based Reimbursement Models for Orphan Drugs

A learning health system to implement a reimbursement reform for orphan drugs in Switzerland

Fresh Ideas for Cancer Care 2.0

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Overview

Introduction

«Setting the scene»

- **Increase** of healthcare costs and drug prices

→ in particular for orphan drugs (R&D, …)

- Public policy challenges:
  - Rewarding effective drugs
  - Cost control / limit
  - Incentivizeing research (orphan drugs!) → orphan drug market expected to grow 12% (=+50% of the non-orphan drug market)

- Window of opportunity:
  - Revision Art. 71 a-d KVV

Reimbursement of Orphan Drugs

«The problem» & «The Status Quo»

Reimbursement and access problems

- **Access** = MA
- **Reimbursement** = WZW Criteria
- Reimbursement has not kept pace with MA
    - Reimbursement via individual case (Off-Label Use) reimbursement --> "shadow SL"
- Reimbursement not to be considered cost-effective
- Often: pay for performance contracts (undisclosed pricing!)
- Lack of data challenges evaluation of orphan drugs
- Revision of art. 71a-d KVV, art. 28 para. 3bis KVV (2017) for data sharing that serves as basis for re-evaluation

Implementing value-based pricing in Switzerland

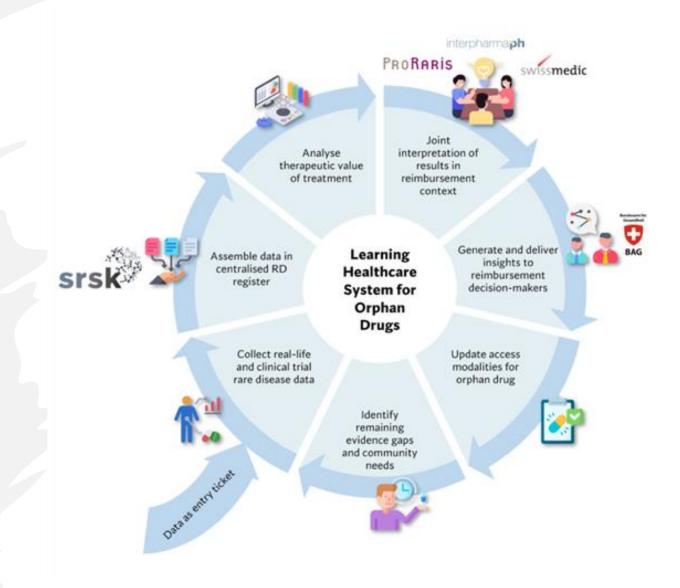*«How do we get from the problem to the solution?»*

Key barriers to change:

- "Sticky regulations" (economic, legal)
  - APV
  - price negotiations

- Data paucity
  - Fragmented data infrastructure
  - Lagging digitalisation of Swiss health sector
  - Lacking patient-centricity

- Common definition of value (different value frameworks)?

- New sandbox article and 59b KVG and 52b KVV

Our approach: **Learning systems** for a dynamic and contextualised implementation of value-based reimbursement in the Swiss healthcare system.

A learning system approach to contextualised implementation of value-based reimbursement of orphan drugs in Switzerland

1. Building a multi-stakeholder **learning community** that offers a depoliticised space and collaborates throughout the cycle

2. The creation of **actionable infrastructure** that facilitate the scale-up from pilot project to federal system change.

Challenges & Limitations

- Data governance
  - Data security
  - (Dynamic) consent

- Data availability
  - Data harmonization
  - Interoperability?

- Funding

- Stakeholder buy-in
  - Cross-agency collaboration
  - Political will

Conclusion

- Access to orphan drugs for patients is unsatisfactory

- Systemic challenges

- Collaboration is key