БЪЛГАРСКА АСОЦИАЦИЯ ЗА РАЗВИТИЕ НА ПАРАЛЕЛНА ТЪРГОВИЯ С ЛЕКАРСТВА

European experts criticize the Drugs Act

Various studies in Europe show that the drug's shortage is not a result of the parallel trade

Sofia, 11 February 2014 - European experts have claimed as unlawful the measures introduced by the amendments to the Act for Medicinal Products in Human Medicine which applies a new licensing regime for export. The new amendments will require each dealer to wait 30 days for an opinion from the Bulgarian Drug Agency (BDA) on any medication on the positive list, which includes nearly 3,000 products.

Heinz Kobelt, Director European Affairs of the European Association of Euro- Pharmaceutical companies and Thilo Baurot, Board Member of the German Association of the parallel importers expressed concern that the amendments were not synchronized with the EU and if law changes enter into force, Bulgaria is threatened to sentence penalties procedure due to the restrictions that the Law imposes on the free movement of goods within the EU. Estonia, Spain, Greece and Portugal have already faced such issues and after the intervention of the Commission they have given more freedom to parallel trade. In Slovakia the adoption of the final decision is yet to come.

Heinz Kobelt noted that last year during a meeting with Dr. Nigyar Jaffer, Chairman of the Health Committee in the Bulgarian National Assembly, he had warned her that Slovakia is not a good role model. However, the Bulgarian legislature decided to follow this particular example, which means that our country can be investigated for breaches of EU law the same way Slovakia is.

The European Commission is actually examining an appeal against this part of the Law that concerns the parallel exports. The complaint stated that the Bulgarian government hinders the free market in the European Union. The violation of the principle of free movement of medicinal products in Bulgaria comes under the pretext of protecting the public interest and public health by stopping the drug shortage main reason for which is the parallel exports. However, the amendments to the Act will not actually affect the shortage of medicines in the country. This is the opinion of Laura Nachkova, Director of the Bulgarian Association for Development of Parallel Trade with Medicines. According to Baurot the obligation to give priority service in order to supply the local market and the following compliance control over it, which is already part of the law, would be a sufficient state measure.

This conclusion is supported also by different analyzes not only by the European Medicines Agency (EMA), but also from researches made by many different sources such as Birgli and the Association itself. According to its latest survey of hospitals across the country who use approximately 80% of the products on the hospital market in Bulgaria, 67% of the hospitals do not experience drug shortages, and the remaining part has shortages due to regulatory issues, such as lack of registration or stopped imports. At the same time the export restrictions directly affect the other side of the parallel trade with drugs – the import – which enables Bulgarian patients to have access to missing drugs on the home market and lower the prices of medicines, claims the Association.

The Association supports the authors of the law in their efforts to lower the drugs shortage on the Bulgarian market as well as to place clear regulatory requirements for the market, so that patients are guaranteed the access to a wider range of medicines at a lower cost.

За допълнителна информация
Българската асоциация за развитие
на паралелната търговия с лекарства
M: +359 878 400 513
E: pr@parallel-trade-development.org