ECJ ruling on dispensing over-the-counter medicines in other EU countries

Exceptions only in case of special medical needs

If a drug may be sold without prescription in one EU member state, this does not automatically mean that it may also be dispensed in other EU states, according to a decision by the European Court of Justice (ECJ) in Luxembourg.

A drug that is not subject to medical prescription in one member state may only be marketed in another member state if that state or the EU Commission also authorises its marketing. According to the ECJ ruling, exceptions are only possible if a special medical need exists.

The ECJ proceedings were triggered by a legal dispute in Hungary. A Hungarian company, Pharma Expressz, contested an official order to halt the distribution of certain medicinal products not covered by a special procedure. The competent Hungarian court requested an ECJ interpretation of the EU Medicinal Products Directive.

Under Hungarian law, the marketing of medicinal products that do not have a marketing authorisation granted by Hungarian authorities or the European Commission is subject to strict conditions. As the ECJ noted, the law stipulates that such uses for therapeutic purposes must be notified to the Hungarian authorities by the prescribing physicians, who must additionally obtain an opinion from these authorities on the intended application.

Violation of EU law?

Pharma Expressz had challenged the decision of the Hungarian authorities before the Fővárosi Törvényszék (Metropolitan Court of Appeal, Hungary), which asked the ECJ to clarify whether requiring compliance with these formalities ahead of marketing the respective medicinal products in Hungary where the same products were approved for dispensation without medical prescription by another member state, was not contrary to European Union law.

No distribution without authorisation

The ECJ pointed out that under the Medicinal Products Directive, a medicinal product may not be placed on the market in a member state unless and until marketing authorisation has been granted by the competent authority of that member state or by the Commission in accordance with the centralised procedure provided for that purpose. Thus, if a medicinal product does not have either (1) a marketing authorisation granted by the competent authority of the member state in which it is offered or (2) a marketing authorisation granted in accordance with the centralised procedure, it may not be dispensed in that state – regardless of the fact that the product may be legally available without a medical prescription in another member state.

No application filed for recognition

The ECJ further notes that the procedure for mutual recognition of a marketing authorisation as provided for in the Medicinal Products Directive is performed under strict conditions and requires for the holder of a marketing authorisation for a given medicinal product in one member state to submit an application for recognition of that authorisation in the other member state or states – which does not describe the circumstances of the case at hand. Consequently, not only does the Medicinal Products Directive not require that, if a medicinal product has been authorised by one member state to be marketed as a non-prescription medicinal product, this product must also be regarded as a non-prescription medicinal product by another member state in which no pertinent marketing authorisation has been issued – on the contrary; the Directive precludes that very possibility.

Exception properly implemented in national law

Finally, the ECJ noted that the formalities established by Hungarian law appeared to be the transposition into Hungarian law of an exception provided for in the Medicinal Products Directive, which allows the dispensation of medicinal products in a member state in order to meet special medical needs, even in the absence of a marketing authorisation granted by that state or by the Commission.

However, since Hungary has properly transposed (implemented) this exception by introducing the above formalities, these formalities cannot be classified as quantitative restrictions on imports or as measures that have an equivalent effect with regard to the principle of the free movement of goods.

Sources: ECJ press release of 8 July 2021
Judgment in Case C-178/20