

## The SPC Framework Recast and Unitary SPC in 2025

### Principles for an Effective SPC in the EU



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### Progress on the SPC Legislation

The ongoing reform of the Supplementary Protection Certificate (SPC) framework — including both the recast of national SPC grant procedures as well as the creation of a Unitary SPC (uSPC) — provides Europe with an opportunity to increase its competitiveness and attractiveness to pharmaceutical investment via efficient, harmonised, predictable, and enforceable intellectual property rights.

As the primary organisation representing the research-based pharmaceutical industry in Europe, the European Federation of Pharmaceutical Industries and Associations (EFPIA) has long advocated for the introduction of a unitary Supplementary Protection Certificate (uSPC) for medicines. Its introduction would fill a critical gap in fully realizing the benefits of the Unitary Patent (UP) and the Unitary Patent Court (UPC). In tandem, the recast proposal can lead to gains in efficiency and harmonisation by centralising both routes to SPC, both Unitary and non-Unitary.

EFPIA is, however, concerned about the legal and practical challenges facing advancement of the SPC package. Thus far, progress on the file toward a viable, effective solution has been limited. At a time when competitiveness and regulatory simplification are strategic priorities, we strongly encourage the European Commission and Member States to advance discussions and explore all viable institutional options that could best achieve these key policy objectives. In this regard, we acknowledge the recent efforts of the Danish Presidency of the Council to put forward new proposals and generate additional momentum for negotiations on the critical elements of the system.

EFPIA members stand ready to contribute to this process and are hopeful that progress can be made balancing speed with the quality and effectiveness of the SPC framework, supporting the competitiveness and harmonisation of the EU IP system and ultimately, patients' health.

### Principles for an Effective and Competitive SPC Framework

While the ultimate arrangement of institutional competence and responsibility could take multiple forms, EFPIA strongly believes that a well-functioning SPC framework should be built upon the following key principles:

**(1) A single, centralized examining body (CEB) with the necessary technical expertise to ensure EU-wide harmonisation in procedures and outcomes.** This body should oversee applications for both uSPCs and national SPCs through a centralized procedure.

Ideally, a CEB would primarily operate as a virtual office, gathering experienced examiners from relevant national patent offices (NPO) currently engaged in substantively examining SPC applications. As such, the specific institution in which the CEB administration and examination would ultimately sit is less relevant than the process and expertise of the examiners that comprise it.

**(2) A unified, competent, and efficient forum for handling invalidity requests and appeals against refusals for uSPCs.** For consistency, this forum should be the Unitary Patent Court (UPC)—with the ability to refer cases to the Court of Justice of the European Union (CJEU) when necessary. This would ensure that legal questions would be handled by a forum with the requisite expertise, a sufficient scope of review, and adequate timelines for specialized intellectual property matters such as SPCs. At the same time, this would also avoid legal uncertainty stemming from potentially divergent decisions of different jurisdictions on related matters (e.g. UPC, national courts, General Court of the EU). These considerations should also help determine which body grants uSPCs in the first place.

**(3) Efficient, timely, and uniform proceedings for both unitary and national SPCs, ensuring predictability and reducing administrative complexity.** In this vein, EFPIA specifically believes that a pre-grant opposition procedure is unnecessary, as it would add undue complexity and weaken the system without addressing any identified substantive need. It is critical to bear in mind that, currently, less than 1% of granted SPCs ever face a revocation action; this number would only go down under a centralized, effective examination procedure leveraging experienced examiners from engaged NPOs.

**(4) To maximize harmonization, coherence, and legal certainty, the uSPC system and the national procedure (SPC recast) legislative proposals should advance together as much as possible,** as an overall consideration. If, for example, a viable uSPC proposal is tabled that incorporates the above key principles, it could later be expanded to national SPC applications via a Patent Cooperation Treaty (PCT)-like mechanism—designating states in which protection is sought—for application to the SPC recast legislation.

In summary, in line with European strategic priorities of competitiveness and regulatory simplification, it is imperative to establish a well-functioning SPC framework that is effective and efficient. This framework must ensure that the critical uSPC system aligns with the existing Unitary Patent regime. EFPIA advocates for the finalisation of these regulations so that European applicants can benefit not only from a modernized framework but also from the unitary patent system and the UPC.