



Navigating Market Access After Conditional Reimbursement: A Communication Roadmap for Disinvesting Orphan Drugs

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Background & Objectives

Orphan drugs, often reimbursed through managed entry agreements (MEAs), pose unique challenges due to their high costs and limited clinical data at time of reimbursement.

With rising financial pressures on healthcare budgets, disinvestment from orphan drugs with persisting clinical uncertainties after conditional reimbursement may become necessary to ensure sustainable healthcare funding.

However, disinvestment decisions must be communicated carefully to address ethical, psychological, and social implications for patients and healthcare providers

Primary goal: To develop a structured communication roadmap to facilitate effective communication of disinvestment decisions to relevant stakeholders

Scope: Focus on orphan drugs within the Belgian healthcare context, with broader applicability for other jurisdictions

Methods

Literature Review: Narrative review of international literature, legal documents, and policy texts on disinvestment strategies

Expert Panels: Conducted three focus groups with nine experts, including clinicians, patient organization representatives, policymakers, and health insurance representatives

Data Analysis: Verbatim transcription and coding of focus group discussions using NVivo software to identify key principles and elements for the roadmap

Importance of a disinvestment communication roadmap

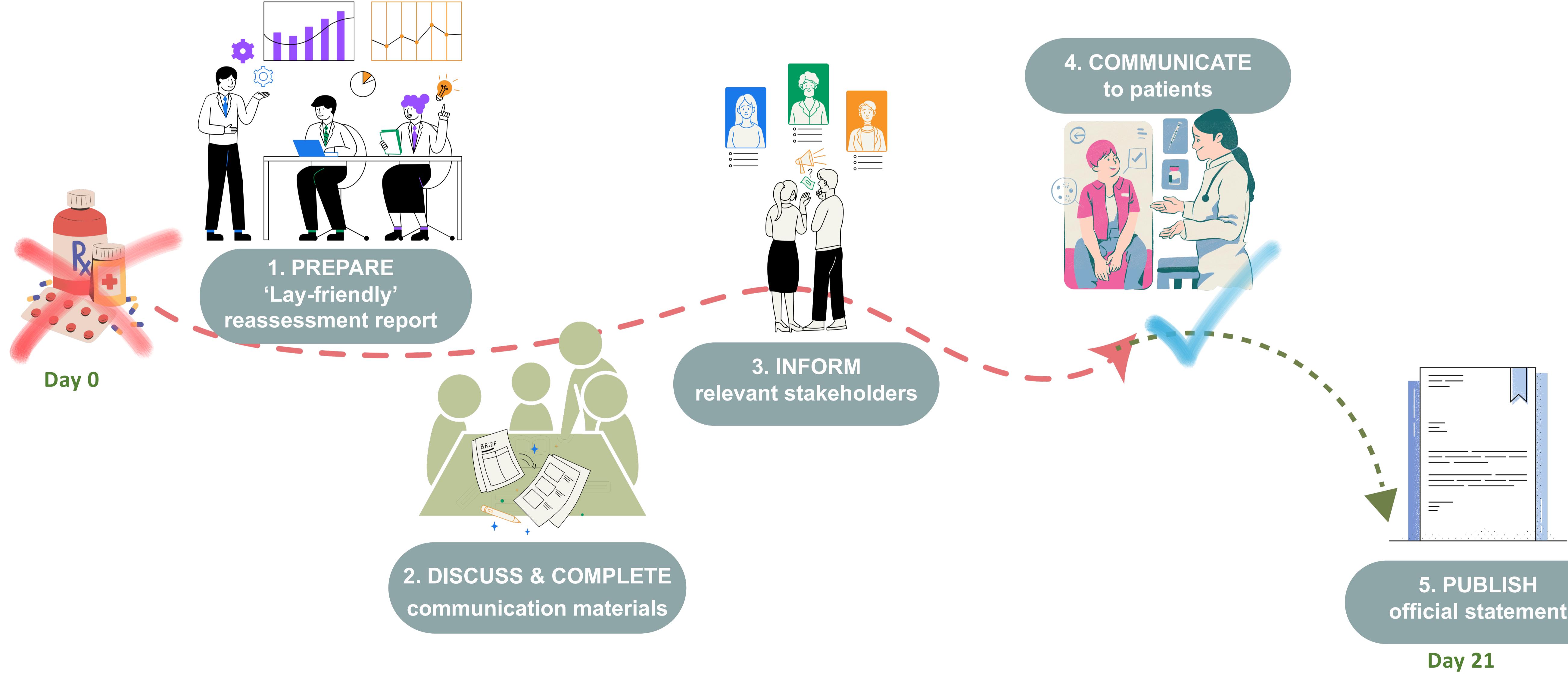
- Clear, evidence-based communication is essential for building trust and acceptance in disinvestment decisions
- Involving stakeholders early on allows to address concerns effectively and reduce potential controversies
- A structured roadmap for disinvestment decisions is critical for maintaining public confidence in healthcare policy

Results

Key Principles for Successful Communication

- Manage Expectations:** Inform patients early about the conditional nature of their treatment's availability
- Use Evidence-Based Decisions:** Base disinvestment decisions on clear and relevant data
- Engage Stakeholders Early:** Involve HTA agencies, clinicians, and patients to build support and provide feedback throughout the MEA process
- Ensure Transparency:** Clearly communicate MEA goals, achieved outcomes, and decision rationale
- Follow a Structured Roadmap:** Use a clear guide to define roles, responsibilities, and efficient steps
- Avoid Information Leaks:** Implement NDAs and limit involvement to essential stakeholders to prevent early disclosure
- Manage Timing and Resources:** Limit progression time between steps, allow a transition period if needed, and ensure sufficient resources
- Tailor for Vulnerable Groups:** Adapt the roadmap to fit specific cases and sensitive patient groups

The Five-Step Communication Roadmap



Conclusions

- This communication roadmap provides a structured, evidence-based approach to managing the complex process of orphan drug disinvestment in Belgium
- By emphasizing transparency, collaboration, and practicality, policymakers can enhance the acceptability and effectiveness of disinvestment decisions, ultimately benefiting both patients and the healthcare system