Global Campaign *for* Clinical Trials

The European Union's Revised Pharmaceutical Legislation:

Impact on Patients & Medical Innovation

The European Commission recently introduced an all-encompassing revisal of pharmaceutical laws, marking the first update to pharmaceutical legislation in almost 20 years.

The legislative package is intended to make medications more available, accessible and affordable. Nearly all aspects of healthcare in the European Union will be impacted. But while the proposal seeks to simplify Europe's healthcare systems, it could unintentionally undermine patient access to clinical trials and new treatments.

What does the European Commission's legislation include?

The legislation is a comprehensive update for the pharmaceutical industry across the European Union. It is made up of a directive, regulation and a Council recommendation. Together, these components focus on the availability, affordability and accessibility of medications.

What would the legislation do?

The legislation lays out reforms designed to improve patients' access to medicines. The proposed policies would:

Create a single market for medications throughout the European Union.

The Commission's proposal seeks to make medicines more accessible throughout the European Union. New incentives and penalties will encourage companies to make their medicines available in all EU countries. The proposal will also revise the European Union's legislation on medicines for children and rare diseases.

Minimise authorisation delays.

The proposal also attempts to speed up authorisation for innovative medicines by simplifying rules and procedures and by increasing patient involvement in the authorisation process. A directive from the proposal lays out the requirements for authorisation, monitoring, labelling and regulatory protection.

Tackle antimicrobial resistance.

The legislation recommends reducing antibiotics' use by 20% and will use incentives to push towards this goal. The proposal also presents strategies on the marketing, authorisation and surveillance of antimicrobials, as well as other recommendations to combat antimicrobial resistance globally.

These policies aim to enhance access, equity and affordability. Many stakeholders, however, are concerned about the consequences for clinical trials and patient access to new treatments.

What does the legislation propose for research, innovation and clinical trials?

The legislation outlines a pharmaceutical regulation framework that:

- Mitigates the environmental impact and improves the sustainability of medications
- Adjusts periods of market exclusivity and regulatory protection
- Streamlines the European Medicines Agency approval process
- Encourages development of treatments for rare conditions

While these policies appear on the surface to offer some benefits, they also introduce a number of uncertain consequences.

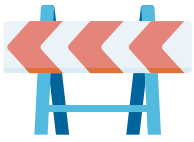
What uncertain consequences could the legislation introduce?

Diverting investment away from medical innovation.

The transition to a single market for medicines may prove financially unfeasible. Companies may determine that the increased costs of the transition are simply too high to justify introducing new medicines to Europe.

Weakening intellectual property protections.

The legislation proposes to shorten the regulatory protection period from eight years down to six. While additional months or years may be granted to manufacturers depending on the unmet needs of patient populations, shortening the patent protection period will limit companies' ability to recoup the significant costs of research and development.



Hindering clinical trials.

Clinical trials access in particular may suffer due to challenges introduced by the legislation. If companies cannot recoup investment in research and development in Europe, those that fund clinical studies may choose trial sites in North America and Asia instead. As a result, patients in Europe will have fewer opportunities to participate in clinical trials.

These consequences could significantly impact patient care and access to innovative medicines.

Conclusions

With this legislation up for review, policymakers now face the challenge of mitigating uncertain consequences. Protecting patient access to clinical trials and new treatments are interconnected priorities that must guide the European Union's policymakers moving forward.

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The Global Campaign for Clinical Trials is a project of the Global Alliance for Patient Access.

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