The CJEU provides additional context regarding what should be considered as an industrially manufactured medicinal product according to Directive 2001/83/EC

Judgment of the Court of Justice of the European Union (CJEU) of 26 October 2016 (Case C -276/15), Hecht-Pharma

Background

Hohenzollern Apotheke (HA), a German pharmacy, produces medicinal products without having a marketing authorisation (MA) under the German law, which excludes medicinal products frequently prescribed by doctors and dentists from requiring said authorisation, when the essential manufacturing steps for such products are carried out in a pharmacy and are to be dispensed to the pharmacy's users, and up to 100 packages per day.

Hecht-Pharma asked the German Courts to order HA to refrain from promoting the aforementioned activities in Germany, alleging that Directive 2001/83/EC prohibits the promotion of medicinal products that do not have a MA pursuant to Community law.

In Germany, the ban on promotion of magistral and officinal formulae is not absolute, as it is in Spain, and only affects products that are required to have a MA on a mandatory basis and yet do not have one. In this context, the German Court referred the case to the CJEU for a preliminary ruling to clarify whether the medicinal products produced by HA required a MA.

Conclusions of the CJEU

The CJEU started by reiterating that only medicinal products manufactured industrially or whose production involves an industrial process, characterised as a succession of mechanical or chemical operations designed to produce a significant quantity of a standardised product, are subject to the Directive, and therefore require a MA. Although these criteria should be assessed by the local Court, the CJEU ruled that in the present case, it would appear that the medicinal products are not produced industrially by an entity operating on a large scale.

The CJEU went on to add that, even if the local Court has a different interpretation of the circumstances of the case, the medicinal products produced by HA would be classified as officinal formulae, which, along with magistral formulae, are excluded from the Directive's scope of application. The CJEU did not question the correctness of the German law that allows that a pharmacy, such as HA, takes charge of the essential phases of the production of a medicinal product and; therefore, seemingly permitting that other phases of such production are outsourced by the pharmacy to third parties.

It is also interesting that the CJEU did not dispute the German legislation restricting the prohibition on advertising merely to medicinal products required to have a MA on a mandatory basis and yet do not have one. The foregoing would seem to suggest that the CJEU believes that national legislations providing for the promotion of magistral and officinal formulae is compatible with Community law.