EUROPEAN
COMMISSION

Brussels, 25.11.2020
SWD(2020) 293 final

COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE EVALUATION

of the

Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products

{SWD(2020) 292 final}

Evaluation of Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products, and Regulation (EC) 1610/96 concerning the creation of a supplementary protection certificate for plant protection products

EXECUTIVE SUMMARY

1. BACKGROUND

This evaluation concerns Regulations 469/2009 and 1610/96 on supplementary protection certificates (SPCs). It is relevant to the analysis of pharmaceutical incentives called for by the June 2016 Health Council[1]. Its findings will feed into the implementation of the *intellectual property action plan* and the *pharmaceutical strategy for Europe*.

SPCs are intellectual property rights that may extend by up to 5.5 years the protection conferred by a patent on a medicinal or plant protection product (PPP).

The objectives identified in the intervention logic underpinning the Regulations are to:

(1) encourage global R&D in the field of new active ingredients of medicines and PPPs;

(2) attract R&D centres and jobs to the EU and prevent R&D relocation;

(3) promote a uniform SPC system in the EU.

This evaluation relies on legal and economic studies as well as on several surveys.

2. MAIN FINDINGS

As regards the **effectiveness** of the SPC Regulations in achieving their objectives:

- SPCs promote innovation and the availability of new medicines and PPPs, as they help companies recoup their R&D investments.
- SPCs promote R&D in Europe to some extent. The EU remains a hub for R&D in the fields of pharmaceuticals and PPPs despite strong global competition. However, R&D location also depends on other factors such as the local availability of skilled labour, public funding and tax schemes. Patents and SPCs may be especially helpful in supporting innovative EU pharmaceutical SMEs, which have fewer resources to embark on lengthy development cycles.
- Although the SPC regimes provide a common framework within the EU, they are administered at national level. This causes fragmentation, leading to high costs and imposing an administrative burden on applicants (especially SMEs) and national administrations. It also leads to legal uncertainty, as the scope of protection can differ across the EU. This has a negative impact on SPC users and generic makers.
- The negative effects of fragmentation are amplified by a lack of transparency, especially from a cross-border perspective, making it difficult to trace what SPC

[1] https://www.consilium.europa.eu/en/press/press-releases/2016/06/17/epsco-conclusions-balance-pharmaceutical-system/

protection exists for which products in which Member States. This affects both SPC holders and generics manufacturers.

As regards **efficiency**, the SPC system appears to be reasonably balanced. SPCs may delay the market entry of generic medicines and PPPs, which may negatively affect the accessibility and affordability of medicines and PPPs. (For a sample of 232 medicines, we estimate that the SPC protection adds 13% of gross profits during the first 12.5 years after market launch). However, this negative effect is offset by the need for companies to recover investments in R&D, amid a steady increase in timelines and the costs of developing new products, and rising global competition. Moreover, SPC protection affects only a fraction of all medicines and PPPs. In many cases it is not the last protection to expire.

The SPC system remains **relevant** today for the following reasons.

- Its three objectives remain of major political importance.
- The COVID-19 crisis highlights the need for Europe to have a strong pharmaceutical sector, and for that sector to remain a world leader in innovation and manufacturing. While SPCs are granted without any condition regarding the place where the protected medicine is to be developed and manufactured, we have found examples of SPCs supporting manufacturing location decisions.
- The SPC system has supported major technical developments in the pharmaceutical and PPP fields that have emerged since 1992, such as biotechnology techniques. However, as the SPC is an incentive based on extending a period of exclusivity of sales, the current SPC regime is not expected to be efficient in encouraging research in areas with low commercial viability, such as medicines for orphan and paediatric conditions.

The SPC Regulations are internally **coherent**, and the CJEU has progressively refined its case law on the most disputed provisions. The Regulations are also coherent with the future unitary patent, and with regulatory legislation on pharmaceuticals and PPPs, notably:

- the EU Bolar exemption[2], which applies to patents and SPCs for pharmaceutical products, despite divergences in national implementation; and
- the legislation on orphan and paediatric rewards, although a recent evaluation found that the national granting of the SPC paediatric extension entails legal uncertainty.

The SPC regime, being defined at EU level, creates **EU added value** through the broad uniformity of the incentives it provides, despite some fragmentation resulting from their national implementation.

3. CONCLUSIONS

The SPC Regulations appear to support research on new active ingredients and to have remained fit for purpose; they are coherent with the patent and related pharmaceutical legislation, and have brought EU added value. However, it is challenging to establish a clear link between SPC protection and the location of R&D, as other factors play a role.

The fact that SPCs are nationally administered and managed undermines the effectiveness and efficiency of the SPC system. This is the system's main shortcoming.

[2] Article 10(6) of Directive 2001/83/EC and Article 41 of Regulation (EU) 2019/6.

It creates legal uncertainty, red tape and extra costs for businesses, especially SMEs. Purely national examination and grant procedures also entail extra costs and administrative burden for national administrations.

In addition, **the overall transparency of the SPC system is suboptimal**, especially in a cross-border perspective. This is detrimental to innovators and generics manufacturers alike.