Pharmaceutical Advertising

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Dr Rosanna Cooper (Summary published by ACQ Magazine June 2011)

When advertising on the Internet, a pharmaceutical company can only place <u>factual</u> information on its website regarding non-prescription medicines. Advertising medicines which have not been granted a marketing authorisation or advertising prescription only medicines (POMs) to the public is banned. The advertisements cannot exaggerate the properties of such non-prescription medicines and cannot be misleading. No benefits can be included on websites about POMs especially the risk of such medicines as they are regarded as promotional claims. The promotion of POMs to the public on the Internet is prohibited.

The two main legislation governing advertising of medicines are The Medicines (Advertising) Regulations 1994 (SI 1994/1932); the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), both as amended ("Advertising Regulations") prohibit advertising of POMs to the public. The Advertising Regulations prohibit advertisements directed exclusively or principally at children (under-16s). In the UK, the advertising of POMs is governed by the Association of the British Pharmaceutical Industry (ABPI) Code of Practice ("Code"), which is regulated by the Prescription Medicines Code of Practice Authority ("PMCPA"). Consumers must not be misled with regard to the benefits of the medicine in comparison to other similar products.

A pharmaceutical company may be prosecuted for any misleading advertisements under The Business Protection from Misleading Marketing Regulations 2008, and The Consumer Protection from Unfair Trading Regulations 2008.

There are four limited exemptions for advertising under the Advertising Regulations:

- The content and form regarding labels and package leaflets as they are regulated separately;
- Correspondence providing answers to specific questions about particular medicines;
- Factual announcements; and
- Information on health and disease with no reference to medicines.

There has been recent clarification on advertising of medicines in the preliminary ruling by the European Court of Justice (ECJ) in the case of *Vestre Landsret* – *Denmark: Criminal proceedings against Frede Damgaard (C-421/07 Judgement of the Court 02/04/2009).*

The ECJ held that under European law "dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising ..., even though the third party in question is acting on his own initiative and completely independently, de jure and de facto, of the manufacturer and the seller of such a medicinal product".

Pharmaceutical companies must ensure that any information about medicines placed on their websites is accurate, factual and well balanced. Any articles, for instance, on such sites must only inform the public rather than promote medicines. Articles discussing potential treatments will not fall within the scope of the Advertising Regulations.

Information on a particular condition or disease may be provided on websites. The advice from the The Medicines and Healthcare products Regulatory Agency ("MHRA") is that "... when providing information relating to POMs. This should be presented in the context of a balanced overview of all treatment options and relevant disease information". Specific POMs should not be promoted as this is likely to encourage the purchase of a POM and contravene the Advertising Regulations.

The Advertising Regulations define advertisements broadly, as any "activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products".

The European Commission (EC) has been looking at ways to improve patient access to information on health and medicines. In September 2008, the European Parliament's Environment, Public Health and Food Safety Committee, gave its verdict on the EC's proposals to legislate direct-to-consumer advertising of prescription drugs.

It had reservations regarding direct communication from pharmaceutical companies to the general public. In particular, they revised the proposal to allow prior approval of any "information" from pharmaceutical companies by health authorities before being made available to the public. There also has to be health authority control for the distribution by health professionals of brochures and "patient-information" from pharmaceutical companies.

Discussions continue to centre on advertising of POMs to members of the public. These discussions are important as there has been a rise in POMs being sold illegally on the Internet via rogue websites.

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