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European Commission,
Directorate General for Internal Market,
Industry, Entrepreneurship and SMEs
Avenue d'Auderghem, 45
1040 Brussels, Belgium

Odense, 08 September 2022

CONTRIBUTION OF ORIFARM GROUP A/S TO THE TRIS NOTIFICATION 2022/405/B (BELGIUM)

To the attention of the European Commission, Directorate General for Internal Market, Industry, Entrepreneurship and SMEs

Orifarm Group of Companies with its headquarter in Odense Denmark is a leading parallel trade company in Europe with subsidiary companies importing pharmaceuticals to Denmark, Germany, Sweden, Norway, Finland, Netherlands, Austria, UK and Belgium. We hereby submit our view in relation to the TRIS notification 2022/405/B (Belgium) regarding the Belgian Draft Royal Decree implementing Article 12-septies (2), of the Law of 25 March 1964 on medicinal products (hereinafter the "Draft Decree") which we believe will have a significant impact on international trade.

Introduction and general feedback

In many national health systems parallel imported pharmaceuticals are an essential and established part of healthcare. The systems rely, due to established supply relationships between parallel importer and e.g. wholesalers, hospitals and pharmacies, tender obligations or rebate contracts with sick funds on the supply of parallel imported medicine to patients. Additionally, national health systems also benefit from parallel import due to often significant cost savings. E.g. in Germany in 2021, direct savings from parallel imported pharmaceuticals amounted to approximately 330 million euro. The indirect saving potential is much higher (around 4.4 billion euros in 2020 in Germany). This is because parallel imported pharmaceuticals stimulate competition, especially in the patent-protected market in which they are the only competitive element.

Due to this intrusions in established sensitive European supply structures must be generally avoided, since they create the risk of medicine shortages.

By implementing the provision included in Article 12-septies (2), of the Law of 25 March 1964 on medicinal products, the Draft Decree regulates the temporary export bans applicable to medicinal products intended for the Belgian market. In its new formulation, which has now been notified to the European Commission via TRIS, the Draft Decree foresees the introduction of an obligation to authorize the export of certain medicinal products to the Belgian market in the event of unavailability, under the conditions laid down in the draft order.

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Specific remarks to the Draft Decree

We would like to revert your attention to three specific points in relation to which we believe that the Draft Decree should be amended, as it contradicts the principles expressed by the European Commission in the Paper on the obligation of continuous supply to tackle the problem of shortages of medicines on May 25, 2018.

1. Assessing the existence of a real shortage

The first problematic aspect concerns Article 4 (1), 1° of the Decree, which states that the export of a medicinal product might be subjected to an authorisation "if the unavailability of the medicine has been notified to FAMHP or noted by FAMHP".

This provision implies that the subjection of the export of a given medicinal product to an authorisation may as one option exclusively depend on the notification made by the Market Authorisation Holder (MAH) stating the existence of unavailability.

According to the principles expressed by the European Commission in the above-mentioned Paper, restrictions of supply for specific listed medicinal products may be considered suitable if the list is established through criteria that are known in advance. Secondly, medicine shortages are dealt with at national level by national competent authorities. Medicines shortage are a multi-factorial issue that can have multiple root causes such as manufacturing and quality issues, economic related issues and supply chain issues. Identifying the root causes of medicines shortages is essential before initiating restrictive measures.

Therefore, merely relying on what is declared by the MAH to stop the export of a given medicinal product is not enough to observe the judgement by the CJEU and fulfil the requirements outlined by the European Commission in 2018 and ensure legal certainty on how shortages are identified. Thus, in this specific case, it should be FAMHP that, following the notification from the MAH, investigates and confirms that a shortage is actually taking place based on pre-defined criteria.

2. Possibility to appeal

The second point for which we would like to raise concerns regards the fact that the Decree does not foresee any possibility to appeal the decision of the Ministry to prohibit the export of a given medicinal product. This omission openly contradicts what has been stated by the European Commission in the above-mentioned Paper in 2018, according to which the decisions on export have to be "open to be contested before the relevant administrative bodies or courts of justice". Thus, we believe that any ministerial decision on the prohibition of export must be subject to an administrative appeal and, subsequently, to a judicial appeal, before the administrative chamber and the contract chamber at the Court of Appeal.

3. Motivation of Ministry decisions

Finally, in order to make the possibility to appeal effective, we believe that each decision of the Minister or his delegate, taken in application of this Royal Decree, shall be duly substantiated, and that the Ministry shall therefore provide adequate reasoning/motivation regarding the decision to ban exports of a given medicine. This will allow proper arguments to be brought by complainants in the context of an eventual appeal as foreseen above. We also think that this reasoning should be notified to the interested parties.

Conclusion

The proposed framework designated by the draft order observe general principles in some aspects. However, based on the considerations expressed herein, we urge the European Commission to take the abovementioned aspects into consideration when examining the notified technical regulation to ascertain its compatibility with EU law and the principles of the free movement of goods and services.

Please do not hesitate to contact us.

Best regards,

Mike Goorman
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