COURT OF JUSTICE
OF THE EUROPEAN UNION

Judgment of the Court in Case C-354/25 | [Waisrinter] [1]

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Medicinal products and labelling: the labelling requirements laid down by the Community Code relating to medicinal products for human use also apply in the case of parallel imports

Furthermore, the exemption from certain labelling obligations which may be granted to a medicinal product that is not 'intended to be delivered directly to the patient' does not depend on whether or not that medicinal product is subject to medical prescription

An Italian company holds a marketing authorisation issued in Germany for a medicinal product for human use for the treatment of prostate cancer (the reference medicinal product) which is subject to medical prescription. That medicinal product is supplied in the form of a solution for injection, sold in two trays sealed with plastic film and contained in a cardboard box. The two trays each contain a syringe, the contents of which must be mixed by screwing one syringe into the other in order to prepare the solution for injection. The medicinal product is for single use only and must be prepared and used immediately after the trays have been opened.

In 2010, the competent German authority granted a German company the authorisation for a similar medicinal product to be imported from Italy into Germany as a parallel import to the reference medicinal product. In 2014, that parallel import authorisation was renewed for the benefit of that company. It was exempted, however, from the obligation, required by the German law on the marketing of medicinal products, to affix certain particulars in the German language to the syringes, even though German legislation does not provide for the possibility of such an exemption. Thus, the renewal of the authorisation specifies that, for reasons of the medicinal product's stability, the parallel importer must not open the thermoplastic trays to label the syringes. In order nevertheless to ensure the clear identification of the medicinal product, the parallel importer had to ensure that certain particulars appeared in Latin characters on the syringes, in particular the name of the medicinal product, its dosage and information making it possible to clearly distinguish the two syringes.

In that context, an appeal on a point of law was brought before the German Federal Administrative Court concerning the question whether the renewal of the parallel import authorisation infringes the applicable labelling requirements. The referring court asks the Court of Justice to clarify the applicability of the labelling rules, derived from EU law, to parallel-imported medicinal products and whether it is possible, under EU law, to derogate from those rules in respect of certain medicinal products. [2]

In its judgment delivered today, the Court of Justice held that **the labelling requirements** laid down by the Community code relating to medicinal products, including those of the labelling and package leaflet appearing in an official language of the Member State where the medicinal product is placed on the market, **also apply to medicinal products for human use which are the subject of parallel imports**. [3] In order to ensure that patients and healthcare professionals have the information necessary to prevent any risk to public health, the parallel-imported medicinal products must be subject to the same requirements as those imposed on medicinal products placed on the market under the marketing authorisation (MA) procedure.

As regards the exemption from the obligation that certain particulars should appear on the labelling of a medicinal product, which may be granted by the competent authorities, where the **medicinal product 'is not intended to be delivered directly to the patient'**, [4] it must be understood as **referring to a medicinal product** the administration of

which requires the intervention of a healthcare professional or a healthcare establishment, **irrespective of whether that medicinal product is subject to medical prescription**.

As regards the possibility of derogating from certain labelling rules in order to permit the parallel importation of medicinal products, the Court of Justice considers that, although such a possibility is not provided for under German law, the German authorities are empowered, under EU law, to examine applications from economic operators seeking to grant them such derogations.

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 of the European Union about the interpretation of EU law or the validity of an EU act.

The General Court has jurisdiction to deal with requests for a preliminary ruling coming exclusively within the following areas (1) the common system of value added tax (VAT), (2) excise duties, (3) the Customs Code, (4) the tariff classification of goods under the Combined Nomenclature, (5) compensation and assistance to passengers in the event of denied boarding or delay or cancellation of transport services, or (6) the system for greenhouse gas emission allowance trading. The Court of Justice has jurisdiction to deal with all other requests for a preliminary ruling.

Neither the Court of Justice nor the General Court decides the national dispute itself. It is for the national court or tribunal to resolve the case in accordance with the ruling by the Court of Justice or by the General Court, which is similarly binding on other national courts or tribunals before which a similar issue is raised.

Unofficial document for media use, not binding on the Court of Justice. The presentation of the facts and the legal context refers to the relevant period and is based on the case file.

The full text and, as the case may be, an abstract of the judgment is published on the CURIA website on the day of delivery.

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Images of the delivery of the judgment are available on 'Curia Web TV'.

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[1] The name of the present case is a fictitious name. It does not correspond to the real name of any party to the proceedings.

[2] More specifically, Article 54, Article 55(3) and Article 63(1) and (3) of 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, as amended by Directive 2012/26/EU.

[3] A parallel import of medicinal products is a situation 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.

[4] Article 63(3), first sentence, of the Directive.