EURALex

European Healthcare Law & Regulatory News

November 2006, Issue 176 • www.euralex.co.uk

News Update

European News

Commentary

Interview

National News

The month in Europe

The acrobat

The recent ECJ Ruling in the parallel trade case between GSK and the European Commission is littered with inconsistencies that generally render the routes taken to arrive at the conclusions obscure. Irrespective of the nature of press statements relating to judicial decisions – which may often twist a clear condemnation into a shining laudatory acclamation – it would seem that this judgement has genuinely allowed both sides to claim victory. It is in essence the equivocation of much of this acrobatic Decision that makes it impossible for a non-legally-minded individual to make much headway. Take, for example, the concept that, where it "cannot be presumed that parallel trade tends to reduce prices", "a specific examination of the situation in the sector leads to the finding that parallel trade permits a limited but real reduction in the price and the cost of medicines". Is this simply just another case of the ECJ walking a tight rope between the warring factions and refusing to provide a judgement that will deliver a knock-out blow to either side? p18

The illusionist

France's medicines agency, Afssaps, is set to implement the requirements of the EU Transparency Directive ahead of schedule. What was hidden is now being brought to light through a painstaking effort on behalf of the authority. The amount of work undertaken by Afssaps to make this possible is an indication of the sheer quantity of information that has been kept out of the public domain. Although this exertion by the agency can only be applauded, it may be worth pointing out that transparency has not been such an issue with the lesser populated countries of the Nordic region, giving rise to the sentiment that perhaps size does not always count (p23). However, the public must be grateful to Afssaps in its drive to reveal that which was once very much concealed.. ..... p21

The clown

The Polish health ministry has published an open letter assuring the public and the pharmaceutical industry about its engagement in fighting corruption in the healthcare system at both international and national level. However, the Polish Doctors' Trade Union has doubts whether the ministerial letter can be taken seriously. As proof of that, it points to a series of issues resulting in corruption in the system, that so far have not been dealt with. In view of this fact, the organisation describes the ministry's statement as a "morbid" joke. p27

Advertising medicinal products in Romania

Cristian Radu

During the course of 2006, the Romanian legal background applicable to the advertising of medicinal products has undergone several changes due to the need to transpose the provisions of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community Code related to medicinal products for human use (Directive 2001/83/EC), says Cristian Radu.

In addition, the Romanian Association of International Producers of Medicines (ARPIM) has attempted to follow this trend by adopting an ethics code concerning the promotion of pharmaceuticals.

...general aspects regarding the content of the applicable legal regulations

There are essentially two types of legal enactments that regulate pharmaceutical advertising: legal enactments applicable specifically to pharmaceuticals and legal enactments that establish rules applicable to advertising in general.

Thus, Law no. 95/2006 on healthcare reform and the Minister of Health Order no. 263/2003 regarding, inter alia, the approval of the regulations on pharmaceutical advertising, set out the specific principles that regulate this type of advertising, by transposing the provisions of Community laws, while Law no. 148/2000 on advertising, Law no. 504/2002 on Radio and Television Broadcasting and the National Audio-Visual Council's Decision no. 187/2006 concerning the regulation of the content of audiovisual program services, provide for general rules applicable to any type of advertising or to advertising on radio and television broadcasting.

...definition of "advertising medicinal products"

The definition provided by Article 797 (1) of Law no. 95/2006 is a faithful reproduction of the definition contained in Article 86 (1) of the Directive 2001/83/EC. Thus, "advertising medicinal products" means the distribution of any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and it shall include in particular:

- the advertising of medicinal products to the general public;
- the advertising of medicinal products to persons qualified to prescribe or supply them;
- visits by medical sales representatives to persons qualified to prescribe medicinal products;
- the supply of samples;
- the provision of inducements to prescribe or supply medicinal products, such as a gift, offer or promise of any benefit or bonus,whether in money or in kind, except when their intrinsic value is minimal;
- the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; or
- the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and, in particular, payment of their travel and accommodation expenses in connection thereof.

It results from this definition that there are two main important categories of advertising in the pharmaceutical sector, each with their specific rules (i.e. advertising of medicinal products to the general public and advertising to persons qualified to prescribe medicinal products). It is obvious that for reasons related to consumer protection, the rules applicable to the first category are stricter than those for the latter.

...important prohibitions to the advertising of medicinal products

Under Romanian law, it is prohibited to advertise to the general public medicinal products that:

- are available by medical prescription only;
- contain psychotropic or narcotic substances, defined as such by the United Nations Conventions of 1961 and 1971 and by local regulations;
- contain specific therapeutic indications such as:

  i) tuberculosis;

  ii) sexually transmitted diseases;

  iii) other serious infectious diseases;

  iv) cancer and other tumoural diseases;

  v) chronic insomnia;

  vi) diabetes and other metabolic illnesses.
- are prescribed and supplied through the public health insurance system, except for vaccination campaigns carried out by the pharmaceutical industry and approved by the ministry of public health.

Furthermore, the direct distribution of medicinal products to the general public by the industry for promotional purposes is prohibited.

... general rules relating to information to be provided when advertising medicinal products

Any type of advertising of medicinal products to the general public shall be set out in such a way as to make it clear that the message is an advertisement and that the product is clearly identified as a medicinal product. Such advertising must include at least the following information:

- the name of the medicinal product, as well as the brand name if the medicinal product contains only one active substance;

continued from page 16

- the information necessary for the correct use of the medicinal product;
- an explicit, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.

Notwithstanding the minimum information to be provided as detailed above, if the advertising of a medicinal product to the general public is intended solely as a reminder, it may only include the name of the medicinal product or its international non-proprietary name, where this exists, or the trademark.

Moreover, Law no. 95/2006 provides for a set of specific rules that set out appropriate guidance when elaborating on such advertisements for those companies that advertise medicinal products to the general public.

It is important to mention, exempli gratia, that such advertising shall not contain any material that suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions, or are better than, or equivalent to, those of another treatment or medicinal product.

In addition, they may not suggest that the health of the subject can be enhanced by taking the medicinal product; be directed exclusively or principally at children; and refer to a recommendation by scientists, health professionals or persons who, because of their celebrity status, could encourage the consumption of medicinal products.

With regard to advertising to persons qualified to prescribe medicinal products, Romanian law provides for specific rules applicable to the minimum content of the information to be provided in an advertisment; the professional training to be undertaken by medical representatives; the limits of hospitality throughout the sales promotion process; and the supply of free samples.

Thus, any advertising of a medicinal product to persons qualified to prescribe or supply such products shall include:

- essential information compatible with the summary of product characteristics;
- the supply classification of the medicinal product.

If the advertising of a medicinal product to persons qualified to prescribe or supply such products is intended solely as a reminder, it may include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark.

...monitoring the advertising of medicinal products and the approval of advertisements for such products

The supervising authority in the pharmaceuticals advertising sector is the National Medicine Agency (NMA). The role of NMA in monitoring the advertising of medicinal products depends very much on the advertising target of these products. Thus, in the case of over-the-counter (OTC) medicinal products, the advertising material intended for the general public is subject to prior approval by the National Medicines Agency, while in the case of advertising material for OTC medicinal products intended for persons qualified in prescribing and supplying medicinal products, NMA only analyses such material after it has been disseminated, randomly, or following certain complaints.

When it becomes aware of violations of the rules applicable to pharmaceutical advertising through the promotion of specific advertising material, NMA shall:

- prohibit the publicatin of such material if the material has already been published; or
- order the prohibition of such material if misleading advertising has not yet been published but this action is imminent. This does not even require proof of actual loss or damage or the intention or negligence on the part of the advertiser.

The second measure shall be taken through the implementation of an accelerated procedure, either with interim effect or with definitive effect.

For the purpose of eliminating the continuing effects of misleading advertising, the cessation of which has been ordered by NMA, the latter shall:

- require publication of that decision in full or in part and in such form as it deems adequate;
- require in addition the publication of a corrective statement.

The National Audio-Visual Council (NAC) also has certain responsibilities in controlling the compliance with the relevant regulations on advertising on radio and television broadcasting and, more specifically, to inform NMA about any possible violations.

"the failure to comply with the provisions related to the advertising of medicinal products can trigger, depending on the actual circumstances of such failure, civil, disciplinary, tort or criminal liability"

The failure to comply with the provisions related to the advertising of medicinal products can trigger, depending on the actual circumstances of such failure, civil, disciplinary, tort or criminal liability. Apart from the sanctions that can be imposed by the Romanian competent authorities, a failure to comply with the applicable legal regulations and with the rules set out by the ethics code referred to in the introduction may trigger sanctions imposed by ARPIM.

...penalties

Thus, when a pharmaceuticals manufacturer breaches for the first time the rules of the ethics code, it will be sanctioned with a fine amounting to a maximum of €5,000; the second incidence of non-compliance will warrant a fine amounting to a maximum of €10,000 while the third and each subsequent non-compliance action will be sanctioned with a fine amounting to €15,000 apiece. ❋

Cristian Radu is an Associate at Bucharest, Romania-based law firm Tuca Zbarcea & Asociatii