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Parallel import of in vitro diagnostic medical devices

Judgment of the Court of Justice of the European Union (CJEU), of 13 October 2016, (Case C-277/15, Roche Diagnostics Deutschland GmbH vs Servoprax GmbH)

Background

Roche Diagnostics markets in vitro diagnostic medical devices in Germany. Servoprax purchased said devices in the United Kingdom, where they were also marketed, and then added a label and instructions in German and sold them in Germany. The product's label in Germany made reference to two units of measurement ("mmol/l" and "mg/dl"), whilst in the United Kingdom, the label only featured one unit ("mmol/l"). Given that the units that Servoprax distributed in Germany only made reference to the latter unit ("mmol/l"), Roche Diagnostics believed that Servoprax could not sell them in such country without previously submitting them to an additional compliance assessment. Servoprax submitted the products to said assessment in December 2010 but, nevertheless, Roche Diagnostics brought suit for alleged damages caused theretofore. The local court, believing that the case was dependent on the interpretation of Directive 98/79/EC, suspended the main proceedings and raised the issue before the CJEU.

Freedom of movement covers the actions of Servoprax

Given that Directive 98/79/EC establishes that in vitro diagnostic medical devices that have been assessed and have obtained the CE marking must be able to enjoy free movement within the EU and given that German laws do not prohibit their distribution when the product information included is solely provided in the "mmol/l" unit of measurement, the CJEU ruled that there was no reason to demand that Servoprax submit the units resold in Germany to a new compliance assessment. In this regard, it asserted that the product compliance assessment is an obligation of the manufacturer who places the product onto the Community market for the first time, and not of the parallel importers purchasing a product in a Member State before subsequently reselling it in another. The foregoing applies, according to the Court, even if the information on the product has to be translated into the official language of the country to which the product is imported to, as established in Directive 98/79/EC.

Inclusion of a label and instructions in German does not involve reconditioning

The Court's comments on the position of the European Commission are worth noting, given that the latter sustained that the parallel importer was obliged to communicate operations to the manufacturer, by way of analogy with the criteria set out in European case law in connection with medicinal products. The CJEU, on the other hand, concluded that the mere fact that a label and instructions translated into the official language of the importing country were included on the product, without changing its packaging or presentation, does not mean it was reconditioned. As a result, it asserted that in such cases, there is no legal basis that calls for the manufacturer to be informed of such operations.