

Legislative analysis regarding the parallel trade of medicines

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Abstract. Although the European Union has long faced the problem of the shortage of medicines, the European Parliament resolution of 17 September 2020 on the shortage of medicines [1] states that due to the increasing global demand for medicines and the COVID-19 pandemic, medicine shortages have become even more acute, affecting Member States' health systems and posing considerable risks to patients' health and care.

The Committee on Industry, Research and Energy, in its opinion of 16.6.2020 [2], recognises that parallel trade can cause a shortage of medicines and calls on the Commission and the Member States to adequately address the problems of parallel trade in medicines in the EU, in order to prevent export shortages caused by considerable differences in the price of a medicine between Member States.

In this context, this article aims to analyse the regulations at the level of the European Union, the case law of the Court of Justice of the European Union, as well as the national legislative measures relating to intra-EU trade on the pharmaceutical market.

Keywords. European legislation, Court of Justice of the European Union, parallel trade, shortage of medicines, distribution of medicines

1. Introduction

Parallel trade in products is a legal form of trade on the domestic market. It is "parallel" in the sense that it involves products that are essentially similar to those marketed through the sales networks of the original manufacturers or suppliers but is conducted outside and often parallel to these networks.

Parallel trade is a result of price differences between pharmaceutical products [3], for example when Member States set or otherwise control the price of products sold on their own markets. In principle, parallel trade creates healthy competition and price reductions for consumers, being a direct consequence of the development of the internal market, which guarantees the free movement of goods.

Although the safety and the first placement on the market of medicines are regulated by the legislation of the European Union, the principles regarding the legality of parallel trade of these products have been established following some decisions of the Court under the provisions of the TFEU [4] on the free movement of goods (Article 34) [5] - [8].

With regard to medicinal products, when the information necessary for protecting public health is already available to the competent authorities of the Member States of destination, as a result of the first placing on the market of a product in that Member State, a parallel

imported product is subject to a license granted on the basis of a proportionally "simplified" procedure (different from a marketing authorization procedure), if the imported product has been granted a marketing authorization in the home Member State and if the imported product is essentially similar to a product which has already been granted marketing authorization in the Member State of destination.

2. Theory

In an attempt to ensure a balance between the rights of parallel traders and the need to maintain public interest objectives such as public health, the Commission has introduced guidelines on parallel imports of proprietary medicinal products for which marketing authorizations have already been granted [9].

In addition, a distinction must be made between parallel trade and reimportation. For example, in the case of pharmaceuticals, reimportation refers to transactions whereby medicinal products are imported into a Member State where they are authorized, after having previously been obtained by a pharmacy in another Member State from a wholesaler in the Member State of origin.

In this regard, the Court held that a product manufactured in a Member State which is exported and then re-imported into that Member State constitutes an imported product in the same way as a product manufactured in another Member [10] - [12]. The Court has shown, however, that these conclusions do not apply if it is found that the products in question were exported solely for the purpose of re-importation in order to evade legislation such as the one in question [13].

3. Results and discussion

Parallel import, or intra-Community trade as this sector of the pharmaceutical market is also called, is based on the free movement of goods, in accordance with Articles 28 and 30 TFEU on the "doctrine of regional exhaustion".

At the European level, the parallel distribution of medicines is managed through a centralized procedure by the European Medicines Agency (EMA).

According to the provisions of art. 77 of Directive 2001/83/EC, for a distributor to become a parallel import authorization holder, it must hold a valid authorization for the wholesale distribution of medicinal products [14].

If the parallel importer intends to make changes in labelling, outer packaging etc., in addition to the distribution authorization, it must also hold a manufacturing authorization.

The parallel importer must comply with the rules of good distribution practice and, if applicable, the rules of good manufacturing practice.

The parallel importer is personally responsible for legal issues related to the brand name of the parallel imported drug.

At national level, parallel import is the operation by which a medicinal product for which a marketing authorization has been issued by the National Agency for Medicines and Medical Devices of Romania (ANMDMR) is brought in Romania through other distribution channels than the ones approved by the marketing authorization holder of the respective medicine. The national authority manages the parallel import of medicines authorized at the national level, through the "purely national" procedure or through the mutual or decentralized recognition procedures.

Order no. 1.962/2008 provides certain conditions that a medicine must meet in order to be brought from another EU member state to Romania through the parallel import mechanism [15].

According to the Court's jurisprudence [16], in order for a parallel import authorization to be issued, the applicant must present data or arguments that make it at least plausible that the efficacy and safety of the directly distributed original medicinal product are also applicable to the parallel imported medicinal product. In general, the efficacy and safety of the original medicinal product are presumed to be applicable to the parallel imported medicinal product when the marketing authorization holder in the exporting country is identical, belongs to the same group of companies as the marketing authorization holder of the original medicinal product distributed directly in Romania or between the two holders there is a license contract or another similar legal situation.

The documentation submitted in order to obtain the parallel import authorization (PIA) contains the same five Annexes that are the basis for obtaining the marketing authorization of a medicinal product registered in Romania.

In addition to these documents, the holder of the PIA has the obligation to notify both the marketing authorization holder of the original directly distributed medicinal product and the brand holder of their intention to introduce to the Romanian market a medicinal product by means of the parallel import mechanism.

More often than not, the notifications bring about certain responses and comments from these entities. This is because the price of medicinal products subject to a parallel import authorization is in the source country than the price of the original medicinal product.

The PIA holder has the obligation to monitor adverse effects and to report to the competent authority any adverse effect or deficiency of a medicinal product subject to a parallel import authorization. The holder of the parallel import authorization also has the obligation to notify any other modification of the parallel medicine such as change of qualitative or quantitative components, changes of the primary packaging or even changes of the design of the pharmaceutical form.

ANM DMR makes the decision to grant the authorization based on as complete information as possible, including by requesting additional information from the competent authorities in the exporting country.

The parallel imported medicine may have a different name than the medicine authorized in Romania or in the exporting country, in compliance with the legislation in force regarding the name of medicines.

Both over-the-counter and prescription medicines may be subject to a parallel import authorization.

In the case of intra-Community trade in OTCs, since their prices are not so strictly regulated, they are easy to market as long as their prices are lower than OTCs distributed through the classical distribution channel.

Prescription medicines and especially those from CANAMED (Catalogul național al prețurilor la medicamentele de uz uman eliberate cu prescripție medicală - National price catalogue of prescription medicines for human use), follow a procedure for obtaining the marketing price which may make it difficult for healthcare professionals and patients to access them.

Moreover, since the entry into force of EU Falsified Medicines Directive [17], transposed into the national legislation [18], in which it is mentioned that the placing on the market of prescription medicines will be done, with very few exceptions, only if they carry the new safety elements, PIA holders have been considered manufacturers, thus having to comply with the new regulations. This complicates the repackaging process and also leads to a significant increase in marketing costs.

To comply, when a parallel distributor imports RXs from another EU country, they must first remove the unique identifiers and decommission those batches from the source country's database. These are then repackaged applying new unique identifiers and recommissioned in the European Medicines Verification System.

4. Conclusions

Considering the benefit brought to the health budget, certain states of the European Union introduced into their national legislation provisions to encourage and support parallel importation. In countries such as Denmark, parallel imported medicines account for 30% of the total sales volume of medicines and in Germany at least 5% of the sales volume at pharmacy level is required by national law to be parallel imported medicines.

The benefits of parallel import for the state budget consist in the fact that authorized medicines can be brought to Romania that are cheaper and can be issued at a price below the price of the already existing ones. Also, parallel importation can be a price control strategy because it gives suppliers and distributors a strong level of bargaining power with manufacturers so that they reduce prices.

One of the most important advantages of parallel import is the continuity of access to medicines withdrawn for certain commercial or manufacturing reasons or discontinued on the domestic market. Through the parallel import procedure, authorized medicines that are missing from the market can be brought in, thus enabling patients to have access to medicines that are so indispensable in the treatment of certain ailments.

Although at the national level, parallel import legislation is not entirely complete, the benefits for both patients and the national budget could lead to legislative changes that could solve the current medicine crisis, being an alternative that could compensate for the gaps in the traditional channel of distribution.

In response to the emerging problem of medicine shortages on the internal market, the European Parliament invited the Commission to assess the impact of parallel trade on medicine shortages in Member States and to adequately address the issues by taking the necessary measures to ensure that medicines reach all patients in the EU in a timely manner. As parallel trade sometimes covers up to 80 or 90% of the demand of some Member States, which weakens the supply chain, the European Parliament appreciates that due to parallel trade there is a discrepancy between the volume placed by producers on a given market, the volume of exports and imports and the needs of patients on the respective market, which can lead to deficits.

References

- [1] European Parliament, P9_TA(2020)0228, *Shortage of medicines - how to address an emerging problem*, European Parliament resolution of 17 September 2020 on the shortage of medicines – how to address an emerging problem (2020/2071(INI)).
- [2] European Parliament, A9-0142/2020, *REPORT on the shortage of medicines – how to address an emerging problem* (2020/2071(INI)), Committee on the Environment, Public Health and Food Safety, Rapporteur: Nathalie Colin-Oesterlé, 22.7.2020.
- [3] Case C-201/94 *Smith & Nephew*, Rec. 1996, p. I-5819.
- [4] Treaty on the Functioning of the European Union (TFEU), consolidated version, published in Official Journal of the European Union C 326 of 26.12.2012.
- [5] Joined Cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure eV and the Commission/Bayer AG*, Rec. 2004, I-00023;
- [6] Case C-53/03, *Syfait and others /GlaxoSmithKline AEVE*, Rec. 2005, I-04609;

- [7] Joined Cases: Case C-468/06 *Sot. Lélos kai Sia EE*, Case C-469/06 *Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proïonton*, Case C-470/06 *Konstantinos Xydias kai Sia OE*, Case C-471/06 *Farmakemporiki AE Emporias kai Dianomis Farmakeftikon Proïonton*, Case C-472/06 *Ionas Stroumsas EPE*, Case C-473/06 *Ionas Stroumsas EPE*, Case C-474/06 *Pharmakapothiki Pharma-Group Messinias AE*, Case C-475/06 *K. P. Marinopoulos AE Emporias kai Dianomis Pharmakeftikon Proïonton*, Case C-476/06 *K. P. Marinopoulos AE Emporias kai Dianomis Pharmakeftikon Proïonton*, Case C-477/06 *Kokkoris D. Tsánas K. EPE and others*, Case C-478/06 *Kokkoris D. Tsánas K. EPE and others/ GlaxoSmithKline AEVE Farmakeftikon Proïonton*, Rec. 2008, I-07139;
- [8] Joined Cases: Case C-501/06 *P GlaxoSmithKline/ Commission*, Case C-513/06 *P Commission / GlaxoSmithKline*, Case C-515/06 *P European Association of Euro Pharmaceutical Companies (EAEPC)/ Commission*, Case C-519/06 *P Asociación de exportadores españoles de productos farmacéuticos (Aseprofar)/ Commission*, Rec. 2009, I-09291.
- [9] Commission of the European Communities, *Commission Communication on parallel imports of proprietary medicinal products for which marketing authorisations have already been granted*, Bruxelles, 30.12.2003, COM (2003) 839 final.
- [10] Case C-322/01 *Deutscher Apothekerverband*, Rec. 2003, p. I-14887, paragraph 127;
- [11] Case 229/83 *Leclerc and others*, Rec. 1985, p. 1, paragraph 26;
- [12] Case C-240/95 *Schmit*, Rec. 1996, p. I-3179, paragraph 10.
- [13] Case C-322/01 *Deutscher Apothekerverband*, Rec. 2003, p. I-14887, paragraph 129.
- [14] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human, published in the Official Journal of the European Union L 311 of 28.11.2001. The consolidated version was published in the Official Journal of the European Union L 87 of 31.3.2009.
- [15] Order no. 1,962 of December 2, 2008 of the Minister of Public Health regarding the approval of the Procedure for issuing parallel import authorizations for medicines for human use, published in the Official Gazette no. 867 of December 22, 2008.
- [16] Judgment of the Court (Fourth Chamber) of 8 October 2020, Case C-602/19 *Kohlpharma GmbH v Bundesrepublik Deutschland*, ECLI:EU:C:2020:804
- [17] Directive 2011/62 / EU of the European Parliament and of the Council of 8 June 2011 amending Directive 2001/83 / EC as regards the prevention of the entry of falsified medicinal products into the legal supply chain, published in the Official Journal of the European Union L 174, of 1.7.2011.
- [18] Law no. 95/2006 on health care reform, republished in the Official Gazette no. 652 of August 28, 2015.