Call on EU Member States to keep the regulatory data protection period at 6 years and to provide further incentives for truly better and accessible medicines

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The ongoing revision of the European pharmaceutical legislation is a long-awaited opportunity to make the pharmaceutical system patient-centred and fit for purpose by addressing unmet medical needs and ensuring availability and timely access to safe, effective, and affordable medicines for all patients in need.

As Member States start to negotiate on the regulatory data protection periods in Article 81 of the proposed pharmaceutical Directive, we call on them to **support compromise text suggested by the Belgian Presidency of the Council of the EU**, as reported in media, which is in line with the European Commission's proposal.

The redesign of the regulatory protection system from 'one size fits all' to a modulated one addresses the issue of unmet medical need and promotes development of **better medicines** by incentivising use of comparative clinical trials or rewarding drugs that have additional therapeutic indications. Moreover, it **improves unequal patient access** to treatments across the EU by incentivising the EU-wide market launch of innovative medicines. Finally, the basic **regulatory data protection period of 6 years** would allow cheaper generic and biosimilar medicinal products to enter the market faster and therefore **substantially improve affordability**.

According to a recent study[1], which analysed EMA approved oncology drugs during the period of 1995 – 2020, **41%** had a negative or non-quantifiable added benefit. Moreover, median time to offset median R&D costs is **three years**, and 91% drugs recovered these costs within eight years. As most oncology medicines recover R&D costs within a few years despite providing little added benefit, the policymakers need to promote development of the most effective ones for patients with the greatest needs and equitable access across Europe.

About the Association of European Cancer Leagues (ECL)

The Association of European Cancer Leagues (ECL) is a non-profit, pan-European umbrella organisation connecting 32 national and regional cancer societies in 27 European countries. ECL's Access to Medicines Task Force 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 and the Organisation of European Cancer Institutes to shed light on medicine pricing and translate findings into evidence-based policy for national and European decision-makers.

[1] Brinkhuis et al. BMJ 2024; 384:e077391