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CASE NOTE

Getting Specific on Non-Specificities: Case C-530/20 *SIA "EUROAPTIEKA"*

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Case-530/20 SIA "EUROAPTIEKA" (not yet published)

A pharmacy offering a discount on the bulk purchase of non-specified, non-prescription medicinal products was contrary to Directive 2003/83/EC, Articles 86 and 87, which applies to promotions for non-specified medicinal products (author's summary)

Directive 2001/83/EC[1] lays out a clear framework for the regulation of advertising of "medicinal products to the general public". The purpose of the legislator was to limit the damage advertising could cause to public health, and it accomplished this by enacting a framework to ban all advertising that did not meet the criteria laid out in the Directive.[2] Article 86 presents a general and broad definition of advertising, including not only traditional advertising, but also any forms of promotions or bonuses. Article 87 requires advertising only not to be misleading and not to encourage irrational use of medication. Article 90 provides a long list of things advertising cannot do (eg suggest that a medicinal product is a cosmetic). Member States are also accorded discretion with regards to banning advertising about price.

Given this strict European framework, manufacturers and sellers of medicinal products have a history of trying to find ways around the rules to promote their products.[3] One major field of dispute has been "non-specific" promotion, by which no particular product is promoted but an incentive is given for the purchase of any medicinal product generally. The contradictions created by *obiter dicta* in previous rulings on the vexed question of non-specificity confused even the Court of Justice. After a first hearing (in December 2021) and a full Opinion from Advocate General (AG) Szpunar, the Court took a second look and had to hold a second hearing (in June 2022), in Case C-530/20 *SIA "EUROAPTIEKA"*, before the Grand Chamber (to which it was belatedly referred).

[1] Arts 86 and 87 of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use, as amended, OJ L 31, of, 28.11.2001, pp 67–128.

[2] Directive, Recital 45.

[3] See, eg, Case C-316/09 *MSD Sharp & Dohme* [2011] ECR I-03249, discussed in AM Seitz, "No Prohibition of Dissemination of Information on Prescription-Only Medicinal Products on a Manufacturer's Website" (2011) 2(3) European Journal of Risk Regulation 447.

I. Facts

A Latvian pharmacy, EUROAPTIEKA, offered a 15% discount to purchasers of three or more non-prescription medicinal products. The Latvian authorities rely on domestic legislation implementing Articles 86 and 87 of the Directive,[4] which specifically bar bulk promotions of medicinal products on the basis that incentives to purchase multiple products encourage irrational use contrary to Article 87(3). As its promotion had quite clearly violated this provision, EUROAPTIEKA resorted to a constitutional complaint to the Latvian Constitutional Court, on the basis that the Directive had harmonised the law with regards to advertising for medicinal products. From that premise, the pharmacy argued that because advertising for non-specific medicinal products was not advertising a *single* medicinal product and because Article 90 of the Directive did not prohibit the discount for bulk purchase, the Latvian rules were precluded by the European Union (EU) legislator's decisions. The Latvian government disputed this, on the basis that "advertising in medicinal products" should be given a wide interpretation to achieve the teleological aim of reducing the irrational use of medicines (which could be prompted by the promotion at hand). The Constitutional Court referred the case to the Court of Justice of the European Union (CJEU).

Before the Court, the Greek and Polish governments, as well as the Commission, initially submitted observations in addition to the parties. A First Opinion was given by AG Szpunar on 9 December 2021. When the case was referred to the Grand Chamber and the oral procedure was reopened, further observations were submitted from the parties and the Commission. AG Szpunar then submitted an additional Opinion (Second Opinion) on 9 June 2022.[5] The AG in both Opinions maintained the same position: the Directive covered non-specific advertising and promotions that could encourage irrational use (and were therefore capable of being banned by Member States), and the list of examples of banned misleading practices was not exhaustive. The Second Opinion confirmed all of these positions while emphasising that the contrasting earlier cases were not to be interpreted as exempting non-specific advertisements.

II. Judgment

The Grand Chamber began with a consideration of the meaning of the phrase "advertising in medicinal products" in Article 86. The EU legislator used broad language, defining advertising as "any form" of information dissemination promoting medicinal products, including "in particular the advertising of medicinal products to the general public". This language did not suggest that non-specific medicinal products were excluded from the ambit of the provision.[6] However, Articles 89 and 90 make specific reference to "a medicinal product", implying specificity. This, however, was not applicable, with the Court noting that Article 89(1) specifies that its definition is without prejudice to Article 88. Furthermore, the specified reference to specific products in Articles 89 and 90 did not abrogate the general wide definition of medicinal product advertising.[7]

The teleological perspective concurred with this analysis. Recital 2 of the Directive made clear that the purpose of the legislation was protecting public health from the harms

[4] Ministru kabineta noteikumi Nr. 378 "Zāļu reklamēšanas kārtība un kārtība, kādā zāļu ražotājs ir tiesīgs nodot ārstiem bezmaksas zāļu paraugus" (Decree No 378 of the Council of Ministers of 17 May 2011 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 medicinal practitioners), of 17 May 2011 (*Latvijas Vēstnesis*, 2011, No 78), para 18.12.

[5] Facts are summarised in paras 11–19 of the Judgment.

[6] Judgment, paras 32–34.

[7] Judgment, paras 35–38.

potentially created by medicinal advertising. This risk could be created even with regards to medicinal products that do not require prescriptions; here, the Court made reference to its previous decision in *A (Advertising and sale of medicinal products online)*.[8] The entire purpose of the regime around all medicinal products was to limit this harm, and such a regime would be compromised if promotions for non-specified items were exempt from any regulatory oversight.[9]

The Court then addressed the reason for the referral to the Grand Chamber: the seeming contradictions created by *A* as well as *DocMorris*, where in asides the Court had indicated that the Directive's scope was limited to particular products.[10] In the former case, general online advertising for medicinal products had been found to fall outside the scope of the Directive, which the Court said governed "advertising for particular medicinal products".[11] The word "particular" implied that the Directive governed specific medicinal products. The direction of *A* was also important: the case involved a finding that the online advertising at issue was outside the scope of the Directive's advertising rules. This circumscription of the legislator's strict rules could be read as indicating that promotions at the edge of the prohibition (like the Latvian pharmacy's) would not be caught by the provision's ambit. In the latter, a prize draw that consumers could enter by fulfilling a prescription order at a certain pharmacy was held not to encourage the irrational use of medicinal products (since it could only influence the choice of pharmacy where the consumer fulfilled their prescription, not the quantity purchased). In concluding this, the Court emphasised that the prize draw was "an advertisement not for a specific medicinal product but for the entire range of medicinal products".[12] Here again was the implication of specificity. Furthermore, the case repeated the pattern of circumscribing the scope of the Directive, which would indicate a direction of interpretation favourable to the pharmacy. Thus, the Court was forced to state that it was deciding the case "notwithstanding" these *dicta* in *A* and *DocMorris*.[13] It consequently found that non-specific promotions were within the scope of the Directive.[14]

The remaining issue was whether the specific Latvian restrictions on promotions were precluded by the harmonisation measures in the Directive. Article 90 provides a specific list of methods that are prohibited in any public advertising, and promotions for buying bundles of non-specific medicinal products are not on that list. The Court had regard to the purpose of the Directive – the elimination of incentives to irrational consumption of medicines – in concluding that specific Member State prohibitions to discourage such irrational use advanced rather than contradicted the harmonisation of EU law on this matter.[15] The Latvian prohibitions constituted that sort of prohibition because advertising encouraging the purchase of non-prescription medicinal products could create incentives for the consumer to purchase medicines without a thorough evaluation of their properties and the consumer's needs.[16] The alteration in the price of the medications was likely to encourage consumption, as alterations of price would for any consumer good.[17] While reducing the price of medicinal goods was important to ensure ready access of patients to goods protecting their health, the Latvian law was tailored so as only to stop promotional

[8] Case C-190/20 (not yet published), hereinafter "*A*", cited at para 40 of the Judgment.
[9] Judgment, paras 44–45.
[10] Case C-190/20 (not yet published).
[11] *A*, para 50, mentioned at para 49 of the Judgment.
[12] *DocMorris*, para 21, mentioned at para 50 of the Judgment.
[13] Judgment, para 51.
[14] Judgment, para 58.
[15] Judgment, paras 63–64.
[16] Judgment, para 66.
[17] Judgment, para 68.

offers and bundling while allowing price reductions in medicinal products. Therefore, it was lawful.[18]

III. Comment

This case is, procedurally, something of an oddity because it had two AG opinions. This quirky aberration reflects the incoherence of the Court's case law on the Directive. On the one hand, there is a line of case law going back to Case C-322/01 *Deutscher Apothekerverband*,[19] which limited the scope of the definition of advertising. Yet, there is also a line of cases, typified by C–421/07 *Frede Damgaard*,[20] which provide for a broad, purposive interpretation of the advertising rules. It was only after having already been through the oral procedure once that it was realised that the outcome of the systematic, contextual and teleological readings mandated (covering non-specific products) was in contradiction to previously decided case law. Admittedly, the adverse points in *A* and *DocMorris* were in passing, but they were also the only authorities to that date on this point. Here, the Court's often unclear written style was an aggravating factor in the confusion, in that the remarks about "particular" medicinal products in *A* were not even clearly tied to any of the four fact patterns at issue in that case. This was a mess of the Court's own making, with the sparse reasoning that typifies EU judgments working to create a phantom authority for a proposition unsupported by legislation.

Unfortunately, the Court's concision in quashing its own decisions (a quick, cursory "notwithstanding") did not quite solve the problem. It would have been preferable to either harmonise this case with the remarks in two earlier ones (say, by reinterpreting the meaning of "particular" in *A*) or to be more explicit about the degree and extent to which the Court was tossing out its decisions in those cases. Did it actually ever decide in *A* that there was a residual category of non-specific products? This remains unclear.

Nevertheless, it is good that the Court has at least saved EU law from the phantom grouping of non-specific products; given that promotions and advertising are often couched in non-specific terms, it would be a gaping hole in harmonisation to omit this. The conclusion, however, is more questionable with regards to the permissibility of the Latvian measure as being within the scope of the Directive. The reasoning of the Court was orthodox for EU jurisprudence but questionable as it applies to the real world. Is the irrational use (a charming EU neologism) of medicinal products really motivated by a promotion of 15% off for three products? The uninspiring promotion seems more likely to influence consumer behaviour by redirecting purchases from one pharmacy to another. This kind of advertising designed to influence consumer choice was upheld for prescription advertising in *DocMorris*.

Of course, unlike prescription products, non-prescription medicinal goods can be selected and purchased as the consumer likes. Yet, is the consumer really as hyper-sensitive to price swings as the Court would have us believe? It does not require *Homo economicus* levels of rational thinking to realise that purchasing an unneeded third product to gain a 15% discount would actually lead to fewer savings than simply purchasing two products. The hypothesised relationship between this kind of measure and irrational use seems, as is so often the case in EU consumer law, utterly disconnected from actual consumer behaviour.

Sadly, this is simply the way the Court approaches cases like this; the test for irrational use does not, paradoxically, need to have any rational connection to what a consumer might really do. It is well known that the "the EU's engagement with behavioral sciences is

[18] Judgment, paras 71–73.
[19] [2003] ECR I-14887.
[20] [2009] ECR I-02629.

far from systematic and remains largely circumstantial",[21] and this creates frustration and confusion in this area of the law (especially because the legislation makes empirical references). The Court is asking its national colleagues to carry out an empirical exercise, but to do so by superstition rather than science. The mere existence of an incentive is enough to bring the Court's concern to peak levels. Pharmacies trying to promote themselves against competition will have to pick other methods.

Competing interests. The author declares none.

[21] A Alemanno and A Spina, "Nudging Legally: On the Checks and Balances of Behavioural Legislation" (2014) 12(2) International Journal of Constitutional Law 429, 441.

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