GPL key messages: RDP

EU Competitiveness and Regulatory Data Protection

Proposals to leverage regulatory data protection (RDP) as a means to tackle uneven access to new medicines across EU member states have proved one of the most divisive issues in the EU General Pharmaceutical Legislation (GPL). For Novartis, a leading European pharmaceutical company, it is clear, that a reduction of RDP would diminish European competitiveness without any guarantee of improved access.

Indeed, ensuring better health outcomes and access to medicines across the EU is an important goal and one that Novartis completely supports. In reality, however, avenues for EU intervention on access are narrow because the Commission's treaty-enshrined competencies do not include the pricing and reimbursement of medicines. Responsibility for access decision-making lies with member states.

To complicate matters for health policymakers, in the current geopolitical climate European competitiveness cannot be neglected. European resilience, supply chain security, and economic prosperity featured heavily in key political platforms of summer 2024 – the publication of the EU Council's Strategic Agenda and Ursula Von Der Leyen's speech to the European Parliament. Mario Draghi's report on the Future of EU Competitiveness further emphasizes the message.

Given the impressive contribution of the pharmaceutical sector to Europe's economy, a competitive lens is essential. It is an industry that, in Europe, employs 900,000 people, generates a trade surplus of €200 billion (far ahead of other high-tech sectors), and invested €50 billion in R&D in 2023[i]. That is before even mentioning the considerable impact on the lives of European patients – for example, Hepatitis-C treatments that cure 95% of patients, a 37% drop in the cardiovascular death rate, an 80% reduction in HIV-related deaths, and the possibility to prevent 12,000 cancer deaths annually by offering HPV vaccinations.[ii]

Modulation of regulatory data protection – the Commission's proposal

RDP is effectively intellectual property. It incentivizes ongoing research on molecules, particularly those which are more advanced in their patent life, by offering a period of market protection which is independent of the patent. Though it often runs concurrently to the patent, for around one third of medicines RDP is the last form of protection to expire[iii].

The text published by the Commission in April 2023 proposes a two-year reduction of the RDP baseline from 8+2 (eight years of data protection, followed by two years of market protection) to 6+2. As an access 'incentive', it offers a theoretical opportunity to regain the lost years if a product is 'launched and continuously supplied' (put differently, if it gains reimbursement) in all 27 EU countries. This would need to be confirmed by every country, within two years of marketing authorization. Two additional, and difficult to achieve, RDP incentives were also included – six months for meeting unmet medical need or running comparative trial.

Bearing in mind the need to preserve or increase EU competitiveness, the text was presented as a win-win. Either – option one – the access conditionality is achieved, improving conditions for patients in countries with lower and slower access while maintaining or even slightly extending the RDP that innovative industry relies upon. Or – option two – the access conditionality is not achieved, and the shortened RDP duration saves money for payers while offering earlier market entry for the generics industry.

The reality, however – now broadly acknowledged – is that the access conditionality cannot be met. Or at least, not with any degree of predictability. And incentives without predictability have little value. Not only do current Member State practices and procedures make EU-wide reimbursement unachievable in a two-year timeframe, but the appeal of earlier generic entry – especially for member states with strong generic industries – actively reduces the likelihood of success of option one.

Handing every one of the 27 member states an effective veto on the duration of RDP defeats the incentive proposal from the outset. In reality, research-based companies, like Novartis, would plan investments based on an assumption of 6+2 years of RDP, influencing decisions about what they research and where. European life science competitiveness would be sacrificed in favour of an illusory (and at best short term) boost for the generic sector. Crucially, the proposal will not achieve better overall access for European patients.

The Parliamentary proposal

In the EU Parliament's draft, formalized in April 2024, the effort to balance life science competitiveness with access equality is both clearer and more realistic. Recognizing the role of member states in reimbursement decision-making, the Parliament's text replaces the Commission's access-RDP linkage with a standalone article proposing that medicine developers be required to submit pricing and reimbursement dossiers at

member state request. This addresses the complaint that companies don't submit timely dossiers in all EU countries, though without guarantee of more uniform access outcomes.

On RDP, the Parliament proposes a baseline reduction to 7.5+2, and offers in exchange for the lost six months some more pragmatic, though still difficult to achieve, RDP incentive periods – one year for unmet medical need, and six months each for comparative trials or conducting R&D in the EU. It caps the maximum RDP duration at 11.5 years, six months above the current maximum, though it is unlikely that many (or any) medicines would be able to meet sufficient conditions to even come close.

The Council weighs the options

The ongoing Council deliberations – under the stewardship of the Belgian and Hungarian EU Presidencies in 2024, passing to Poland in Jan 2025 – have seen a proliferation of proposals on ways to reduce and/or leverage RDP, many unrelated to access objectives. Using RDP to incentivize clinical trials, is one example – a comprehensible goal, but one that would be best addressed by a revision of the EU Clinical Trials Regulation.

Various, more or less onerous, versions of the Parliament's proposal on an obligation to file for pricing and reimbursement are also under discussion. For countries with hugely varying health systems, different ambitions for life sciences, and diverse industrial footprints – with some adopting a binary narrative of innovative vs generics – the challenges of alignment are clear. All of which is made more difficult by the inherent limitations of the GPL as a tool to improve access in Europe.

Build competitiveness, support access – Novartis call to action for policymakers

Retain the current eight-year period of RDP. RDP is a critical investment consideration. Reducing it would hasten the decline in Europe's competitiveness. The US offers stronger protection against patient infringements, speed of access, smoother reimbursement processes and longer RDP for biologic medicines. The EU's RDP is a rare point in its favour, at least for small molecules. The R&D investment gap between the US and the EU has already grown from approximately €2 billion in 2000 to approximately €25 billion in 2022.[iv]

De-link access objectives from RDP. Additional RDP is not an incentive if the conditions cannot be met. Companies will not, therefore, adapt their access approaches, but will instead adapt their R&D decision-making, likely leading to the loss of 50 potential new medicines over the next 15 years.[v] Patients in the lower access countries will not get faster access to new medicines and innovation will be foregone for all patients.

Choose achievable access provisions in the GPL. While not ideal, the Parliament's proposal on an obligation to file for reimbursement at member state request is currently the most balanced option on the table. Meaningful access outcomes demand dedicated policies which are beyond the GPL's scope.

Support a strong value chain. Generics build on the foundations laid by research-based companies, relying on both the data generated from research and clinical trials and on the markets established by innovative companies. The innovative sector relies on generics to provide headroom in healthcare budgets for investment in new medicines. Positioning one against the other can only harm the value chain and overall availability of medicines for European patients. It is possible, and desirable, to support a strong generic supply chain in Europe without reducing the EU's appeal as a destination for research, clinical trials and advanced manufacturing.

Apply a cross-directorate competitiveness lens. If the Commission and Council's competitiveness vision is to succeed for life sciences, it will be crucial to consider the big picture of policies and legislations which apply to the sector. For example, beyond the GPL, implementing a European Health Data Space that achieves its big data promise while ensuring appropriate confidentiality, and delivering a proportionate and fair implementation of the Urban Waste Water Treatment Directive to protect medicines availability.

Build a policy environment that brings innovation to European patients. Between 2019-2022, 38 new medicines which gained approval in the U.S. were either not submitted for, or were not successful in obtaining, marketing authorization, in the EU. More than half of these target neurology and cancer and nearly half were designated by the FDA as First-in-Class.[vi] Encouragingly, there are clear opportunities to rebalance this trend and restore European life science competitiveness. The GPL could deliver a modern world-beating regulatory system and competitive protections for innovation. The EU HTA Regulation could remove duplication in clinical assessments. A review of the Clinical Trials Regulation could boost trials in Europe. Access could be improved by a commitment to invest in health. We urge policymakers to seize these opportunities.

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[i] "The Pharmaceutical Industry in Figures", EFPIA.

[ii] https://www.efpia.eu/about-medicines/use-of-medicines/value-of-medicines/ and https://www.efpia.eu/media/676701/efpia-power-of-innovation.pdf

[iii] Protection Expiry and Journey into the Market - IQVIA

[iv] "The Pharmaceutical Industry in Figures", EFPIA.

[v] "Revision of the General Pharmaceutical Legislation: Impact Assessment of European Commission and EFPIA Proposals," Dolon, 2023.

[vi] Assessing availability of new drugs in Europe, Japan and the US, IQVIA data on file