EXECUTIVE SUMMARY

Study for the JURI committee

European Parliament

The potential impact of the unitary Supplementary Protection Certificate on access to health technologies [1]

ABSTRACT

In April 2023, the European Commission adopted regulatory proposals introducing a Unitary Supplementary Protection Certificate (SPC) and a centralised assessment procedure for SPCs for medicinal products. This study analyses the potential impacts of these proposals on access to medicines, the administrative burden to applicants and the cost to national health systems.

This document was prepared by Policy Department for Citizens' Rights and Constitutional Affairs at the request of the JURI Committee.

Background to the study

On 27 April 2023, the European Commission published a set of legislative proposals concerning the Supplementary Protection Certificate for medicinal products. Specifically, this concerns proposals for a:

- Regulation on the unitary supplementary protection certificate for medicinal products, and
- Recast of the Regulation on the SPC for medicinal products, introducing a new centralised procedure for the granting of national SPCs, as well as amendments to the current and remaining national procedure for the grant of national SPCs.

These proposals follow the introduction of the Unitary Patent and of the Unified Patent Court, stemming from the Agreement on a Unified Patent Court (AUPC), and intersect with various EU policy and legislative developments in the pharmaceutical space.

The JURI Committee for the European Parliament commissioned a team of experts, led by Technopolis Group, to conduct an analysis of the proposals and assess their potential impacts on access to medicines in the European Union. This document presents the results of that study. It aims to assist Members of the European Parliament in their assessment of the proposed Regulations.

The current SPC system

The Supplementary Protection Certificate (SPC) system was introduced by Regulation in the European Union in 1992. Its main purpose is to provide additional protection to patent holders for up to 5.5 years after the end of the basic patent, thereby allowing pharmaceutical companies more time to recover their research investment. This protection is crucial as the extensive testing and lengthy regulatory processes before medicinal products can be marketed eat into the patent's term. The SPC system aims to encourage pharmaceutical research and development, make the EU an attractive location for R&D investments, harmonize the internal market, and create a homogeneous SPC system.

[1] Full study in English: https://www.europarl.europa.eu/RegData/etudes/STUD/2023/753104/IPOL_STU(2023)753104_EN.pdf

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To be eligible for an SPC, a product must have a basic patent in force, have a marketing authorisation in the EU, not have received a previous SPC, and be the first product with marketing authorisation in the EU. The duration of an SPC is calculated by subtracting five years from the time between the patent filing date and the marketing authorisation date, capped at a maximum of five years. An extension of this with six more months is possible for products for which an agreed paediatric investigation plan has been completed. The average duration of SPC protection is approximately 3.5 years. Whilst the conditions for granting are regulated at the EU level, SPC applications are currently submitted to national patent offices which assesses the application and grants or rejects it.

Despite the SPC Regulation's uniform criteria, national interpretations and practices vary across Member States. This includes differences in granting SPCs, their scope, expiry dates, and the availability of third-party observations. Transparency also differs among Member States, affecting the publication of SPC information. This situation leads to duplication of work, high costs, and inefficiencies. Furthermore, the territorial limitations of SPCs are seen as misaligned with the new unitary patent system. To address these issues, the Commission is proposing the introduction of a unitary SPC and amending the SPC Regulation.

Proposal for a new SPC system

The commission has explored five different policy options, ultimately settling on a combination of two of the options: 1) a centralised procedure resulting in the grant of national SPCs in some or all Member States, and 2) a unitary procedure resulting in the grant of a single SPC in the Member States where the basic unitary patent is in place. An application combining these two options will also be possible. The current route of granting purely national SPCs will remain for nationally authorised products. Thus, with the proposed additions, there will effectively be four routes to obtaining an SPC in the EU.

The unitary SPC

The introduction of the unitary SPC is motivated by that of the unitary patent. It follows that a unitary SPC can be granted only for products protected by a unitary patent as the basic patent. This ensures that the patent claims are identical across all Member States. A second condition is that the marketing authorisation must have been granted through the EMA centralised procedure. All other requirements remain the same as under the current Regulation. The duration of a unitary SPC is calculated the same way as for a national SPC.

Applicants must apply for a unitary SPC with the EU Intellectual Property Office (EUIPO) within six months of receiving marketing authorisation or after unitary effect has been attributed to the basic patent. Applications can be filed in any official EU language. Application fees, as well as other possible fees (e.g., appeals or renewals), must be paid to the EUIPO.

Once an application has been filed, the EUIPO first assesses the formal admissibility of the application. Next, a central examination panel performs a substantive examination, focusing on eligibility conditions for a unitary SPC. During this time, third parties, including Member States, can provide written observations on the application's validity. The examination panel considers these observations but is not obliged to incorporate them into their decision. If the panel finds conditions are met, a positive examination opinion is issued; if not, a negative opinion is issued. The examination opinion is translated into all official EU languages.

Third parties can initiate an opposition procedure within two months after the publication of a positive examination opinion. Opposition applications are examined by an opposition panel and decided on within six months. The panel's decisions may be further appealed at the central level.

Once all processes for assessment, opposition, and appeal have been completed, the EUIPO decides whether to grant or reject the unitary SPC application. A unitary certificate confers the same rights and limitations as the basic patent in all Member States where the basic patent has unitary effect.

After granting, third parties still have the possibility to have an SPC invalidated, but only if it can be demonstrated that specific conditions have not been, or are no longer, met. An action for a declaration of

invalidity must be filed before the EUIPO. Appeal against a decision to (not) declare an SPC invalid is possible at different levels, including the Boards of Appeal and the European General Court. Counterclaims for invalidity can also be filed before the Unified Patent Court (UPC).

The centralised SPC application

Alongside the unitary SPC, the Commission is proposing a second route based on a centralised assessment of applications, with a binding opinion issued by the examination authority. Centralised SPCs can be applied for using a European patent without unitary effect as the basic patent, provided the product has been authorised through the EMA's centralised procedure. Unlike unitary SPCs, which are automatically valid in all countries participating in the unitary patent court, centralised SPCs may be valid in only one or several Member States, depending on the countries mentioned in the SPC application. Purpose of the centralised examination is to simplify the examination process and reduce legal uncertainty.

Analogous to the unitary SPC application, centralised SPC applications must be submitted to the EUIPO within six months of receiving marketing authorisation or after granting the basic patent. Applications may be filed in any official EU language. The application content is similar to that for unitary SPCs but includes a requirement to specify the Member States for which certificates are sought under the centralised procedure. Application fees and possible procedural fees are payable to the EUIPO.

The EUIPO assesses applications for each designated Member State. It's possible that the application may fulfil requirements for some but not all Member States, leading to a mix of positive and negative examination opinions. As with the unitary SPC, substantive examination is performed by the central examination panel, with provisions for filing written observations. The panel issues a binding opinion. If this opinion is positive, the formal granting of the certificates is handled by the competent national authority in each applicable Member State, following their respective national rules and procedures. Member States can only decline issuing a certificate if material circumstances have changed since the centralised application was filed.

Similar opportunities for opposition and appeal exist as for the unitary SPC. However, as separate examination opinions are issued for each Member State to which the application refers, separate proceedings must also be initiated for each opinion.

For centralised SPCs there is no provision for filing a declaration of invalidity at the EUIPO. Instead, such proceedings must occur under the national law of the authority that granted the SPC and the territorial scope of decisions on invalidity is limited to that jurisdiction.

Combined SPC applications

The SPC proposals include a third option, which effectively combines the unitary SPC route with the centralised application. This option exists as not all EU Member States participate in the AUPC. Under the combined application procedure, the SPC applicant must follow procedural routes and opposition and appeal options for each of the two streams, i.e. the unitary SPC route to obtain an SPC for those Member States that have ratified the AUPC, and the centralised non-unitary SPC route to obtain national SPCs for those Member States that have not.

National SPCs

The proposals allow for the continued existence of purely national SPCs in much the same form as currently. The procedure will, however, remain available only for products that a) have not been authorised through the centralised marketing authorisation procedure or b) are protected by a national patent. It is expected that, over time, this route will become largely obsolete.

Examination authority

The EUIPO has been put forward as the central examination authority for both unitary SPC applications and centralised applications. For this, it must create a new SPC division, develop guidelines for practice and appoint Boards of Appeal. It must also set up an examination panel, including qualified examiners sourced from national patent offices or other competent authorities in two Member States. In the composition of the panels geographic balance and workloads will be considered.

Intersection with the EU general pharmaceutical legislation

The SPC proposals were published alongside another major piece of legislative reform: the proposals for revision of the EU general pharmaceutical legislation. The proposals for this intersect with the SPC proposals at several points:

- The 'sunset clause' states that a marketing authorisation ceases to be valid if a medicine is not placed on the Union market within three years of authorisation or if the medicine is no longer actually present for three consecutive years. A marketing authorisation also needs to be renewed after the first five years on the basis of a re-evaluation of the risk-benefit balance. Triggering of the sunset clause or failure to renew the authorisation automatically results in invalidation of the SPC. The current proposal for revision of the legislation intends to abolish both clauses entirely. Conditions relating to market placement will instead become associated with the duration of regulatory protections. While this change may allow SPC protection to persist even if a product is not launched and enable strategic use of the system by innovators to delay generic entry, the conditions for such use are rare. Moreover, new provisions in the legislation may counteract such system manipulation.
- The proposed revisions intend to better balance incentives for innovation with conditions for access and affordability, as well as better direct innovation to areas of greatest unmet medical need. To do so, it is introducing changes to its system of regulatory protections, making their duration conditional upon fulfilment of various criteria, including for market availability. Such changes may shift the relative economic value of different forms of market protection, potentially increasing the importance of SPC protection to innovators. They may also encourage wider market launch and thus incentivise patent holders to apply for SPCs in a greater number of countries, if not already covered by a unitary SPC.
- Changes to the conditions under which a waiver can be obtained from paediatric investigations may result in a very small increase in the number of products eligible for the paediatric SPC extension.
- The revision foresees expansions to both the mandatory and the optional scope for the centralised procedure for marketing authorisation. However, as currently most innovative products are already authorised through this route, this change is expected to have very little impact on the number of products eligible for the unitary or centralised non-unitary SPC routes.
- The Commission intends to introduce a transferable data exclusivity voucher to reward the development of priority antimicrobials. The voucher will extend regulatory protection by 12 months and is available for no more than 10 products over 15 years. This extension is most valuable for products that would otherwise no longer be protected by any other form of market protection, including an SPC, and is therefore of little consequence to the SPC proposals.

Potential impacts

Harmonisation and administrative simplification

One of the primary objectives of the proposals is to reduce divergence in granting decisions among Member States. By introducing a unitary SPC and centralised assessment most differences in decision outcomes would be eliminated, although some inherent differences may persist due to national factors like patent types or marketing authorisations.

The proposals also aim to improve the quality of SPC certificates by centralising assessments and relying on a shared pool of expertise. While this can enhance the rigour of examinations, criteria like geographical balance among examiners could pose challenges in maintaining high standards.

The likelihood of litigation under the new system depends on several factors. While centralisation could lead to higher-quality assessments and less litigation based on erroneous evaluations, the proposals introduce new procedures for opposition, appeal, and invalidation, that may increase the use of legal proceedings and concomitant costs.

Administratively, the new system simplifies the application process for unitary SPCs by allowing a single point of application and payment to the EUIPO. However, for non-unitary SPCs, the situation remains complex as separate examination opinions for each country could lead to parallel opposition and appeal proceedings. The introduction of a procedure for the declaration of invalidity by third parties before the EUIPO might also add complexity to the system and increase litigation.

Cost implications

The Commission has estimated the cost implications of the proposals in an impact assessment. This study has not independently examined the validity of these estimates. According to the Commission, there will be no impact on the EU budget as the system will be self-funded from application fees. The estimated EUR 1.5 million needed to set-up the EUIPO's new functions will be financed from the EUIPO's accumulated budgetary surplus. Recurring annual costs related to administrative processing, examination, appeals, and system maintenance are expected to be around EUR 1.8 million.

Additional costs to applicants from higher application fees would typically be offset by savings on maintenance fees and agent/attorney fees and reduced translation costs, resulting in a net cost saving. However, for applicants seeking SPC protection in a relatively limited number of countries, the new system could increase costs rather than produce savings.

Access to medicines

Access to innovative medicines is to a large extent determined by national market characteristics, such as market size, availability of treatment alternatives and economic factors regarding pricing and reimbursement. These factors lead to strategic decision-making by marketing authorisation holders about where and when to launch a product. It is unclear how intellectual property rights, including SPCs, and regulatory protections factor into this decision making, particularly as these are largely identical in all EU Member States. It is therefore unlikely that current divergence in national practices involving SPCs have played a significant role in the observed unequal access to innovative medicines in the EU. Whilst administrative simplification may be helpful in making the EU a more attractive market as a whole, the introduction of the unitary SPC and the centralised assessment will do little to address underlying market factors. It is therefore not expected that the SPC proposals will significantly impact access to innovative medicines. Proposed revisions to the EU general pharmaceutical legislation may prove more relevant as a way of promoting equitable access to innovative medicines.

Concerning access to generic and biosimilar medicines, the SPC proposals may have some more consequences even though the criteria that determine which products are eligible for some form of SPC protection will remain largely the same. The duration of SPC protection is similarly not affected by the proposals. The main impact that may be expected results from the territorial scope of protection for unitary SPCs. At present generic entry is allowed from the moment the patent and any remaining regulatory protections have expired, even if the reference product remains under SPC protection elsewhere. However, the introduction of the unitary SPC would bring any country that has ratified the AUPC automatically within the territorial scope of protection, including those countries where at present SPC protection is often not sought. This could mean that generic entry remains prohibited even when the reference product is itself not on the market. This may present a risk

of further hindering access to medicines in countries where access is already problematic. However, such markets may remain unattractive even for generic manufacturers as long as SPC protection remains in other markets.

The new SPC system would increase the number of opportunities for generic manufacturers to oppose or appeal granting of an SPC. If this results in fewer SPCs being granted, timely access to generic medicines may increase, but the magnitude of this impact is uncertain. A further possible benefit of the proposed system is that centralised invalidation proceedings will synchronize access to generic medicines among AUPC countries.

Transparency of information

The SPC proposals mandate the creation of public registers of both applications and certificates to enhance transparency. These registers aim to provide open access, enabling third parties to access information without charge. A separate, restricted, database will contain any supporting documentation provided by applicants and third parties. This move towards publicly accessible registers is significant, particularly for generic manufacturers. Currently, obtaining information on SPC status across Member States is cumbersome and not readily available. A centralised register will simplify this process, although some concerns have also been raised about the possible misuse of the register to facilitate the prohibited practice of patent linkage.

Impact on healthcare budgets

The impact of the SPC proposals on Member States' healthcare budgets is closely linked to their effects on access to generic and biosimilar medicines. The proposals could have both positive and negative impacts on such access, depending on various factors. They may improve transparency and legal certainty for generic manufacturers, facilitating market entry. However, the introduction of the unitary SPC could also delay generic entry in some countries. The Commission estimated that this delay could cost countries up to EUR 37 million annually. The Commission suggests these costs could be offset by investments in research and development, but this is uncertain.

Regarding access to innovative medicines, administrative simplification may encourage marketing authorisation holders to enter more markets. If so, this may raise costs to the health system through inclusion of the medicines into the package of reimbursed care. However, improved availability of innovative medicines is generally considered a positive development and national authorities still have the autonomy to decide what treatments they will fund.

Recommendations

A set of recommendations has been developed, focusing narrowly on the unitary SPC and the centralised assessment for SPC applications. Considerations concerning the SPC system more generally were not within the scope of this study. Recommendations were formulated from the perspective of the Pharmaceutical Strategy for Europe, in particular focusing on the strategy's objectives to ensure access to affordable medicines for patients and support competitiveness, innovation and sustainability of the EU's pharmaceutical industry.

The recommendations offered are aimed at Members of the European Parliament to allow them to seek clarification from the Commission on certain points or suggest amendments to the proposals. Specifically, it is recommended:

- To monitor, in negotiations on the proposals for revision of the EU general pharmaceutical legislation, the status of provisions aimed at increasing access to medicines in all Member States. If such provisions are weakened, alternative provisions could be considered linking eligibility for grant of an SPC to marketing obligations.
- To monitor, following the Regulations entering into effect, whether parties that obtain a unitary SPC certificate use this right to block generic access in participating countries where the reference product has not been offered for or placed on the market.

- To assess, based on results from the previous recommendation, the necessity of adding a clause that unitary SPC protection applies only in markets where the holder of the unitary SPC has offered the product to the market within a specified time of the SPC protection taking effect.
- To review the necessity for the multitude of opposition and appeal procedures available and, where justified, reduce these. In particular, the added value of the central application for declaration of invalidity at the EUIPO should be carefully considered, given that there is already a possibility to invalidate the unitary SPC before the Unified Patent Court.
- To allow applicants to convert an SPC application into a centralised SPC application for those countries where the conditions for a unitary SPC are not fulfilled.
- To request the Commission to update and further explain its estimates for the set-up costs for the EUIPO. Additionally, the Commission together with the EUIPO could outline an action plan for development of the needed capacity at the EUIPO to ensure the continuity and quality of the system, including a risk management plan.
- To request clarity from the Commission on the levels of compensation to NPOs resulting from the transfer of responsibilities to the EUIPO.
- To request further clarification from the European Commission on how it intends to balance assurance of the highest quality standards in the examination with geographic balance.
- To consider whether SPC examiners should be precluded from serving on the Boards of Appeal.
- To request further clarification from the Commission on how it has prepared its cost estimates for applicants, including underlying assumptions about the frequency of use of procedures. If estimates must be revised upwards, carefully consider the impact of this on SMEs.

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