

Advertising of Pharmaceutical Products

By

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To advertise a pharmaceutical product or medicine in the UK, the medicine must have a valid marketing authorisation and there are national and European legislations that have to be adhered to regarding the contents of advertisements and promotions in relation to the prescription, supply, sale and/or consumption of medicinal products.

Regulations

The two main legislations are the Medicines (Advertising) Regulations 1994 (SI 1994/1932); the Medicines (Monitoring of Advertising) Regulations 1994 (SI 1994/1933), both as amended (“Regulations”). The Regulations govern advertisements by prescribers or suppliers of medicines and the purchase of over-the-counter medicines by the public.

The Regulations prohibit advertising of prescription-only medicines to the public. The Regulations prohibit advertisements directed exclusively or principally at children (under-16s). Advertisements directed at the public:

- Should make it clear that the product being advertised is a medicine;
- Must include the name of the medicine and the common name where the product contains only one active ingredient;
- Must include one or more indications for use of the product;
- Should include a clear and legible invitation to read carefully the instructions on any leaflet (within the package) or on the label;
- Containing a reference to the label alone, should be made only where there is no leaflet provided or the label has a clear and specific instruction to refer to the enclosed leaflet.
- For medication where a medical diagnosis is necessary before self-treatment or treatment is likely to be successful, only if continuous, should clearly reflect those conditions in the material. Advertisers must ensure safe and responsible advertising for such medicines.

The Regulations do not apply to factual informative statements or announcements, trade catalogues and price lists, provided no product claims are made in any media such as articles in published journals, magazines and newspapers, display on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and materials posted on the Internet. Point-of-sale materials, leaflets, booklets and other promotional materials that include specific product claims and which are supplied separately from the product may also be considered advertisements.

In addition to the Regulations, there are Codes of Conduct that a company will have to comply with.

Advertising Codes

The advertising of prescription-only medicines 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”). The advertising of over-the-counter medicines to the general public is governed by the Proprietary Association of Great Britain (“PAGB”) Consumer Code and the advertising of over-the-counter medicines to qualified persons prescribing or supplying medicines is governed by the PAGB Professional Code.

The Code relates to the supply of samples, and the requirement for all promotional material to include a prominent statement regarding reporting of adverse events.

The ABPI Code sets out the requirements for the promotion of medicines for prescribing to UK health professionals and appropriate administrative staff. The Code also includes detailed provisions for the supply of information about prescription-only medicines to patients and the public. The Code extends beyond UK legal requirements. Compliance with the Code is a condition of membership of the ABPI. Self regulation is usually the first means of dealing with complaints. Both the PMCPA and the MHRA deal with complaints whatever their source.

MHRA

The Medicines and Healthcare products Regulatory Agency (“MHRA”) is responsible for enforcing the Regulations. The MHRA works with other statutory regulators and self-regulatory bodies to ensure advertising is fully compliant with EC and UK medicines law. These include:

- Advertising Standards Authority (general advertising).
- Proprietary Association of Great Britain (over-the-counter medicines).
- Prescription Medicines Code of Practice Authority (prescription medicines).

However the MHRA focus is on pre-vetting, dealing with complaints other than intercompany complaints and dealing with complaints that are not covered by the ABPI Code.

The Blue Guide, Advertising and Promotion of Medicines in the UK (2005), issued by the MHRA, includes guidance on the relevant UK law for advertising to health professionals. The MHRA ensures that medicine advertising is fully compliant with UK medicines law.

The Regulations allow the MHRA to require sight of advertising before it is issued.

Misleading Advertising

Consumers must not be misled with regards to the benefits of a medicine in comparison to other products in the category. The Business Protection from Misleading Marketing Regulations 2008, and The Consumer Protection from Unfair Trading Regulations 2008 also govern advertising of medicines.

Advertising on the Internet

In the UK, the promotion of prescription-only medicines to the public on the Internet is prohibited.

Predictions

We are seeing a number of European companies coming to the UK to do business such as virtual trading in pharmaceutical products. For the time being if those companies are based in

the UK and exporting medicines outside the European Union there are less restrictions. The self-regulation of pharmaceutical advertising is going to tighten as more pharmaceutical companies enter the UK market.

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