

Barriers and Policy Solutions in Off-Patent Drug Repurposing: A Full-Lifecycle Perspective

HPR34

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INTRODUCTION

- Drug repurposing leverages existing medicines (previously studied) to reduce time and costs for exploring new therapeutic indications.
- Despite the potential benefits, entities considering repurposing an off-patent medicine face numerous financial and regulatory challenges.
- The main barriers are the lack of private incentives because generics are subject to a competitive market, the active ingredient prescription system, and the lack of knowledge and resources on the part of academic researchers(AcaRes)/NGOs to carry out regulatory processes.

OBJECTIVE

- First, to analyse the barriers and, above all, the potential solutions to support drug repurposing projects, including the role of different funding mechanisms.
- Second, to provide an overview, including real-world experiences, of the entire drug repurposing lifecycle, from the identification of a candidate to its inclusion in clinical practice

METHODS

This research contains a theoretical (literature review) and a practical perspective (interview with experts on drug repurposing):

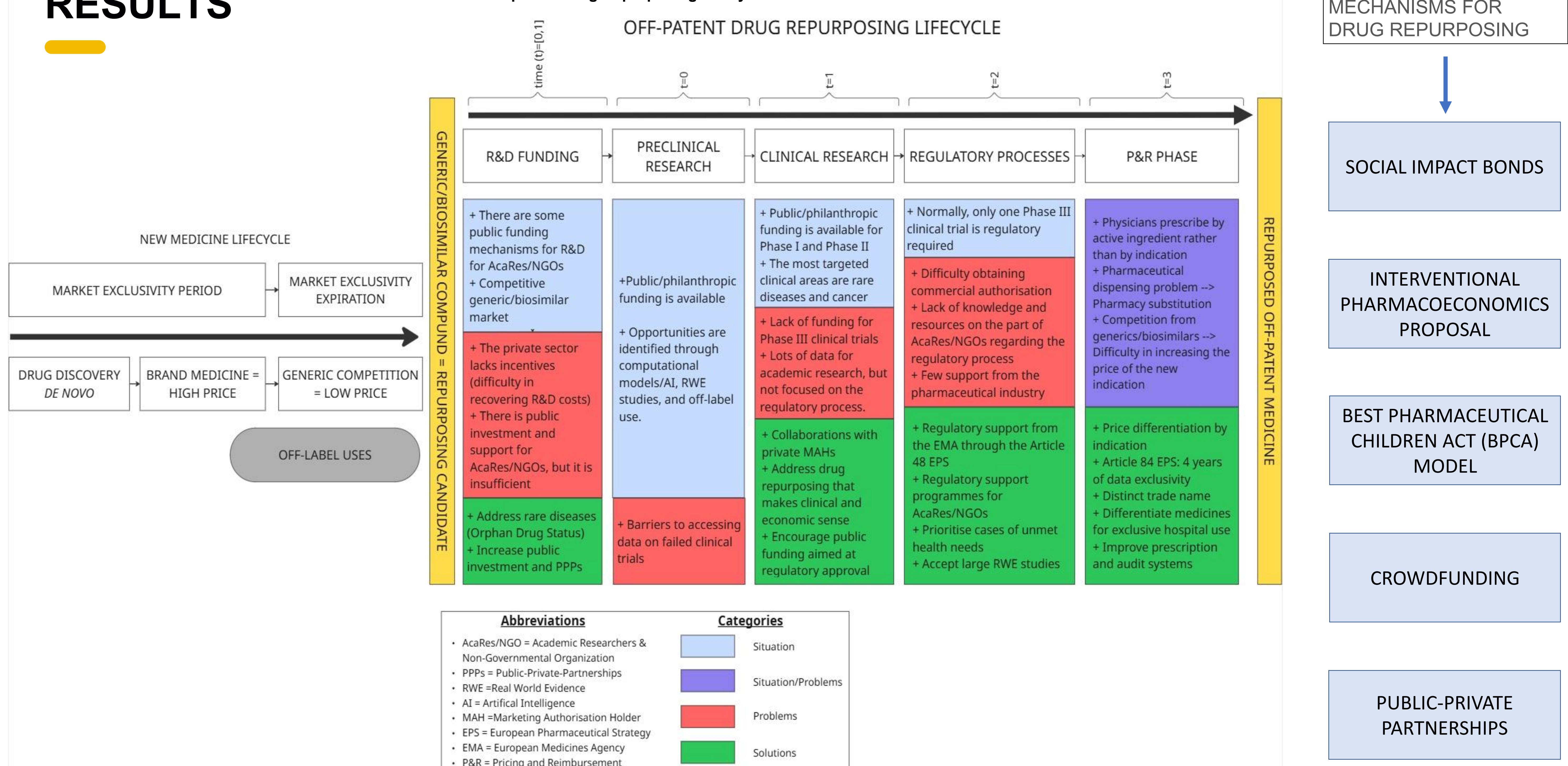
- Narrative literature review:** literature on regulatory solutions, pricing and reimbursement (P&R) solutions, government support for R&D and AcaRes/NGO research, and public intervention mechanisms for drug repurposing.
- Experts on drug repurposing interviews:** practical information on the next blocks around the drug repurposing lifecycle: Challenges, Research, R&D funding, Regulatory aspects, P&R phase and Role of public bodies

TABLE 1.
Profile of 25
experts
interviewed

Pharmaceutical industry
Academic Researcher
Health-related NGO
Hospital manager
Regulatory agency
Policymaker

RESULTS

FIGURE 1. Off-patent Drug Repurposing Lifecycle



CONCLUSIONS

Great financial and regulatory barriers in drug repurposing

Academic Researchers and NGO play a key role in drug repurposing R&D

VS
Governments are providing some solutions throughout the life cycle

Efforts are still insufficient

Structural challenges persist

KEY REFERENCES

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