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Press Release: **Good news for patients and drug manufacturers: The Committee on Legal Affairs of the European Parliament (JURI) has endorsed the abolition of restrictions concerning production of generic medicine**

The European Parliament's Committee on Legal Affairs (JURI) adopted yesterday a report regarding supplementary protection certificates for medicinal products, which lifts restrictions on the production of medicines after the expiry of patent protection. According to the regulations in force, the production of drugs that are subject to patent protection must not take place after its cessation if the medicinal product is covered by an additional protection certificate (SPC), which may cover a maximum period of 5 years after the expiration of the patent. Formally, this period is not part of the patent itself, however, it still constitutes a form of an additional legal and economic barrier for generic drug manufacturers to enter the market.

Polish business organisations – the Polish Association of Employers of the Pharmaceutical Industry in cooperation with the Polish Confederation Lewiatan and the Union of Entrepreneurs and Employers – indicated the possibilities of restricting competitiveness in manufacturing of generic drugs to markets where SPC protection is not applicable. The cooperation of Polish organisations with the European Commission, Permanent Representations at the EU, and the European Parliament helped to adjust EU legislation, allowing the abolition of competitive barriers for European enterprises on the global pharmaceutical market.

The shadow rapporteur of the project in the European Parliament, representing European Conservatives and Reformists, was MEP Kosma Złotowski, member of the Law and Justice party.

"Such barriers constitute a significant obstacle also for Polish pharmaceutical companies that wish to produce generic drugs for export to third countries where SPCs do not apply. Additional protection certificates bind their hands and force them to move their production facilities and research centres outside the European Union. Of course, pharmaceutical companies from China or Russia take advantage of these restrictions without any problems and they may freely produce generic drugs on their territory

and sell them, for example, to the US or Asian countries. This report removes these constraints, thereby bringing equilibrium between the conditions of competition on the pharmaceutical market for drug manufacturers from the EU and from other continents. Owing to that, both investments and jobs in the pharmaceutical industry will not leak, for example, from Poland to Ukraine or Kazakhstan," commented Kosma Złotowski on the voting in the Committee on Legal Affairs.

Złotowski also stressed that much more was achieved during the negotiations than had been proposed by the European Commission in its draft. In addition to the abolition of restrictions on the production of generic drugs for exports, the barriers for drug production for the European market were also significantly reduced. Pharmaceutical companies will be able to start the research process and production after the expiry of a patent still and before the expiry of the supplementary protection certificate, in order to be able to enter the market with a ready, high-quality drug on the first day after the SPC's expiry. This way, patients in the European Union will get access to a wide range of modern products and cheaper medicines faster.

The Polish Association of Employers of the Pharmaceutical Industry emphasises the significance of what was achieved as well. *"We also want manufacturers of SPC-protected counterpart drugs to be able to prepare stocks of these products in warehouses before an SPC expires. Only then will they have equal conditions to compete with companies from outside Europe. They will be able to introduce medicine to European pharmacies the day after the SPC expires. It is also important that the regulations introduced become effective from 2021 and cover all applicable SPCs, and not only those granted after the regulations' entry into force,"* says Grzegorz Rychwalski, Vice-President of the Polish Association of Employers of the Pharmaceutical Industry.

"Thanks to bringing equilibrium to the opportunities in third markets for small and medium-sized pharmaceutical companies from the European Union, they will be able to accumulate capital not only to produce in the generic and biosimilar medicines sector, but also to build their own facilities for research and development of new medicines. Moreover, they will not be forced to move production outside the EU, which will in turn, of course, translate into new jobs opportunities for highly qualified staff. Ultimately, the changes are also intended to guarantee that patients get faster and better access to safe generic medicines produced in the EU immediately after the SPC's expiry," added Tadeusz Zwiefka, Vice-Chair of the European People's Party group in the European Parliament.

"The report in the JURI Committee was optimal from the point of view of entrepreneurs, allowing smaller European entities to increase their competitiveness, while safeguarding intellectual property rights protection. We would like to thank the Polish Members of the European Parliament, and in particular Mr Kosma Złotowski, for their great involvement in the works on the report and advocacy of constructive solutions within the European Parliament," commented Marcin Nowacki, Vice-President of the Union of Entrepreneurs and Employers immediately after the vote.