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Restrictions of Parallel Trade in Pharmaceuticals – Carte Blanche from the Bulgarian Competition Authority?

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The Bulgarian Competition Protection Commission ("**CPC**" or "**Commission**") has recently issued an important decision regarding the parallel trade of pharmaceuticals and the possibilities for its limitations. In September 2013 ,- Sopharma Trading JSC ("**Sopharma**"), which is the affiliated distributor of one of the leading Bulgarian pharmaceutical companies, filed with the CPC a complaint against several other companies with respect to practices, alleged to be measures to control or limit parallel trade. The CPC initiated a procedure, against two companies – Abbott Products Ltd. ("**Abbott**") and Sting Ltd. ("**Sting**"). In December 2014, the CPC rendered its decision, which gave rise to extensive discussions by pharmaceutical companies, distributors as well as legal professionals. The reason is that the decision was interpreted by some commentators as giving a green light for the restriction of parallel trade of pharmaceuticals.

Facts and Sopharma's allegations

Under Bulgarian law, the level of reimbursement of medicinal products by the National Insurance and Health Fund ("**NHIF**") is different for different medicinal products. In some cases, this level of reimbursement is less than 100% of the price of the respective product. The medicinal product that was at the core of the dispute (Humira) is among the products whose level of reimbursement by the NHIF amounted to 75% of the total price. The patients had to cover the remaining 25% of Humira's price. Apart from this, the product was also available in the free market as well.However, the quantities sold on the free market were limited.

Considering the high price of Humira, Abbott initiated a co-payment program. By virtue of this program, Abbott provided a 25% discount to the patients through the wholesalers and the pharmacies. Abbott sold the product to the wholesalers at its full price. The latter sold the product at 75% of its price to the pharmacies and they, respectively at 75% of product's price to the patients, including the legally determined margin of the wholesaler and the pharmacy. In order to receive the 25% paid for each product, the wholesalers reported the volume and the specific pharmacies, where Humira had been sold on a reimbursed price (the so-called "**NHIF channel**").

Sopharma alleged that the above scheme aimed to provide Abbott with sensitive commercial information about the retail sales of Humira through the NHIF channel. As a result of having such information, Abbott practically was able to "paint" a detailed picture of Humira's distribution on reimbursed price. Thus, deducting the amount of Humira, sold through NHIF channel from the total amount of Humira, sold by Abbott to the wholesalers, the amount of Humira, sold on the free

market could be easily predicted. This provides Abbott with the ability to control the deliveries of Humira for the free market and therefore to restrict the parallel export of the medicinal product. According to Sopharma, the co-payment program of Abbott breached Art. 15 of the Bulgarian Competition Protection Act ("**CPA**"), corresponding to Art. 101 of the TFEU.

Sopharma alleged also a second violation – breach of Art. 21 of CPA, corresponding to Art. 102 TFEU. According to Sopharma the anticompetitive behavior included the conclusion of an agreement for exclusive distribution of Humira through the NHIF channel (i.e. which would be reimbursed) between Abbott and Sting. Sopharma based this allegation on the ground that during the past three years, Abbott systematically and gradually narrowed the circle of its distributors, participating on the market of Humira, reimbursed by the NHIF. The parties did not conclude an explicit agreement and their relationship was governed by Abbott's General Terms and Conditions as well as other internal documents.

Commission's decisions

Following its previous case-law, the CPC first defined the relevant product market as "*realization of Humira through NHIF's channel*" (i.e. it distinguished between the distribution of the product on reimbursed prices and on the free market) and the geographic market as "*national*" (i.e. covering the whole territory of the country). Afterwards, it concluded that Abbot did not have dominant position on the relevant market.

In respect to the eventual prohibited agreement between Abbott and Sting, CPC concluded that the accepted General Terms and Conditions and other internal documents of Abbott, do not lead to breach of competition law, since they do not place Sting in the position of an exclusive distributor. The Commission grounded its ruling with the facts that (i) the number of the wholesalers on the free market increased, (ii) there were two wholesalers of Humira on reimbursed prices and (iii) Abbott did not have control over wholesaler's choice of Humira's channel of distribution. Thus, the CPC considered Sopharma's allegations groundless.

In its analysis of the **reporting aspect of the co-payment program**, the Commission showed a rather flexible approach. Instead of considering those reports as an attempt to restrict parallel trade that could result in higher prices of Humira, it accepted that in the first place, the reporting requirements aimed to avoid abuses by pharmacies and wholesalers that ultimately deprived patients of the co-payment of 25% of Humira's price. In Commission's view, another advantage of the said reporting requirements is Abbott's ability to evaluate whether the pharmacies selling Humira through NHIF channel had contracts with NHIF and whether they fulfilled the legal requirements to perform such sales. Considered in their entirety, according to CPC, the reporting requirements allowed Abbott to control the appropriate spending of the funds, intended for the 25% discount of Humira's price. Hence, the Commission concluded that the monthly reports did not constitute a breach of competition law.

The additional forms of control over the pharmacies, imposed by Sting and approved by Abbott, i.e. concluded contracts with NHIF, documents compliant with the relevant legal requirements for receipt of reimbursement by the NHIF, obligation for ordering Humira in amounts corresponding to the respective pharmacies' health insured patients (i.e. with right to benefit from NHIF reimbursement), prohibition for wholesale trade with Humira (including import and export) were considered as functionally related to the mechanism for co-reimbursement by Abbott and therefore were considered permissible under Bulgarian competition law by the CPC.

It should be noted that Sopharma withdrew its application, since an agreement with Abbott was reached.

Conclusion

The decision shows that the Commission was concerned about the proper spending of the funds, intended for Abbott's co-payment program and ultimately about the patients' ability to benefit from the 25% discount from Humira's price. As a consequence, the CPA ruled that the co-payment program of Abbott was compliant with Bulgarian competition law.

It would have been useful to see the Commission's reflections on the impact of Abbott's and Sting's reporting requirements on the parallel trade of Humira (i.e. the impact of the price of the medicinal product). Unfortunately, in its reasoning, CPA only mentioned the restriction of parallel export but it did not elaborate on the consequences of the collection of data about the exact amount of Humira's sales through NHIF channel over such export. This approach prevented the CPC from assessing the positive and the negative impact over competition of the measures. The CPC did not elaborate on the negative impact of the co-payment programs comprising collection of detailed information about the sales, realized through NHIF channel and thus, currently its approach towards such programs is rather unpredictable. However, this has been interpreted by certain market stakeholders as a carte blanche for such disputed practices.

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