

Press Release

Medicines for Europe Statement on Unitary SPC Legislative Process

Brussels, 19 November 2024

In consideration of the ongoing negotiations taking place in the Council of the EU on the European Commission's proposals for a Unitary Supplementary Protection Certificate (SPC) regulation and the recast of the SPC regulation, Medicines for Europe would like to stress its strong support for a positive development of the discussions on these important files.

We support the European Commission's effort to continue the work on this file regularly and believe it is key that Member States rapidly reach a consensus on a general approach of the Council, advancing the legislative process in the interest of legal certainty and quality of the SPC system.

In this regard, while the role of national patent offices is clearly going to be prominent in the examination of future SPC applications, Medicines for Europe underlines the importance of shaping a system in which the granting body be fully transparent, efficient and accountable to EU institutions and affected stakeholders, with regular reviews and reports on its work.

Moreover, a quality SPC system cannot exclude a pre-grant opposition mechanism, as carefully calibrated by the European Commission in its proposals. Through a pre-grant opposition mechanism, third parties could oppose a panel's examination opinion before any (non-innovative) SPC protection is granted and enforced via unnecessary litigation and ultimately invalidated in Court with distortions of competition, as experienced recently (see [here](#)). As stressed in the proposal, this would be done by providing justified reasons and new evidence, which could therefore also be submitted to the same examination panel, making the procedure smoother. The Commission's proposal to foresee a pre-grant opposition mechanism is strongly supported by the European Parliament and is essential to ensure immediate SPCs' scrutiny and the highest quality of the SPCs ultimately granted.

Medicines for Europe confirms its strong and constructive support to finding a good solution for a future bullet-proof and quality SPC system.

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. 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 LinkedIn and X @medicinesforEU.