VitalTransformation
The impact of health technology made simple

PRESS RELEASE

NEW STUDY FINDS THE EUROPEAN GENERAL PHARMACEUTICAL LEGISLATION WILL LEAD TO $4 BILLION FEWER BIOTECH INVESTMENTS, A GREATER THAN 50% REDUCTION IN BIOTECH START UPS

AT CURRENT GROWTH RATES, EU MEMBER STATE CLAWBACK PROGRAMS WILL EXCEED THE TOTAL SALES OF NEW MEDICINES BY 2033.

Read the research study here

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BRUSSELS, BE – The European Commission has stated that their proposed revisions to the General Pharmaceutical Legislation (GPL) will enhance the supply security to ensure medicines are available to patients throughout the EU and that it will incentivise biopharma investments by providing an attractive and innovation-friendly environment for the research, development, and production of medicines in Europe.

A new study from research firm Vital Transformation warns that if the GPL were implemented as it was initially proposed, particularly with the two-year reduction in regulatory data protection (RDP) intact, their results would cast serious doubts on the regulation's ability to improve access for patients to needed new medicines in all 27 EU member states nor arrest the continued marked decline in global EU biopharmaceutical sector competitiveness.

The study finds that rather than incentivise the EU biopharma ecosystem, the proposed legislation will likely have the exact opposite effect.

"While it is always a challenge to model the impact of an event that has not yet occurred, we do have overwhelming evidence of an enormous decline in EU competitiveness that began well before the pandemic. For example, we have seen a 78% decrease in EU biopharma startup firms over six years," said Vital Transformation CEO Duane Schulthess. *"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 time to develop a drug. Shortening RDP will increase risks on the investments required to bring a drug to market and exacerbate the current competitive disequilibria between the U.S. and EU innovative biopharma sectors."*

Nancy Travis (VP of international affairs for BIO) said: *"BIO's core mission is to not only support the development of life-saving medicines, but to ensure they are available for patients. This report shows that the proposed revisions to the General Pharmaceutical Legislation will not only negatively impact patient access in the short term, but will potentially harm the biotech pipeline affecting long-term access to these life-saving medicines."*

Key Findings of the Study:

The European Commission has estimated that over 30% of all current EMA-approved therapies will see revenues impacted by reducing RDP by two years; modelling the cohort to meet these criteria found a 15% drop (-$64 billion) in total EU revenue measured in constant 2013 $USD.

The growth rate in member state clawbacks currently exceeds annual sales by roughly 20% per year; assuming no changes in member state policies, total clawbacks will exceed sales revenues by 2033.

Assuming every company in the test cohort were to exercise the incentive to seek market access in all 27 EU member states to obtain a further two years of regulatory data protection (RDP), the study finds a total loss of over $400 million USD, calculated by the net present value of the investments.

In the instance it would be possible to exercise all the proposed available EU incentives to gain 12 years of RDP, the study conservatively finds a loss of over $1.2 billion USD in their cohort and states the losses would likely be far worse under this scenario as the finding is based on highly optimistic costs.

The decline of European Life Sciences competitiveness began its marked decline in 2018, before the COVID-19 pandemic, and was driven, at least in part, by the global impact of US Corporate tax changes.

The RDP reduction will likely lead to a drop in biotech investments from roughly $18 billion USD in 2024 to $14 billion USD in 2030.

The new study issued today by Vital Transformation analysed the European Commission's GPL proposal, including its incentives, to determine the regulation's likely outcomes and consequences, both by design and unintended. This VT report outlines the GPL in the context of the EU's goals of promoting world-class innovation and 'stable rules.' The study was executed by Vital Transformation's Consulting Economist Harry P. Bowen, Research Partner Gwen O'Loughlin, and CEO Duane Schulthess.

This project was made possible with the financial support of the Biotechnology Innovation Organization (BIO), AbbVie, and Amgen.

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About Vital Transformation

Vital Transformation understands the implications of new medical procedures, technologies, and policies. We measure their impact on current clinical practices in close collaboration with health care professionals, researchers, and regulators. Through our web platform, client network and Vital Health Podcast series, we can communicate our findings with international decision makers and stakeholders.

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