

# Kluwer Competition Law Blog

## Bulgarian Competition Authority applies effect-based Approach to an Abuse of Dominance Case

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At the end of 2023, the Bulgarian Commission for Protection of Competition (“CPC”) issued a key decision related to an abuse of dominance case in the pharmaceutical sector. The decision, which is expected to have a significant impact on the parallel export of pharmaceuticals, provides a clue to the CPC’s approach when parallel export concerns medicines with significant shortages on the Bulgarian market.

To make a long story short, the case was initiated by a complaint of Sting AD (“**Sting**”) – a major local wholesale distributor, against Phoenix Pharma (“**Phoenix**”) – also a major wholesale distributor, which is also the sole importer of the relevant drug. Both companies are key distributors of pharmaceuticals in Bulgaria with almost similar market shares and technical and logistical capabilities. The investigation concerned a key respiratory product – Ventolin Solut Resp 5 mg/ml (“**Ventolin**”). The market authorization holder (“**MAH**”) of the product is GSK which had appointed Phoenix Pharma as the exclusive importer of the product and part manager of GSK’s portfolio in the country, including Ventolin. Being an exclusive importer of Ventolin, all requests for deliveries of Ventolin are addressed directly to Phoenix. Phoenix does not conclude specific agreements with other distributors and the relationship is based on purchase-order principles. Until 1 June 2021, Sting alleges that there were no shortages, and all the requested quantities were delivered by Phoenix. Following this date, Phoenix started to refuse delivery of all ordered quantities due to a lack of Ventolin and distributed the quantities applying a proportional principle. As a result, Sting submitted a complaint before the CPC.

The CPC found that the relevant product market is narrow, i.e., the market of distribution of the very specific product (Ventolin Solut Resp 5 mg/ml) on the territory of the Republic of Bulgaria. The analyzed behaviour includes the delivery of Ventolin by Phoenix to distributors and does not include any retail trade of the product. Considering the EU dimension of the potential breach, the CPC concluded that the alleged abusive behaviour has the potential to affect trade between member states.

Being the exclusive importer of Ventolin for Bulgaria, Phoenix was considered to be the dominant undertaking on the relevant product market. When deciding on the market position of Phoenix on the relevant product market, the CPC also considered the existence of a parallel importer of a similar product. The relevant state authorities admitted that in certain months of the investigated period, the parallel importer had even higher sales compared to Phoenix. Nevertheless, the CPC considered that the product from the parallel import must not be taken into account when

determining the market share of Phoenix. This was because Phoenix had strong market power despite the presence of an alternative product, since Ventolin is the standard product that is prescribed by healthcare professionals. When visiting the pharmacy, the patient cannot switch to a different product (such as the one from the parallel import), unless he/she visits again the healthcare provider with a request to correct the prescription. Based on these arguments, the CPC decided that Phoenix is dominant on the market and the parallel import of similar pharmaceuticals has only an ancillary function.

Concerning the potential breaches of competition law, the CPC started its investigation with the analysis of potential illegal refusal to supply by Phoenix to other distributors, but the Commission promptly excluded this breach since Phoenix applies a proportional scheme of delivery to all distributors that requested quantities, where pharmacies and hospitals were directly supplied by Phoenix. The Commission continues its analysis by identifying behaviour that might by its result limit or control production, trade, or technical development to consumers' disadvantage (Art. 21, item 2 of the Bulgarian Competition Protection Act (“BCPA”). This form of breach of competition law sanctions the result but not the behaviour itself. Examples of breaches under Art. 21, item 2 of the BCPA include cases where the importer intentionally reduces the requested quantities or ceases to deliver the product for a certain period with the objective to force the buyers to agree on higher prices once the deliveries are reinstated. Following the investigation, the CPC found that Phoenix reduced the quantities ordered by the distributors with national coverage (Sting, Sopharma Trading AD and Pharment AD) and redirected quantities to retailers (pharmacies) and major direct clients (hospitals). Nevertheless, Phoenix continued to deliver to distributors although with considerable limitation of the usual quantities.

In addition to the CPC's analysis of the effect on the relevant product market, the Commission collected aggregate information demonstrating that with or without Ventolin the market share and strength of the distributors will not be considerably affected. However, this conclusion does not apply to the affected market but considers the overall income from distribution of the competitors of Phoenix – Sting and the other two distributors with national coverage (Pharmanet AD and Sopharma Trading AD). In conclusion, the CPC viewed Ventolin as a tool for a wider portfolio for the distributors but not as an essential product for all their operations in the market of distribution of pharmaceuticals. In addition, the CPC considered that the period between June 2021 and April 2023 (the relevant period for the investigation), is too short to have the potential to have long-lasting effects on the market. As a conclusion, the CPC ruled that Phoenix had not breached competition law. The decision is subject to appeal before the Sofia Regional Administrative Court.

## Conclusion

This decision contains three key aspects. First, the CPC approach when determining the market position of Phoenix by completely excluding the similar pharmaceuticals imported by a parallel importer. Second, the effect-based approach when deciding on the existence of a potential breach along with CPC's arguments related to the overall effect of the presence of Ventolin in the portfolio of the other distributors. Third, the lack of any analysis of whether Phoenix's behaviour could have resulted in a limitation of parallel export of Ventolin.

Several years ago, the [CPC issued a decision related to the co-payment program of the drug Humira](#), where the case involved some reporting that might have constituted a hardcore restriction

of competition by means of limitation of parallel trade with pharmaceuticals. The procedure ended with the withdrawal of the complaint by the applicant but still, CPC made some hints that might be seen as encouraging the limitation of parallel export of drugs.

The decision subject to the present discussion contains very similar signals and an interesting aspect to be considered is the absence of any analysis related to parallel trade with pharmaceuticals. CPC did not consider that reduction of quantities to distributors with national coverage and direct delivery to pharmacies and hospitals might be an act of limitation of parallel export of Ventolin. It is true that the Bulgarian market struggled with shortages of Ventolin but there is a legal framework that deals with the limitation of export by the Bulgarian Drug Agency, where there is a procedure to be followed in order for the BDA to issue an act that prohibits export of drugs that is proven to be insufficient for the needs of the local market, namely in order to limit the parallel export of pharmaceuticals (the Bulgarian Drug Agency must issue an act in this regard, where specific terms and conditions under the Drugs in the Human Medicine Act must be met). It would be an extrapolation that the investigation of the limitation of parallel export argument would have ended differently but still considering the facts of the case, there is a huge gap in the CPC's analysis. When determining the market position of Phoenix, the CPC must have considered also the presence of an alternative product on the market because the practice of the pharmacies in Bulgaria is not to refuse selling an alternative product (as argued by the Commission), if only the brand name is on the prescription (although the law stipulates otherwise). Second, a more detailed analysis regarding Phoenix's behaviour in light of the limitation of parallel export with pharmaceuticals would not be superfluous, since there were rumours on the market that the shortages of Ventolin in Bulgaria are due to parallel export of the product to neighbouring markets.

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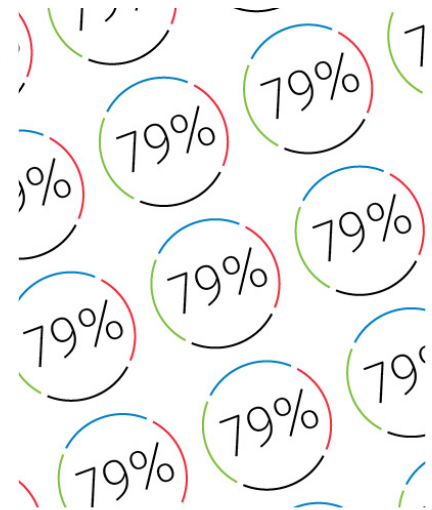
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