A Reconstruction and Validation of the Rationale Underlying the European Commission's Proposal to Make Regulatory Data Protection (RDP) Conditional Upon Supply in EU Member States

HPR221

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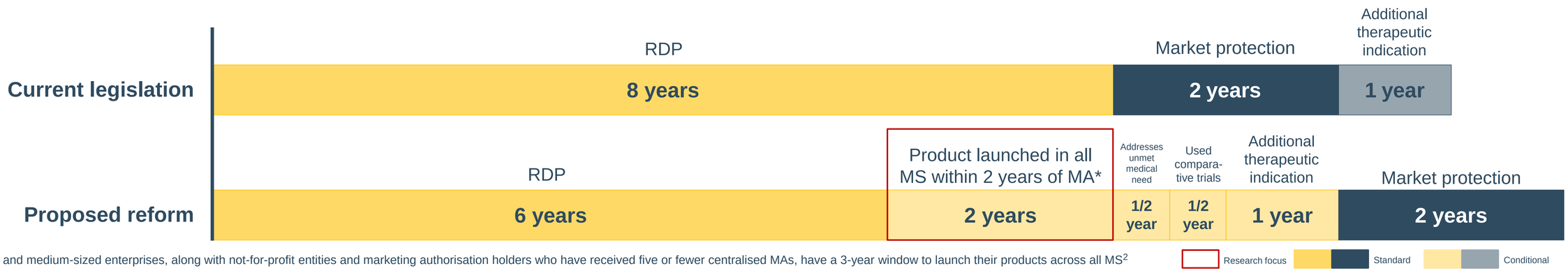
Introduction

In April 2023, the European Commission (EC) adopted a proposal for a new Directive and a new Regulation to replace the existing general pharmaceutical legislation, representing the first major revision in almost 20 years[1]. One of the measures outlined by the EC is the reduction of the standard period of Regulatory Data Protection (RDP) from 8 years to 6 years, with the possibility of obtaining additional periods of RDP contingent upon the fulfilment of specific criteria[2]. The most significant period of conditional RDP available is an extra 2 years of data protection if a medicinal product launches and is supplied in accordance with the needs of all Member States (MS) within 2 years of marketing authorisation (MA)[2].

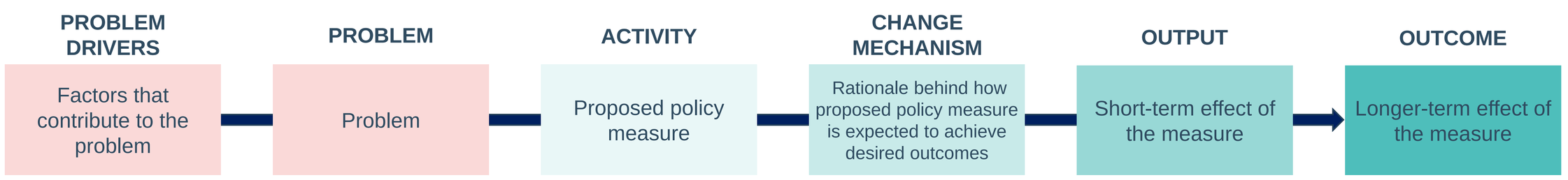
Whilst this measure has been introduced to increase and accelerate access to new medicines across the EU, industry associations have expressed concerns regarding the feasibility, the impact, and effectiveness of the proposed measure[3,4]. Nonetheless, the reform of the EU pharmaceutical legislation still needs to be considered by the EU Parliament and Council[1]. Thus, it is unclear whether the proposed changes to RDP will be adopted. The objective of this research is to use a Theory of Change (ToC) framework[5] (see Figure 2) to re-construct how the proposed measure is expected to lead to the desired outcome/change, and to identify the evidence-base that validates these assumptions.

Figure 1. Changes to regulatory data protection (RDP) and market protection according to the proposal submitted by the European Commission



*Small and medium-sized enterprises, along with not-for-profit entities and marketing authorisation holders who have received five or fewer centralised MAs, have a 3-year window to launch their products across all MS[2]

Figure 2. Adapted ToC framework used to reconstruct and validate the rationale behind the proposed measure



Methodology

Based on a review of EC documents, including the proposals for a new Regulation and Directive, and an impact assessment report, a ToC framework was constructed outlining the expected chain of events that are anticipated to lead to the desired outcome.

Secondary research was used to identify arguments and data that either validate or contradict the assumed chain of events.

Conclusion

More data is needed to confirm EC assumptions regarding the share of products (change mechanism) and manufacturers (output) that are affected as envisaged by the proposal.

Some assumptions regarding the outcome of the measure – including the projected increase in access to medicines across the EU and the expected public cost savings stemming from products that fail to comply with the measure – appear to be contradicted by currently available evidence.

Results

Seven key assumptions, underlying the rationale for the proposed change, were identified and mapped against the ToC

Component of the Theory of Change	#	Assumption[6]	Validation	Rationale
PROBLEM DRIVERS	1	Manufacturer launch and withdrawal decisions are key drivers of unequal access to medicines	**Validated (to an extent)**	✓ Initial results from the European Access Hurdles Portal identified that there is **not a single country where all products have been filed for reimbursement** and that the **percentage of products that have been filed for pricing and reimbursement (P&R) is higher in larger markets**[7]. This suggests that manufacturer launch decisions are driving unequal access. × The results from the European Access Hurdles Portal also suggest that low availability of medicines can be attributed to **delays between P&R filing and P&R decisions**[7]. This suggests that factors outside of a manufacturer's control are driving unequal access.
CHANGE MECHANISM	2	Not launching in all MS within 2 years of marketing authorisation will lead to an average 15% loss in a product's gross profit	**Validated (to an extent)**	✓ If a company fails to comply with the measure, it will **lose exclusivity during their two highest-revenue years** resulting in a significant lifetime profit loss[6]. × The 15% loss in gross profit was obtained from an average sales revenue-volume graph derived from a cohort of 36 drugs. This cohort contains very few biologics[6]; however, the biologics pipeline is growing and will likely make up a larger share of future products[6]. According to a pipeline review update published by EFPIA in 2021, **more than 50% of drugs in the pipeline are biologics**[8]. This could impact the average sales/volume model used to predict the economic impact of this measure, as the true proportion of biologics may be significantly larger in the future[6].
CHANGE MECHANISM	3	The proposed measure will only impact products which have regulatory protection as their last layer of protection. Within this group, the highest compliance (i.e., launching in all MS within 2 years of MA) is expected from manufactures of 'higher sales' drugs	**Insufficient data**	? This assumption will heavily depend on whether manufacturers can accurately predict their product's sales trajectory, i.e., to what extent can manufacturers predict whether their product will have high enough sales to justify the investment of launching in all MS within 2 years of MA? An article by McKinsey & Company reported that around two thirds of drug launches don't meet their prelaunch sales expectations for their first year on the market[9] ? Variability in the **proportion of drugs** that have **regulatory protection as their last layer of protection** has been observed across **different therapeutic areas and product types**[10]. This has not been explicitly considered by the EC.
OUTPUT	4	It is estimated that manufacturers of ~66% of drugs with regulatory protection as their last layer of protection will comply with this measure	**Insufficient data**	? It is unclear how the 66% compliance rate has been derived. × Considering some of the negative responses that the proposed measure has received from industry associations[3,4], one would expect less than **66% of impacted drugs to comply.**
OUTPUT	5	Not launching in all MS within 2 years means generic competition will start earlier	**Validated**	✓ MA applications for generics can **be submitted once the period of data exclusivity** of the **reference medicine** has **expired**[11].
OUTCOME	6	Compliance will lead to a 15% increase in the share of EU population with access to medicines	**Contradicted**	× This assumption is based on the 66% compliance rate (see assumption 4) and fails to consider other factors that could impact access to medicines (i.e., delays in P&R decision making process) (see assumption 1).
OUTCOME	7	Non-compliance from 'low-sales' drugs (with regulatory protection as last protection layer), will result in earlier generic competition, generating savings for the public	**Contradicted**	× Low-sales medicines are less likely to be contested by generic competition[6] and this has not been accounted for in computing the savings generated for the public.

References

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Abbreviations

EC: European Commission; EFPIA: European Federation of Pharmaceutical Industries and Associations; EU: European Union; MA: Marketing Authorisation; MS: Member State; P&R: Pricing and Reimbursement; RDP: Regulatory Data Protection; ToC: Theory of Change