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European Commission revisits parallel trade in the pharma sector

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The European Commission has announced a new, tougher policy on parallel trade in the European pharmaceutical sector. Given the new Slovak reference pricing legislation, pharmaceutical companies in Slovakia are likely to be affected.

What is parallel trade?
Parallel trade is caused by the fact that while the European Union forms an internal market, drug prices are regulated at national levels. A certain drug may consequently be sold for different prices in different Member States. Since internal borders in the European market have been abolished, parallel traders (wholesalers) can benefit from price differences by purchasing large volumes of pharmaceuticals in a low-price Member State and reselling them in a high-price Member State. In other words, if the regulated price of a certain drug in, let's say, Slovakia is 10, while the regulated price of the same drug in Austria is 12, Slovak wholesalers can purchase the drug in Slovakia and sell it for a higher price in Austria.

Obviously, parallel trade poses a problem for pharmaceutical companies, as it decreases their profit margins in high-price Member States and cuts supplies in low-price Member States. Therefore, they have always tried to curb parallel trade. Most commonly, they have imposed various mechanisms including contractually restricting wholesalers in one Member State from reselling drugs in other Member States, limiting volumes of supplies to cover only the demand in the relevant Member State or imposing dual pricing mechanisms depending on whether the drugs are earmarked for the domestic market or for export.

Why is parallel trade relevant to Slovakia?
Under the recent overhaul of Slovak pharmaceutical regulations, the maximum prices of drugs will be set according to the second-lowest price in the EU. Thus, by definition Slovakia is one of the low-price Member States from which parallel traders can export drugs to achieve higher margins in other Member States.

It feels like travelling back in time. Just like 15 years ago, parallel trade is getting a hot topic for the Commission.

At the same time, Slovak pharmaceutical companies are also under regulatory pressure, because if a certain drug is absent from the Slovak market (even if this is attributable to parallel trade), the company might face regulatory sanctions and the drug may even be de-registered in Slovakia.

This brings pharmaceutical companies to an interesting position: they have to sell their drugs for a relatively low price in Slovakia and they are obliged to supply the Slovak market with sufficient volumes. If they fail to do so, they may face regulatory sanctions including de-registration. In addition, their conduct may raise competition law issues.

Can parallel trade raise competition law issues?
Any attempts to prevent distributors from re-exporting drugs earmarked for the Slovak market to other Member States may fall foul of competition rules and be sanctioned by fines of up to 10% of their annual turnover.

In recent years, the main attention of competition authorities has shifted to competition between originator and generic companies. Parallel trade has largely escaped regulatory scrutiny. The last major case was a 2009 ruling in GlaxoSmithKline regarding parallel exports from Spain.

Now the European Commission's attention seems to be shifting back to parallel trade. Speaking in Washington in April, the EU Competition Commissioner Mr Almunia said that although parallel trade was an "old issue", his attention has turned to it again. He indicated that although no formal proceedings have been opened yet, this cannot be excluded in the future.

Mechanisms curbing parallel trade have often been viewed with suspicion by competition authorities. First, they can restrict competition among wholesalers. Second, these contractual mechanisms effectively divide the European market into national markets. Therefore, they have frequently been interpreted as restrictive vertical agreements or as conduct amounting to the abuse of a dominant position and have been sanctioned by significant fines.

Given Mr Almunia's recent statements, it seems likely that the European Commission will take a closer look at this issue and, presumably, the Slovak Anti-Monopoly Office will follow suit.

How to eliminate the resulting risk?
It seems certain that pharmaceutical companies are trying to curb parallel trade and indeed, not all restrictions are prohibited by competition law. Depending on the market shares of the participating companies, some contractual restrictions are automatically exempted from the scope of competition scrutiny. And even if a contractual restriction does not fall under any of the automatic exemptions, the pharmaceutical company can still argue that such restriction does not restrict competition and should thus be exempted. But unfortunately, given the complexity of existing case law, it is practically impossible to formulate a general rule. To minimise competition law risks, any mechanisms will have to be assessed on a case-by-case basis, which is not only costly, but it also undermines the legal certainty of pharmaceutical companies.


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