

Half a billion euro a year saves Europe from parallel imports, Bulgaria is lagging behind due to regulatory obstacles

Data was provided by the European Association of Euro-pharmaceutical Companies at BAMPTD Round Table on "Encouraging Parallel Imports of Drugs in Bulgaria", which took place in Sofia at 18th of September

Parallel imports create competition on the drug market with a price effect benefitting patients and a quick solution to overcoming shortages. This became clear at a Round table dedicated to promoting parallel imports in Bulgaria. The event was organized by the Bulgarian Association for Medicines Parallel Trade Development (BAMPTD) under the auspices of the European Association of Euro-pharmaceutical Companies (EAEPC). Detailed results of shortage signals across the country were presented at the event. In 53% of cases, patients are looking for withdrawn products or medicines with discontinued imports, stated the BAMPTD CEO Boryana Marinkova quoting the interim results of BAMPTD drug shortage online platform. 20% are the cases closed with provided information where the medicine is available, and in more than 60% the senders are directed to their doctor. Signals refer to120 products from altogether 182 signal for 63 months. Each author had received feedback within 24 hours, and the average time to complete a case was 32 hours. The first internet-platform for drug shortage signals works under a Memorandum of Understanding between BAMPTD and Federation of Bulgarian Patients' Forum to achieve a durable solution for medicinal products, expand access to medicines of guaranteed origin and quality from the European Union, modern methods of early detection of shortages, etc.

That is why the two organizations asked for urgent changes of the Ordinance for Regulation and Registration of Prices of Medicinal Products. Since 2014, this act has established a restrictive regime for imports at competitive prices and restricts patients' access to medicines. BAMPTD will also insist on changes to LMPHM to allow imports of deregistered drugs that are still being sought by patients.

BAMPTD Chairman Hristofor Ivanov stressed that parallel imports could lower prices a lot. Similar examples were given by EAEPC Secretary General Casper Ernst from the Czech Republic, Poland and Italy. Regarding the Bulgarian regulatory authorities, Ernst emphasized that speed is the key to overcoming drug deficiency. "We can ensure that for 3 weeks fully respecting the regulations the medicines required can be provided by parallel distributors, but we need to be heard and parallel imports to be encouraged at national level," he said. In recent years, more than 50% of exports have been from the high-income countries with an ever-increasing involvement of the Scandinavian countries, and the benefits to countries with low income from imports are rising with a 5 to 37% reduction in drug prices.

"We have became traveling suitcases that buy medicines all over Europe," said Ivan Dimitrov, President of the Federation of Bulgarian Patients' Forum. "Patients can not be forced to do so after normal European practice. We want medicines to be available in our country, not only because of the cost, but also because of our safety. We demand that any administrative or regulatory obstacle to the import of medicines be abolished", Dimitrov said.

Hristofor Ivanov gave an example of a rapid import when there was no cardiovascular disease medicine since the manufacturer have declared that he could not provide the necessary stocks. "Luckily, we had product licenses issued

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and both parallel importers secured supplies during the summer," he stated. "Under the current price regulation, this would not be possible, and patients would not have had treatment for more than 2 months," Ivanov said.

BAMPTD and EAEPC have declared their commitment to continue to be a strategic and reliable partner of the institutions and their determination against the violations of the drug supply chain in Bulgaria and the EU. They stressed that there were a number of cases in which parallel distributors cooperated with the authorities to detect counterfeit drug and unregulated practices. Parallel Distributors are also one of the five actors in Europe-wide drug verification initiative, whose primary goal is to combat drug falsification.