4 April 2022

Deutsche Sozialversicherung
Europavertretung

Feedback from the European Representation of the German Social Insurance on the Consultation on Medicinal Products and Plant Protection Products - Uniform Procedure for the Granting of Supplementary Protection Certificates (SPC)

The European Commission is examining measures to optimise the existing system of SPCs, thus making it more transparent and efficient.

SPCs are an intellectual property protection tool that has the effect of extending the term of protection of a patent for pharmaceuticals by up to five years. SPCs are intended to have a compensatory effect since companies can only market patented products after successful authorisation procedures with mandatory clinical trials. SPCs are currently granted by the national patent offices of the individual EU Member States. The granting procedures do not always follow the same considerations, so that the period of validity of the SPCs may also differ from one EU Member State to another. According to the European Commission, the existing fragmentation of the system also affects the competitiveness of EU-based manufacturers of generics and biosimilars.

In its pharmaceutical strategy, the European Commission emphasises how important the development of and access to innovative and affordable medicinal products is for high-quality healthcare. Differences among Member States in the application of intellectual property rights – particularly with regard to SPCs – which safeguard such innovative products would increase costs and prevent transparency. The conclusions of the European Commission's 2020 evaluation of SPC legislation underscore this problem.

The European Commission is considering, among other things, the option of establishing a centralised system for supplementary protection certificates in the EU with unitary SPCs to complement the future unitary patent and a uniform procedure for granting national SPCs.

The development costs of new medicinal products are usually amortised within the first few years after market authorisation. The significantly longer duration of trademark and patent protection prevents the rapid availability of competitors and access to biosimilars and generics. In the opinion of the German Social Insurance (DSV), the introduction of uniform protection certificates must therefore **not mean an extension of patent protection**. This would have no added value whatsoever for patients, but would serve solely to maximise manufacturers' profits inappropriately.

The DSV welcomes the fact that access to medicinal products as well as transparency and competition are to be strengthened as part of the pharmaceutical strategy. Access to medicinal products must be guaranteed and at affordable prices. The DSV welcomes the fact that the European Commission wants to take into account a faster nationwide market authorisation of generics and biosimilars in the redesign of the SPC rules in order to relieve the national healthcare budgets and to enable an affordable pharmaceutical supply. The pursued uniform procedure for issuing SPCs is supported if it leads to more transparency, effectiveness and legal certainty and contributes to more efficient care.

A uniform SPC process would have the advantage of not only reducing costs and administrative effort, but also creating more transparency for all parties involved. Generics and biosimilars enter the market when the patent or SPC for that market expires. Improved market launch and competition could be fostered by building a **digital database** of expiring patents and SPCs. This increases transparency as well as planning reliability. A transparent and uniform SPC system could improve the competitive opportunities for generics and biosimilars. The relevant information should also be made available for health authorities and health insurance funds to consider in their national care planning.