COLLECTIVE INTELLIGENCE

The EU's New Pharma Rules:

A Once-in-a-Generation Opportunity or a Missed Chance?

Agnes Brandt, Francesca Scassellati Sforzolini, Claire Alexander, Niels Guchelaar and Kelan Murphy
April 2024

Europe is updating its rules for how it regulates the pharmaceutical and life sciences industry – with far-reaching implications for its life sciences ecosystem. With the fine print to be negotiated over the coming months, companies still have time to make the case for innovation and ensure Europe doesn't miss out on a once-in-a-generation opportunity.

Are you ready for Europe's new pharma rules?

In the run-up to elections in June, Europe is getting ready to finalise new rules for pharmaceuticals. The aim is to increase access and affordability, improve resilience and foster innovation. But in a regulatory environment that is already perceived as burdensome by many in the industry, the proposals – which include curbs on the period of exclusivity for new medicines – have sparked fears that Europe could end up putting off investors and undermining competitiveness.

The coming months will be crucial to ensuring the final legislative text strikes the right chord for a European innovation ecosystem that must compete with the US and China – both of which have recently seen much faster growth in pharma R&D investment.

What's at stake

The EU's general pharmaceutical legislation and the rules covering orphan and paediatric medicinal products are the fundamental framework through which medicines reach the European market. In updating the framework, Brussels wants a future-proof and crisis-resistant medicines regulatory system that provides access to affordable medicines for patients, improves security of supply, adapts to new scientific and technological advances, encourages innovation and reduces red tape.

The new rules are designed to work hand-in-hand with other initiatives, including the recently announced Biotechnology Initiative, which declares biotech as one of 10 critical technologies, and promises better coordination and streamlined regulation to make Europe more competitive.

The stakes are high. While there is broad agreement that the current framework needs updating, there are real fears that the choices being made could deter investment and actually end up damaging the life sciences innovation ecosystem.

"It is difficult to understand how reducing incentives to research, develop and manufacture new medicines and vaccines could ever be in the best interest of Europe or European patients, particularly at a time when Europe recognises that it needs to boost competitiveness to compete for global investment with ambitious nations like the US and China." – Nathalie Moll, European Federation of Pharmaceutical Industries and Associations (EFPIA) Director General

"Today's plenary vote by the European Parliament on pharmaceutical reforms marks a significant stride forward for the 30 million Europeans living with rare diseases and their families. Against the backdrop of 94% of rare diseases still lacking a dedicated treatment, we welcome the genuine political will that has been demonstrated to improve treatment development and access." – Valentina Bottarelli, Public Affairs Director at EURORDIS – Rare Diseases Europe

What to expect

Almost a year after the first legislative proposals were put forward by the European Commission, the European Parliament this week held a milestone vote in favour of a common negotiating position on the 'pharma package'. After the European elections (6-9 June), the EU Member States are expected to agree on their position, which will then be negotiated in so-called trilogue negotiations between representatives of the European Parliament, Member States and the European Commission to come to the final legislative texts – with timing hard to predict at this stage. Once adopted, the rules will be binding and apply in all 27 EU Member States 18 months after entering into force.

Key changes proposed to the current framework include the tightening of the incentives system for medicines and orphan drugs, including by tying incentives to certain conditions such as meeting new definitions of unmet medical need and high unmet medical need.

One of the hottest topics in the debate has been the reduction of the regulatory data protection (RDP) period for medicines. While the Commission's original proposal was to reduce the baseline RDP period from eight years to six years, the Parliament compromised on a period of 7.5 years, following contentious discussions. Under the Parliament's position, RDP can be extended up to a maximum of 8.5 years if certain conditions are met; for instance, if the product meets an unmet medical need. Two years of market protection are also granted. Since it may be unclear early on whether a product will meet the criteria for an RDP extension, planning might become more difficult, increasing unpredictability.

Market exclusivity for orphan medicinal products (OMPs) has also been on the radar. The Parliament has kept the reduction of baseline exclusivity period at nine years (down from 10 currently), with the possibility to increase to 11 years for medicines addressing high unmet medical need, as defined in the legislation. Medicines that are awarded a new indication can also get an extra year of market exclusivity, with a maximum of two indications.

Other fiercely debated issues include how to best address medicines shortages and supply chain concerns, measures to tackle antimicrobial resistance (AMR) such as the introduction of transferable exclusivity vouchers (TEVs), regulatory sandboxes and the introduction of stricter environmental risk assessment (ERA) requirements for the pharma industry.

According to an impact assessment commissioned by EFPIA, the Commission's proposals to reduce incentives (i.e., reducing baseline RDP from eight to six years) would have resulted in the European share of global biopharmaceutical R&D spend falling to an estimated 21% in 2040, compared to 32% currently.

On the other side of the argument, according to the German Social Insurance European Representation (DSV), every year that generic competition is delayed costs the Statutory Health Insurance system in

Germany more than 1 billion euros. Across the EU, costs for each additional year of regulatory document protection amount to more than 3 billion euros.

What does this mean for business?

The policy landscape for the healthcare and life sciences sector is changing in Europe.

Healthcare is increasingly seen as a driver of global competitiveness in a complex geopolitical landscape. The revamp of Europe's pharma framework is only one way in which Europe seeks to boost its competitiveness, stimulate innovation and keep companies in Europe. But whether these new rules will achieve these goals – or miss the mark – is yet to be seen. While the proposed changes aim at boosting innovation in areas where it is most needed for patients, doubts remain as to what actual effect they will have on Europe's life sciences innovation ecosystem.

While it is difficult to predict when exactly the fine print of the proposed changes will be ready and enter into legislation, it is important for businesses affected by the new rules to continue to engage over the coming months and make their voices heard around what Europe's future frameworks for pharmaceuticals and biotechnologies should look like in order to truly incentivize innovation and to build a system that can compete with the US and China.

To continue the conversation

Dr. Agnes Brandt
Director, Brussels
abrandt@brunswickgroup.com

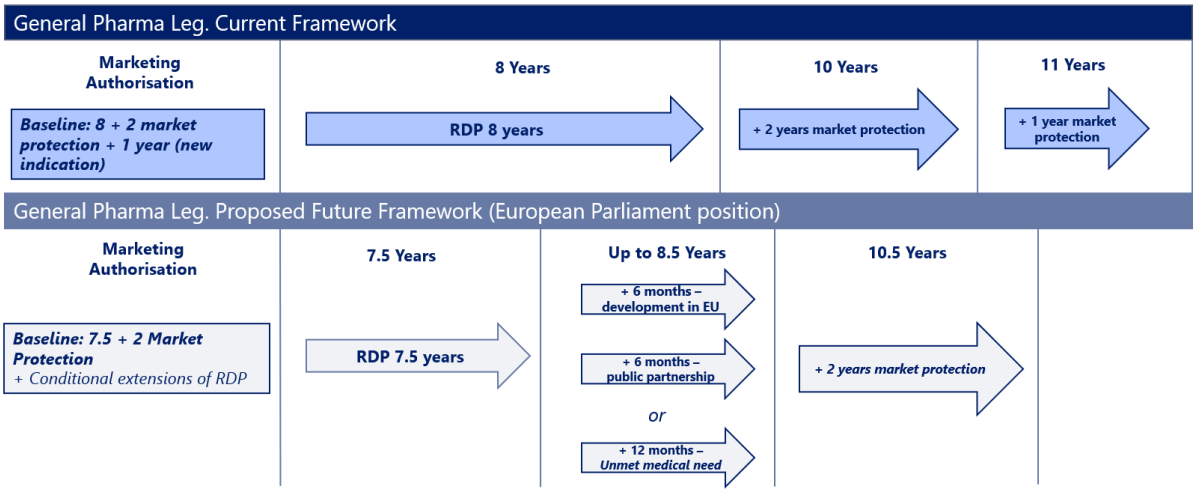
Agnes has extensive expertise in the EU policy and regulatory field. As an expert in health and climate policy, she has led a range of European and global public affairs programs for her clients spanning horizontal themes as well as disease-specific matters.

Francesca Scassellati Sforzolini Partner, Healthcare & Life Sciences Sector Group Lead, Europe
Fsforzolini@brunswickgroup.com

Francesca is a senior government relations and corporate affairs professional with deep knowledge of the Healthcare and Life Sciences sector and EU healthcare policy. She has spent more than 20 years designing and managing pan-European, multi-stakeholder strategies and leading public affairs and communications campaigns for global organisations.

Annex

A New Regulatory Data-Protection Timeline



The European Parliament's Position on the EU's New Pharma Rules: Key Changes

While the broad objectives of the European Commission's proposal published on 26 April 2023 appear to be shared by Members of the European Parliament, there are some fundamental differences between the current set of rules, the initial Commission proposal from April 2023 and Parliament's position.

Regulatory data protection (RDP)

The Commission originally proposed reducing the current baseline RDP period from 8 to 6 years, with the possibility to extend it to a maximum of 10 years subject to different conditions being met (including launching in all Member States within a set timeframe). The Parliament has compromised on a baseline RDP period of 7.5 years. Under the Parliament's position, RDP can be extended up to a maximum of 8.5 years if certain conditions are met, including: if the product meets an unmet medical need (+12 months), or if the applicant conducted comparative clinical trials to support the initial market authorization application (+6 months), and/or if a significant share of R&D took place in the EU and at least partly in collaboration with public entities (+6 months). Two years of market protection are also granted.

Market exclusivity for orphan medicinal products (OMPs)

The Commission had proposed 9 years of baseline market exclusivity for OMPs, which is one year down compared to 10 years in the current legislation. Under the Commission proposal, OMPs would have received one extra year (equaling 10 years) of market exclusivity if they addressed a high unmet medical need. The Parliament has kept the baseline period at 9 years, but increased market exclusivity to 11 years for those addressing high unmet medical need. Medicines which are awarded a new indication can also get an extra year of market exclusivity, with a maximum of two indications.

The Parliament has also gone further on rare diseases by tabling a "**European Framework for Rare Diseases**" to be proposed by the Commission within 24 months of the entry into force of the regulation. The aim of this Framework would be to bridge relevant legislation, policies and programmes, and support national strategies with a view to better meeting the unmet needs of people living with rare diseases and

their carers. The Framework should be developed in consultation with Member States, patient organisations, and other stakeholders where relevant.

Defining Unmet and High Unmet Medical Need (UMN & HUMN)

The Commission's proposal introduces new definitions for Unmet Medical Need (UMN) and High Unmet Medical Need (HUMN) to incentivize innovation for rare disease medications, and other areas where development is lacking. The Parliament has kept these definitions in its position, with the same wording proposed by the Commission. The Parliament also includes that the concept of morbidity in the definition of 'unmet medical need' should encompass a multiplicity of factors, including quality of life of patients, a high burden of disease and treatment and the inability to perform daily life activities.

Addressing inequality through a new market launch mechanism

The Parliament has abandoned the contentious Commission proposal to provide 2 additional years of RDP to companies which launch in every Member State within 2 years. Instead, the Parliament proposes a new system which empowers Member States to request drugmakers to file for reimbursement within their country within 1 year of EMA approval, or 2 years for SMEs, not-for-profits or those with 5 or less central marketing authorisations. It also proposes a "conciliation mechanism" which emboldens the Commission to decide on disputes (based on the expert opinion of the European Medicines Agency) between companies and states in the pricing and reimbursement filing process.

Transferable Exclusivity Vouchers (TEVs) and tackling Antimicrobial Resistance

AMR has recently been recognised as a crisis in the making, and there is no mention of it in the existing pharmaceutical legislation. Though a sticking point in the negotiations, the Parliament's proposal has kept the Commission's proposed introduction of new Transferable Exclusivity Vouchers (TEVs), with slight amendments. The additional year of market exclusivity will only be given to developers which create antimicrobials that are considered "critical" based on the WHO's priority pathogen list, within 9 months and 6 months respectively for those considered "high" and "medium" priorities. Aside from other requirements such as developing "global access plans" and ensuring manufacturing capacity, the Parliament also proposes the creation of a subscription-based joint procurement model that both Member States and the Commission can sign up to, based on the current Swedish model.

Regulatory Sandboxes

Regulatory Sandboxes are a key learning from Europe's flexible regulatory approach taken with the COVID-19 vaccine. The Parliament has maintained the Commission's proposal for the introduction of so-called regulatory sandboxes for the temporary approval of new technologies when the existing regulatory framework is not appropriately adapted. The only difference is that the Parliament wishes to mandate the Commission to issue a report every 5 years on the application of adapted frameworks.

Compulsory licensing

A competent authority can grant a compulsory license (CL) to a party other than the intellectual property rights holder in times of a crisis. Currently, this is done at the national level. The Commission proposed that market and data protection should be suspended when a CL has been granted to tackle a public health emergency, as far as the CL requires and for the duration period of the compulsory license. The Parliament tightens this by changing the wording of granted "to tackle a public health emergency" to "under conditions laid down in Union law and in compliance with international agreements". In addition, Parliament adds that data and market protection should only be suspended in the Member State(s) where the CL has been granted, and that the marketing authorisation holder for the medicinal product for which a CL has been granted shall be informed of the decision without delay. Note that there is currently a

separate legislative process ongoing for CL to create an EU level compulsory licensing framework to address EU crises.

Addressing environmental concerns

Since 2006, a prospective Environmental Risk Assessment (ERA) is required for new medicinal products submitted for market authorisation. The Commission's proposal expanded the current scope to require drugmakers to evaluate the environmental impact of use and disposal of the medicinal product. The Commission's proposal also introduced the requirement of proposed risk minimisation measures and gave the EMA the authority to refuse approval on ERA grounds. The Parliament has now expanded the ERA requirements proposed by the Commission further to require producers to conduct a risk assessment for the entire lifecycle, including manufacturing, and propose risk minimisation and mitigation strategies.

Health Emergency Response Authority (HERA)

HERA was officially established in 2021 as a response to the COVID-19-pandemic, aiming to enable the EU to be ready for future pandemics and cross-border health emergencies. The Parliament adds an article in which it proposes that HERA, currently a standalone department within the Commission, become a "separate structure" within the framework of the European Centre for Disease Control (ECDC). In addition, Parliament proposes adding representatives to the authority's board: one from each Member State, two of the Commission and two of the European Parliament.