



JAN. 23

INFORMATIVE NOTE

HEALTHCARE, LIFE SCIENCES & PHARMACEUTICALS

Restrictions on advertising rules for medicinal products

The Court of Justice of the European Union (CJEU) issued a decision in the EUROAPTIEKA case on 22 December 2022. In the decision, the CJEU concluded that a national provision prohibiting the advertising of medicinal products on the basis of price (by announcing a promotion or a package sale with other medicines or products) is compatible with EU law, even when that advertising does not mention a particular medicine. According to the CJEU, price-based promotional campaigns do not encourage the rational use of the medicine, so they should be prohibited by Member States.

A national provision prohibiting the advertising of medicinal products on the basis of price (by announcing a promotion or a package sale with other medicines or products) is compatible with EU law.

The case dates back to March 2016, when EUROAPTIEKA, a Latvian company operating in the field of medicinal products, carried out an advertising campaign in which it advertised a price reduction on the purchase of any medicine when customers purchased at least three products. That advertising campaign was prohibited by the Latvian Public Health Inspectorate. The decision was based on a national provision prohibiting the inclusion, in the advertising of medicinal products to the general public, of information which encourages the purchase of the medicinal product on the basis of price, by announcing special promotions or indicating that the medicinal product is sold in a package with other medicinal products or products. In January 2020, EUROAPTIEKA appealed this decision to the Latvian Constitutional Court. In the appeal it argued, among others, that the national provision did not comply with Directive 2001/83 of the Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ("the Directive"). Here, using the preliminary reference mechanism, the Latvian Constitutional Court asked the CJEU whether (i) the concept of "advertising of medicinal products" in Article 86(1) of the Directive covers advertising for non-specific medicinal products; and whether (ii) Member States are entitled in their national legislation to prohibit advertising methods other than those prohibited by Article 90 of the Directive.

In response and in line with Advocate General Szpunar's submission, the CJEU stated that Article 86(1) must be interpreted as meaning that "the dissemination of information which encourages the purchase of medicinal products by justifying the need for such a purchase on the basis of the price of those medicinal products, by announcing a special sale or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other products, falls within the concept of 'advertising of medicinal products', within the meaning of that provision, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products".

Eduardo Nogueira Pinto Joana Baeta Vieira Tiago Linhares Carneiro Healthcare,

Life Sciences & Pharmaceuticals team

1/2. Transformative Legal Experts www.plmj.com

According to the CJEU, price-based promotional campaigns do not encourage the rational use of the medicine.

The grounds for the decision are based on several arguments:

- i) First, the court points out that the term "advertising of medicinal products" is defined in the Directive as "any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products". This refers to a very broad definition including "any form" of provision of information, including the "advertising of medicinal products to the general public", while the reference to "medicinal products" is made in the plural. Therefore, the interpretation cannot be that advertising of indeterminate medicinal products is excluded from this concept.
- ii) The definition falls within the provisions of the Directive that set out the general and fundamental rules on advertising medicinal products and therefore apply to any action designed to promote the prescription, supply, sale or consumption of medicinal products.
- iii) The objective of ensuring the protection of public health would be circumvented if the concept of "advertising of medicinal products" did not include actions that do not target a specific medicinal product. The CJEU held that the purpose of the message is important in order to distinguish it from simple advertising of information. Therefore, a message intended to promote the prescription, supply, sale or consumption of medicinal products must be covered by the concept of advertising within the meaning of the Directive.

As regards the second question asked by the referring court, the CJEU interprets Articles 87(3) and 90 of the Directive "as not precluding a national provision that prohibits the inclusion, in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, information which encourages the purchase of medicinal products by justifying the need for that purchase on the basis of the price of those medicinal products, by announcing a special sale, or by indicating that those medicinal products are sold together with other medicinal products, including at a reduced price, or with other types of products." According to the CJEU's reasoning, the aim of the Directive is to achieve complete uniformity of the laws of the Member States on the advertising of medicinal products by establishing the restrictions and prohibitions to which that advertising must be subject. For that reason, Member States may only make the advertising of medicinal products subject to the requirements laid down by the Directive. As regards, in particular, non-prescription or non-reimbursed medicinal products, Article 90 of the Directive contains a list of advertising particulars that may not be included. However, according to the CJEU, this list must be read in conjunction with (ii) Article 87(3) of the Directive, which obliges any advertising to promote the rational use of the medicinal product, and (ii) $Recital\ 45\ of\ the\ Directive, which states\ that\ ``advertising\ to\ the\ general\ public\ of\ non-prescription\ medicinal\ and\ problem and\ p$ products could affect public health if it were excessive and ill-considered."

In short, the CJEU held that Article 90 of the Directive does not contain an exhaustive list of prohibited advertising methods. In its national legislation, each Member State can prohibit the inclusion in advertising to the general public of information encouraging the purchase of medicinal products on the basis of price, by announcing promotions or package sales with other medicinal products or products, because these methods are likely to encourage the non-rational use of medicinal products.

PLMJ COLAB ANGOLA - CAPE VERDE - CHINA/MACAO - GUINEA-BISSAU - MOZAMBIQUE - PORTUGAL - SÃO TOMÉ AND PRÍNCIPE - TIMOR-LESTE

This document is intended for general distribution to clients and colleagues, and the information contained in it is provided as a general and abstract overview. It should not be used as a basis on which to make decisions and professional legal advice should be sought for specific cases. The contents of this document may not be reproduced, in whole or in part, without the express consent of the author. If you require any further information on this topic, please contact Eduardo Nogueira Pinto (eduardo.nogueirapinto@plmj.pt.

2/2. Transformative Legal Experts www.plmj.com