

## E-ALERT | Life Sciences

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### ADVERTISING OF MEDICAL PRODUCTS AND SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) BEFORE THE EUROPEAN COURT OF JUSTICE

#### INTRODUCTION

The EU Court of Justice just issued two long awaited rulings on the interpretation of the rules governing advertising of medicines in Europe. They address (i) the requirement that all advertising must comply with the prescribing information (SmPC) for the product and (ii) the distinction between advertising and information with regard to posting approved product labelling on a company website.

The rulings provide general principles that will assist in the interpretation of the relevant legal provisions. However, the Court's rulings clearly reflect the background of the actual disputes in question and it will be difficult to distill concrete guidance for other fact patterns, especially as the two legal provisions in question must be applied on a case by case basis.

#### NOVO NORDISK CASE (C-249/09)

In April 2008, Novo Nordisk published a journal advertisement for Levemir, a prescription-only medicinal product. The Estonian Medicines Agency (Ravimiamet) ordered Novo Nordisk to cease using the advertisement on the grounds that certain claims were not based on the SmPC of the product. Novo Nordisk challenged the decision before the Estonian courts. The appeal court asked the EU Court of Justice for guidance on the interpretation of Article 87(2) of Directive 2001/83, which requires medicines advertising to "comply with the particulars listed in the summary of product characteristics" (SmPC). The key question was to what extent advertising claims must be based on wording in the SmPC.

#### Key Findings

The Court of Justice avoided an overly restrictive interpretation on Article 87(2). The key points in the ruling are:

- Claims in advertisements for a medicinal product must not conflict with the SmPC.
- Claims in advertisements for healthcare professionals (HCPs), who have a higher level of scientific knowledge than the general public, do not have to be "included in or be derivable from" information in the SmPC. They can also contain additional information, provided that:
  - the claims "confirm or clarify" – and are compatible with – the details in the SmPC, and do not distort the latter;
  - the claims are not misleading and they encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties (as required by Article 87(3) of Directive 2001/83);
  - the claims are accurate, up-to-date, verifiable and sufficiently complete to enable the HCP to form his or her own opinion of the therapeutic value of the medicinal product, and the quotations, tables and other illustrative matter taken from scientific articles are faithfully reproduced and the precise sources indicated (as required by Article 92(2) and (3)).

- The Court does not provide further guidance on what kind of additional information would “confirm or clarify” information in the SmPC. In his advisory opinion to the Court, the Advocate General provided some examples and also suggested that advertising might include additional information that is not normally in the SmPC, such as patient compliance data and technical information on methods of administration. The Court did not comment on these examples.
- In reaching its decision, the Court took into account the fact that HCPs are more knowledgeable than the general public. It did not, however, set specific standards with regard to advertisements to the public and how the requirement for compliance with the SmPC must be interpreted in that context.

### MSD CASE (C-316/09)

MSD posted on its German website a reproduction of the packaging, therapeutic indication, and package leaflet of Vioxx and Fosamax, two prescription-only products. The website was accessible to the general public, and a competitor launched a lawsuit on the grounds that MSD was infringing the prohibition of direct-to-consumer advertising for prescription-only medicinal products. The lower courts considered that although the information was factual and not typically commercial in nature, it constituted advertising and thus was prohibited.

The German *Bundesgerichtshof* asked the EU Court of Justice whether the prohibition of direct-to-consumer advertising for prescription-only medicinal products applies to an open website: (i) that only contains information which was approved by the regulator in the marketing authorisation procedure and was accessible to every person acquiring the product; and (ii) where the information is not made available on an unsolicited basis but can be accessed only through the internet when the party concerned takes steps to do so. Thus, the question in essence was whether copies of the SmPC, package leaflet and labelling approved by the regulator qualified as advertising when posted by pharmaceutical companies on their websites.

### Key Findings

- The key basis for distinguishing non-promotional information from advertising is the purpose of the communication. As soon as the communication is intended to promote the prescription, supply, sale or consumption of medicines, it will qualify as advertising.
- The fact that a communication is from a pharmaceutical company does not necessarily demonstrate a promotional intent. Pharmaceutical companies may, for instance, wish to provide objectively accurate information about their products in general.
- As intentions are very hard to determine, the Court refers to various objective factors that should be taken into account. The first two are the “object of the communication” (the English version of the decision refers to “purpose”, but this term seems less accurate in light of the French and German version of the decision) and the content of the communication. For both, the Court in particular looks at the practical effect of the communication and how this may affect public health, which is the underlying concern of the entire EU pharmaceutical legislation. It concludes that for prescription-only products, dissemination of product information cannot lead directly to a decision to purchase the product, may support the dialogue between the patient and the doctor, and may also assist patients who have lost the package leaflet of the medicine they use. As to the content of the communication, the Court holds that the official labelling text (on packaging and in the leaflet) and the SmPC must be considered objective, officially approved and non-promotional in nature and that its dissemination does not undermine the protection of public health. The Court stresses that this may not be the case if the communication contains “selected or rewritten” parts of the approved texts, as this may show an advertising purpose.

- Finally, the Court also takes into account the “pull service” nature of the communication. Patients and other members of the public must actively look for the information on the website, which is a passive platform. They do not receive the message unexpectedly, as would be the case for a pop-up (which qualifies as a “push service”).
- The Court stresses that it is up to the national court to determine, on the basis of the criteria provided in the decision, whether the communication in question constituted advertising.
- MSD also tried to have the validity of the general ban on advertising prescription-only medicines to the public assessed by the Court under basic principles of EU law, such as the freedom of information, freedom to take care of one’s own health and freedom of enterprise. The Court refused this because these aspects were not included in the reference for preliminary ruling.

### What is Next?

The Court of Justice has taken a rather conservative approach to information to patients, although it does recognise the importance of the distinction between push and pull services. A new balance will have to be struck through legislation and the Commission is currently preparing a revised proposal for the “information to patients” package.

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