

Principles for an Effective SPC Framework in the EU

Towards a Unitary SPC and centralized SPC framework



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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 for 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 the filing and examination procedures for both unitary and national SPCs.

EFPIA is, however, concerned about the legal and practical challenges facing advancement of the SPC package. At a time when competitiveness and regulatory simplification are strategic priorities, we strongly encourage the European Commission and Member States to advance discussions to achieve these key policy objectives. Co-legislators have thus far explored various institutional options for designating the managing and granting office, in particular for the uSPC. In this regard, we acknowledge the efforts of the Danish Presidency of the Council to push for an agreed approach on critical elements of the system.

To ensure the proposed SPC legislative package achieves its goals and supports a well-functioning, competitive SPC framework for Europe, EFPIA has put forward a series of principles that should guide efforts to build the uSPC system (see below).

Provided these principles are respected, and absolute **legal certainty** is ensured with respect to the legal basis and compatibility with the EU legal framework, EFPIA encourages the co-legislators to evaluate and develop a forward-looking framework with the **European Patent Office (EPO)** at its center. EFPIA believes the **EPO** is well-placed to achieve the objectives of the legislation and the fundamental principles we outline below.

EFPIA members stand ready to contribute to this process and are hopeful that progress can be made balancing legal certainty, speed, quality and effectiveness of the SPC framework. This would support the competitiveness and harmonisation of the EU IP system and ultimately, the research and development of innovative solutions for patients.

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

This CEB should primarily operate as a virtual office, relying on experienced examiners from relevant national patent offices (NPO) currently engaged in substantively examining SPC applications, to deliver decisions to grant or reject applications for unitary and/or national SPCs through the centralized (recast) procedure. Considering its existing competence with respect to European Patents with Unitary Effect, the EPO is a well-placed option to host the CEB and formally grant uSPCs according to CEB examination and decision.

(2) **GRANT & JUDICIAL REVIEW. 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).

A legally sound and straightforward route to both the UPC, and then on to the CJEU when needed, must be provided. These considerations should help determine which body grants uSPCs: a viable option would entrust the EPO with the formal grant of uSPCs, according to CEB examination and decision, and on behalf of Member States represented by the CEB.

(3) **PROCEEDINGS. 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) **CONSISTENCY. 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. A viable uSPC proposal that incorporates the above key principles could easily be combined and expanded through the SPC Recast legislation, to national SPC applications via a Patent Cooperation Treaty (PCT)-like mechanism—designating states in which national protection is sought in Member States not participating to the unitary patent.

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 simple, effective and efficient. To that purpose, it would be logical for the unitary SPC system to align with the existing Unitary Patent regime. EFPIA thus urges the co-legislators to focus on developing a legally sound model, consisting of the CEB as an examination and substantive decision body, and the EPO as a formal uSPC granting body.

We believe this option, subject to legal feasibility, is the most likely route to a viable and effective system, such that European applicants can fully benefit not only from a harmonized SPC framework but also, critically, from the unitary patent system and the establishment of the UPC.