Healthcare & Life Sciences - Austria

New legislation on advertising of medicinal products fails to match EU law

Contributed by **Preslmayr Attorneys at Law**

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Article 87(2) of the EU Directive on the Community Code relating to Medicinal Products for Human Use (2001/83/EC) provides that all parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics. Article 91(1) of the directive provides that any advertising of a medicinal product to persons qualified to prescribe or supply such products must include essential information compatible with the summary.

Until 2009 Section 50a(3)(3) of the Act on Medicinal Products provided that advertising of a medicinal product must not contain claims or illustrations that are inconsistent with the summary. In relation to persons qualified to prescribe or supply medicinal products, the Supreme Court ruled that this provision did not require that claims be expressly covered by the summary and that only advertisements that are inconsistent with or contradict the summary infringe that provision, provided such advertisements are not misleading.

The legislature wished to correct this case law and therefore amended Section 50a(3)(3) by the words "or exceed the summary of product characteristics". In *Novo Nordisk* (C-249/09) the European Court of Justice (ECJ) ruled on a similar Estonian provision which required that advertising of medicinal products should not contain information that was not in the summary. The ECJ (in line with the Austrian Supreme Court) held that advertising may include claims supplementing the summary, provided that the information is:

- faithfully reproduced;
- indicates its precise source;
- is not misleading; and
- does not contravene the other requirements of the directive.

Following the introduction of the EU Directive on Pharmacovigilance (2010/84/EC), the Parliament enacted an amendment to Section 50a(3) of the Act on Medicinal Products, providing that advertising of medicinal products to persons qualified to prescribe or supply such products must not contain claims or illustrations that are inconsistent with the summary of product characteristics (provided that these claims do not contradict the summary, but rather confirm or clarify the information given in the summary without distorting it).

However, with regard to advertising to laypersons, the amendment still provides that claims must not exceed the summary. The explanatory remarks in the materials to the bill note that the amendment will implement *Novo Nordisk*. According to this decision, with regard to advertising to professionals, it is not necessary that all claims be contained in the summary or be derived from the summary. It was admissible to supplement the summary of product characteristics, provided that these claims confirmed or specified the summary without distorting it. This possibility applied only in the context of advertising to professionals; advertising to laypersons should strictly comply with the summary.

Comment

The legislature's decision to bring the rules on advertising of medicinal products to professionals in line with the jurisdiction of the ECJ should be welcomed. Nevertheless, contrary to the explanatory materials to the bill, the limitation in relation to advertising to laypersons is not in compliance with EU law. The ECJ clearly stated that

Article 87(2) of Directive 2001/83/EC is a general rule applicable to all advertising for medicinal products (marginal number 30) and thus applies to advertising to both professionals and laypersons.

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