Medicines (Labelling) (Special Transitional) Regulations, 1978, Stationery Office, The, Stationery Office, 1978, 011083190X, 9780110831909, . .

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There is a specific licensing system for medicines, operated in the UK by the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA is the Government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. Its work is underpinned by robust and fact-based judgements to ensure that the benefits to patients and the public justify the risks. Its licensing schemes cover the whole range of medicines for human use, from registration for herbal and homeopathic remedies to marketing authorisation for the latest innovative advanced technology medicinal products. This guide uses the general term â€˜licenceâ€™ to refer to all these schemes.

The MHRA also contributes to the work of licensing medicines in the European Union (EU), co-ordinated by the European Medicines Agency (EMA). The EMA operates a centralised procedure for the scientific review of applications for innovative medicines, leading to a marketing authorisation from the European Commission that is valid across the EU.

Advertising of medicines is acceptable provided it is in line with legislation and agreed standards of good practice. Society demands that advertising of any commodity, service or anything that may be of interest to the consumer, should be of a high standard. It should not include anything that could cause serious or widespread offence, create unrealistic expectations in the consumer or be misleading. In other words, there are rules and regulations that apply to advertising in general. These need to be taken into account when advertising a medicine, to ensure required standards are met and that consumer protection is not compromised.

Over and above the general legislation and controls on advertising, there is additional specific legislation that applies to the advertising of medicines. All advertising and promotion of medicines, both for self-medication and to healthcare professionals where medical prescription is required, must be responsible and of the highest standard.

The legislation lays down the requirements and restrictions for advertising, aimed at either prescribers or suppliers of medicines to the public, or at the public as purchasers of over-the-counter medicines. Central to this is the principle that advertising of prescription only medicines to the public is prohibited. The decision to prescribe a certain medicine is taken by a qualified healthcare professional on the basis of informed discussion with the patient.

The MHRA has a clearly defined role and acts on behalf of Health Ministers to protect public health by promoting the safe use of medicines. In seeking to ensure advertising is fully compliant with UK

and European medicines law, the MHRA works closely with other statutory regulators and self-regulatory bodies to ensure a consistent approach so that public health and safety is not compromised in any way. A description of the MHRAâ€™s activities and functions in regulating medicines advertising and those of the other regulatory bodies is provided in chapters 8 to 10 of this guidance.

The Appendix to the Guide includes stand-alone guides, based on the general principles in the Blue Guide, as they apply to specific areas. These include guidelines on disease awareness campaigns, homeopathic and traditional herbal medicines and advice for journalists and web-based treatment service providers.

The MHRA aims to be transparent about its activities and performance. The MHRA publishes on its website the outcome of the complaints it investigates. Statistics on advertising cases are provided in the MHRA Annual Report and a separate report on advertising is published each year providing more detailed information and an overall review of the activities of the MHRA Advertising Standards Unit in the year. These are available on the MHRA website.

The original Blue Guide - Advertising and Promotion of Medicines in the UK (Guidance Note No. 23) - was published in 1999. It was intended to explain the provisions and requirements laid down in the legislation on advertising medicines and provide additional clarification, where necessary, on the interpretation of the law and its application to certain commonly found situations.

This third edition has the same aim as its predecessors. Since 2005, the MHRA has developed specific guidance in several areas including advertising traditional herbal medicines, medicinal treatment services and homeopathic medicines. In addition the MHRA has undertaken a comprehensive consolidation and review of all the medicines legislation since the original 1968 Medicines Act. This has included the regulations covering advertising. There have also been changes to the general legislation and regulatory procedures governing all forms of advertising, including that of medicines. The new Blue Guide incorporates all these changes and provides additional advice derived from cases considered over the six years since the last edition was published.

Further guidance can be found in the individual Codes of Practice of self-regulatory and regulatory bodies concerned with the advertising and promotion of medicines referred to in chapter 10. Further advice can also be obtained as necessary from the MHRA Advertising Standards Unit at advertising@mhra.gsi.gov.uk.