The differences in the procedures for the authorisation of medicinal products are not sufficient to reject a parallel import

Judgement of the CJEU, of 3 July 2019, Case C-387/18, Delfarma sp. z o.o. v Polish Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Background

This judgement is about a question referred for preliminary ruling by the Regional Administrative Court of Warsaw (Poland) regarding the compatibility of the Polish legislation on parallel imports with EU law. Polish national law requires imported medicinal products to: (i) have the same active substance, the same strength, the same route of administration, and the same form and therapeutic effect as the medicinal product authorised in Poland; and (ii) have been approved in accordance with the same legal basis than the medicinal product authorized in Poland; that is, both the product authorized in Poland and the one to be imported must have been approved as generics (abridged dossier) or as reference medicinal products (full dossier).

Position of the Polish authorities

Polish authorities rejected the application placed by Delfarma for the issue of a license for parallel import of a medicinal product (Azithromycin) from the UK after stating that such product to be imported was a generic medicinal product authorised in the UK on the basis of an abridged dossier, whereas the product authorised in Poland (Sumamed) was a reference medicinal product. According to the Polish authorities, such circumstance made it impossible for them to determine whether the differences between Azithromycin and Sumamed could be considered significant from the point of view of safety and efficacy. The Polish Court, however, had doubts about the compatibility of these national provisions with the EU case-law regarding the free movement of goods and referred a question to the CJEU for preliminary ruling.

Judgment of the CJEU

According to Polish authorities, Polish national provisions are necessary in order to guarantee that both the product authorized in Poland (in this case Sumamed) and the one to be imported (in this case Azithromycin) are sufficiently similar, as well as to prevent the risk that, through a parallel import, the standard authorisation and registry procedures of medicinal products are avoided. The CJEU, however, concluded that the EU law does not allow national authorities to reject an application for parallel import merely because two medicinal products have been authorised in the EU under different procedures. The CJEU recalled that, according to EU case law, the Member State of importation must ensure that the medicinal product imported as a parallel product and the medicinal product which is the subject of the marketing authorization in the Member State of importation, even if not identical in all respects, have the same therapeutic effect, and that the imported medicinal product does not pose a problem of quality, efficacy or safety. If the result of this assessment is satisfactory, there should be no obstacle for the imported medical product to benefit from an abridged approval procedure in the Member State of exportation.

As long as national Polish law prevents this assessment from being completed, the CJEU concluded that such national law is incompatible with EU law.