



Medicinal products for human use. The Court of Justice of the EU rules on the advertising by price of medicinal products not subject to medical prescription and not reimbursed

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📖 EUROPEAN AND COMPETITION LAW, FARMACEUTICAL AND LIFE SCIENCES, LITIGATION

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On 22 December 2022, the Court of Justice of the European Union held its judgement in Case C-530/20, *SIA «EUROAPTIEKA»*, on the interpretation of Article 86(1), Article 87(3) and Article 90 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 use¹. The request has been made in proceedings brought by ‘EUROAPTIEKA’ SIA (“EUROAPTIEKA”), a company established in Latvia which is part of a

group which owns a network of pharmacies and companies distributing medicinal products for retail, concerning the legality of a national provision prohibiting certain forms of advertising of medicinal products.

In March 2016, EUROAPTIEKA announced a promotion on its website and in its monthly magazine, offering a 15% reduction on the purchase price of any medicinal product where at least three products were purchased. On the basis of the *Ministru kabineta noteikumi Nr. 378 ‘Zāļu reklamēšanas kārtība un*

¹ OJ L 311 of 28.11.2001.

kārtība, kādā zāļu ražotājs ir tiesīgs nodot ārstiem bezmaksas zāļu paraugus (Decree No 378 of the Council of Ministers on the detailed rules for the advertising of medicinal products and detailed rules pursuant to which a medicinal product manufacturer may give free samples of medicinal products to medical practitioners)², however, the *Veselības inspekcijas Zāļu kontroles nodaļa* (Medicinal Product Control Section of the Health Inspectorate) banned EUROAPTIEKA from the dissemination of advertising relating to that promotion. The latter, therefore, brought an appeal before the *Latvijas Republikas Satversmes tiesa* (Constitutional Court of Latvia; the “referring court”) which, in light of the need to interpret the relevant European legislation, decided to stay the proceedings and to refer to the Court of Justice three questions for a preliminary ruling.

By its first question, the referring court asked whether Article 86(1)³ of Directive 2001/83 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.

The Court preliminarily reminded that European law provisions must be interpreted taking into consideration not only their wording, but also the context in which they occur as well as the objectives pursued by the rules of which they are part⁴. In this regard, advertising of medicinal products is liable to harm public health⁵, one of the objectives pursued by Directive 2001/83, in light of the serious consequences for health which may arise from improper use or overconsumption of medicinal products available only on prescription⁶, as well as the risks which may also arise from excessive or ill-considered use of medicinal products not subject to such prescription⁷. Medicinal products, indeed, stand out from other goods because of

² Subparagraph 18.12 of Decree No 378 provides: “... *It is prohibited to include in advertising to the general public of a medicinal product any information which encourages the purchase of the medicinal product by justifying the need to purchase that medicinal product on the basis of its price, by announcing a special clearance sale, or by indicating that the medicinal product is sold as a bundle together with other medicinal products (including at a reduced price) or other types of product...*”.

³ Article 86 of Directive 2001/83 at paragraph 1 provides: “... *For the purposes of this Title, “advertising of medicinal products” shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products; it shall include in particular:*

- *the advertising of medicinal products to the general public,*
- *advertising of medicinal products to persons qualified to prescribe or supply them,*
- *visits by medical sales representatives to persons qualified to prescribe medicinal products,*
- *the supply of samples,*
- *the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind, except when their intrinsic value is minimal,*
- *sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products,*
- *sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith...*”.

⁴ ECJ 22.06.2021, Case C-872/19 P, *Venezuela v Council (Whether a third State is affected)*, paragraph 42.

⁵ ECJ 05.06.2011, Case C-249/09, *Novo Nordisk*, paragraph 32.

⁶ ECJ 05.06.2011, Case C-316/09, *MSD Sharp & Dohme*, paragraph 30.

⁷ ECJ 01.10.2020, Case C-649/18, A (*Advertising and sale of medicinal products online*), paragraphs 80 and 94.

their therapeutic effects⁸, which imply that, if consumed unnecessarily or incorrectly, they may cause serious harm to health without the patient being in a position to realise that when they are administered⁹.

The essential aim of safeguarding public health, therefore, would be greatly compromised if Article 86(1) of Directive 2001/83 were to be interpreted as meaning that an activity of door-to-door information, canvassing or inducement seeking to promote the prescription, supply, sale or consumption of medicinal products without making reference to a specific medicinal product did not fall within the concept of “advertising of medicinal products” within the meaning of that provision and, as such, avoided the prohibitions, conditions and restrictions laid down by that directive on the subject of advertising. To the extent that advertising for non-specified medicinal products, such as that of an entire class of medicinal products intended to treat the same pathology, may relate equally to medicinal products subject to medical prescription and to those the cost of which may be reimbursed, indeed, to exclude such an advertising from the scope of the provisions of Directive 2001/83 on the subject of advertising would result in the

prohibitions laid down in Article 88(1)(a) and Article 88(3)¹⁰ of that directive being deprived of their effectiveness to a large extent, by allowing any advertising that does not refer to a specific medicinal product within that class to escape those prohibitions.

In the specific case, the activities to which Decree No 378 applies do not relate merely to dissemination to the public solely of information about medicinal products, such as the objective information as to their price, but are activities which encourage the purchase of medicinal products by justifying it on the basis of the price, by announcing a special sale, or by offering a sale that is bundled together with the sale of other medicinal products, as the case may be at a reduced price, or with the sale of other products sold by the pharmacy concerned. Such activities, therefore, appear to have a promotional purpose and, consequently, fall within the concept of “advertising of medicinal products” according to Article 86(1) of Directive 2001/83.

By the second and third questions, instead, the referring court asked, on the one hand, whether Article 87(3)¹¹ and Article 90¹² of Directive 2001/83 must be interpreted as precluding a national

⁸ ECJ 18.09.2019, Case C-222/18, *VIPA*, paragraph 73.

⁹ ECJ 19.05.2009, Joined Cases C-171/07 e C-172/07, *Apothekerkammer des Saarlandes and o.*, paragraphs 32-33.

¹⁰ Article 88 of Directive 2001/83 at paragraph 3 provides: “... Member States shall be able to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed...”.

¹¹ Article 87 of Directive 2001/83 at paragraph 3 provides: “... The advertising of a medicinal product: - shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties, - shall not be misleading...”.

¹² Article 90 of Directive 2001/83 provides: “... The advertising of a medicinal product to the general public shall not contain any material which:

(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;

(b) suggests that the effects of taking the medicine are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;

(c) suggests that the health of the subject can be enhanced by taking the medicine;

(d) suggests that the health of the subject could be affected by not taking the medicine; this prohibition shall not apply to the vaccination campaigns referred to in Article 88(4);

(e) is directed exclusively or principally at children;

(f) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;

provision that imposes restrictions not provided for in that Article 90, by prohibiting the inclusion, in advertising to the public of medicinal products, of information that 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 offering a sale of those medicinal products bundled together with other medicinal products, including at a reduced price, or with other products and, on the other hand, whether such a national provision may be regarded as promoting the rational use of medicinal products, within the meaning of Article 87(3) of that directive.

The Court preliminarily reminded that since Directive 2001/83 brought about complete harmonisation in the field of advertising of medicinal products, where the option of laying down different rules is not given to Member States expressly, the only conditions they need to abide by are those laid down by that directive¹³. As regards the relationship between the requirement that advertising promotes the rational use of medicinal products and the restrictions referred to in Article 90 of Directive 2001/83 in the form of a list of banned advertising methods, the fact that the directive does not contain any specific rules concerning certain advertising material does not preclude that, with the aim of preventing any excessive and ill-considered advertising of medicinal products which could affect public health, Member States may prohibit that material to the extent that it encourages the irrational use of medicinal products¹⁴. It is for Member States, therefore, to prohibit the inclusion of material other than that referred to in

Article 90 of Directive 2001/83 in advertising to the general public of medicinal products that are neither subject to medical prescription nor reimbursed, where that material is of such a nature as to encourage the irrational use of those medicinal products.

As regards medicinal products which are neither subject to medical prescription nor reimbursed, it is frequently the case that the end consumer himself or herself evaluates, without the assistance of a doctor, the usefulness or need to purchase them. Since that consumer does not necessarily have the specific and objective knowledge enabling him or her to evaluate their therapeutic value, advertising may exercise a particularly strong influence on the evaluation and choice about the quality as well as the amount of the medicinal product to purchase. In that context, advertising methods such as those referred to in Decree No 378 are of such a nature as to encourage consumers to purchase medicinal products which are neither subject to medical prescription nor reimbursed according to an economic criterion connected with the price of those medicinal products, thereby being likely to lead them to purchase and consume those medicinal products, without an objective evaluation based on the therapeutic properties of those products and on specific medical needs.

An irrational and excessive use of medicinal products may also arise as a result of advertising material that, like Decree No 378's one, by referring to promotional offers or bundled sales of medicinal products and other products treats the first ones in the same way as

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- (g) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product;
(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;
(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
(j) refers, in improper, alarming or misleading terms, to claims of recovery;
(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof;
(l) mentions that the medicinal product has been granted a marketing authorization...".

¹³ ECJ 08.11.2007, Case C-374/05, *Gintec*, paragraphs 20 and 25.

¹⁴ *Ibidem*, paragraphs 50, 55 and 59.

other consumer goods, which are in general the subject of discounts and price reductions where a certain level of expenditure is exceeded. Prohibitions such as Decree No 378's ones do not cover the dissemination of merely informative statements, which lack any promotional intent, about those medicinal products, but rather the dissemination of content that seeks to encourage the purchase of those medicinal products, whether by reference to their price, to a special sale or a sale bundled with other medicinal products, including at a reduced price, or with the sale of other products. Despite the effective protection of health and life of humans demands that medicinal products be sold at reasonable prices and that, therefore, price competition could be capable of benefiting the patient¹⁵, therefore, Decree No 378 merely prohibits advertising of promotional offers or bundled sales and advertising on the basis of price, without prejudice to the possibility, recognised under Latvian law for undertakings that trade in medicinal products, to grant discounts and price reductions when selling medicinal products and other health products.

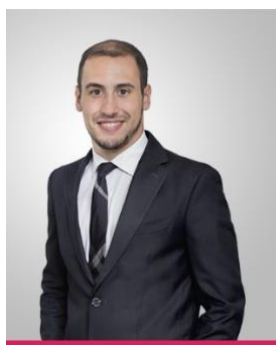
In light of the above, the Court therefore established that:

“Article 86(1) 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 2004/27/EU of the European Parliament and of the Council of 31 March 2004, must be interpreted as meaning that the dissemination of information that 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 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.

Article 87(3) and Article 90 of Directive 2001/83, as amended by Directive 2004/27, must be interpreted 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, of 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”.

¹⁵ ECJ 19.10.2016, Case C-148/15, *Deutsche Parkinson Vereinigung*, paragraph 43.



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