Court of Justice of European Union Rules on Updating of Documentation of Medicinal Products Subject to Parallel Import Licence

On 8 October 2020, the Court of Justice of the European Union (***CJEU***) held that, in situations where the marketing authorisation (***MA***) of the reference product in the Member State of importation has expired, a parallel importer should be able to update the documents and particulars pertaining to the medicinal product imported in parallel on the basis of the documentation of another medicinal product with the same therapeutic indication which (i) is covered by an MA in both the Member State of importation and the Member State of exportation; and (ii) contains the same active ingredient but in a different pharmaceutical form. However, this assumes that (i) the parallel import (***PI***) licence at issue is still valid; and (ii) there is no or at least insufficient evidence of a risk to the effective protection of the life and health of humans.

The CJEU handed down its judgment at the request of the Administrative Court of Cologne, Germany, in a dispute between the parallel importer kohlpharma GmbH (***kohlpharma***), no novice to parallel trade cases before the CJEU, and the German medicines agency (*Bundesinstitut für Arzneimittel und Medizinprodukte* – ***GMA***) regarding the interpretation of Articles 34 and 36 of the Treaty on the Functioning of the European Union (***TFEU***), *i.e.*, the rules on the free movement of goods.

The GMA had refused to approve specific amendments to the information leaflet and dosage instructions of the medicinal product which kohlpharma imported into Germany, namely Impromen 5 mg, tablets, which is a prescription medicine with active ingredient bromperidol indicated for the treatment of certain forms of psychosis. Although the German reference product for kohlpharma's PI licence was Impromen 5 mg, tablets, Kohlpharma had based itself for these amendments on the dosage instructions for the same product in drop form (Impromen Tropfen 2 mg/ml) considering that, at the time of kohlpharma's request, the reference product (in tablet form) was no longer available on the German market. The GMA objected to this approach and rejected the proposed amendments.

The CJEU started its analysis by reiterating its ruling in *Ferring* (judgment of 10 September 2002 in Case C-172/00, EU:C:2002:474) that Article 34 TFEU precludes national legislation under which the withdrawal of the MA of reference for a medicinal product on application by its holder automatically entails the end of validity of the PI licence for that product. According to the CJEU, this approach also applies to the situation in the case at hand as neither the withdrawal nor the expiry of the MA of reference in itself calls into question the quality, efficacy and safety of a medicinal product covered by a PI licence on the basis of that MA of reference. As a result, the validity of kohlpharma's PI licence could not be disputed.

Next, the CJEU held that the German requirement to have all amendments to the documents and particulars relating to a medicinal product that is the subject of a PI licence approved by the GMA qualifies as a measure having an effect equivalent to a quantitative import restriction within the meaning of Article 34 TFEU. In this regard, the CJEU noted that such a requirement "*is capable of preventing the importer of that medicinal product from presenting its particulars and documents in the manner that it considers the most appropriate for the prescription of that medicinal product and, thus, of hindering the marketing of that product*" (§39). In our view, this reasoning is questionable. The CJEU erroneously

seems to assume that the information leaflet and other particulars of a prescription medicine are advertising tools. In doing so, the CJEU ignores that these first and foremost channel information, with a strictly regulated content, aimed at ensuring the safe use of the product in relation to which national competent authorities must be able to exercise their tasks of supervision to ensure compliance with applicable regulatory requirements.

Given its assessment that the German measure falls within the scope of Article 34 TFEU, the CJEU went on to examine whether the measure could be justified under Article 36 TFEU based on the need to protect public health. While reiterating its established case law that "*it is for the Member States to determine the level of protection which they wish to afford to public health and the way in which that level is to be achieved*" (§40), the CJEU noted that Member States must observe the principle of proportionality. Turning to the facts of the case, the CJEU held that the GMA's refusal to approve the amendments proposed by kohlpharma was not appropriate and necessary, and thus disproportionate, to achieve the objective of protecting public health. In this regard, it considered that (i) it was not in dispute that kohlpharma's PI licence was still valid; (ii) the referring court had stated that there was insufficient evidence of a risk to the effective protection of the life and health of humans; and (iii) the GMA's refusal to approve the amendments was capable of posing health risks in that the product "*would continue to be marketed accompanied by particulars and documents which are outdated and therefore do not take account of possible new information relating to that medicinal product*" (§45). Furthermore, the CJEU dismissed the GMA's argument that parallel importers are not under an obligation to submit periodic safety reports because "[p]*harmacovigilance satisfying the relevant requirements of Directive 2001/83 can ordinarily be guaranteed for medicinal products that are the subject of parallel imports through cooperation with the national authorities of the other Member States by means of access to the documents and data produced by the manufacturer in the Member States in which those medicinal products are still marketed on the basis of a marketing authorisation still in force*".

While given in a specific factual context, the judgment is noteworthy in that it shows little confidence in the assessment made by the competent authority of the Member State of importation.

(CJEU, 8 October 2020, Case C-602/19, *kohlpharma*, EU:C:2020:804)

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Van Bael & Bellis