Patients should benefit from greater access under new patent package proposals

Brussels, 27 April 2023

The proposal for a patent package should reduce fragmentation and ensure timely competition and more equitable access to medicines especially in emergencies.

An EU-wide compulsory licensing system will be a last resort measure for major crises. While Medicines for Europe believes that voluntary licensing agreements are relevant for health crises, we will contribute constructively to the EU-wide compulsory licensing system. As foreseen in art. 31(k) of the TRIPS Agreement*, compulsory licencing should also be a remedy for anti-competitive abuses of the patent system.

The Unitary Supplementary Protection Certificate (SPC) and the centralised system for granting national SPCs could reduce legal fragmentation in the Internal Market if certain safeguards are in the law, but they will also increase the geographical scope of SPC protection, which only cover 20 out of 27 Member States on average today.

To ensure timely competition and to prevent misuses of the system, the legislation should ensure:

- The highest quality and transparency in examination procedures.
- Timely and effective mechanisms for scrutiny of SPC applications.
- Real accountability of the granting body to EU institutions.

Commenting on the launch of the patent package, Medicines for Europe Director General Adrian van den Hoven said *"The proposal for a reform in the SPC system has the potential to reduce fragmentation in Europe but the legislation must ensure improved quality and transparency of granting procedures to prevent misuse by right holders to delay competition. Medicines for Europe is ready to work constructively to ensure that the right safeguards, transparency and due process are included for timely patient access to medicines".*

Resource hub

*TRIPS Art. 31 (k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

The documents published by the European Commission relating to proposals for a Unitary Supplementary Certificate, and Compulsory licencing for medicines are available at https://single-market-economy.ec.europa.eu/publications_en

Medicines for Europe

Medicines for Europe represents the generic, biosimilar and value-added medicines industries across Europe. Its vision is to provide sustainable access to high quality medicines, based on 5 important pillars: patients, quality, value, sustainability and partnership. Its members directly employ 190,000 people at over 400 manufacturing and 126 R&D sites in Europe and invest up to 17% of their turnover in R&D investment. Medicines for Europe member companies across Europe are both increasing access to medicines and driving improved health outcomes. They play a key role in creating sustainable European healthcare systems by continuing to provide high quality, effective generic medicines, whilst also innovating to create new biosimilar medicines and bringing to market value added medicines, which deliver better health outcomes, greater efficiency and/or improved safety in the hospital setting for patients. For more information, please follow us at www.medicinesforeurope.com and on Twitter @medicinesforEU.