Warsaw, May 9th, 2018

POSITION OF THE UNION OF ENTREPRENEURS AND EMPLOYERS

ON the SUPPLEMENTARY PROTECTION CERTIFICATE FOR MEDICINAL PRODUCTS

Beginning with Council Regulation (EEC) No 1768/92 of June 18th, 1992, followed by Regulation (EC) No 469/2009 of the European Parliament and of the Council of May 6th, 2009, concerning supplementary protection certificates for medicinal products, the EU legislator introduced into the legal order an instrument to extend the protection of medicinal products beyond the duration of basic patent protection. In accordance with Article 2 of this Regulation, any medicinal product protected by a patent within the territory of a EU Member State and before being launched on the market may be the subject of a supplementary protection certificate. The terms and conditions for obtaining such a certificate are described in Article 3: the product must be protected by a basic patent remaining in force, admitted to be traded on the basis of a valid permit, which must be the first authorisation for the product to be placed on the market as a medicinal product, and additionally the product could not be the subject of a certificate in the past. Under Article 5 of this Regulation, the certificate confers the same rights as are granted under the basic patent. The design thereof is such that the supplementary protection certificate is in a sense an extension of the patent. Ultimately, the medicinal product is thus protected for 20 years by a patent and then, for a maximum of 5 years, by the said certificate.

The state of affairs described above, means in practice that even for 25 years after obtaining the patent protection of a given drug, it is impossible to produce generic and biosimilar drugs based on it in the European Union. SPC prevents the production of generic and biosimilar drugs even for the markets of countries outside the European Union, in which the regulation does not apply. The result is easy to predict. Manufacturers of medicines from countries such as India and China, immediately after the expiry of patent protection, begin the production of generic and biosimilar drugs, and sell them to non-European markets. From the point of view of a multinational corporation, SPC is not a huge problem, because such a corporation can always open production outside of Europe.

The supplementary protection certificate is an important development barrier, especially for smaller pharmaceutical companies. Compared with their competitors from other continents, as well as with huge, international corporations that benefit, among others, from the economies of scale and because of their huge revenues also possess significant staff resources, smaller entities do not have too many advantages on their side. The current shape of SPC regulations only deepens this disproportion. In a situation in which entrepreneurs from Asian countries, or the afore-mentioned global corporations, start production of generics and biosimilars shortly after the expiry of patent protection, smaller enterprises operating in the European Union *de facto* have their hands tied. Not only individual EU Member States lose out on this solution (the competitiveness of their pharmaceutical industry is diminished), but so does the economy of the European Union understood as the sum of the potentials of the economies of individual EU Member States.

In connection with the above conclusions, it seems reasonable to present a legislative proposal that would maintain the basic value resulting from the supplementary protection certificate, i.e. the extension of up to five years of the protection of a medicinal product on the market of the European Union, while allowing European entities to compete with other companies on the markets of third party countries. Strengthening the position of European drug manufacturers is particularly important in the context of the added value that this industry provides to individual economies. One must keep in mind that pharmacy and biotechnology are one of the fastest growing industry branches, and one can assume that their importance will only grow in the decades to come. For this reason then, the dynamic development of this industry should be of particular interest to decision-makers in EU Member States, as well as the whole Union as such, which as a Community will have to compete with other huge markets.

Therefore, it is proposed to introduce the SPC MW mechanism (SPC Manufacturing Waiver), which would enable the production of medicines in Europe (while SPC protection is in force) for export only to third party markets where protection under SPC does not apply. This way, the primary objective of the supplementary protection certificate will be maintained – the mechanism will not infringe intellectual property rights or the essence of SPC regulations, at the same time allowing smaller European entities to produce medicines for third party markets, while protecting them with additional certificates. It seems

that this proposal would set the optimal shape of the regulations in question and would constitute a sensible compromise between taking into account the interests of those interested in prolonged protection of intellectual property and the needs resulting from the necessity to increase the competitiveness of European enterprises. Introducing the postulate into the legal order would require the European Commission to take a legislative initiative, i.e. to submit a draft of an amendment to the regulations both to the Council of the European Union and the European Parliament. We hope that our arguments will be taken into due consideration by key decision makers and that such a project will be put forward to the above-mentioned EU bodies in an appropriately short period of time.

At this very moment, timing is important. Therefore, it is of such paramount importance that the European Commission put forward a legislative proposal in the current term, which ends in 2019.

The Union of Entrepreneurs and Employers