Memorandum

Court of Justice of European Union Creates Questionable Regulatory Shortcut for Parallel Imports of Generic Medicines

On 3 July 2019, the Court of Justice of the European Union (***CJEU***) delivered its judgment in Case C-387/18, which pits Delfarma Sp. z o.o. (***Delfarma***), a Polish parallel trader, against the Polish health authorities concerning the latter's refusal to issue a parallel import (***PI***) licence for the importation of a generic medicinal product (Azithromycin 500 mg) from the UK into Poland (CJEU, judgment of 3 July 2019 in Case C-387/18, *Delfarma sp. z o.o.* v. *Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych*, ECLI:EU:C:2019:556).

Background

In its application for a PI licence, Delfarma had used a Polish originator product (Sumamed 500 mg) as the reference product. The Polish competent authority had refused to issue a PI licence on the basis of national legislation that requires that the imported medicinal product and the domestic reference product (i) are both originator products authorised on the basis of a full marketing authorisation application or (ii) are both generic medicinal products authorised on the basis of abridged documentation as equivalent to a reference medicinal product (the ***Contested Legislation***). In the ensuing litigation initiated by Delfarma before the Regional Administrative Court of Warsaw, Poland, the question arose whether the Contested Legislation is compatible with the free movement of goods as set forth in Articles 34 and 36 of the Treaty on the Functioning of the European Union (***TFEU***). The Warsaw Court decided to stay the proceedings and seek clarifications from the CJEU in this regard under the preliminary ruling procedure.

Findings of CJEU

The CJEU held that the Contested Legislation constitutes a measure having equivalent effect to a quantitative restriction on imports prohibited by Article 34 TFEU. Furthermore, it held that the measure *cannot* be justified by considerations relating to the protection of health and life of humans referred to in Article 36 TFEU. It reached

this conclusion on the basis of highly debatable reasons which seem to confuse the rules on generic marketing authorisations[1] and the rules governing parallel trade.

First, the CJEU considered that the case had to be assessed exclusively under the provisions of the TFEU on the free movement of goods. In this regard, it noted that "*Directive 2001/83 cannot apply to a medicinal product covered by a marketing authorisation in one Member State which is being imported into another Member State as a parallel import of a medicinal product already covered by a marketing authorisation in that other Member State, because the imported medicinal product cannot, in such a case, be regarded as being placed on the market for the first time in the Member State of importation*" (§19). As we will explain below, we believe that this premise is debatable given the facts of the case.

Second, the CJEU noted that the free movement of goods implies that "*a Member State must not obstruct parallel imports of a medicinal product by requiring parallel importers to satisfy the same requirements as those which are applicable to undertakings applying for the first time for a marketing authorisation for a medicinal product*" (§22). According to the CJEU, the task of the Member State of import is limited to ensuring that:

(i) the imported medicine and the domestic reference product, without being completely identical, have at least been manufactured according to the same formulation, have the same active ingredient and have the same therapeutic effect; and

(ii) the imported medicine does not pose a problem of quality, efficacy or safety (§23).

If the Member State of import confirms that these criteria are satisfied, the imported product "*must be regarded as having already been placed on the market in that Member State and, consequently, must be entitled to benefit from the marketing authorisation issued for the medicinal product already on the market, unless there are countervailing considerations relating to the effective protection of the life and health of humans*" (§24).

Third, turning to the facts of the case, the CJEU held that the Contested Legislation actually obstructs parallel trade. It impedes market access for generic medicinal products in that it prohibits the issue of a PI licence for a generic medicine by referring to an originator reference product in the Member State of import.

---

[1] *See*, in particular, Article 10 of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311, 28.11.2001, p. 67 (***Directive 2001/83***).

Accordingly, the CJEU concluded that the Contested Legislation qualifies as a measure having equivalent effect to a quantitative restriction on imports (§26).

Fourth, the CJEU examined whether the Contested Legislation could be justified under Article 36 TFEU by considerations relating to the effective protection of the life and health of humans, as the Polish government had argued. It concluded in the negative, holding that the Contested Legislation goes beyond what is necessary to achieve the objective pursued. In this regard, the CJEU considered the following elements:

(i) Rather than requiring the Polish competent authority to verify, based on the data available, if the imported product and the Polish reference product are essentially similar, the Contested Legislation allows it to refuse to grant a PI licence based on purely formal grounds.

According to the CJEU, the competent authority of the Member State of import must undertake a genuine similarity assessment. Should the authority consider that it has insufficient information to determine the similarity of the imported product and the nationally authorised reference product, it must request such information from the applicant and/or from the national competent authority of the Member State of exportation, in the context of the cooperation between Member States (§35). Still according to the CJEU, the national competent authority must only refuse issuing the PI licence if, in spite of those verifications, it still lacks sufficient information or still has doubts as to whether the imported medicinal product poses a problem in relation to quality, efficacy and safety (§36).

(ii) Contrary to what the Polish government had claimed, the Contested Legislation is not necessary to avoid the risk of applicants bypassing the requirements of Directive 2001/83 to obtain a marketing authorisation. Both procedures (*i.e.*, both the requirements under Directive 2001/83 and the assessment in the context of parallel trade) are capable of establishing that the products concerned are essentially similar and meet the criteria of efficacy, quality and safety.

Implications and Assessment

The judgment is expected to have far-reaching implications for parallel trade in medicines across the EU. It represents a clear setback for the innovative pharmaceutical sector in that it creates an arguably unjustified regulatory shortcut for parallel imports of generic medicines. By allowing parallel traders to import generic medicinal products into EU Member States in which these products do not have a marketing authorisation, the judgment seems to introduce a *de facto* Community marketing authorisation for generic medicines. Although it asserts the opposite, we

therefore believe that the judgment undermines the existing pharmaceutical regulatory framework under Directive 2001/83.

The judgment's premise that there is parallel trade in the case at hand appears wrong. This is because the CJEU ignores that, for parallel trade to occur, the parallel traded product and the reference product in the Member State of import must necessarily have a "*common origin*"[2]. Parallel trade indeed refers to importation by a third party of validly authorised goods from a specific manufacturer into a country where the same goods are already validly marketed by the same manufacturer. Parallel trade takes place outside (*i.e.*, in parallel to) the manufacturer's distribution system and is typically driven by price differences between countries. In the Delfarma case, however, there was no trade "in parallel" since the generic medicine which Delfarma imported from the UK into Poland was not authorised and marketed in the country of importation, Poland, by the same generic manufacturer as in the UK. In the absence of genuine parallel trade, the judgment could not validly ignore and set aside the regulatory requirement of Directive 2001/83 that a medicine first put on the market in Poland should secure a marketing authorisation in that country.

Van Bael & Bellis

5 August 2019

[2] As follows from the CJEU's case law, a "*common origin*" is considered to exist if the imported product and the reference product have been manufactured by (i) the same manufacturer; (ii) a manufacturer which operates as an associated company (*i.e.*, which is part of the same group of companies); or (iii) a manufacturer which operates under licence on behalf of the manufacturer of the reference product (*see*, for instance, CJEU, judgment of 27 October 2016 in Case C-114/15, *Audace And Others*, ECLI:EU:C:2016:813, §47).