ECL and EFPN call on EU member states to increase access to medicines and their affordability through reduced regulatory data protection to 6 years and modulated incentives as proposed by the European Commission

11 September 2024

The ongoing revision of European pharmaceutical legislation presents an opportunity to address existing imbalances within the market and improve availability and timely access to safe, effective, and affordable medicines for all patients in need.

The proposed **reduction of the basic regulatory data protection (RDP) period from 8 to 6 years**, coupled with a **modulated system of incentives**, **strikes the right balance** between incentivising the development of novel treatments in the areas where they are most needed and their broad access across Europe while ensuring the sustainability of health systems.

Improving affordability and access while fostering innovation

Reducing the RDP period will allow for earlier entry of generics and biosimilars into the market. These products offer substantial savings with the same patient outcome - generics provide an average of 80%[1] cost savings, and biosimilars offer approximately 20%[2] compared to their originator products. Estimates suggest that European health systems would **save approximately €1.13 billion annually**[3], due to earlier generic competition. This competition will relieve pressure on national health systems, which are increasingly strained by the rising costs of innovative medicines and will allow to reinvest in other critical areas of healthcare.

In addition, the reduction of the basic RDP period should not have a detrimental effect on the European pharmaceutical sector's ability to innovate, as the proposed system compensates by providing additional incentives, such as extended protection for products addressing unmet medical needs (UMN) and for conducting comparative clinical trials. This ensures that innovation, particularly in high-need areas, is still adequately rewarded, which supports continued investment in research and development. However, the total regulatory protection period should never exceed the current maximum of 11 years. In addition, the incentives for UMN should be targeted effectively, and we therefore call for a creation of a clear and consistent EU-wide definition of UMN that both regulators and pharmaceutical companies can use.

Furthermore, the modulated system of incentives rewards originator companies for placing their products on all EU markets within two years of approval by offering an additional two years of data protection. This measure is particularly impactful in smaller and less economically attractive markets, where access to new medicines has traditionally been limited. The incentives would create a win-win scenario: if companies comply, access is expanded; if they do not, generics can enter the market sooner, leading to improved affordability.

[1] Mestre-Ferrandiz, J., Towse, A. & Berdud, M. Biosimilars: How Can Payers Get Long-Term Savings? PharmacoEconomics 34, 609–616 (2016).
[2] https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars#/
[3] Impact assessment report accompanying the revision of the general pharmaceutical legislation SWD (2023) 192 final.

Mitigating concerns about competitiveness

While concerns have been raised that reducing the data protection period might affect pharmaceutical companies' profits and weaken their competitive position, data suggests otherwise. In comparison with other major economies, such as Canada, Switzerland, USA, Israel, China or Japan, the EU ranks high on the generosity of RDP periods[4]. Only around one-third of new medicines rely on regulatory protection as their final layer of market defence[5]. Additionally, many new medicines benefit from supplementary protections such as supplementary protection certificates (SPCs) and patents, which extend their exclusivity beyond the regulatory data protection period. These additional protections often enable companies to maintain market exclusivity for up to 14-16 years, especially for high-revenue biological products.

Even under the reduced protection period, developers stand to gain through the broader market access facilitated by these changes. Moreover, the expansion of the Bolar provision will further ease the entry of generics, lowering the overall cost burden on health systems and enhancing competitiveness for both generics and originators[6].

Conclusion

The reduction of the data protection period from 8 to 6 years, paired with modulated incentives, strikes a fair balance between encouraging pharmaceutical innovation and improving access and affordability for patients across Europe. By accelerating the entry of generic medicines and incentivising broad market access, this approach delivers significant cost savings for health systems and ensures continued investment in critical medical innovation. With appropriate protections for high-need areas and well-designed incentives, the European pharmaceutical industry can maintain its global competitiveness while addressing the healthcare needs of its population.

About the Association of European Cancer Leagues (ECL)

The Association of European Cancer Leagues (ECL) is a non-profit, pan-European umbrella organisation connecting 33 national and regional cancer societies in 27 European countries. ECL's Access to Medicines Task Force (A2M TF) aims to make safe and effective medicines available to all cancer patients in Europe by insisting on accessibility, availability, affordability, and increased transparency related to medicine prices, which will make healthcare systems more sustainable.

About the European Fair Pricing Network (EFPN)

In November 2020, ten European cancer societies launched the European Fair Pricing Network (EFPN) – the first-ever EU-wide collaborative network to improve transparency, access, and affordability of cancer medicines for the benefit of cancer patients. EFPN has invested €1 million to team up with the Netherlands Cancer Institute (NKI) and the Organisation of European Cancer Institutes (OECI) to shed light on medicine pricing and translate findings into evidence-based policy for national and European decision-makers.

[4] Impact assessment report accompanying the revision of the general pharmaceutical legislation SWD (2023) 192 final.
[5] Impact assessment report accompanying the revision of the general pharmaceutical legislation SWD (2023) 192 final.
[6] Impact assessment report accompanying the revision of the general pharmaceutical legislation SWD (2023) 192 final.