JONES DAY

APRIL 2008

A THERAPY AGAINST NATIONAL BARRIERS–LIBERALIZATION OF EUROPEAN PHARMACEUTICAL ADVERTISING

CAUSE AND EFFECT

In retrospect, the European pharmaceutical industry may well wonder why it owes the liberalization of advertising to a ginseng product. Ginseng is usually not the first ingredient that springs to mind when thinking of pharmaceutical products in Europe. However, it's true that small causes can have great effects: what started out as just one of the hundreds of disputes initiated in Germany each year over pharmaceutical advertising triggered the most significant ruling on European pharmaceutical advertising to date, resulting in the creation of a uniform legal framework for advertising throughout Europe and the liberalization of national restrictions.

This butterfly whose flapping wings caused not a tornado but a fresh breeze was the German advertising campaign of a distributor of ginseng products. The campaign used patient testimonials as well as a prize drawing in which consumers could win the product in question—advertising tools that are both prohibited by German law. In its appearance, the campaign did not differ much from the campaigns of distributors of comparable products; its impact, however, differed a great deal. Not only did the case, initiated by a fair-trade association, go all the way to the German Federal Supreme Court ("*Bundesgerichtshof*"), but the court requested a preliminary ruling of the European Court of Justice ("ECJ") on whether the German legislation was compatible with Directive 2001/83/EC of the European Parliament and of the Council of November 6, 2001, on the Community Code Relating to Medicinal Products for Human Use, as amended ("the Community Code").

MINIMUM STANDARDS VS. MAXIMUM STANDARDS

The first question put to the ECJ, which lends the case its fundamental importance, concerned the relationship of the Community Code to national legislation with regard to advertising. Does the Community Code

provide minimum standards only, allowing the Member States of the European Union to impose stricter rules on advertising, or does it at the same time set a definitive maximum standard, limiting regulation by the Member States? This question had also been disputed among the Member States, the majority taking the stance that the Community Code sets minimum standards and allows for stricter national legislation. The ECJ, however, in its judgment dated November 8, 2007, took the latter position (*Gintec International Import-Export GmbH v Verband Sozialer Wettbewerb eV*, Case C-374/05). The court held that the Community Code aims to remove barriers to trade between Member States. Disparities in national legislation on advertising may impair the functioning of the internal market. The Community Code expressly states in which cases Member States may adopt stricter legislation on advertising. In the absence of such an option, the Community Code sets not just a minimum standard but a maximum at the same time. This is in line with a decision rendered two months earlier in which the ECJ decided that the procedures for obtaining a marketing authorization laid down in the Community Code are exhaustive, preventing the Member States from implementing additional procedures (judgment dated September 20, 2007, *The Netherlands v Antroposana et al.*, Case C-84/06).

NO CURE FOR THE DEFENSE

One of the ironies of the case lies in the futility of the ginseng distributor's efforts to defend the advertising campaign in question. By answering two further, specific questions on the prohibitions of German law, the ECJ pointed out that the campaign in question was not in line with the Community Code either. First, the testimonials claimed to improve health in general. This is incompatible with the prohibition of the Community Code on any suggestion that the health of the subject could be enhanced by taking the medicine. At the same time, the testimonials attributed effects to the product that in all likelihood had to be considered misleading, as the product did not possess such properties. Second, while prize drawings in general are not prohibited under the Community Code, the court pointed out that any excessive and ill-considered advertising is prohibited. Advertising must encourage the rational use of medicine, and offering a medicinal product as a prize does not encourage rational use. Also, according to the court, offering this product as a prize has to be equated with free distribution, which violates the prohibition on direct distribution of medicinal products to the public by the pharmaceutical industry for promotional purposes. (The distribution of free samples is limited, under specific conditions, to persons who prescribe medicinal products.)

Therefore, the German Federal Supreme Court—which has not yet rendered its final decision subsequent to the ruling of the ECJ—might have decided the case directly because European law, in this specific case, does not lead to a different result than German law. However, that would have prevented the ECJ's landmark decision.

A THERAPY AGAINST NATIONAL BARRIERS

Based on this ruling, European pharmaceutical companies now can develop Europe-wide advertising campaigns observing the limitations of the Community Code but disregarding stricter national legislation where such legislation is not provided for in the Community Code. Particularly with regard to over-the-counter ("OTC") medications, for which brand recognition and consumer awareness are important, advertising campaigns can now leverage the European scale. At the same time, the liberalization of advertising for prescription-drug products is on the horizon, even if the recent proposal of the European Commission refers to "information to patients" and not to advertising. The possibility of presenting information on prescription-drug products directly to patients will again contribute to a Europe-wide liberalization.

The following sections highlight specific aspects of national legislation in various Member States where liberalization is expected. It is of note that unless the Member States implement the provisions of the Community Code on advertising verbatim into their national legislation, there always will remain grounds for dispute based on how far the national legislation exceeds the Community Code. Also, until the Member States revise their legislation, it will in all likelihood take time and effort to convince national authorities and courts of the impact of the ECJ's judgment. Where the Member States have implemented the Community Code as it stands, national courts must not interpret it differently throughout Europe and ultimately have to request an interpretation of the ECJ, which again will take some time. Nonetheless, the following observations may serve as a starting point to develop European advertising campaigns.

FRANCE

The provisions of the French Code for Public Health are, word for word, those of the Community Code, except for very limited nuances. For this reason, the ruling of the ECJ regarding the advertising of OTC products should not raise major issues in France.

As permitted by the Community Code, advertising for pharmaceuticals requires prior authorization from the French drug agency, AFSSAPS ("*Agence Française de Sécurité Sanitaire des Produits de Santé*").

Currently, advertising for an OTC product may not refer to claims of recovery because the French Code for Public Health imposes an absolute ban on such claims. However, under the Community Code and as affirmed by the ECJ, such claims are banned only if they are improper, alarming, or misleading. In this respect, and in line with the ECJ ruling, the French drug administration will be prevented from considering any claim of recovery unlawful.

Finally, the French Code for Public Health specifically prohibits offering the public gifts, products, or other material advantages, direct or indirect, of any nature. This goes further than the Community Code, which prohibits making offers to doctors and pharmacists only. According to the ruling of the ECJ, prize drawings for the public are allowed unless they are incompatible with the reasonable use of the product, *e.g.*, by awarding the product itself or inciting consumers to purchase the product in order to participate in the drawing. It remains to be seen which further offers will be considered compatible with the Community Code.

GERMANY

The current restrictions of the German Act on Advertising for Health Products ("*Heilmittelwerbegesetz*") extend significantly beyond the Community Code.

The most notable liberalizations will occur in OTC advertising directed at the public. Advertising campaigns will be more creative and will be permitted to demonstrate the action of a pharmaceutical product, visually represent the disease, and feature testimonials unless they are improper, alarming, or misleading. With regard to particular marketing tools, not only are prize drawings allowed, but promotional activities in general are permitted within the general limits of the reasonable use of the product. In addition, German case law has so far considered references to scientific literature to be equivalent to the recommendations of scientists and health professionals. However, the Community Code does not contain specific wording to this end. Legal literature and case law have invoked the prohibition on recommendations of doctors and scientists, but quoting the results of a clinical trial appears to be structurally different from a doctor's recommendation. Most likely the ECJ will have to decide on the scope of the Community Code in this respect.

Relevant for both OTC and prescription drugs is the question of whether the promotional activities of doctors and pharmacists will be able to shed the extreme restrictions imposed by German case law; again, it is probable that the ECJ will have to rule on the interpretation of "inexpensive" gifts as defined in the Community Code.

Regarding the content of both OTC and prescription-drug advertising, the current German prohibition on advertising off-label use is not explicitly laid down in the Community Code. Once again, the ECJ may well have to decide whether the existing prohibition on advertising for a product without marketing authorization extends to a prohibition on off-label advertising.

Last but not least, the minimum information to be included in advertising material, both for OTC and prescription-drug products, will have to be reviewed.

ITALY

The Italian law on advertising OTC products basically mirrors the Community Code; the same wording is used by the Code of Self-Regulation in Advertising. Accordingly, the *Gintec* decision, which sets a maximum standard for controls on advertising a medicinal product to the public, will have a double impact: the adoption in the future of stricter rules by Italian authorities will be prevented, and the interpretation of the ECJ regarding specific advertising methods will automatically apply to Italian provisions as well.

Each advertising message concerning OTC products (other than ads in print media that merely reproduce data contained in the information leaflet and a picture of the outer packaging) has to be authorized by either the Italian Ministry of Public Health or the Authority of Self-Regulation in Advertising. Such authorization now will have to take into account the interpretation of the ECJ. For example, regarding recommendations by scientists, health professionals, or persons well known to the public, the ECJ requires the assessment of the specific content of the relevant statement. This will influence the application of the blanket prohibition on such recommendations in advertising. In the past, Self-Regulation case law considered the picture of a doctor a medical recommendation, providing a broader interpretation of the relevant provisions than the ECJ.

With reference to prize contests and other promotional activities relating to OTC advertising, the *Gintec* decision will influence Italy's Law Decree No. 248 of July 4, 2006, which has allowed the sale of OTC products in stores other than pharmacies. The Decree specifies that prize contests, prize drawings, and below-cost sales of OTC products are expressly forbidden. In contrast, according to the ECJ, only a prize drawing that "encourages the irrational use of the medicinal product and leads to its direct distribution to the general public and to the presentation of free samples" is prohibited under Community law. Apart from the Decree, Italy has very restrictive regulations for any kind of prize drawings: competent governmental authorities must be notified of the drawings in advance, which must be performed under the control of these authorities and, more significantly, entirely managed in Italy. We expect that any prize drawings for OTC products having a multinational approach will trigger discussions with the authorities.

SPAIN

The current regulation on advertising of medicinal products (*Ley 29/2006 de garantías y uso racional de los medicamentos y productos sanitarios* ("LM"), *Real Decreto 1345/2007 Procedimiento de autorización, registro, y condiciones de dispensación de los medicamentos de uso humano fabricados industrialmente* ("RD 2007"), and *Real Decreto 1416/1994 por el que se regula la publicidad de los medicamentos para uso humano* ("RD 1994")) extends beyond the harmonized regulation provided in the Community Code, and it does so for both OTC and prescription-drug products.

Advertising of OTC products in Spain must always include a recommendation to consult a pharmacist on the correct use of the product, which is not required in the Community Code. Further, no single testimony on the virtues of the product is currently allowed, while after *Gintech*, it seems clear that testimonials may be allowed as long as they comply with the principles of the Community Code. As regards marketing authorizations, the Spanish provision still prohibits mentioning—as an advertising method—the fact that a product has obtained the required health approvals and sanitary registrations or has undergone the health controls or analysis prescribed by law. Such prohibition was eliminated from the Community Code by Directive 2004/27. In addition, it will be interesting to see how the discretion currently enjoyed by national health authorities to limit, control, or prohibit advertising of medicinal products on the grounds of public health or the security of persons will be affected from now on. Finally, the national provision prohibiting prizes, gifts, competitions, bonuses, or similar methods for the promotion or sale of medicines should be revised, as it is now clear that within the general rationale of the Community Code, the promotion of products is allowed.

The Spanish regulation concerning advertising activities aimed at health professionals will most likely have to be revised. In particular, the focus is on the current prohibition against pharmaceutical salesmen acting as health professionals in the prescription, provision, or administration of medicines; the current need for the advertising company to provide an estimate of the total cost of the treatment in addition to the price of the product; the ability of the media to perform an *ex ante* control of the campaign's compliance with regulations; and the restrictive regulation of free samples (which now provides that samples may be given out only when the products have either a formula that is new in the therapeutic field or a new preparation, dosage unit or concentration, or therapeutic indication). Given the particularities of the Spanish legislature (with both the State and the Autonomous Communities setting rules on advertising), it will take time until the national regulation is fully harmonized with the Community Code.

THE UNITED KINGDOM

Title VIII of the Community Code concerning the advertising of medicinal products is implemented in the U.K. mainly under its Medicines (Advertising) Regulations 1994 and Medicines (Monitoring of Advertising) Regulations 1994 (both as amended). These regulations largely mirror the requirements under the Community Code. Liberalizations brought about by Directive 2004/27/EC have also been transposed into the U.K. legislation. These include removal of prohibitions on advertising medicinal products for certain diseases and on mentioning that a medicinal product has been granted a marketing authorization. Accordingly, the ECJ judgment on the *Gintec* case will have little impact in the U.K. in general.

However, in respect of advertisements relating to medicinal products directed at persons qualified to prescribe or supply them, additional content is required to be included in the U.K. compared to the two requirements in the Community Code. These extra requirements will presumably fall away.

Regarding the promotion of medicinal products to persons qualified to prescribe and supply them (as discussed in the section on Germany above), "inexpensive" gifts are considered by the U.K. regulatory body to be those that do not cost a company more than £6 each and represent a similar value to the recipient.

Another instance where the U.K. goes further than the Community Code is the U.K. policy-based prohibition on advertising medicinal products for the purpose of inducing abortion. It will be interesting to see how the apparent conflict between the *Gintec* decision and U.K. public policy resolves itself.

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