Court of Justice of the European Union
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Press and Information

Judgment in Case C-178/20
Pharma Expressz

A medicinal product not subject to medical prescription in one Member State may not be placed on the market in another Member State unless that Member State, too, has granted its marketing authorisation

In the absence of such an authorisation, it may nevertheless be possible to supply that medicinal product where its use meets, in accordance with EU law, special medical needs

In March 2019, the Hungarian authorities ordered Pharma Expressz, a Hungarian company, to stop its practice consisting in placing on the market in Hungary, without complying with the formalities laid down in Hungarian law in that regard, of medicinal products which have been granted marketing authorisation by another Member State as a medicinal product and which are available without medical prescription. According to the Hungarian legislation, medicinal products without a marketing authorisation ('MA') issued by the Hungarian authorities or the European Commission may be placed on the market only where their use for medical purposes is notified to those authorities by a medical practitioner prescribing medicinal products, who must obtain from those authorities a declaration concerning that use.

Pharma Expressz disputes that decision of the Hungarian authorities before the Fővárosi Törvényszék (Budapest High Court, Hungary), which requests the Court of Justice to clarify whether it is not contrary to EU law to require compliance with those formalities for the placing on the market, in Hungary, of medicinal products which have been granted marketing authorisation by one Member State and which are available without medical prescription.

By today's judgment, the Court recalls that, pursuant to the 'Medicines Directive', [1] no medicinal product may be placed on the market of a Member State unless an MA has been issued by the competent authorities of that Member State or, under the centralised procedure established to that end, by the Commission. Therefore, **if a medicinal product does not have an MA** issued by the competent authorities of the Member State in which it is offered for sale or an MA issued following the centralised procedure, **it may not be placed on the market in that State, regardless of whether that same medicinal product may be sold in another Member State without a medical prescription.**

As regards the procedure of mutual recognition of an MA, laid down in the 'Medicines Directive', the Court finds that it takes place under strict conditions and that it is conditional on a request by an MA holder for a given medicinal product in a Member State with a view to recognising that MA in the other Member States, a situation which does not correspond to the circumstances of the present case.

Consequently, **not only does the 'Medicines Directive' not require that a medicinal product which has been granted marketing authorisation by a Member State as a medicinal product available without medical prescription also be classified as a medicinal product not subject to medical prescription in another Member State which has not authorised its placing on the market but, on the contrary, it precludes such a possibility.**

[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).

Lastly, the Court finds that the formalities which arise from the Hungarian legislation appear to transpose into Hungarian law a derogation provided for by the 'Medicines Directive' allowing, with a view to meeting special medical needs, medicinal products to be placed on the market in a Member State even if no MA has been issued by that State or by the Commission. However, since, in adopting those formalities, Hungary correctly transposed that derogation, those formalities cannot be classified as quantitative import restrictions or as a measure having equivalent effect with regard to the principle of the free movement of goods.

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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