Reformed SPC regulation would enhance timely access to essential medicines

Brussels, 24 October 2023

The first drafts of the European Parliament position on the proposals for Unitary SPC and SPC Regulation recast proposed by the Rapporteur Tiemo Wölken and published last week by the European Parliament are a step in the right direction for access to medicines across Europe.

The report focuses on the necessary transparency and quality of examination procedures for the grant of Unitary or national SPCs. As the SPC will extend monopolies on blockbuster drugs for up to 5 years with healthcare budget and access to medicines impacts for all Member States, safeguards are needed to prevent any misuse of the system.

The quality of SPCs will be an important part the new system under the EUIPO. The report rightly identifies the necessary safeguards for scrutiny of the SPC application before the granting of an SPC. This will prevent invalid (non-innovative) SPCs from delaying access to generic and biosimilar medicines, as experienced recently for HIV and other essential medicines.

Critically, the SPC expiry dates in the register should not be misused to implement unlawful and anti-competitive patent linkage strategies to delay generic and biosimilar medicines in Member States.

Commenting on the report, Adrian van den Hoven, Director General of Medicines for Europe said "*The report goes in the right direction and rightfully bans patent linkage. This will serve access to medicines by preventing pricing and reimbursement or tender procedure delays for generic and biosimilar medicines" said Adrian van den Hoven, Director General of Medicines for Europe. Medicines for Europe is ready to continue its constructive cooperation with the EU institutions to ensure the most efficient, quality, and fair possible SPC system of the future."*

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.