INFORMATION NOTE

Regulation of Claims and Advertising of Medicines in the United Kingdom and the United States

1. Introduction

1.1 The Bills Committee on Undesirable Medical Advertisements (Amendment) (No.2) Bill 2004, at its meeting on 17 January 2005, requested the Research and Library Services Division to provide information on the regulation of claims and advertising of medicines in overseas places. This information note provides the Bills Committee with information in the United Kingdom and the United States.

Table - Regulation of Claims and Advertising of Medicines in the United Kingdom and the United States

	The United Kingdom	The United States
Legislation governing claims of medicines	The Medicines Act 1968.	The Federal Food, Drug, and Cosmetic Act (FD&C Act).
Claims allowed	Medicinal claims approved by the Medicines and Healthcare Products Regulatory Agency (MHRA) that purport to treat or prevent diseases, or to interfere with the normal operation of a physiological function of the human body. These claims include statements which describe the intended uses of the medicine, and can be expressed in consumer-friendly language. In any event, care should be taken that consumers are not misled as to the benefits of the medicine.	Disease claims approved by the Food and Drug Administration (FDA) that purport to diagnose, cure, mitigate, treat or prevent diseases. These claims include statements which describe the intended uses of the medicine, and can be expressed in consumer-friendly language. In any event, all claims require substantial supporting evidence[1].
Legislation governing advertising of medicines	The Medicines (Advertising) Regulations 1994 govern the contents of advertisements. The general principles of these Regulations are: (a) advertisements of a medicine should comply with the particulars listed in its summary of product characteristics[2]; (b) advertisements of a medicine should encourage the rational use of that medicine by presenting it objectively and without exaggerating its properties; and (c) advertisements should not be misleading. The Trade Description Act 1968 and its supporting Regulations regulate consumer advertising in general. This Act makes it an offence if a trader: (a) applies a false trade description to any goods; (b) supplies or offers to supply any goods to which a false trade description is applied; or (c) makes certain kinds of false statement about the provision of any services, accommodation or facilities. The Broadcasting Acts 1990 and 1996 and the Communications Act 2003 regulate broadcast advertising in general.	The Federal Trade Commission Act (FTC Act) governs advertising of over-the-counter medicines, i.e. medicines that are available without prescription. The FTC Act contains rules on the following: (a) advertising must be truthful and non-deceptive; (b) advertisers must have competent and reliable scientific evidence to back up their claims; and (c) advertisements cannot be unfair. The FD&C Act governs advertising of prescription medicines, i.e. medicines that are available on prescription only. The FD&C Act requires that all advertisements contain the following: (a) the established name and brand name of the medicine; (b) the formula showing quantitatively each ingredient; (c) information on side effects, contraindications and effectiveness; and (d) information on risk stipulated in the label approved by FDA.

[1] Evidence includes tests, studies, or other objective data.

[2] A summary of product characteristics sets out the agreed position of the medicine as distilled during the course of the assessment process.

Table - Regulation of Claims and Advertising of Medicines in the United Kingdom and the United States (cont'd)

	The United Kingdom	The United States
Medicines allowed for advertising	(a) Medicines available under the supervision of a pharmacist (P); and (b) Medicines available in general retail outlets such as supermarkets.	(a) Over-the-counter medicines; and (b) Prescription medicines.
Medicines not allowed for advertising	(a) Prescription only medicines (POM); (b) Medicines for the treatment, prevention or diagnosis of chronic insomnia; diabetes and other metabolic diseases; malignant diseases; serious infectious diseases including HIV-related diseases and tuberculosis; and sexually transmitted diseases[3]; (c) Medicines used for the treatment of cancer; (d) Medicines used to procure an abortion; and (e) Some medicines which contain psychotropic or narcotic substances.[4]	Nil.
Whether prior scrutiny is required for advertising of medicines	Advertising materials of medicines are required to be submitted to trade associations for the pharmaceutical industry for pre-vetting against their Codes of Practice as a condition of membership. Materials which are intended for television or radio broadcasting must comply with the relevant Advertising Standards Codes issued by the Broadcast Committee of Advertising Practice[5]. Advertising materials of the following medicines may be required to be submitted to MHRA for prior scrutiny: (a) Newly licensed medicines[6] which are subject to intensive monitoring by MHRA; (b) Reclassified medicines, e.g. medicines reclassified from POM to P; and (c) Medicines which had breached the advertising regulations previously.	No prior scrutiny for the advertising materials of both over-the-counter and prescription medicines.
Restrictions on information contained in advertisements	Information suggesting that one product is better than (or equivalent to) another identifiable product, or that the effects of taking it are guaranteed should be avoided. Materials referring in improper, alarming or misleading terms to claims of recovery are not allowed.	Information cannot be false or misleading, nor can it omit material facts. A fair balance between effectiveness and risk information must be provided. The phrase "medicine of choice" or similar phrase requires substantial evidence to support that claim.

3 Regulations prohibiting advertising of medicines for the treatment, prevention or diagnosis of the diseases listed in (b) will be relaxed towards the end of 2005 when Parliament passes legislation to implement the European Union Directive 2001/83/EC.

4 Source: *Medicines and Healthcare Products Regulatory Agency*. (2005) Available from: http://www.mhra.gov.uk/ [Accessed March 2005].

5 The Broadcast Committee of Advertising Practice is an industry body responsible for drafting and enforcing codes of practice that govern television and radio advertising.

6 According to MHRA, newly licensed medicines refer to medicines that (a) contain a new active substance; (b) contain a new combination of active substances; (c) their administration is via a novel route or medicine delivery system; or (d) a significant new indication which may alter the established risk/benefit profile of those medicines.

References

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