JONES DAY

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PRESCRIBING A REVOLUTION: LEGISLATIVE PROPOSAL FOR INFORMATION TO PATIENTS

The European Commission has tabled a legislative proposal that, for the first time, would allow industry to provide information on prescription drugs to patients in Europe. The controversial proposal is currently under review by the European Parliament. The proposal merits comments to improve the practical implementation of the legislation. Industry should voice such comments in the ongoing legislative process, to avoid impractical outcomes.

A CONTROVERSIAL PROPOSAL

After a consultation process in 2007–2008, the European Commission originally had announced a proposal for a Pharmaceutical Package for September 2008. However, the draft prepared by the Directorate-General Enterprise and Industry was withdrawn at the eve of the session of the Commission, in view of objections raised by the Directorate-General Health and Consumer Affairs, among others. It was finally adopted in December. Discrepancies between the draft and the accompanying memorandum betray last-minute changes. So what has stirred emotions at the otherwise rather complacent Commission?

The proposal aims at harmonizing the dissemination of information on prescription drugs to the general public in the European Union. The controversy rages on the role industry may or may not take in such dissemination. While the proposal is positioned to allow information on, but not advertisement for, prescription drugs, the dispute focuses on the distinction between "information" and "advertisement," and on the means of control. Some stakeholders speak against allowing industry to disseminate information to patients altogether.

THE PROPOSAL IN DETAIL

The proposal enumerates the information that is eligible for dissemination, as opposed to advertisement. Advertisement for prescription drugs shall continue to

be banned. First, all authorized texts—namely, the summary of product characteristics ("SPC"), the labeling of the packaging, and the package leaflets—may be used. The contents of these text may also be rephrased. Second, factual information without claims on efficacy, *e.g.,* on prices, packaging changes, and alerts to adverse events, shall be allowed. Third, medical product-related information on non-interventional scientific studies, on accompanying measures for prevention and medical treatment, or on the context of the condition to be treated shall be allowed. The proposal does not define "non-interventional scientific studies." However, the GCP Directive contains a definition on "non-interventional trials" (a study where the medicinal product is prescribed in the usual manner in accordance with the terms of the marketing authorization). There is no indication that the proposal would use a different definition. The possibility of informing patients of results of non-interventional trials would increase the importance of Phase IV studies.

Only a limited set of communication channels is available: health-related publications (to be defined by the Member States), internet websites, and written answers to requests for information. No information may be disseminated via TV or radio, or direct mailing or other unsolicited material. Websites may not contain web-TV, and they may not allow the identification of internet users accessing the web site. "Appearance" in websites of unsolicited material actively distributed to the users is not allowed. From a technical perspective, the ban on "unsolicited material actively distributed" to users requires further elaboration. Unsolicited material in an internet context usually refers to emails, which do not "appear" on a web site. The ban might refer to pop-up windows, although the term "actively distributed" appears out of place in that context.

A score of quality criteria have to be met, which for the most part are self-evident, *e.g.,* to be up-to-date and based on evidence. However, the level of evidence also has to be stated, which makes it important to carefully categorize the scientific material on which the information is based. Information has to be unbiased and must contain a statement of risks if the information refers to the benefits. It may not contradict the SPC. The proposal lays down mandatory items any information must include, among them the statement that the drug is available on prescription only. Several specific restrictions are set out. The information, for example, may not contain comparisons with other drugs. In addition, the specific bans on advertisement to the general public that apply to OTC drugs shall also apply for information to patients on prescription drugs.

From a practical perspective, the most important aspect of the proposal is the suggested monitoring procedure. Here, the political split becomes most apparent. The draft now is based on the principle of control of the information prior to its dissemination. This is a last-minute turnabout. The accompanying memorandum still addresses the principle of control after dissemination. The exercise of control does not have to be confined to public administration. Member States may provide for voluntary control by self-regulatory or co-regulatory bodies, provided that recourse can be taken against decisions of such bodies.

The proposal provides two exceptions to the general rule of prior control. One applies to information that has already been approved by the competent authorities. It is unclear whether this exception is limited to prior information to patients that has already been approved, or whether it also encompasses information whose source has been approved by authorities, without itself having received prior approval. In a nutshell, the question is whether information based, for example, on the SPC, which is an approved document, still requires prior approval. The legislation should be clarified in this respect.

The second exception allows for control after dissemination, if a mechanism applies that ensures the equivalent level of adequate and effective monitoring as prior control. It is difficult to envisage such a mechanism, since it is effectiveness, and not efficiency, that counts. Obviously, prior control will impose a cumbersome procedure. Industry should point out to the legislator that prior control is impractical and thus inefficient. In this context, the Commission's estimate on information to be controlled deserves close scrutiny. The proposal confers prior control of information on non-interventional studies and similar scientific information (as outlined above) for drugs with a centralized marketing authorization to EMEA. The Commission budgets this control on the assumption that for the 400+ drugs with a centralized marketing authorization,

only 100 to 150 applications for review shall be filed in the upcoming years, *i.e.,* only one application every four years for each drug. This appears to be a significant underestimate, already heralding an administrative bottleneck at this stage.

A specific procedure shall apply to information disseminated via the internet. Prior to its publication, a website has to be registered in a Member State according to the top level domain ("TLD") or, in the absence of a country-specific TLD, in a Member State of choice. This Member State shall then be responsible for controlling and monitoring the website, and the other Member States shall recognize replications, including translations of this site under other TLDs. The proposal is unclear as to the scope of such recognition. It allows for providing the information on other websites if the contents are identical. The legislation should clarify whether this requires identical layout of the website. The proposal provides for a dispute settlement mechanism between Member States, should doubts arise as to the conformity of the web site with the requirements of the legislation.

NEXT STEPS

The proposal is currently under review of the European Parliament. The rapporteur in the Committee on the Internal Market and Consumer Protection has endorsed the proposal. A first report in the Committee on the Environment, Public Health and Food Safety, which has the lead on the proposal, was expected by March; however, it has not yet been presented. It is doubtful whether it will still materialize before the elections to the European Parliament in the first week of June. The proposal is contained in the Pharmaceutical Package of the European Commission, which also addresses amendments to the rules on pharmacovigilance and on the prevention of counterfeited drugs. These two other proposals are currently prioritized. In view of the elections and the following traditional August break, it is fair to assume that the parliamentary debate will resume this autumn, which would open the way for an adoption of the proposal late in 2009 or early in 2010. This leaves industry some, but not too much, time to provide input on the open practical issues resulting from the proposal.

LAWYER CONTACT

For further information, please contact your principal Firm representative or the lawyer listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com.

Christian B. Fulda
49.89.20.60.42.200
cfulda@jonesday.com