Court of Justice of the European Union
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Press and Information

Judgment in Case C-488/20
Delfarma

EU law precludes national legislation under which a parallel import licence of a medicinal product is to expire automatically after one year from the expiry of the marketing authorisation for the reference medicinal product, without carrying out an examination whether there is any risk to the health and life of humans

That automatic expiry goes beyond what is necessary to protect the health and life of humans

Delfarma is an undertaking engaged in parallel import of medicinal products into the Polish market. A licence for the parallel import from the Czech Republic of the medicinal product Ribomunyl, granules for oral solution, 0.750 mg + 1.125 mg, was granted to Delfarma by decision of the Polish Minister for Health in 2011, and subsequently extended by decision of the Prezes Urzędu Rejestracji Produktów Leczniczych, Wyrobów Medycznych i Produktów Biobójczych (President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland) ('the President of the Office') in 2016. That licence had been granted on the basis of a marketing authorisation ('MA') for Ribomunyl, the reference medicinal product, in the territory of Poland.

Since that MA expired in 2018, the President of the Office, by decision of 24 September 2019, declared, on the basis of the Law on medicinal products, that the parallel import licence for the medicinal product Ribomunyl expired with effect from 25 September 2019.

That decision was confirmed, in response to a request for re-examination made by Delfarma, by a decision of the President of the Office of 18 November 2019. Delfarma brought an action against that decision.

It is against that background that the Wojewódzki Sąd Administracyjny w Warszawie (Regional Administrative Court, Warsaw, Poland) referred the matter to the Court of Justice for a preliminary ruling.

In its judgment delivered today, the Court recalls, first, that a situation such as that at issue in the main proceedings, where a medicinal product covered by an MA in one Member State is imported into another Member State in which an essentially similar medicinal product is already the subject of an MA, constitutes a parallel import of a medicinal product. Since, in such a situation, the imported medicinal product cannot be regarded as being placed on the market for the first time in the Member State of importation, such a situation does not fall within the scope of Directive 2001/83. [1] Such a situation, in contrast, falls under the provisions of the TFEU on the free movement of goods and, in particular, Articles 34 and 36 TFEU which, in essence, prohibit Member States from imposing quantitative restrictions on imports and measures having equivalent effect which may, however, be justified, inter alia, on grounds of the protection of health and life of humans.

Next, the Court observes that a provision according to which the parallel import licence for a medicinal product expires automatically after one year from the expiry of the MA of reference in that Member State constitutes a restriction on the free movement of goods.

[1] 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 use (OJ 2001 L 311, p. 67), as amended by Directive 2012/26/EU of the European Parliament and of the Council of 25 October 2012 (OJ 2012 L 299, p. 1).

As regards the justification of such a restriction, the Court points out that a measure having equivalent effect to a quantitative restriction on imports can be justified, for example, on grounds of the protection of the health and life of humans only if that measure is appropriate for securing the achievement of the objective pursued and does not go beyond what is necessary in order to attain it. The Court notes in that regard that the expiry of the MA of reference provided for by the Polish legislation at issue is not based on an examination of the specific risks to the health and life of humans arising from maintaining the medicinal product on the market of the Member State of importation or, a fortiori, on the existence of such risks, with the result that there is no specific reason relating to the protection of public health requiring that the parallel import licence for medicinal products automatically expire due to the expiry of the MA of reference.

The Court examines the argument that, in the case of expiry of the MA of reference, the national authority responsible for pharmacovigilance in the Member State of importation is deprived of a significant source of information and data on the safety of the medicinal product at issue. It finds that such a circumstance does not, however, constitute a reason of a general nature which may justify the automatic expiry provided for by the national legislation at issue. Where the medicinal product in question is still marketed in a Member State on the basis of an MA still in force, that authority may obtain from other national authorities relevant information in so far as EU law [2] requires the European Medicines Agency (EMA), the national competent authorities and the MA holder to inform each other when new risks, changes to existing risks or changes to the benefit-risk balance are found. That authority may also have access to the periodic safety update reports. Those reports are made available to the national competent authorities by means of a repository. Furthermore, the adverse reactions to medicinal products reported by the MA holders, healthcare professionals or patients are listed in the Eudravigilance database which is fully accessible to the competent authorities of the Member States.

The Court also notes that the national authority responsible for pharmacovigilance in the Member State of importation is informed where the medicinal product poses serious difficulties in the Member State of exportation or in the Member States in which it is still marketed on the basis of an MA that is still in force. An emergency procedure [3] enables all Member States to be informed where a medicinal product poses such difficulties that the measures relating to its MA are proposed. Furthermore, the absence of an MA of reference in the Member State of importation does not, according to the Court, mean that the package leaflet of the medicinal product which is the subject of parallel imports cannot be updated. The holder of the MA in the Member State of exportation must ensure that that document is updated, the translation of which is facilitated by the use of certain internationally recognised terminology.

The Court concludes from this that the automatic expiry of the parallel import licence for a medicinal product solely on the basis that the MA of reference has expired, without carrying out an examination of the risks arising from that product, goes beyond what is necessary to protect the health and life of humans.

Lastly, in the view of the accessibility of the information, the administrative burden of searching for and analysing information relating to the medicinal product and the resulting public expenditure do not exceed, even where several medicinal products are the subject of parallel imports, the limits of what can reasonably be required of national authorities responsible for pharmacovigilance.

NOTE: A reference for a preliminary ruling allows the courts and tribunals of the Member States, in disputes which have been brought before them, to refer questions to the Court of Justice about the interpretation of European Union law or the validity of a European Union act. The Court of Justice does not decide the dispute itself. It is for the national court or tribunal to dispose of the case in accordance with the Court's decision, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

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[2] Article 28a(3) of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ 2004 L 136, p. 1), as amended by Regulation (EU) No 1235/2010 of the European Parliament and of the Council of 15 December 2010 (OJ 2010 L 348, p. 1).

[3] Initiated by Articles 107i, 107j and 107k of Directive 2001/83.

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