VitalTransformation

The impact of health technology made simple

The EU General Pharmaceutical Legislation & Clawbacks

Calculated impacts – both designed and unintended

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The Executive Summary

European competitiveness in the innovative healthcare sector is facing increasing global challenges from both established competitors such as the United States, as well as emerging economies such as China. It is important for the future of the European Life Sciences sector to optimize policies to promote innovation, job growth, and access to new medicines for European patients.

Unfortunately, our study sees an accelerating decline in several European life science key performance indicators within the EU.

In particular, the combination of unsustainable "clawback" policies that require companies to pay back revenues resulting from arbitrary budget limits, as well as proposed reductions in IP protection undermining direct incentives for innovation upon which life sciences companies rely, threatens to accelerate an already negative trend which puts the European life sciences ecosystem at a disadvantage with the United States. Our study finds a profound decrease in revenues, the creation of fewer EU biotech companies, the movement of investment flows out of Europe, and the development of fewer EU innovated medicines.

Further, these policies will incentivise emerging global life sciences challengers such as China.

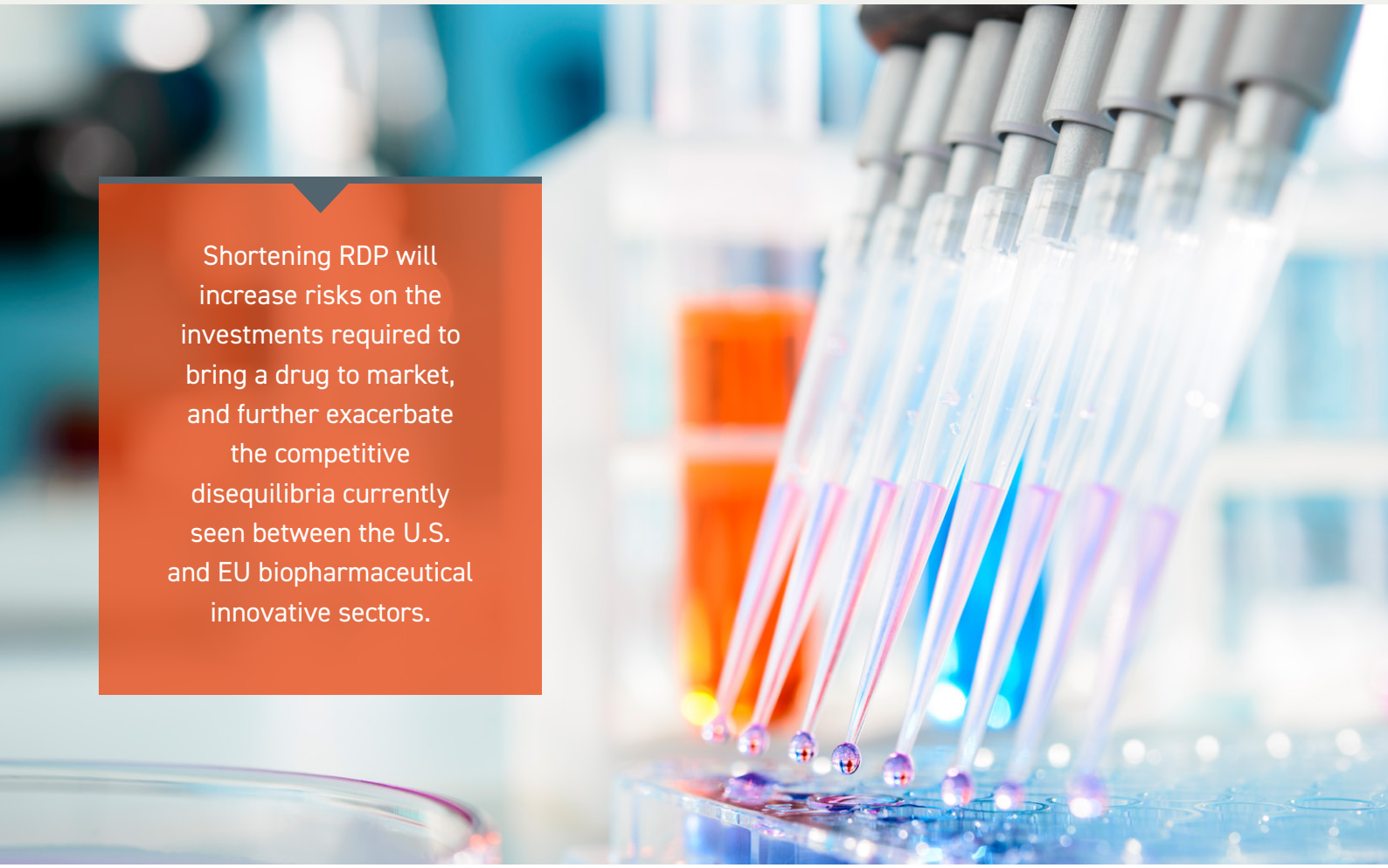
For example, the European Commission has proposed that the revised General Pharmaceutical Legislation will replace the current base of 10-years of regulatory data protection with a base of 8-years. The General Pharmaceutical Legislation then provides for a series of carrots and sticks to act as incentives for investors, innovators, and industry to 'improve' EU biopharmaceutical innovation, and gain back those lost years of regulatory data protection. As well, under some scenarios, innovators may have the ability to extend regulatory data protections to 12 years.

The challenge for investors and drug developers regarding the potential risks created by two years of lost regulatory data protection is that there is never a 100% certainty that patent protection alone will satisfy the length of time to develop a drug.

Shortening RDP will increase risks on the investments required to bring a drug to market, and further exacerbate the competitive disequilibria currently seen between the U.S. and EU biopharmaceutical innovative sectors.

Shortening regulatory data protections will leave investors unsure if they will be exposed to more regulatory changes and risks, after they have undertaken an investment which, at minimum, will take 10 years on average before the EMA grants a new drug's approval.

In relation to clawbacks, the situation is entirely unsustainable, where actual revenues would be eclipsed by the obligated pay back mechanisms if current trends remain unchanged.



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This study outlines the following core findings:

Impact of Reducing Regulatory Data Protection

- From our cohort of 25 EU invented drugs, we find that 2 will be directly impacted by 24 months of lost regulatory data protection (RDP), with a total fiscal impact of -€1.22 billion Euros ($1.3 billion USD).
- However, the European Commission has estimated that over 30% of all current EMA approved therapies will see revenues impacted by reducing RDP by 2 years; modelling our cohort to meet these criteria we find a 15% drop (-$64 billion) in total EU revenue in our 24-drug cohort, measured in constant 2013 $USD.

-15%

Drop in total EU revenue in our 24-drug cohort

Impact of Clawbacks

- The growth rate in member state clawbacks currently exceeds that of annual sales in our cohort by roughly 20% per year; assuming no changes in member state policies, total clawbacks will exceed our 24 drug cohort's sales revenues by the year 2033.

-20%

Member state clawbacks exceeds that of annual sales in our cohort

Cost of Proposed Measures Needed to "Regain" RDP

- Assuming every company in our cohort were to exercise the incentive to seek market access in all 27 EU member states to obtain a further two-years of RDP, we calculate a total NPV loss in our cohort of over $400 million USD.
- Assuming every company in our cohort were to exercise the opportunity to seek all available incentives to gain 12 years of RDP, we conservatively calculated a total NPV loss in our cohort of over $1.2 billion USD, we assume the actual results of this cost scenario will be substantially worse.

-$400m

Calculated total NPV loss in our cohort

Impacts of Proposed GPL Changes and Clawbacks on European Competitiveness

- The decline of European Life Sciences competitiveness began accelerating in 2018, driven at least in part by the global impact of US Corporate tax changes. Adding market uncertainty with changes to RDP will negatively impact the EU biopharmaceutical ecosystem and further accelerate its decline in relation to the US and other global competitors.
- The RDP reduction through proposed amendments to the GPL projects a decrease in EU biotechnology startup firms from 19 in 2024 to 4 in 2030. Subsequently, there is a drop in biotech investments from roughly $18 billion USD in 2024 to $14 billion USD in 2030. These projections elevate the EU's biopharmaceutical market ambiguity and incentivize investors to move capital outside of the EU where there is less risk and RDP is more favourable.
- Finally, the incentive measures needed to restore the lost years and/or provide additional regulatory data protection included in the General Pharmaceutical Legislation require significant financial and operational resource allocation, with a very uncertain result within 24 months of EMA's approval. This study calls into serious question their practicality in improving access for patients to needed new medicines in all 27 EU member states or in arresting the continued marked decline in global EU biopharmaceutical sector competitiveness.

-$4b

Drop in biotech investments by 2030

The full written report can be accessed here.

The opinions included in this work are those of Vital Transformation BVBA and are not necessarily those of the project's sponsors. The analysis was performed by Vital Transformation's Consulting Economist Dr. Harry Bowen, Project Director Gwen O'Loughlin, and CEO Duane Schulthess.

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The data used in this analysis can be accessed here.