Position Paper

Unitary SPC & Unified Mechanism for the Granting of SPCs

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Introduction

This paper describes the Medicines for Europe position in relation to the possible Unitary Supplementary Protection Certificate (SPC) and the discussions around the introduction of a Unified Mechanisms for the Granting of SPCs.

Considering the very delicate nature of intellectual property (IP) for its impact on generic and biosimilar medicines market access, healthcare budgets and patient access, any changes to the current IP system need to be fully justified and thoroughly reflected upon to be carefully calibrated against all the interests at stake.

The points and arguments described below represent key considerations to avoid that any measure introduced in Europe will actually unjustifiably change the delicate IP balance and create any unintended effects, from which the SPC, over the years, has demonstrated not to be exempted (*e.g.*, forced delocalisation, extension of its scope, lengthy litigation, *etc.*).

1. Unitary SPC

Background

In the Single Market Strategy of 2015, the European Commission put forward a proposal for the introduction of a Unitary SPC title. The Unitary SPC is intended to complement the legal framework of the unitary patent system. According to the European Commission, it would have the objective to increase predictability, transparency and certainty in the framework of protection of innovative medicines.

Medicines for Europe Position

A Unitary SPC system would potentially increase legal certainty in so far as it would solve discrepancies and fragmentation within the EU legislative system. However, a debate around a possible Unitary SPC cannot disregard the following points that need to be clarified before any decision is taken on the introduction of a unitary SPC system:

i) **A Unitary SPC would actually increase the geographical scope of the protection**: today, on average, SPCs are not registered in 8 out of 27 Member States. In these countries, in the absence of an SPC protection, generics/biosimilars can be launched in advance of the other SPC protected countries. With a Unitary SPC, the protection may extend to all UPC countries, potentially delaying access to treatment in those countries

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that today are not covered by SPC protection. The impact is very significant for treatments for which the level of access increases significantly once a generic or biosimilar enters the market.

ii) **The Unitary SPC should not prevent equitable access to treatment**: the lack of SPC protection in certain EU Member States is due to the fact that there are markets where the innovative products are not launched. In a scenario where the Unitary SPC covers countries where the protected product is not launched, the Unitary SPC would inevitably delay access to treatments in those countries, where no innovative product is launched and at the same time generics/biosimilars cannot enter the market due to the Unitary SPC protection.

iii) **Quality, transparency & accountability of the granting body**: the options for a granting body seem to be several, from a virtual office to the EUIPO to the EPO. A virtual office would guarantee the use of existing human resources, but its practical functioning would need to be clarified. The EUIPO would guarantee transparency and accountability towards EU institutions, but should create a new SPC-related infostructure. The EPO would guarantee a consistent approach with the granting of patent rights, but would also need to create a new SPC-related infrastructure. It is fundamental that whatever granting body would guarantee the highest quality and transparency of the granting procedures, as well as clear accountability for its decision-making process. Considering the huge impact of a granted SPC on healthcare budgets and on access, as well as litigation, the granting body should also be able to review and adapt its granting decisions to the case law.

iv) **Procedural transparency**: it is fundamental, for the sake of legal certainty, to ensure the highest level of transparency in the SPC granting procedures, in line with the best practices at national levels, in relation, for instance, to the publication of applied SPCs, to assessment procedures, etc.

v) **3rd party observations**: the system should be transparent and inclusive, foreseeing the possibility to file 3rd party observations.

vi) **Opposition periods**: it should include clear opposition periods for generic/biosimilar companies.

vii) **The Marketing Authorisation for SPC calculation**: for the sake of coherence and clarity, Unitary SPCs should cover only products with European marketing authorisations.

2. Unified Mechanism for the Granting of SPC titles

Background

The European Commission is considering the possibility to introduce a unified mechanism for the granting of SPCs. This mechanism would allow companies to file a single SPC application for multiple designated Member States.

Medicines for Europe position:

The real need for a unified mechanism for the granting of SPCs is still to be demonstrated. Its primary objective would be limited to reducing burdens for SPC applicants. However, while it is still unclear how such a system would work, several key elements need to be taken into consideration:

i) **European Parliament oversight of the granting body**: any granting body should be fully accountable and under the oversight of the European Parliament.

ii) **Coherent and unified SPC lifecycle**: in line with the concept of EU uniformity justifying this measure, since the purpose of the SPC is to reward the development of one innovative product that is the same country by country, there should be no different application or decision on such SPCs country by country. Therefore:

a. any mechanism should foresee that if an SPC is revoked in one country, the body should revoke the title automatically in all EU the countries covered.

b. for the same reasons, also the procedure for invalidating the SPCs (i.e. oppositions) should be unified.

iii) **The Marketing Authorisation for SPC calculation**: in line with the concept of EU uniformity justifying this measure, a unified mechanism for SPC granting should only cover products with European marketing authorisations. If it had to cover nationally granted marketing authorisation, then the purpose of a uniform European mechanism would fail.

iv) **Procedural transparency**: it is fundamental, for the sake of legal certainty, to ensure the highest level of transparency in the SPC granting procedures, in line with the best practices at national levels, in relation, for instance, to the publication of applied SPCs, to assessment procedures, etc.

v) **3rd party observations**: the system should be transparent and inclusive, foreseeing the possibility to file 3rd party observations.

Conclusions

Medicines for Europe believes that, as it has always been the case, any change to the IP system in Europe should be thoroughly reflected upon, in consideration of the potential impact on generic and biosimilar medicines market entry, healthcare budgets and access to medicines for patients.

A Unitary SPC would be created for coherence with the unitary patent system and with the objective to tackle fragmentation and legal uncertainty. However, the considerations made above about both its concrete impact on the current EU IP system and the way it would practically function should be carefully assessed in order to avoid any unintended effects, which the SPC, over the years, has demonstrated to have produced on different aspects (*e.g.*, forced delocalisation, extension of its scope, lengthy litigation, *etc*.).

The rationale and actual need of a Unified Mechanism for the Granting of the SPC should be further justified and clarified. While such justifications will be further developed and more clarity will be made, the key elements described above provide a way for calibration of any possible unified mechanism.

Medicines for Europe is ready to further contribute constructively to the debate around these two topics.