

The Blue Guide Advertising and Promotion of Medicines in the UK

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Medicines and Healthcare products Regulatory Agency

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General advice and information on advertising and promotion of medicines, including a copy of this guidance, is available on the MHRA website at www.mhra.gov.uk

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For general enquiries about the MHRA

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Contents

Chapter 1	
General Introduction	09
Chapter 2	
How to Complain	
2.1 Introduction	11
2.2 When to complain	11
2.3 What will happen next?	11
Legal Requirements for Medicines Advertising in the UK	12
Chapter 3	
The Legislative Framework	
3.1 Introduction	13
3.2 The legal basis for the control of medicines advertising	13
3.3 Scope of the Regulations	13
3.4 Other legislation relevant to medicines advertising	14
3.5 Where to get the legislation	14
Chapter 4	
General Rules	
4.1 Introduction	15
4.2 Prohibition on advertising unlicensed medicines	15
4.3 Quality standards	15
4.4 Who is responsible?	16
4.5 Keeping records	16
4.6 Special requirements for traditional herbal medicinal products (THMs)	16
4.7 Special requirements for registered homoeopathic medicines	17
Chapter 5	
Advertising to the Public	
5.1 Introduction	19
5.2 Medicines suitable for advertising to the public	19
5.3 Prohibition of certain material	19
5.4 Children	19
5.5 Information necessary for the correct use of a medicine	19
5.6 Advice on claims	20
5.7 Recommendations and endorsements	21
5.8 Sponsorship	21
5.9 Samples for promotional purposes	21
5.10 Advertising on the Internet	21
5.11 Disease awareness and health education campaigns	22
5.12 Promotion of services	22

5.13	Multiple purchase promotions for analgesics	22
5.14	Prescription only medicines: Press releases and other information to the media	23
5.15	Prescription only medicines: Responses to enquiries from the public	23

Chapter 6

Advertising to Persons Qualified to Prescribe or Supply

6.1	Introduction	25
6.2	Scope of “persons qualified to prescribe or supply”	25
6.3	Advertising on the Internet	25
6.4	Provision of information - full advertisements	26
6.5	Provision of information - abbreviated advertisements	27
6.6	Messages given in advertising	27
6.7	Urgent safety restrictions or safety variations	27
6.8	Trade advertisements	28
6.9	Promotional aids	28
6.10	Advertising intended for international publication	28
6.11	International meetings	28
6.12	Professional samples	28
6.13	Medical sales representatives	29
6.14	Gifts, inducements and other benefits	29
6.15	Interpretation of “inexpensive” and “relevant to the practice of medicine or pharmacy”	30
6.16	Hospitality	31
6.17	Provision of medical or pharmaceutical education, goods and services	31
6.18	Co-promotion	31

Regulation of Medicines Advertising in the UK 32

Chapter 7

The Role of the MHRA

7.1	Introduction	33
7.2	Vetting of advertising material	33
7.3	Scrutiny of current advertising material	34
7.4	Complaints about medicines advertising	34
7.5	Corrective statements	36
7.6	Seeking advice on advertising	36

Chapter 8**Statutory Action**

8.1	Introduction	39
8.2	Taking statutory action	39
8.3	Independent Review Panel (IRP)	39
8.4	Determinations	40
8.5	Sanctions	40

Chapter 9**Self-Regulation**

9.1	Introduction	41
9.2	The regulatory regime	41
9.3	Vetting of advertising material	42
9.4	Investigation of complaints	43
9.5	Medicines Advertising Liaison Group (MALG)	43

Annexes

1.	Relevant legislation	45
2.	Medicines which are promoted for use during Pregnancy: Guidance for the Pharmaceutical Industry	49
3.	Disease Awareness Campaign Guidelines	53
4.	Particulars to be included in Advertisements to the Public	56
5.	Particulars to be included in Advertisements to Persons Qualified to Prescribe or Supply	57
6.	Particulars to be contained in Abbreviated Advertisements	58
7.	Implementation of Title VIII of Directive 2001/83/EC into UK law	59
8.	Other Regulatory and Self-Regulatory Bodies	60

Glossary

61

Index

63

Chapter 1

General Introduction

Advertising is highly used and well recognised in our consumer society. It comes in different forms, sizes and shapes, plays an important part in our daily life and affects the choices and decisions we make (although some will not admit this!).

Most of us have agonised over which car, TV, or soap would be the best choice for us and best value for our money or which holiday package or hotel would suit us. We may have seen a poster or billboard, adverts in a magazine or on TV or heard about it on the radio. Any decision we make will generally be based on the information available to us and advertising is one of the ways we can get that information.

Advertising, including that 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 product or anything for that matter, 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 legislation that applies to the advertising of medicines.

Medicines cannot be treated as an ordinary general commodity. They have the potential for harmful as well as beneficial effects and can cause serious problems if not used safely. For this reason, there are specific Regulations that strictly control the advertising and promotion of medicinal products in the UK. All advertising and promotion of medicines must be responsible and of the highest standard to ensure the safe use of medicines both in self-medication and where medical supervision is required.

In recent years great progress has been made in information and communications technology and this is a fast and constantly evolving medium which also has considerable impact on medicines advertising in general. All means and methods used in the promotional marketing of medicines are subject to the legislation controlling advertising.

Medicines advertising in the UK is regulated by a combination of national and European legislation. Full descriptions of the legislation on medicines advertising and what this requires are provided in Chapters 3 to 5 of this guidance.

The Regulations lay 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 the Regulations prohibit advertising of prescription only medicines to the public. Prescription only medicines are generally potent drugs that must be taken under medical supervision. In many cases, patients need to be closely monitored to ensure that their treatment is appropriate. The decision to prescribe a certain medicine is taken by a qualified health professional on the basis of informed discussion with the patient.

The control of medicines advertising in the UK is based on a long established system of self-regulation supported by the statutory role of the Medicines and Healthcare products Regulatory Agency (MHRA), acting on behalf of Health Ministers. Self-regulation is permitted under European law covering medicines advertising.

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 Agency 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 Agency's activities and functions in regulating medicines advertising and those of the other regulatory bodies is provided in Chapters 7 to 9 of this guidance.

During 2003, the Advertising Unit of the MHRA reviewed all its internal procedures for regulation of medicines advertising including investigation of complaints, monitoring published advertising and vetting of advertisements prior to issue. The aim of the review was to ensure that the processes operated by the Advertising Unit are robust and effective in protecting public health. The outcome has been published.¹ The Agency also aims to be transparent about its activities and performance. From 1 December 2003, the Agency has been publishing the outcome of the complaints it investigates on its website. Statistics on advertising cases are provided in the MHRA Annual Report and, from 2005-6, a separate report on advertising will also be published providing further information and an overall review of the activities of the Advertising Unit in the year.

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 Regulations and provide additional clarification, where necessary, on the interpretation of the Regulations and their application to certain commonly found situations.

Whilst the aim of this revised edition remains the same, the MHRA has provided further clarification on many issues based on experience over the last five years. This latest guidance is also intended to reflect the changes that have occurred in legislation governing the advertising of medicines and the developments that have taken place in the Agency's policy and procedures. This includes reflecting the Government's response² to the report of the Health Select Committee³, in particular with regard to vetting of advertising for new active substances.

A Glossary of relevant terms, acronyms and abbreviations is provided at the end of this guidance.

The guidance should be read alongside the Medicines Act 1968, the Medicines (Advertising) Regulations 1994, SI No.1932 and the Medicines (Monitoring of Advertising) Regulations 1994, SI No.1933, both as amended.

References in the guidance to the "Advertising Regulations" and to the "Monitoring Regulations" are to the Regulations above, as amended.

The guidance does not replace, or constitute, formal decisions of Health Ministers and should not be taken as a complete or definitive statement of the law.

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 9. Further advice can also be obtained as necessary from the MHRA Advertising Unit.

A list of references to the statutory documents to which the guidance refers is provided at Annex 1.

¹ International Journal of Pharmaceutical Medicine 2003; 17: 185-6.

² Government Response to the Health Committee's Report on the Influence of the Pharmaceutical Industry. September 2005. Cm 6655.

³ The Influence of the Pharmaceutical Industry. House of Commons Health Committee. March 2005.

2.1 Introduction

This chapter describes how to complain about an advertisement for a medicinal product, whether it is aimed at healthcare professionals or the public.

2.2 When to complain

The MHRA investigates complaints received from anyone who has seen an advertisement for a medicine that in his or her view is misleading or otherwise fails to comply with the legal requirements.

To make a complaint, details of when and where the advertisement was seen should be provided, if possible with a copy of the advertisement, together with details of the concerns about the advertisement. The MHRA is particularly keen to receive complaints where the advertisement may have an adverse impact on public health. Alternatively, a complaint may be made to any one of the other regulatory bodies listed in Chapter 9 which regulates the type of advertisement concerned. These bodies operate Codes of Practice that often cover additional issues such as “taste and decency” in addition to the legal requirements and have their own mechanisms for investigating complaints. There is no need to complain to more than one body. Contact details for all the regulatory and self-regulatory bodies can be found in Annex 8.

The MHRA will normally investigate complaints received but may refer cases to one of these bodies (with the agreement of the complainant) if it seems that investigation by another body would be the most appropriate course of action to resolve the issue.

2.3 What will happen next?

The Agency acknowledges receipt of all complaints and will contact the advertiser concerned to investigate the case. Full details of how the MHRA investigates complaints and the actions that may be taken are provided in Chapter 7 of this guidance. During correspondence with the advertiser the identity of the complainant will remain anonymous.

We will endeavour to complete the investigation within 30 days. This time may be extended where there is detailed discussion between the Agency and the company, or when statutory action is taken. Should the investigation take longer, the complainant will be updated on progress. When closing the case the Agency will provide the complainant with details of the outcome and a summary report that will then be published on our website.

Note for pharmaceutical companies who have a complaint:

The MHRA can and does use its powers to take immediate action where serious public health concerns are raised and, if urgent action is required, then the issue should be raised with MHRA. Normally, if an advertisement is identified that is believed to be in breach of the Advertising Regulations the first consideration and point of contact for companies should be the marketing authorisation holder or advertiser outlining the concerns regarding their advertising. Should this route fail to resolve the issue the complaint should normally be referred to the relevant self-regulatory body, for example the Prescription Medicines Code of Practice Authority regarding medicines promoted to health professionals for prescribing or information provided to the public about medicines so promoted. Where such an organisation cannot deal with the matter, the complaint may be referred to the MHRA.

Checklist for complainants:

- Copy of the advertisement or when and where it appeared.
- Reasons for your concern over the advertisement, e.g. what you consider is wrong with it.
- Contact details so that we may contact you for clarification and to advise you of the outcome of the case.
- A copy of any information regarding any communication that you have been involved in with the advertiser prior to complaining to the MHRA.
- Send to MHRA Advertising Unit, Room 14-150, Market Towers, 1 Nine Elms Lane, LONDON SW8 5NQ.

Legal Requirements for Medicines Advertising in the UK

The European and UK legislation regulating the advertising of medicines applies to all forms and means of advertising licensed medicines including branded and generic products for supply by prescription only and over-the-counter products for sale through pharmacies and on general sale. Special provisions are also made, where appropriate, for particular categories of products, for example, registered homoeopathic remedies.

UK Regulations set out the rules for medicines advertising in general and the specific requirements and restrictions for advertising directed at the public and for advertising directed at healthcare professionals. They also set out the statutory powers available to the MHRA in carrying out its functions and taking any necessary action on behalf of Health Ministers where a potential breach has been identified. It makes it the responsibility of “any person” who promotes a medicine, including the marketing authorisation holder, a private individual or any third party such as journalists, publishers or public relations agencies, to ensure compliance with the Regulations.

This legal framework is summarised in the following chapters. The legislation provides a means of enforcement and includes both criminal and civil sanctions. Details of the regulatory framework are provided in Chapters 8 to 10.

Chapter 3

The Legislative Framework

3.1 Introduction

This chapter describes the specific European and UK legislation that regulates the advertising of medicines and provides definitions of the terms used. There is also general legislation on advertising which extends to medicines advertising.

3.2 The legal basis for the control of medicines advertising

The relevant European legislation on advertising is contained in Title VIII of European Directive 2001/83/EC as amended (“the Codified Directive”). Title VIII contains rules on the contents of advertising and promotions and requirements for national monitoring of advertising.

The relevant UK legislation is the Medicines (Advertising) Regulations 1994 (“the Advertising Regulations”) and the Medicines (Monitoring of Advertising) Regulations 1994 (“the Monitoring Regulations”), both as amended. These implement Title VIII of the above Codified Directive.

The Advertising Regulations contain rules on the contents of advertisements and promotions. The Monitoring Regulations contain provisions for enforcing the Advertising Regulations, including the making of complaints about advertisements, applications to court by the Health Ministers, and the making of determinations by the Health Ministers as to whether the Advertising Regulations have been breached. The Regulations have been amended several times and a detailed explanation and a full listing of all the relevant legislation are given in Annex 1.

Following a review of European medicines legislation, Title VIII of the Codified Directive has been amended by Directive 2004/27/EC. This guidance reflects the changes transposed into UK legislation on 30 October 2005. These include removal of the prohibitions on advertising medicinal products for certain diseases and on mentioning that a product has a marketing

authorisation. There are also minor changes concerning the provision of hospitality and the information that may be included on promotional aids.

3.3 Scope of the Regulations

The Advertising Regulations apply to “advertisements” for “relevant medicinal products”.

‘Advertisement’ has a broad definition under the Advertising Regulations. Advertisement has the meaning assigned to it by regulation 2(2) of the Advertising Regulations by reference to section 92 of the Medicines Act 1968. This is underpinned by the definition of “advertising of medicinal products” at article 86 of the Codified Directive which introduces the important concept of activities “designed to promote the prescription, supply, sale or consumption of medicinal products”.

Advertising is understood to encompass written or spoken words intended to encourage prescription or supply by health professionals and use of medicines by the general public, generally by means of highlighting qualities of the medicine (“product claims”). The Regulations exclude from that definition reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make a product claim.

The definition of advertising applied to medicines is not limited to specific media, and includes articles in published journals, magazines and newspapers, display on posters and notices, photographs, film, broadcast material, video recording, electronic transmissions and material 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. Words forming part of a soundtrack or video recording are within the definition of advertising as is the spoken word.

Generally speaking, the labelling and package leaflet of a product which comply fully with the requirements of SI 1994/3144 and Title V of European Directive - 2001/83/EC, would not fall to be considered here.

A 'relevant medicinal product' is defined at regulation 2(1) of the Advertising Regulations. The term 'relevant medicinal product' covers the vast majority of medicines⁴. Products that typically fall outside the definition are homeopathic medicines covered by product licences of right⁵ (registered homeopathic medicines are caught) and unlicensed herbal medicines.

Since October 2005, the definition of a 'relevant medicinal product' has also included traditional herbal medicinal products (THM) with a "traditional herbal registration" under the Traditional Herbal Medicines Registration Scheme (THMRS) which implements Directive 2004/24/EC (the Traditional Herbal Products Directive). This Directive applies the requirements of Title VIII of the Codified Directive to advertisements for herbal medicines registered under Directive 2004/24/EC. This has been implemented through amendments to the Advertising Regulations.

It is worth noting that not all the provisions of the Advertising Regulations apply to all advertisements or all relevant medicinal products. For example, Part III only applies to advertisements to the public, Part IV only applies to advertisements to health professionals and Part V only applies to registered homeopathic medicines.

3.4 Other legislation relevant to medicines advertising

The Trade Descriptions Act 1968 and supporting Regulations, in particular the Control of Misleading Advertisements Regulations 1988 [SI 1988/915], regulate consumer advertising generally, including the advertising of medicines. This legislation is administered by the Office of Fair Trading and the Advertising Standards Authority on behalf of the Department of Trade and Industry.

The Broadcasting Acts 1990 and 1996 and the more recent Communications Act 2003 regulate broadcast advertising generally, including the broadcast advertising of medicines. This legislation is administered by the Advertising Standards Authority on behalf of the Office of Communications (OFCOM).

3.5 Where to get the legislation

Copies of the Regulations can be purchased from The Stationery Office (TSO), PO Box 29, Norwich NR3 1GN or through TSO book shops or from official agents for government publications. They are also available on the Office of Public Sector Information website (<http://www.opsi.gov.uk/stat.htm>). The relevant SI numbers for the Advertising and Monitoring Regulations and other Regulations that control medicines advertising are listed in Annex 1.

Copies of the European Directives are available from the Eur-lex website at <http://europa.eu.int/eur-lex/lex/en/index.htm>

⁴ A medicinal product (medicine) is broadly speaking a substance that either claims to, or has the actual function of, treating or preventing disease in human beings or animals. Further information on the definition of a medicinal product is available in MHRA Guidance Note No. 8 (A Guide to what is a Medicinal Product")

⁵ The advertising of homeopathic medicines with a product licence of right remains subject to the Medicines Act 1968 and the Medicines (Labelling and Advertising to the Public) Regulations 1978 [SI 41/1978]

4.1 Introduction

This chapter sets out the general rules for advertising medicines. Specific information on advertisements aimed at health professionals and the general public can be found in the following chapters.

4.2 Prohibition on advertising unlicensed medicines

By Regulation 3 of the Advertising Regulations, medicinal products which do not have a valid marketing authorisation may not be advertised for medicinal purposes (with the exception of products registered under the homoeopathic registration scheme). The Agency Borderline Section will offer advice on the status of products where it is not clear whether they should be licensed as medicines. It is in breach of the Regulations to issue any promotional material for a licensable medicine until the marketing authorisation has been granted. Exceptionally companies can disseminate limited factual information to persons such as health authorities or trust hospital budget-holders where that information may be significant to the planning of their expenditure over future years, for example, for novel medicines or new means of administration where the changes may have significant cost implications. The information should be targeted at those who need to make budgetary decisions rather than to prescribers. Companies may also provide relevant factual information where this is required by national public advisory bodies such as the Scottish Medicines Consortium, All Wales Medicines Strategy Group or the National Institute for health and Clinical Excellence.

4.3 Quality standards

By Regulation 3A of the Advertising Regulations, an advertisement must:

- (1) comply with the particulars listed in the summary of product characteristics (SPC);

- (2) encourage rational use by presenting the medicine objectively and without exaggerating its qualities;
and
- (3) not be misleading.

The provisions are not mutually exclusive.

(1) Compliance with the SPC

An advertisement must not promote a medicine outside the therapeutic indications listed in the approved SPC for that medicine. This means an advertisement cannot promote a medicine for use in treating or preventing conditions or illness for which it has not been licensed. Nor can an advertisement promote a medicine for use by a patient group not indicated. For example, an advertisement which depicted a baby where the medicine was not indicated below the age of 2 years would be in breach of this provision. An advertisement may include statements not included in the SPC provided these can be substantiated.

(2) Encouraging rational use

An advertisement must encourage the correct and proper use of a medicine; this is a positive obligation. This might include when a medicine should be taken, how much should be taken, the route of administration, by whom it should be taken and special precautions.

An advertisement must present information which is factually correct and those facts should not be exaggerated in any way by the presentation of the advertisement. The factual accuracy should be independently verifiable. For example, an advertisement for a product offering symptomatic relief should not imply that it cures the underlying condition. An advertisement would not be 'objective' where it relies solely on the feelings or opinions of the advertiser or others.

An advertisement would not be objective if it failed to refer to any significant limitations that were relevant to the claims made for the product. Similarly an advertisement that includes data, trials or studies that

are not presented accurately or in context would be considered as exaggerating the properties of a product.

(3) Not misleading

This is a widely drawn prohibition. It will catch any advertisement which leads to an erroneous belief of any nature about the medicine. In particular it will catch advertisements which mislead as to the potential benefits or possible risks of a medicine.

Often advertisements which fall foul of this provision will already have breached Regulation 3A(1) or (2). A factually accurate advertisement may also be misleading due to the overall impression given. An example could be the use of a driving image in an advertisement for a medicine where caution is required over impairment of driving ability.

4.4 Who is responsible?

The primary responsibility for the content and dissemination of all advertising and promotion of a medicine lies with the marketing authorisation holder, who is also responsible for the training and conduct of medical representatives. A company will normally delegate final approval of all promotional material to qualified signatories. Although it is not a legal requirement, the appointment of qualified signatories to certify advertising material is a requirement of both the ABPI Code of Practice and of the PAGB Code of Practice for Health Professionals. Companies are asked also to inform the MHRA of such appointments and of any subsequent changes.

Whilst the responsibility for ensuring that all advertising and promotional material for a medicine complies with the Regulations lies predominantly with the marketing authorisation holder, the Regulations provide that it is an offence for “any person” to breach Regulations. This allows enforcement action to be taken against others involved in the promotion of medicines, such as publishers.

4.5 Keeping records

A marketing authorisation holder (MAH) also has a duty under the Regulations to keep samples of advertising materials available, to respond to requests for information on advertising materials by providing such items as the MHRA may request for consideration and to comply with any decisions taken by the MHRA in respect of advertising and promotional material. Failure to do so is a criminal offence under the Regulations.

The MHRA also has powers to require copies of any published advertisement from any person appearing to be involved in its publication, and again failure to comply is an offence. All advertisers must therefore have arrangements to ensure that copies of all advertising material are retained, either by themselves or on their behalf.

To comply with these legal requirements, the MHRA considers that the minimum time that materials should be kept for by MAHs and/or other parties is a period of three years after either the last use of the piece or the conclusion of any regulatory or self-regulatory action, whichever is later. Where pieces are likely to be in use by recipients for a period of time, the three years should start from the end of the expected normal period of use. Companies should consider the need to retain material for a longer time if there are other reasons, particularly if there has been a safety concern or a complaint about advertising for the product.

4.6 Special requirements for traditional herbal medicinal products (THMs)

In addition to the requirements set out in Chapters 4 to 6, all advertisements for herbal medicinal products with a traditional herbal registration should include the following additional statement:

“Traditional herbal medicinal product for use in *[specify one or more indications for the product consistent with the terms of the registration]* exclusively based upon long-standing use as a traditional remedy”.

The words “as a traditional remedy” have been added to the statement required by law to ensure that consumers are not misled as to the length of time they need to use the product. This wording has been agreed with advertising regulatory bodies and the industry’s Herbal Forum.

Care should be taken in devising advertising for these products to ensure that claims are in line with the approved indication for the product and do not mislead as to the efficacy of the product. Where the indication states “traditionally used for ...” or similar wording, this information should be stated in advertising materials. Claims such as “clinically proven” or “effective in ...” are not acceptable for THMs since the registration is based exclusively on long-standing use.

4.7 Special requirements for registered homoeopathic medicines

Only the information specified on the labelling may be used in the advertising of registered homoeopathic products. No mention of a specific indication may be made. Specific guidance on advertising registered homoeopathic medicines is provided in a separate guidance note (Guidance Note 17) available from the MHRA and they are not discussed further in this Guide.

Chapter 5

Advertising to the Public

5.1 Introduction

This chapter explains the legal requirements and restrictions on advertising aimed at the public. Advertisers have a responsibility to ensure that advertising of medicines available for self-medication does not in any way put patient and consumer safety at risk.

Part III of the Advertising Regulations sets out the provisions for advertising aimed at the general public. In addition the general rules set out in Chapter 4 apply.

5.2 Medicines suitable for advertising to the public

Advertising to the public is permitted for medicines legally classified pharmacy sale (P) or General Sale List (GSL), subject to compliance with Part III of the Advertising Regulations. The Regulations prohibit the issue of any advertisement wholly or mainly directed to the general public which is likely to lead to the use of a prescription only medicine (POM).

Government controlled vaccination campaigns that have been approved by Health Ministers are exempt from this prohibition.

The Cancer Act 1939 ("the Cancer Act") prohibits any advertisement to the public that contains an offer to treat any person for cancer, or to prescribe any remedy for its treatment, or to give any advice in connection with the treatment of the condition. The Cancer Act is administered and enforced by the Trading Standards Service

Medicines which contain psychotropic or narcotic substances cannot be advertised to the general public with the exception of products listed in Schedule III to the Narcotic Drugs Convention 1961 as amended (Cm 2631, available from The Stationery Office) or exempted under paragraphs 2 and 3 of Article 3 of

the Psychotropic Drugs Convention 1971 (Cm 7330, available from The Stationery Office) (those products containing narcotic or psychotropic substances in such quantities as to be exempt from the stringent controls of the Conventions). Products used to procure an abortion may not be advertised.

5.3 Prohibition of certain material

Advertising to the general public should not suggest that one product is better than (or equivalent to) another identifiable treatment or product, or that the effects of taking it are guaranteed. Material which refers in improper, alarming or misleading terms to claims of recovery must not be included.

Advertising should not give the impression that a medical consultation or surgical operation is unnecessary, for example by offering a diagnosis or suggesting treatment by post, FAX or telephone. Nor should it suggest that health can be enhanced by taking a medicine or that health could be affected by not taking the medicinal product.

5.4 Children

Advertising of medicines should not be directed exclusively or principally at children (under-16s). Nor should advertising material aimed at parents and carers be included in non-promotional material aimed at children.

5.5 Information necessary for the correct use of a medicine

Advertisements directed at the public should be presented in such a way that it is clear that the message or material is an advertisement and that the product being advertised is a medicine. Annex 4 sets out the statutory particulars to be included in advertising to the public.

Advertisements to the public must include the name of the medicine and the common name where the product contains only one active ingredient. They must also include the information necessary for correct use of the medicine, which is interpreted to mean one or more indications for use of the product.

There should be a clear and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label as the case may be. A reference to the label alone should be made only where no leaflet is provided or where the label carries a clear and specific instruction to refer to the enclosed leaflet. Codes of practice for the other regulatory and self-regulatory bodies concerned with the advertising of medicines set out further rules for the scheduling of broadcast advertisements and the clarity and discernability of statutory particulars.

Safe use of some medicines depends on compliance with certain conditions, which should be clearly indicated in advertising material. For example, where a medical diagnosis is necessary before self-treatment, or treatment is likely to be successful only if continuous, the advertising material should clearly reflect those conditions. Examples of such products include those indicated for irritable bowel syndrome where a medical diagnosis is necessary and slowing hair loss in male pattern baldness requiring continuous treatment.

In the area of self-medication particular care should be taken to ensure that vulnerable patient groups are not put at risk. One particular example is the use of medicines during pregnancy. Advertising should not convey the message that it is usual for pregnant women to take medicines. The MHRA has developed guidelines on the advertising of medicines for use during pregnancy in consultation with industry representatives and advertising regulatory bodies. These make recommendations for advertisers to ensure safe and responsible advertising for medicines which may be promoted for use in pregnancy. A copy of the guidelines can be found at Annex 2.

5.6 Advice on claims

Claims which suggest a product is as good as the best such as “Nothing acts faster than . . .” are not prohibited under the legislation but care should be taken that consumers are not misled as to the benefits of the medicine in comparison to other products in the category.

Advertising should not suggest that a product does not have any side-effect or that its safety or efficacy is due to the fact that it is natural. Nor should it include any description or detailed representation of a case history that may lead to erroneous self-diagnosis.

Similarly, claims that a product has been manufactured in such a way as to make it purer or otherwise of better quality to a similar product should not be misleading regarding the benefits to the patient.

Claims for fast action should be related to a condition where speed of onset is relevant and may not be appropriate for chronic conditions or those not requiring immediate relief. The time scale for which “fast” claims are appropriate will depend on the clinical indication and the speed of action of other products in the category.

For a 24-hour relief claim, data must show clinical effect over the 24-hour period. The product should be for once daily dosing but a once daily dosing interval alone is insufficient to support a 24-hour claim.

The MHRA discourages advertisements in which the products promoted are linked with other products with similar names also marketed by the company. Such references to other products in advertising may cause confusion. Where an advertisement promotes more than one product with similar names, companies should be very careful to avoid causing confusion, especially where there is a potential risk to public health, for example where one product may be indicated for infants or children whilst the other is not.

All messages conveyed to the audience should support safe use of the products concerned.

5.7 Recommendations and endorsements

Advertisements to the general public should not contain material which refers to recommendations by scientists or health professionals, or which refers to recommendations by celebrities or well known organisations who, because of their celebrity, could encourage consumption of products.

Advertisers should not suggest that their product is “special” or different from or better than other medicines because it has been granted a marketing authorisation or registration. Nor should an advertisement state that a product has MHRA or Department of Health “approval”.

5.8 Sponsorship

Sponsorship linked to a brand of medicine would be acceptable in principle for products classified for over-the-counter sale. Any endorsement by individual celebrities would not be considered acceptable. (See also section 5.7 above). Sponsorships by manufacturers or pharmaceutical companies should not include any promotion of prescription only medicines (POM), whether directly or indirectly. Schemes, charities or like activities cannot be sponsored in the name of a POM.

5.9 Samples for promotional purposes

The Advertising Regulations prohibit the sale or supply of samples of relevant medicinal products to any member of the public for promotional purposes by:

- marketing authorisation holders and persons acting on their behalf (such as distributors), and
- commercial undertakings including registered pharmacies, general retailers and third parties acting on behalf of, or with the consent of, these persons.

Supply via published media or by post, for example with magazines, is similarly unacceptable. The distribution of vouchers for free products or free coupons to potential consumers to enable them to obtain the pack for free or for an unreasonably low sum so as to be almost free is considered to fall within this prohibition.

There is no prohibition under the Advertising Regulations on the sale of small-sized packs of medicines for supply through normal trade outlets on normal business terms provided the necessary authorisation has been obtained to market the product.

5.10 Advertising on the Internet

The Internet is used widely to provide information to both consumers and healthcare professionals. Website providers should ensure that materials posted on the Internet do not contravene the Advertising Regulations. Material posted on UK websites and/or aimed at the UK audience is subject to UK medicines advertising legislation. As for other media, the promotion of prescription only medicines to the public on the Internet is prohibited.

Companies may include in a website disease-related information in accordance with the guidance provided in Section 5.11 below, together with approved patient information leaflets (PILs), SPCs and public assessment reports (PARs) for their POM products. Further guidance on this issue is given in Section 6.3.

Where companies include links from their UK site to their websites serving other countries, it should be clear to UK users that they have chosen to access material aimed at users from other countries. Users should not need to access non-UK parts of the website to obtain basic information about the company's products such as PILs, SPCs and PARs and other non-promotional information. It is good practice for each page of the website to include a statement that makes clear the intended audience.

5.11 Disease awareness and health education campaigns

Campaigns relating to human health directed at the general public with a view to providing information, promoting awareness or educating the public about a particular condition or disease are encouraged. Care must be taken to ensure that the information provided does not make product claims for the material to remain outside the definition of an “advertisement” under the Regulations. In particular, use of brand names, restricting the range of treatments described in the campaign or drawing attention to the campaign by advertising which is likely to lead to the use of a specific prescription only medicine or medicines can all lead to a potential breach of the Regulations.

The MHRA has developed supplementary guidance to help ensure that information provided by pharmaceutical companies and others on health and disease does not fall within the advertising legislation by promoting prescription only medicinal products to the public, and to promote good practice. A copy of the guidelines can be found at Annex 3.

5.12 Promotion of services

Clinics and other organisations may promote the service they provide, e.g. medical services for those with a certain condition or travel immunisations. They may also provide information on the condition and its management, which may include a balanced overview of the range of therapeutic options available. Such material should not draw attention to specific prescription only medicines since this is likely to breach the Advertising Regulations by encouraging individuals to request a particular treatment (see section 5.11, above). The appropriate management for a condition in an individual patient is for the prescriber and patient jointly to consider and this may include a number of medical factors as well as a range of therapeutic options.

As an example, advertising for cosmetic clinics and beauty salons may promote the service provided, e.g. “treatment for lines and wrinkles”, as this is non-specific and may include various procedures.

Advertising must not mention product names such as “Botox” or “botulinum toxin”.

Information on the cost of specific POM products should only be provided as part of the prescribing process or after a prescription has been issued.

5.13 Multiple purchase promotions for analgesics

When Resale Price Maintenance for medicines came to an end in 2001, the longstanding restrictions on price competition for OTC medicines were lifted. This meant multi-buy offers for medicines such as “3 for the price of 2”, “buy one get second half price” and “buy one get one free” were possible.

The Government introduced legal restrictions on pack sizes for aspirin and paracetamol in 1998 to reduce toxicity in overdose particularly related to impulsive gestures which may be associated with stocks of medicines in the home. The Agency is concerned that the sale and supply of large quantities of analgesic medicines or volume-based price promotions of them could undermine the intention of the legislation on pack-size restrictions.

The MHRA discourages companies and retail suppliers of medicines from undertaking any volume-based promotion which includes any products containing analgesics (aspirin, paracetamol and ibuprofen in solid dose and other formulations) that could encourage unnecessary purchases of medicines and put consumer safety at risk. This is an area of voluntary action but the MHRA closely monitors price-related promotions involving analgesics. All persons responsible for approving proposals for price promotions for medicinal products should take into consideration consumer safety.

Department of Health Ministers have made it clear that if price-related promotions pose a risk to public health, the option of legislation would have to be reviewed should self-regulation in this area be shown to be ineffective in protecting public health.

Guidelines issued by trade associations of the pharmaceutical industry such as the Proprietary Association of Great Britain (PAGB) aim to encourage “good practice” in this area and ensure that there is a level playing field across the industry.

5.14 Prescription only medicines: Press releases and other information to the media

Press releases e.g. at the time of launch should not be used as a mechanism to promote prescription only medicines. Information on prescription only medicines which is provided to the lay press, television or radio or by press releases must be factual and non-promotional, where appropriate putting the treatment in the context of the effects of the disease. It should not encourage the general public to ask their GP to prescribe the product.

The MHRA considers that press releases should be genuinely newsworthy rather than having the intention of promoting a product. Care must be taken when drafting press releases to ensure that the material does not breach the Advertising Regulations.

In order to promote balanced media coverage, press releases should provide the context in which the medicine will be used and the population for which it has been licensed. It is helpful to set the product and any relevant results in context of alternative treatments and of current practices for the treatment of the indicated condition. The use of brand names should be kept to a minimum and the tone and content of the press release must be factual and not sensationalised. The material included should be appropriate for the target audience and written in terms likely to be understood by the majority of readers.

Where statements from healthcare professional are included these should be balanced and informative. Anecdotal reports from patients should focus on the disease and the impact it has on the patients rather than the specific medicine, otherwise readers are likely to extrapolate statements about the medicine’s benefit to all patients who receive the product.

Particular care should be taken in providing information in response to direct approaches from the media where a company has little or no control over the final production, for example, with television programmes, and which could result in the promotion of prescription only medicines to the general public.

Companies may provide appropriate information on their medicines to the UK business and financial press in line with their obligations to keep shareholders and the like fully aware of developments which may be material to their UK share price. Business press releases should identify the commercial importance of the information and should be factual and balanced.

5.15 Prescription only medicines: Responses to enquiries from the public

Companies responding to enquiries from the public about prescription only medicines should ensure that such responses are factual, non-promotional and limited to the subject matter of the enquiry. Companies may also provide SPCs, PILs and PARs and direct responses to questions. Information provided must be appropriate to the enquiry, must be balanced and must not promote a prescription only medicine.

In all cases, companies should take care that they do not inappropriately impact on the relationship between the patient and their healthcare provider.

Chapter 6

Advertising to Persons Qualified to Prescribe or Supply

6.1 Introduction

This chapter provides guidance on advertising of medicinal products, both prescription only and over-the-counter medicines, targeting health professionals who are “persons qualified to prescribe or supply” (PQPS) medicines as defined in the Advertising Regulations.

Part IV of the Advertising Regulations sets out the provisions for advertising aimed wholly or mainly at PQPS outside the veterinary field. They include persons who in the course of their profession or in the course of a business sell or supply medicinal products. In addition the general rules set out in Chapter 4 apply.

6.2 Scope of “persons qualified to prescribe or supply”

The scope of “persons qualified to prescribe or supply” is interpreted as including persons (and their employees) who, under the current UK systems of control and supply of medicinal products, are legally entitled to choose which medicinal product is supplied, or to supply such a product even if it is chosen by the consumer or by another person legally entitled to make that choice on the consumer's behalf. PQPS will include all persons who are capable of influencing or determining which product is purchased by or supplied to an end consumer.

Persons qualified to prescribe or supply (PQPS) include:

- (a) persons who in the course of their profession or in the course of a business sell or supply medicinal products;
- (b) persons who are entitled to choose which medicinal product is supplied (including all persons “legally entitled” to prescribe medicinal products);
and
- (c) any person who is capable of influencing or determining which product is purchased by or supplied to an end consumer at point-of-sale.

Examples of PQPS would include doctors, dentists, nurses, pharmacists, pharmacy assistants, optometrists, chiropodists, midwives and other ancillary health workers and retail staff who are entitled to supply medicinal products directly to members of the public. It would also include persons who are legally entitled to decide which medicine is supplied in a particular outlet, e.g. buyers.

Recent legislative changes have expanded the number of professionals qualified to supply medicines under Patient Group Directions (PGD). This category includes Dietitians, Occupational Therapists, Speech and Language Therapists, Prosthetists and Orthotists. These occupations are now considered to be PQPS. Any promotion of medicines should take account of the range of medicines they are entitled to prescribe or supply.

The definition of PQPS does not include intermediate suppliers of medicinal products, e.g. wholesalers.

6.3 Advertising on the Internet

Internet advertising of medicines is acceptable provided it complies with the Advertising Regulations. The MHRA considers that advertisements for POMs are acceptable only on websites whose nature and content are directed at health professionals. Sections of a website aimed at health professionals and containing promotional material should ideally be access restricted. If no restriction is applied and websites provide both information for consumers and information aimed at health professionals that includes advertising, the sections for each target audience should be clearly separated and clearly marked for the target audience. In order to be able to demonstrate that material on an open access website is “wholly or mainly directed” at PQPS, adequate non-promotional information must be provided in public areas so that individuals do not need to access sections for health professionals unless they choose to seek further detailed information. Members of the public should not be encouraged to access information which is not intended for them. Actively directing members of the

public to advertising material for POMs is likely to be contrary to the Regulations. See also Section 5.10 for further advice.

A journal which is published or posted on the Internet and which is expressly stated to be for health professionals is considered to be directed at persons qualified to prescribe or supply medicines and the advertising contained within the journal should comply with Part IV of the Advertising Regulations. Each page of an advertisement for a prescription only medicine (POM) should be clearly labelled as intended for health professionals.

6.4 Provision of information – full advertisements

Essential information compatible with the summary of product characteristics (SPC) of the product(s) must be given but the wording of this information can be adjusted to take account of the varying levels of technical knowledge of individuals falling within the class of PQPS. Regulation 14 and Schedule 2 of the Advertising Regulations lay down the particulars to be contained in advertisements to PQPS. In any case all the particulars referred to in Annex 5 must be given. Annex 5 clarifies the particulars set out in Schedule 2 to Regulations 14 and 15 of the Advertising Regulations.

The requisite information should be presented clearly and legibly and be positioned for ease of reference. It is not acceptable for the information to be presented in such a way that the reader has to turn the material around to read the text, for example, diagonally or around the borders of the page.

The Regulations require such advertising to include information about the medicine which is sufficiently comprehensive to enable the reader to form an opinion as to its suitability for use, taking into account its safety, quality and efficacy. There are separate but overlapping requirements for “abbreviated advertisements” (see Section 6.5, below).

This information is intended as a reference for health professionals. It is not a substitute for reading the SPC but should convey all the key information from the SPC to be considered before prescribing or supplying the medicine.

Schedule 2 to the Regulations requires one or more of the licensed indications to be provided as well as a succinct summary of the entries in the SPC for the dosage and method of use. A succinct summary of the SPC information relating to side-effects, precautions and contra-indications is also needed and the route of administration should be shown when not obvious. The information must also include the actual product name, active ingredients, licence number, legal status and the name and address of the licence holder. In addition the cost is required, except for audio-visual advertisements and advertisements in journals printed in the UK but with a circulation outside the UK of more than 15% of its total circulation.

SPC statements need not be included verbatim but key messages should be clearly conveyed. Companies should assess the need for inclusion of information from the SPC on an individual basis. The reader must be presented with the key information from the SPC about who should and should not be given the medication, how to prescribe it and what effects may be observed.

With regard to side-effects where those listed in the SPC for certain products may be quite extensive, as a minimum, the particulars should indicate all the common side effects likely to be encountered in clinical practice and also those which are rarer but may be serious, together with an indication that other uncommon effects are listed in the SPC. It is also helpful to include information on reporting of adverse reactions.

Where an advertisement is directed at treatment of a particular group of patients, companies should ensure that the information includes all the relevant SPC particulars. For example, where a product is being

promoted for use in children, the particulars should convey all the information in the SPC relevant to that group. This would probably dictate greater detail than would be required in an advertisement for the same product targeting a more general patient population.

Whilst there is no legal requirement to include data on interactions (unless they are warnings) the mention of significant interactions is strongly encouraged. Any interactions that pose a potentially serious health risk to patients should be included. Reducing the efficacy of the contraceptive pill or an interaction with warfarin are examples.

6.5 Provision of information - Abbreviated advertisements

Abbreviated advertisements, defined under regulation 2(1), may only appear in professional publications as an integral part of the publication. They must be no larger than 420 sq. cm. and cannot be issued in the form of a loose insert.

They must contain essential information compatible with the product SPC, although exempt from the need to provide detailed prescribing information for the product. Abbreviated advertisements must include a reference to an indication for the use of the medicinal product or two or more related indications consistent with the product SPC and any required warning. The particulars to be contained in abbreviated advertisements are given in Regulation 16 and Schedule 3 of the Advertising Regulations. In any case all the particulars referred to in Annex 6 must be given. Annex 6 reproduces Schedule 3 to regulation 16 and provides additional clarification about abbreviated advertisements.

6.6 Messages given in advertising

Advertising which states or implies that a product is “safe” is unacceptable. All medicines have the potential for side-effects and no medicine is completely risk-free as individual patients respond differently to treatment.

For example the term “placebo-like” in relation to safety or side-effects in general is considered to be misleading as it implies that there are no drug-associated side-effects. By implication the medicine could be assumed to be 100% safe, when no medicine is completely risk-free. Claims that a drug is well tolerated or has a well established safety profile including claims relating to the overall incidence of side effects versus placebo in clinical trials, may be acceptable if supported by evidence, provided a misleading impression is not given.

Promotional claims which refer to the tolerability of a medicine should be factual and based on the available evidence from clinical trials and surveillance.

Care should be taken to ensure that prescribers are not misled by promotional claims in advertising which suggests that a particular product is safer than an alternative medicine unless this is supported by evidence.

6.7 Urgent safety restrictions or safety variations

It is the responsibility of the marketing authorisation holder (MAH) to ensure that prescribers are made fully aware of important changes to product information in their promotional campaigns. Following an urgent safety restriction (USR) or similar safety variation advertisers should take care to ensure that subsequent advertising gives due prominence to important safety restrictions and should include a strap-line or equivalent highlighting the changes.

Whilst the abbreviated prescribing information (API) of an advertisement is likely to include updated information following any change to the SPC, it is not appropriate for this to be the only part of the advertisement to be amended following a USR. In view of the seriousness of the public health risk generally involved in a USR, the MHRA takes the view that the body of the advertisement should be amended to ensure that any healthcare professional

reading it will be informed or reminded of the restriction to the licence on the basis of safety. Information on where to find further information on the changes, such as a link to the MHRA website, should be provided.

6.8 Trade advertisements

The Advertising Regulations provide that “reference material, a factual, informative statement or announcement, a trade catalogue or a price list shall not be taken to be an advertisement,” provided that it does not make product claims. Advertisements for medicines issued in trade publications in the form of an informative announcement, for example of a new introduction or notification of planned TV marketing spend would fall to be considered outside the definition of an advertisement under the Regulations provided they do not make product claims. Such an advertisement should not contain any recommendation relating to the use of the medicinal product other than as part of the name of the medicinal product or a therapeutic classification. A true representation of the approved pack may be included.

This form of advertising may be particularly useful when advertising GSL medicines to purchasers who may not have specialist medicines expertise.

6.9 Promotional aids

A “promotional aid” is a non-monetary gift made for a promotional purpose by a commercially interested party (e.g. the supply of an item such as a pen, notepad or mug).

Advertisements relating to products which are on a promotional aid and which consist solely of the name of the product are exempt from the need to include other essential information. The international non-proprietary name (INN) or the trademark, interpreted as the brand or umbrella, brand name, are permitted alternatives to the name. The cost of such items to the donor should be valued at £6 or less (excluding VAT), represent a similar value to the recipient and must comply with the requirements of Regulation 21.

This value is updated periodically to take account of inflation. Items used as promotional aids must also be relevant to the practice of medicine or pharmacy.

6.10 Advertising intended for international publication

Advertising material in professional journals intended primarily for circulation in the UK whether or not in the English language must comply with UK legislation and with the UK marketing authorisation for the product.

International journals which are in English are subject to UK legislation if their primary affiliation and/or base is the UK and all journals with a European intended audience are subject to the requirements of Directive 2001/83/EC. The MHRA takes action with other regulators and with UK company affiliates where advertising in international journals not based in the UK causes concern on public health grounds.

6.11 International meetings

Material relating to products that do not hold UK marketing authorisations which is displayed or available on request at international symposia, conferences and other meetings is permitted provided that a significant proportion of the attendees are from countries outside the UK where the product is licensed (this should include at least one major developed country). The material should be relevant, proportional to the purpose of the meeting and should clearly and prominently indicate that the product is unlicensed in the UK.

Self-regulatory codes also operate in other European countries under the auspices of EFPIA (European Federation of Pharmaceutical Industries and Associations) and globally by the IFPMA (International Federation of Pharmaceutical Manufacturers and Associations).

6.12 Professional samples

Regulation 19 applies to the supply of a free sample of a medicinal product to a person who receives it for the purpose of acquiring experience in dealing with

the product. Such a sample may only be supplied to a person qualified to prescribe medicinal products, and on the following conditions:

- (i) they shall be supplied on an exceptional basis only;
- (ii) a limited number only of samples of each product may be supplied in any one year to any one recipient;
- (iii) they should be supplied only in response to a written request, signed and dated, from the recipient;
- (iv) suppliers shall maintain an adequate system of control and accountability;
- (v) they shall be no larger than the smallest presentation available for sale in the UK;
- (vi) they must be appropriately labelled in line with the requirements of Article 54 of Directive 2001/83/EC and be marked “free medical sample – not for resale” (or similar); and,
- (vii) every sample shall be accompanied by a copy of the approved SPC.

Samples cannot be supplied under regulation 19 to persons qualified only to supply medicines.

Samples of medicines containing psychotropic or narcotic substances which are controlled under the Narcotics Drug Convention or the Psychotropic Substances Convention are prohibited except for those listed under Schedule III or Paragraphs 2 and 3 of Article 2 of the respective Conventions.

Short-term supplies provided on request to medical practitioners for use in emergency situations, i.e. out-of-hours and in the patient’s home (so-called “starter packs”) are not considered to be samples for promotional or advertising purposes under the Advertising Regulations.

6.13 Medical sales representatives

Medical sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and complete as possible about the products they are promoting. Both the Association of the British Pharmaceutical Industry (ABPI) and the Proprietary Association of Great Britain (PAGB) provide training programmes for representatives. (Further details are available from the addresses in Annex 8.)

Representatives should, during each visit, give to all persons whom they visit, or have available for them, a copy of the summary of product characteristics (SPC) for each product which they promote at that visit. They must also report all information relating to the safety of a product which they receive from health professionals directly to scientific services set up by the marketing authorisation holder under the Advertising Regulations.

6.14 Gifts, inducements and other benefits

Regulation 21(1) of the Regulations provides that “where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person shall supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy”.

Regulation 21(1) works in two stages. First it sets the broad outer limits for its application: it catches any promotion of medicines to PQPS including advertising, price promotions, loyalty schemes, bonus schemes, linked share offers, public relations exercises and merchandising offers. Then, from within that broad spectrum, it identifies the particular type of promotion that is prohibited because of its potential to adversely impact on public health. That type of promotion is the supply, offer or promise of pecuniary advantage or benefit to PQPS (subject to the inexpensive and relevant to medicine/pharmacy exception).

This means that any promotional activity which encourages the purchase, supply or sale of a relevant medicinal product by PQPS will be caught by regulation 21(1) if it offers a collateral benefit which does not satisfy the “inexpensive” and “relevant to the practice of medicine or pharmacy” tests, unless it is exempt under regulation 21(4).

Regulation 21(4) provides an exemption to the prohibition in regulation 21(1) for promotional activity in the form of “Measures or trade practices relating to prices, margins or discounts which were in existence on 1 January 1993”. These are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts and similar offers such as “14 for the price of 12”, provided they are clearly identifiable and invoiced.

Cash returns to individuals and other personal benefits “*in lieu*” of discounts such as preferential loans, share options, gifts or special prices for travel, insurance deals, office equipment or computer software are not exempt under regulation 21(4).

Any “person” promoting medicines to PQPS will be subject to regulation 21(1). “Person” covers bodies corporate and unincorporate as well as individuals and includes manufacturers and distributors of medicines, including wholesale dealers.

For example, a wholesale dealer’s scheme that rewards PQPS for purchasing medicines through it by awarding points, based on volume of purchase, exchangeable for a discounted investment opportunity or personal reward scheme is likely to be in breach of regulation 21(1). This is because the scheme promotes the purchase of medicines and offers a collateral benefit for doing so which is unlikely to be inexpensive and/or relevant to the practice of medicine/pharmacy.

Breach of regulation 21(1) is a criminal offence. It is an offence for any person qualified to prescribe or supply medicines to solicit or accept any gift, pecuniary advantage, benefit in kind, hospitality or sponsorship prohibited under the Regulations.

6.15 Interpretation of “inexpensive” and “relevant to the practice of medicine or pharmacy”

The item or benefit offered must be both inexpensive and relevant to the practice of medicine or pharmacy for it to fall outside the prohibition in Regulation 21(1) of the Advertising Regulations. That is, both conditions must be satisfied. Inexpensive items are considered to be those which do not cost a company more than £6 (excluding VAT) and represent a similar value to the recipient. This figure is updated periodically to take account of inflation. The criterion of “relevance” is met by items which have a clear business use and may include such items as pens, notepads, calculators, computer accessories, diaries, calendars, surgical gloves, tissues and coffee mugs.

A similar approach applies to membership schemes and cumulative points schemes which have the effect of conferring benefits in the form of free or reduced price goods or services. The goods or services must comply with the criteria for relevance and be “inexpensive”.

The legislation does not preclude competitions which are open to PQPS and which are linked to the promotion of a relevant medicinal product but any prizes must be both inexpensive and relevant to the practice of medicine or pharmacy. The maximum prize figure considered appropriate for a competition is £130 (excluding VAT). The number of prizes should be restricted to a few only and should not exceed six for UK-wide and three for smaller competitions. All such promotions will in addition need to comply with relevant prize competition law and industry codes (e.g. The British Code of Advertising, Sales Promotion and Direct Marketing).

The £6 value for promotional aids and other benefits may be updated periodically to take account of inflation. Should any change occur an announcement will be posted on the Agency's website.

6.16 Hospitality

The restrictions of regulation 21(1) do not prevent the offer of hospitality to PQPS at events purely for professional or scientific purposes under the conditions laid down under regulation 21(2) which include the conditions that the hospitality should be strictly limited to the main objective of the meeting and should not be offered to persons who are not health professionals e.g. partners.

Regulation 21(3) (dealing with offers of hospitality where the purpose of the event is the promotion of products) provides that hospitality can also be offered to health professionals at meetings or events held to promote medicines, provided it is strictly limited to the main purpose of the meeting or event. Hospitality should be "reasonable" in level.

6.17 Provision of medical or pharmaceutical education, goods and services

Schemes which are launched by the pharmaceutical industry offering sponsorship of research posts, study visits and suchlike may well be acceptable provided that there is no element of promotion of individual products associated with them. The provision of goods or services to hospitals and health care units for the benefit of patients should not be dependent upon, or subject to, the prescription or supply of medicinal products and should not refer to them by name.

6.18 Co-promotion

Co-promotion of a medicinal product by the marketing authorisation holder and one or more companies nominated by him is not prohibited in the UK.

Regulation of Medicines Advertising in the UK

The control of medicines advertising in the UK is based on a long-established system of self-regulation. The statutory powers of the MHRA, acting on behalf of Health Ministers, underpin and support this system, which is permitted under European legislation on advertising, by providing a means of enforcement should self-regulation fail.

The self-regulatory bodies provide advice on various aspects of the promotion of medicines and are essentially divided into those that provide advice on the promotion of medicines for purchase by the general public and those that provide advice on the promotion of medicines for prescription.

To fulfil its statutory duties, the MHRA has the power to require sight of advertisements in advance of publication, a procedure known as vetting. The Agency also carries out monitoring of medicines advertising and investigates complaints about advertising from any source, including health professionals and the public. Whilst carrying out its statutory duties the MHRA will assess each case on its own merits and in light of the available evidence.

The following chapters describe how medicines advertising is regulated in the UK.

Chapter 7

The Role of the MHRA

7.1 Introduction

This chapter outlines the various methods used to regulate the promotion of medicinal products, to ensure that advertising complies with the legislation and where necessary the sanctions that MHRA may use to ensure compliance with the legislation.

A key function of the MHRA is to protect public health by promoting the safe use of medicines. On advertising, this statutory role, acting on behalf of Health Ministers, supports the system of self-regulation.

The MHRA conducts a number of activities relevant to advertising control:

- (i) checking advertising for compliance with the law prior to publication (vetting) in clearly defined circumstances,
- (ii) monitoring of published advertising material for medicines,
- (iii) handling of complaints about advertising, and
- (iv) enforcement in relation to materials not compliant with the Regulations

Each of the above four activities is described in more detail below.

7.2 Vetting of advertising material

In order to perform its supervisory functions under the Regulations, the MHRA monitors not only published advertisements but also advertisements prior to publication. To perform that task, advertising material for certain products may be required to be submitted for scrutiny prior to issue (vetting). The MHRA has statutory powers under the Schedule to the Monitoring Regulations to require companies to submit advertising material for vetting. Most companies voluntarily agree to submit advertising materials for vetting when asked.

Circumstances where vetting may be required include:

- (i) where a newly licensed product, subject to intensive monitoring, is placed on the market;
- (ii) where a product is reclassified, such as from POM to P;
or
- (iii) where previous advertising for a product has breached the Regulations.

Within the first criterion above and as a matter of policy, the MHRA has committed to vet initial advertising for all new chemical entities.

The period of vetting of all advertising for a product will normally be no longer than six months. The marketing authorisation holder (MAH) will be advised of the requirement for vetting and of the reasons for, and duration of, the requirement in each case. This time period may be reduced or extended depending on the quality of the initial advertising material submitted and other relevant factors.

Promotional material submitted for vetting to the MHRA should indicate the target audience (public or PQPS) and include references in support of claims in the promotional material. All material should have already undergone a full set of internal quality control and compliance checks before submission to the MHRA.

The MHRA will undertake to give its opinion on the advertising material within a given time-scale and will take account of any realistic deadlines indicated by the company involved. Normally five working days should be allowed for assessment but where substantial data are submitted this will not be possible and the MHRA will give an estimate of the time necessary to complete the assessment if a delay is unavoidable. The company may be asked to advise the MHRA of the form of the advertisement, the intended audience and the intended date and duration of issue for each piece of copy submitted.

Where advertising material is assessed for vetting the opinion of the MHRA is based upon the information provided at the time and the current state of scientific knowledge. The MHRA has a statutory function to monitor advertisements on a continuing basis and to consider complaints made to it in the future. The above opinions will therefore be given without prejudice to the Agency's ability to perform this function.

7.3 Scrutiny of current advertising material

In order to perform its supervisory functions under the Regulations, the MHRA is obliged to monitor published advertisements. The MHRA examines various health professional and consumer journals and other types of media for advertisements relating to any medicinal product, which are then checked against the Advertising Regulations for compliance. Should there be a cause for concern the Agency will contact the MAH for supporting evidence, comment or clarification on advertising and will initiate action as for a complaint if necessary (see below for further details).

7.4 Complaints about medicines advertising

A complainant can choose to refer directly to any self-regulatory or regulatory body which deals with complaints, including the MHRA. Please see Chapter 2 – "How to complain".

Where a complaint is made directly, the MHRA (acting on behalf of Health Ministers) has a general duty under the legislation to consider that complaint. If the complaint involves an alleged breach of regulation 9 or Part IV of the Advertising Regulations, the Monitoring Regulations provide that the complaint may be passed to a suitable self-regulatory body for investigation where both the MHRA and the complainant agree. Where a complaint has not been dealt with in a satisfactory manner within a reasonable time scale by the designated self-regulatory body the MHRA is required to investigate the complaint.

The MHRA generally investigates all complaints received but may refer a case to a self-regulatory body where an initial investigation has found no breach of the legislation but a potential breach of a Code of Practice. The MHRA may at its discretion also refer other cases (with the agreement of the complainant) if it seems that investigation by another body would be the most appropriate course of action to resolve the issue.

Complaints about broadcast advertising which are received solely by the MHRA are its responsibility and will be investigated or referred in the way described above. Where a complaint about a broadcast advertisement is received by both the Agency and the Advertising Standards Authority (ASA) or by the ASA alone, it is the responsibility of ASA to investigate the complaint. The ASA acts as a co-regulator on behalf of the statutory body, OFCOM which has enforcement powers under Regulation 11 of the Monitoring Regulations. This enables the ASA to prevent the publication or further broadcast of the advertisement, subject to an obligation to give reasons and review by the courts.

The following sections explain the procedure for complaints made directly to the MHRA.

All complaints are acknowledged by the MHRA on receipt. When the Agency receives a complaint about an advertisement for a medicine, an anonymised copy of the complaint is usually sent to the advertiser immediately with a request for a response to the issues raised and any relevant material.

If appropriate the MHRA will, at the same time, request a copy of the advertisement in question, if this has not been sent with the complaint. In the event of a refusal by the company, the MHRA may issue a notice under paragraph 1(a) of the Schedule to the Monitoring Regulations formally requesting a copy of the advertisement in question.

All complaints are considered by the MHRA's Advertising Unit as a whole at its regular weekly meeting. Accelerated action is taken on any case that is judged to pose a serious risk to public health. In these cases, the Agency may provide a view indicating the reasons for such a view at this initial stage and ask for immediate withdrawal of the advertisement.

The Agency aims to turn complaints around quickly at each stage of an investigation and expects companies to do so as well. Short deadlines – usually seven calendar days – are set to ensure that any action is timely. If advertisements which are the subject of a complaint are immediately suspended or withdrawn, additional time may be allowed for a full response from the advertiser, if requested.

Once the company's response is received, the advertisement is reviewed in detail by the Agency, taking into consideration the complaint and the response of the company. It may be referred to medical or other professional assessors for advice. When reviewing advertising complaints, assessors take into account the public health implications of any potential breach (i.e. the potential for inappropriate prescribing and/or use of the product to result in a risk to health) and try to take a broad view of the impact of the advertising material on the safety of patients. The law is drawn widely precisely because an advertisement as a whole can be misleading, even if the words on the page can be justified in isolation. The MHRA's Advertising Unit also calls on an Advertising Action Group, consisting of senior professional assessors and other staff with experience of advertising regulation, for advice if needed.

Many cases are resolved at an early stage, either because the Agency decides there is no case to answer or the company recognises the concerns of the complainant and the Agency and takes appropriate action. In certain circumstances, the complaint may be referred to another regulatory or self-regulatory body for consideration, for example if it related to taste and decency.

Should potential breaches of the legislation be identified, a letter is sent to the advertiser outlining the Agency's provisional view of the advertisement. This will generally list the potential breach(es) and any public health risk identified where appropriate, along with any action the advertiser is asked to take. This may include a request to:

- amend the advertisement,
- withdraw the advertisement,
- issue a corrective statement, and/or
- submit future advertising for the product to the MHRA for review prior to issue (vetting).

If the advertiser agrees that the advertising material may be in breach and agrees to amend the material before issue, or withdraw material already issued, any revised material should be submitted for assessment before it is issued.

Most remaining cases are resolved once the company responds to this letter. If action is not agreed, the Agency will review the case again and then consider what further steps are appropriate. The Agency, on behalf of Health Ministers, may issue a notice that it is minded to make a determination that the advertisement is in breach of the Advertising Regulations. Details of the statutory procedures are provided in the next chapter. Cases may also be referred, at any stage, to the Enforcement & Intelligence Division of the Agency for consideration of enforcement action.

Once a decision on a complaint has been reached (at any stage of this process), both the complainant and the advertiser are advised of the outcome of the investigation and receive a copy of the draft outcome report. This details the date of origin of the complaint, an anonymised source (unless it is a competitor company), substance of the complaint, the MHRA conclusion and any agreed action. If the complainant is not happy with the decision they may ask for the case to be re-investigated.

The report is then published on the Agency's website. Occasionally, the MHRA may also issue a statement about a particular case in order to highlight concerns and provide guidance on good practice.

The MHRA endeavours to complete investigations of complaints within 30 days. This time may however, be extended where there is detailed discussion between the Agency and the company, or when statutory action is taken.

7.5 Corrective statements

The MHRA website report may not be sufficient to correct any misconceptions which may have led to inappropriate prescribing or use of the product and potential risk to public health. In this situation the MHRA may request a corrective statement to be issued. The MHRA has statutory powers to compel the publication of a corrective statement where advertising has been found to be in breach of the Regulations, although most companies agree voluntarily to issue the correction.

The following provides guidance on the recommended format of a corrective statement:

- **Opening statement:** This should clearly indicate that this is a corrective statement issued at the request of the MHRA and the product concerned. Example wording: "The MHRA have asked . . . to provide a corrective statement regarding the promotion of . . ."
- **Description of the case:** This should include when and where the original advertisement was used and what type of advertisement/promotional material it was and whether it has been withdrawn or not.
- **Statement on the breach:** This should outline how the advertisement was in breach of the Advertising Regulations without repeating the original wording and give a description of the correct facts including a summary of the MHRA view.

- **An expression of regret and apology.**
- **Contact information:** Details of the company contact should readers have any further questions about these matters or about the product.

The tone and content of the corrective statement should convey the message that this is an informative publication, without giving the impression of promoting the product again, and keeping mentions of the product name to a minimum.

Whilst most corrective statements would fit within this format there may be circumstances where it would not be appropriate to use it and in such cases the Agency would consider an alternative format.

The corrective statement should be targeted to the audience who saw the original advertisement, e.g. via a journal, mailing, or "Dear Doctor" letter and should be proportionate in size to the original material.

In addition, where a corrective statement has been required for misleading advertising, the MHRA may require that new advertising uses different visual images to ensure that it is not linked in any way to the previous material that breached the Regulations.

7.6 Seeking advice on advertising

Should a company, or an agency or trade association acting on behalf of that company, have a specific query regarding an advertisement they should submit the advertisement to the MHRA for review and advice on its suitability for issue. The MHRA will assess the advertising in the normal way and provide suggested amendments, if any, where appropriate. If the material is issued without amendment, and the MHRA considers that it is potentially in breach of the Advertising Regulations, consideration of enforcement will be initiated. This service is provided to assist in those cases where there is genuine uncertainty over the legal requirements and the point at issue needs to be clearly defined. The MHRA is not, however, able to provide a routine vetting service on request.

In the first instance companies should refer queries to their trade association or the relevant self-regulatory body (e.g. PAGB or PMCPA). For advertising to the public, the Committee of Advertising Practice (CAP) operates a free copy advice service for non-broadcast advertisements and pre-clearance centres also exist for radio and television advertising. Further details about these bodies can be found in chapter 8 and at Annex 8.

8.1 Introduction

This chapter describes the formal statutory procedures that the MHRA may use to regulate the advertising of medicinal products and the provision for review by an Independent Review Panel (IRP). The MHRA can and will resort to formal procedures if it considers there to be a public health justification, either in the form of notices issued at any stage during the investigation of a case or through enforcement action and prosecution.

8.2 Taking statutory action

Although the Monitoring Regulations clearly set out the statutory powers available to the MHRA, it is expected that, in the majority of cases, companies will work with the MHRA to issue acceptable advertising without the need to resort to the formal procedures laid down under the Schedule to the Monitoring Regulations. The MHRA can serve a “minded to” notice upon any person responsible for the issue or publication of an advertisement, although such action is usually taken against the MAH.

The Regulations provide for representations made by the person on whom a “minded to” notice has been served to be considered by the Health Ministers.

The advertiser may be issued with a notice under the Schedule to the Monitoring Regulations advising him that:

- (i) the MHRA is “minded to” determine that the advertisement, if published, would be in breach of the Advertising Regulations and the reasons why they are “minded to” make such a determination;
- (ii) if such a determination is made, that person may be required to refrain from publishing that advertisement;
and,
- (iii) the person on whom the notice is served has twenty-one days from the date of the notice in which to make written representations that the proposed determination should not be made.

The notice may require that person to refrain from publishing the advertisement until such time as the notice has been withdrawn by Health Ministers. In deciding whether to include such a requirement, the MHRA will take into account all the interests involved and, in particular, the public interest. Cases may also be referred, at any stage, to the Enforcement & Intelligence Division of the Agency for consideration of enforcement action. Once a case is referred, any further contact or correspondence about the case will only be with the E&I Division.

In addition, the MHRA is entitled to seek an injunction to prevent the publication of an advertisement in the courts as part of its investigation of a complaint or of its own volition.

The MHRA may also issue statutory notices to require that a copy of a published advertisement be provided to the MHRA or to require that all advertising for a product is submitted to the Agency for review prior to publication. The notice may also require that person to refrain from publishing the advertisement. In all cases reasons for the notice will be provided. These powers are normally only used if agreement has not been reached voluntarily. In addition, the MHRA is entitled to seek an injunction in the courts as part of its investigation of a complaint or of its own volition.

8.3 Independent Review Panel (IRP)

The Monitoring Regulations make provision for the advertiser to make written representations as to why the proposed determination should not be made. These representations, if made, are referred to a non-statutory body, the Independent Review Panel for Advertising (IRP) for consideration. The IRP’s view on whether the advertisement breaches the Advertising Regulations must be taken in to account by the MHRA when making a final determination on behalf of the Health Ministers.

The IRP will usually consist of a legally-qualified chairman and two other members, one with medical or pharmacy expertise and the other representing the interest of the consumer.

Specific guidance for companies on how to make representations to an IRP, including further details of the procedure, is available on the MHRA website.

8.4 Determinations

If, following consideration and having taken into account the views of the IRP, the MHRA decides that the advertisement would not be in breach of the Advertising Regulations, a notice will be issued informing the advertiser of that decision and withdrawing the previous notice.

Alternatively, the MHRA may, in the light of advice received from the Independent Review Panel, make a determination that the advertisement, if published, would be in breach of the Advertising Regulations. In this case, a notice under the Schedule to the Monitoring Regulations will be issued, stating the reasons for the determination on behalf of Health Ministers and possibly requiring the advertiser to refrain from publishing the advertisement.

Where the publication of an advertisement has been prohibited and that advertisement has previously been published, the advertiser may be required to publish the reasons for the determination and a corrective statement within a specified time and in an appropriate form.

Once the MHRA's final decision has been made and communicated by statutory notice, the matter is closed, subject only to any judicial review of the decision before the Courts or any criminal prosecution.

8.5 Sanctions

A breach of any of the provisions of the Advertising Regulations listed in Regulation 23 of those Regulations is a criminal offence. This covers the vast majority of requirements set down by the Advertising Regulations. The penalty is a fine and/or imprisonment for up to two years in most cases.

A failure to comply with any requirement imposed by a notice served under the Monitoring Regulations is a criminal offence. The penalty is a fine and/or imprisonment for up to two years.

Where the MHRA believe that a criminal offence has been committed, it will always consider enforcement action, i.e. prosecution.

Civil sanctions are also available under the Monitoring Regulations, for example, requiring publication of a corrective statement where Health Ministers have prohibited publication of an advertisement for breaching the Advertising Regulations. Further guidance on the format of corrective statements is provided in Section 7.5.

9.1 Introduction

This chapter describes the various bodies involved in the process of self-regulation and the responsibilities each organisation has to regulate the advertising industry with specific reference to medicines advertising.

9.2 The regulatory regime

The control of medicines advertising in the UK is based on a long-established system of self-regulation. The statutory powers of the MHRA, acting on behalf of Health Ministers, underpin and support this system. There are a number of regulatory bodies the majority of which operate their own Codes of Practice. These are described below. Details of how to contact all these bodies are provided in Annex 8.

Prescription Medicines Code of Practice Authority (PMCPA)

The PMCPA, which operates independently of the Association of the British Pharmaceutical Industry (ABPI), administers the ABPI Code of Practice for the Pharmaceutical Industry. The Code applies to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff and to information made available to the public about those medicines. The Code also applies to a number of areas which are non-promotional.

The Code is drawn up in consultation with the British Medical Association (BMA), the Royal Pharmaceutical Society of Great Britain (RPSGB) and the MHRA. It is a condition of membership of the ABPI to abide by the Code and most of the other companies operating in the UK which are not members of the ABPI have given their formal agreement to abide by the Code and accept the jurisdiction of the PMCPA.

The ABPI Code refers to the training requirements for all relevant personnel including medical representatives. The PMCPA runs seminars on the Code which are open to any interested party. Details are available from the PMCPA (contact details appear in Annex 8). Details of the ABPI Representatives Examination may

be obtained directly from that body (contact details appear in Annex 8).

Proprietary Association of Great Britain (PAGB)

The PAGB is the largest trade association and self-regulatory body for the over-the-counter (OTC) medicines industry. Its *Codes of Practice for Advertising Over-The-Counter Medicines* include a Consumer Code that lays down standards for the advertising of OTC medicines to the general public.

The PAGB Codes also include a Professional Code for advertising directed at persons qualified to prescribe or supply medicines. These Codes are drawn up in consultation with the MHRA, ASA, CAP, OFCOM, BACC and RACC.

PAGB provides training programmes on its Advertising Codes. (Further details about these training programmes are available from the PAGB – see contact details in Annex 8.)

Health Food Manufacturers' Association (HFMA)

The HFMA is a trade association operating on behalf of the UK specialist health product industry. They operate a Code of Advertising Practice covering advertising to the public and to healthcare professionals.

British Dental Trade Association (BDTA)

The BDTA is a group of manufacturers, wholesalers, distributors and suppliers of products and services to the dental profession. They provide a Code of Practice for their members to follow to ensure the highest quality of service.

Office of Communications (OFCOM)

OFCOM is the independent regulatory and competition authority for the UK communications industries. It has a statutory role to ensure that the contents of programmes and broadcast advertising meet appropriate standards. It was established under the Communications Act 2003. In November 2004 OFCOM established a co-regulatory partnership with the ASA by transferring responsibility for broadcast advertising content regulation to the ASA.

Advertising Standards Authority (ASA) and Committees of Advertising Practice (CAP)

The ASA is responsible for ensuring that all advertising, wherever it appears, is honest and decent. For more than forty years, the ASA has been responsible for administering the British Code of Advertising, Sales Promotion and Direct Marketing (the CAP Code) to uphold advertising standards in non-broadcast media.

In November 2004, the ASA also assumed responsibility for television and radio advertisements, in a co-regulatory partnership with OFCOM, thus creating a 'one-stop shop' for all advertising content complaints.

The ASA is the established means for enforcing the Control of Misleading Advertisements Regulations 1988, with the Office of Fair Trading acting as a legal backstop in these cases. For broadcast advertising, the ASA is able to refer particularly serious cases to OFCOM. OFCOM is able to levy fines and revoke licences.

The Committee of Advertising Practice (CAP) is responsible for maintaining the CAP Code. The Broadcast Committee of Advertising Practice (BCAP) is responsible for maintaining the TV and radio advertising Codes.

The contact details of the ASA, CAP and BCAP can be found in Annex 8.

9.3 Vetting of advertising material

Several trade associations for the pharmaceutical industry provide, as a condition of membership, that advertising material should be submitted to them for vetting against their Codes of Practice before issue. Material which is intended for television or radio broadcast must also be approved as complying with the relevant BCAP Advertising Standards Code.

Bodies which vet advertising for medicines include:

Proprietary Association of Great Britain (PAGB)

As a condition of membership, all advertising material directed to consumers must be submitted for approval against the Consumer Code before issue.

Health Food Manufacturers' Association (HFMA)

As a condition of membership, advertising to the public must be submitted for vetting to the HFMA's Labelling Authority and Promotional Advice Division (LAPAD).

Broadcast Advertising Clearance Centre (BACC)

BACC is a specialist body and has two principal functions: the examination of pre-production scripts and the pre-transmission clearance of finished television advertisements. The BACC approves advertising for television against the BCAP *Television Advertising Standards Code* and provides advice on broadcast advertising, producing comprehensive guidelines on all aspects of the code.

Radio Advertising Clearance Centre (RACC)

The RACC is responsible for ensuring that medicines advertising on radio complies with the BCAP Radio Advertising Standards Code. The Commercial Radio Companies Association (CRCA) manages the Radio Advertising Clearance Centre (RACC) which clears national and special category advertisements prior to broadcast. All radio advertising must comply with the BCAP Radio Advertising Standards Code.

Committee of Advertising Practice (CAP)

Although there is no compulsory vetting of advertising, CAP offers on request to non-broadcast advertisers and publishers a free copy advice service, which is confidential from competitors, for advertisements covered by the *British Code of Advertising, Sales Promotion and Direct Marketing*. ASA adjudications on complaints about non-broadcast advertising frequently require the advertiser to seek CAP copy advice for future advertisements.

9.4 Investigation of complaints

In addition to the statutory regime established by the Advertising and Monitoring Regulations, there are a number of self-regulatory bodies of which the three most important are:

Prescription Medicines Code of Practice Authority (PMCPA)

Complaints about the promotion of medicines for prescribing and complaints about information made available to the general public about medicines so promoted are considered by the Prescription Medicines Code of Practice Authority under the ABPI Code of Practice for the Pharmaceutical Industry. Complaints which are made under the Code about promotional activities and associated activities and material are considered by the Code of Practice Panel, the decisions of which can be appealed to the Code of Practice Appeal Board. Reports on completed cases are published quarterly in the Code of Practice Review and are available on the PMCPA website at <http://www.pmcpa.org.uk/>.

Proprietary Association of Great Britain (PAGB)

In addition to its Consumer Code the PAGB also operates a Professional Code for advertising directed at persons qualified to prescribe or supply medicines. However the PAGB does not vet advertising directed at professional or trade audiences. Complaints under the PAGB Professional Code are considered by the Complaints Committee and can be appealed to the Appeal Board. Case reports are published on the PAGB website at <http://www.pagb.co.uk/>.

Advertising Standards Authority (ASA)

The Advertising Standards Authority investigates complaints about published medicines advertisements and ensures compliance with the *British Code of Advertising, Sales Promotion and Direct Marketing* and the Broadcast Advertising Codes. All these Codes include sections on medicines advertising. Advertisements directed at healthcare professionals are exempt from these Codes. The ASA publishes its adjudications weekly on its website at <http://www.asa.org.uk/>.

For products classified as Pharmacy (P) or General Sale List (GSL) but which are also prescribed, complaints about promotional material intended to result in an OTC recommendation are matters for the PAGB, whereas materials intended to result in the writing or dispensing of a prescription fall for consideration by the PMCPA under the ABPI Code of Practice.

Addresses for all the bodies mentioned above are given in Annex 8.

9.5 Medicines Advertising Liaison Group (MALG)

The MHRA works closely with the other bodies involved in the regulation of medicines advertising. MALG is a forum that meets about twice a year to discuss current issues in advertising control. The group includes representatives from the AA, BACC, RACC, PMCPA, PAGB, ASA, CAP, BDTA and the MHRA. The MHRA liaises with these groups to develop guidance and a common understanding of the Advertising Regulations, providing clarification of the law where necessary and raising current issues for discussion and dissemination.

Annex 1

Relevant Legislation

The Principal UK Legislation for the Advertising and Monitoring of Medicines

The Medicines Act 1968

The Act introduced provisions to control all matters and activities relating to medicinal products and came into effect on 1 September 1971.

Part VI of the Act makes provisions for promotion of medicines (most of which have been superseded by subsequent legislation) and Section 92 defines the meaning of “advertisement”.

The Medicines (Advertising) Regulations 1994, SI No. 1932

These Regulations (“the Advertising Regulations”) implement Title VIII of Codified Council Directive 2001/83/EC (previously Directive 92/28/EEC) into UK law. The Advertising Regulations set out the provisions for advertising, including homoeopathic medicines and advertising directed at the public and health professionals. The Regulations make provisions for breaches that constitute a criminal offence and specify the penalties.

The Medicines (Monitoring of Advertising) Regulations 1994, SI No. 1933

The Regulations referred to as “ the Monitoring Regulations” implement Articles 97 98 (part) and 99 of Directive 2001/83/EC by specifying procedures whereby advertisements which are considered to be inconsistent with the Advertising Regulations can be acted upon, either by reference to an administrative body established for that purpose or by civil proceedings.

The Advertising and Monitoring Regulations came into force on 9 August 1994 and reinforced existing controls on advertising under the Medicines Act 1968.

Both these Regulations have been amended as described below.

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, SI No. 3144

These Regulations implement for the United Kingdom the provisions of the Codified Directive. Schedule 7 to these Regulations includes consequential amendments to the Medicines (Advertising) Regulations 1994.

The Medicines (Advertising) Amendment Regulations 1996, SI No. 1552

These Regulations amend the Advertising Regulations (SI 1994/ 1932) to allow the advertising of products for the prevention of neural tube defects and for the treatment of the symptoms of sprains or strains, or the pain or stiffness of rheumatic or non-serious arthritic conditions.

The Medicines (Advertising and Monitoring of Advertising) (Amendment) Regulations 1999, SI No. 267

These Regulations amend the Advertising and Monitoring Regulations and make further provisions to implement Title VIII of the Codified Directive. They introduce a new Schedule in the Monitoring Regulations that contains a statutory procedure for making decisions on alleged breaches of the legislation on medicines advertising, and provides an opportunity for written representations to be made to Health Ministers before they reach their decision or determination as well as a procedure for requiring publication of corrective statements.

The Medicines (Monitoring of Advertising) Amendment Regulations 1999, SI No. 784

These Regulations amend the Monitoring Regulations and the Schedule inserted by SI 1999/267 to correct a technical error. They clarify the maximum penalty available on summary conviction of an offence under advertising legislation.

The Medicines (Codification Amendments Etc.) Regulations 2002, SI No. 236

These Regulations make consequential amendments to the references in the Advertising Regulations and other medicines legislation following the adoption of Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use.

Communications Act 2003 (Amendment of the Medicines (Monitoring of Advertising) Regulations) Order 2003, SI No. 3093

The Order amends the Monitoring Regulations as a consequence of the Communications Act 2003 to reflect the regulatory functions taken over by the newly-established OFCOM. These were previously the responsibility of the Independent Television Commission, the Radio Authority and the Welsh Authority in respect of S4C.

The Medicines (Advertising) Amendment Regulations 2004, SI No. 1480

The Regulations amend the Advertising Regulations to remove the prohibition on advertising to the public of medicinal products for the treatment, prevention or diagnosis of certain diseases.

The Medicines (Advertising Amendments) Regulations 2005, SI No. 2787

These Regulations implement Directive 2004/27/EC in so far as it amends Title VIII of the Codified Directive. In particular, they remove the prohibition on advertising medicinal products for certain diseases, remove the prohibition on mentioning the grant of a marketing authorization in an advertisement for a medicinal product and change the wording of the provision relating to hospitality at events where medicinal products are promoted and at scientific meetings.

These Regulations also implement Directive 2004/27/EC by bringing traditional herbal medicines with a traditional herbal registration under the scope of the Regulations and specify additional wording required in advertising for these products.

Other UK Legislation that affects Medicines Advertising

The Cancer Act 1939

This Act makes provision for, amongst other things, the prohibition of certain advertisements relating to cancer.

The Trade Description Act 1968 and the Control of Misleading Advertising Regulations 1988, SI No. 915

The 1988 Regulations implement the European Directive 84/450/EEC on misleading advertising and require the Director-General of Fair Trading to consider complaints about misleading non-broadcast advertisements where they may not have been dealt with adequately by the relevant authorities or bodies, including local authority trading standards departments and self-regulatory bodies. They also cover the area of comparative advertising following the transposition into UK law of Directive 97/55/EC, which amended Directive 84/450/EEC concerning misleading advertising so as to include comparative advertising.

The Trade Descriptions Act 1968 and the Control of Misleading Advertisements Regulations 1988 [SI 1988/915], regulate consumer advertising generally, including the advertising of medicines. This legislation is administered by the Department of Trade and Industry.

The Broadcasting Acts 1990 & 1996 and the Communications Act 2003

The Broadcasting Acts 1990 and 1996 and the more recent Communications Act 2003 regulate broadcast advertising generally, including the broadcast advertising of medicines. This legislation is administered by the Office of Communications (OFCOM).

The 2003 Act provides, amongst other things, that OFCOM takes over the regulatory functions for broadcast advertising that were previously the responsibility of the Independent Television Code and the Radio Authority. It also confers powers on OFCOM to regulate advertising standards.

The Contracting Out (Functions relating to Broadcast Advertising) and Specification of Relevant Functions Order 2004, SI 2004/ 1975 permits the contracting out of functions of OFCOM relating to the Regulations of broadcast advertising, including medicines, under varied legislation. Under the Order OFCOM, the regulator for the communications industry, is given permission to contract out some of its functions to a self-regulatory body with regard to broadcast (radio and television) advertising. OFCOM has taken advantage of these provisions and the day-to-day responsibility for TV and radio advertising standards now rests with the ASA.

UK Legislation for Medicines other than “Relevant Medicinal Products”

The Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975, SI No. 1326

These Regulations apply to products such as Product Licences of Right (PLRs) that do not fall within the definition of “relevant medicinal products”. Amongst the provisions, they require particulars relating to medicinal products in certain advertisements issued to health professionals to be consistent with the relevant data sheet and that such advertisements must contain a notice that a data sheet would be sent on request to any doctor and dentist.

The Medicines (Labelling and Advertising to the Public) Regulations 1978, SI No. 41

The Medicines (Labelling and Advertising to the Public) Regulations 1978, SI No. 41 were amended by the Advertising Regulations so that they do not apply to “relevant medicinal products”.

The 1978 Regulations continue to apply to products such as Product Licences of Right (PLRs) that do not fall within the definition of “relevant medicinal products”. The Regulations made under the Medicines Act 1968 impose requirements for medicinal products and other substances and articles for human use that relate to the prohibitions, restrictions and requirements for advertisements directed to the public. They prohibit the promotion of prescription-

only-medicines to the public and make provisions for the content and form of advertisements for, and the containers and packages of, spermicidal contraceptives and leaflets supplied with such products. They also contain transitional provisions and penalties for criminal offences relating to these Regulations and the 1968 Act.

European Directives

Council Directive 2001/83/EC – The Community code relating to medicinal products for human use.

Title VIII of this Directive (the “Codified Directive”) relates to advertising and contains the rules on the content and control of medicines advertising in Member States.

The following three Directives which included provisions for medicines advertising are now repealed and re-enacted by Directive 2001/83/EC:

- Council Directive 92/28/EC on the advertising of medicinal products for human use.

This Directive introduced requirements for advertising medicinal products and was fully implemented into UK legislation by SI 1994/1932 and SI 1994/1933, both as amended.

- Council Directive 65/65/EC (as amended) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

This Directive was the basis of EC rules and set out EC-wide requirements for marketing authorisations.

- Council Directive 92/73/EC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products.

This Directive widened the scope of Directives 65/65/EEC and laid down additional provisions on homeopathic medicinal products.

Council Directive 84/450/EEC relating to the approximation of the laws, Regulations and administrative provisions of the Member States concerning misleading advertising.

This Directive was implemented into UK legislation by the Control of Misleading Advertisements Regulations, SI 1988/915.

Council Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

This Directive amends Directive 2001/83/EC and introduces further changes following the review of European medicines legislation. The changes have been implemented into UK legislation with effect from 30 October 2005.

Council Directive 2004/24/EC – The Traditional Herbal Medicinal Products Directive.

The Directive requires advertising and promotion of traditional herbal medicines that fall within the Registration Scheme to meet the requirements of Articles 86 to 99 of Directive 2001/83/EC. It was implemented into UK legislation on 30 October 2005.

The Directive provides a seven-year transitional period for herbal medicines already on the market on 30 April 2004 when it came into force. Manufacturers of traditional herbal medicines have until 30 April 2011 to register their products under the traditional Herbal Medicines Registration Scheme.

Council Directive 97/36/EC – The Television Without Frontiers Directive.

This Directive makes provisions for medicines advertising, in particular the prohibition on the promotion of prescription only medicines to the public.

Annex 2

Medicines which are promoted for use during Pregnancy

Guidance for the Pharmaceutical Industry

1. Purpose of this Guideline

This guidance has been developed by Medicines and Healthcare products Regulatory Agency (MHRA), in consultation with industry representatives and advertising regulatory bodies.

This guidance is supplementary to the regulatory framework as set out in the Advertising Regulations [The Medicines (Advertising) Regulations 1994 No.1932 (SI 1994/1932) and The Medicines (Monitoring of Advertising) Regulations 1994 No. 1933 (SI 1994/1933) (both as amended)].

This guidance is intended for advertisers to ensure safe and responsible advertising of medicines which may be promoted for use during pregnancy. It reflects the general principles that caution should always be taken when medicines are used during pregnancy and that advertising should not convey messages that it is usual for pregnant women to take medicines. It is anticipated that this guidance will raise awareness of the risks of taking medicines during pregnancy and encourage women who are or may be pregnant to take medicines only when absolutely necessary and to seek professional advice.

The decision on whether a particular advertisement complies with the Advertising Regulations will be taken by the MHRA on a case by case basis, having regard to the facts of the particular case.

2. Scope of Guidance

- This guidance covers the advertisement of any licensed medicine which is being promoted for use during pregnancy.
- The guidance covers both advertising to the public and promotion to 'persons qualified to prescribe or supply' for all licensed medicines.
- This guidance may not apply in its entirety to advertisements for folic acid or other health promotional campaigns where the use of the product provides a general benefit to pregnant women.

3. General Statement

An important general principle is that caution should always be taken when medicines are prescribed/taken during pregnancy and the risks to both the mother and fetus should always be considered.

The British National Formulary (BNF) states that drugs can have harmful effects on the fetus at any time during pregnancy and that it is important to bear this in mind when prescribing for a woman of childbearing age. Appendix 4 (Pregnancy) of the BNF includes the following boxed warning:

Drugs should be prescribed in pregnancy only if the expected benefit to the mother is thought to be greater than the risk to the fetus, and all drugs should be avoided if possible during the first trimester. Drugs which have been extensively used in pregnancy and appear to be usually safe should be prescribed in preference to new or untried drugs; and the smallest effective dose should be used.

Few drugs have been shown conclusively to be teratogenic in man but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.

4. Principles

The following principles apply for the advertising of any licensed medicine which is promoted for use during pregnancy:

4.1 Advertising to the General Public

Part III of the Advertising Regulations lays down the requirements and restrictions on advertising medicines to the general public. In addition, the following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:

- (a) Advertisements to the general public mentioning the use of the product during pregnancy are only acceptable for medicines where the Summary of Product Characteristics (SPC) supports the use of the product in pregnancy – providing the other principles/guidance are followed (see below). This does not preclude the general advertising of other products for common conditions, even where the advertising may be seen by pregnant women, provided that the advertisement does not promote, in words or images or context, the use of the product in pregnancy.
- (b) Advertisements should not convey the message that it is usual for pregnant women to take medicines. Advertisers are encouraged to include advice on non-pharmacological measures where appropriate.
- (c) Advertisements should not state or imply that the advertised product, or any other medicine, cannot harm the developing fetus and ultrasound scans or images of a fetus should not be used in promotion of a medicine.
- (d) Advertising should reflect any warning statements on the licence concerning use at particular times during pregnancy (for example, a product which should not be used close to the expected date of delivery).
- (e) Advertisements should actively encourage seeking advice from a doctor, pharmacist or other healthcare professional concerning use of the product at any time during pregnancy.
- (f) All advertisements for medicines promoting use in pregnancy directly to pregnant women should include a general warning message appropriate to the medium being used (e.g. print, television, radio). An example of appropriate wording is given below. We would also encourage the inclusion of such a warning in any general advertising for a systemic medicine where the target audience is mainly pregnant women (e.g. in a pregnancy magazine).

“Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before taking any medicine in pregnancy”.

4.2 Advertising to ‘persons qualified to prescribe or supply’

Advertising to health professionals includes promotion of prescription only medicines and Over-The-Counter products. Part IV of the Advertising Regulations lays down the requirements and restrictions for advertising medicines to persons qualified to prescribe or supply. In addition the following guidance is provided for the advertising of any licensed medicine which is promoted for use during pregnancy:

- (a) Where there is a specific indication for use in pregnancy in section 4.1 of the SPC, medicines may be promoted for use in pregnancy.
- (b) Where there is not a specific indication for use in pregnancy in section 4.1, textual information may be included in the advertising material (additional to the prescribing information) regarding the use of the product during pregnancy, reflecting section 4.6 of the SPC. The use of images of pregnant women is not appropriate in this situation.
- (c) All the information contained in the pregnancy and lactation section of the SPC (section 4.6) should be conveyed in the prescribing information in the advertisement.
- (d) Advertisements should never state or imply that the advertised product, or any other medicine, cannot harm the developing fetus. The use of ultrasound scans or images of a fetus may be considered inappropriate in the advertising of medicines for use in pregnant women.
- (e) Advertising should reflect any warning statements on the licence concerning use at particular times during pregnancy (for example, a product which should not be used close to the expected date of delivery).

- (f) All advertisements for medicines promoted for or providing information on use in pregnancy should include a general warning message appropriate to the medium being used.

An example of appropriate wording is as follows:

“Care should be taken when prescribing in pregnancy as medicines can cross the placenta and may affect the fetus.”

5. The Marketing Authorisation

The general requirements on advertising are set out in the Advertising Regulations and state that advertising should always comply with the Summary of Product Characteristics (SPC).

The SPC for all licensed medicines contains a section dealing with pregnancy and lactation (section 4.6). The European guideline on the SPC (MHRA EuroDirect Publication No. EC5/99) specifically addresses the points which should be included in this section.

In summary the SPC guideline states that the following should be mentioned:

- Facts on human experience and conclusions from preclinical toxicity studies which are of relevance for the assessment of risks associated with exposure during pregnancy.
- Recommendations on the use of the medicinal product at different times during pregnancy in respect of gestation.
- Recommendations on the management of the situation of an inadvertent exposure, where relevant.

In the SPC guideline there are 10 examples of the wording for section 4.6 of the SPC. These are replicated at Annex 1 (attached). Marketing Authorisation holders are encouraged to use the appropriate template from this annex for section 4.6 of all SPCs. Where the data do not correspond to the statements proposed in the SPC guideline, the

wording in Section 4.6 should accurately reflect the information on exposure and evidence of safety that is available.

Annex 1 – Examples of wording on use in pregnancy

1. [Generic name] causes/is suspected to cause serious birth defects when administered during pregnancy.
[Tradename] is contraindicated (only in case of a strict contraindication see Section 4.3) in pregnancy;

and if necessary

Women of childbearing potential have to use effective contraception during (and up to x weeks after) treatment.

2. [Generic name] has harmful pharmacological effects on pregnancy and/or the fetus/newborn child.

[Tradename] should not be used during pregnancy unless clearly necessary (these circumstances should be specified).

3. There are no adequate data from the use of [Generic name] in pregnant women.

Studies in animals have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown; or

Animal studies are insufficient with respect to effects on pregnancy /and-or/embryonal/fetal development/and-or/parturition/and-or/ postnatal development (see section 5.3). The potential risk for humans is unknown.

[Tradename] should not be used during pregnancy unless clearly necessary (these circumstances should be specified where possible).

4. For [Generic name] no clinical data on exposed pregnancies are available.

Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3).

Caution should be exercised when prescribing to pregnant women.

5. Data on a limited number (. . .) of exposed pregnancies indicate no adverse effects of [Generic name] on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available. Animal studies have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown.

or

Animal studies are insufficient with respect to effects on pregnancy/and-or/embryonal/fetal development/and-or/parturition/and-or/postnatal development (see section 5.3). The potential risk for humans is unknown.

Caution should be exercised when prescribing to pregnant women.

6. Data on a limited number (. . .) of exposed pregnancies indicate no adverse effects of [Generic name] on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/fetal development, parturition or postnatal development (see section 5.3).

Caution should be exercised when prescribing to pregnant women.

7. Data on a large number (. . .) of exposed pregnancies indicate no adverse effects of [Generic name] on pregnancy or on the health of the fetus/newborn child. To date, no other relevant epidemiological data are available.

Caution should be exercised when prescribing to pregnant women.

8. Well-conducted epidemiological studies indicate no adverse effects of [Generic name] on pregnancy or on the health of the fetus/newborn child.

[Tradename] can be used during pregnancy.

9. In case of interaction with oral contraceptives information should also be given in section 4.5.

[Generic name] adversely interacts with oral contraceptives (OCs). Therefore, an alternative, effective and safe method of contraception should be used during (and up to x weeks after) treatment.

or

The concomitant medication [Generic name] adversely interacts with oral contraceptives (OCs). Therefore an alternative, effective and safe method of contraception should be used during (and up to x weeks after) treatment.

10. In case of male-mediated effects on pregnancy outcome information should also be given in section 4.4.

Both sexually active men and women should use effective methods of contraception during (and up to x weeks after) treatment.

Annex 3

Disease Awareness Campaign Guidelines

Introduction

1. There is general agreement on the importance of providing high quality information to patients and the public about health and disease. This guideline addresses the content of Disease Awareness Campaigns (DACs).
2. DACs are concerned with providing information, promoting awareness or educating the public about health, diseases and their management. DACs must not promote medicinal products to the public. The advertising of medicinal products is regulated by Title VIII of European Directive 2001/83/EC, which codifies Directive 92/28/EEC (Advertising of medicinal products for human use), and the UK implementing legislation; The Medicines (Advertising) Regulations 1994 (S.I. 1994/1932) and The Medicines (Monitoring of Advertising) Regulations 1994 (S.I. 1994/1933), as amended. A key provision of this legislation is the prohibition of advertising of prescription only medicines direct to the public. Campaigns that include no direct or indirect references to medicinal products fall outside the scope of Title VIII of Directive 2001/83/EC.
3. DACs are an increasing feature of medical information in the UK. They can provide a valuable source of information to the public on diseases and conditions, aid recognition of symptoms and highlight appropriate sources of advice. This guideline sets out principles on how to ensure that DACs remain informative without constituting advertisements that fall within the scope of Title VIII of Directive 2001/83/EC and provides additional advice to promote good practice. Evidence-based general guidance on how to write health and disease related leaflets in terms that recipients can understand and identify with is available from other sources and this guideline is intended to supplement, but not replace, this.

General Principles

4. The primary purpose of a DAC must be to increase awareness of a disease or diseases and to provide health educational information on that disease and its management. It should not promote the use of a particular medicinal product or products. Campaigns which aim to stimulate demand by the public for a specific medicine or specific medicines, are likely to be considered promotional, falling within the scope of Title VIII of Directive 2001/83/EC.
5. A DAC may make reference to the availability of treatment options (which may include medicines as part of a range of possible management options) but this should not be of such a nature that an individual would be encouraged to approach a prescriber to request a particular medicinal option. The emphasis of the material should be on the condition and its recognition rather than on the treatment options.

The appropriate treatment for each disease is for the health care professional to decide in consultation with the patient.

6. DACs for diseases or conditions where there is only one, one leading or few medicinal treatments potentially draw attention to one medicinal product, albeit indirectly, regardless of whether it is referred to or not. DACs in these circumstances require particular care. It is particularly important that these campaigns focus on health and disease education, with details of where to get appropriate advice.
7. DACs should include information that is:

Accurate: The information in a DAC should be carefully checked for accuracy so that the public is not misled.

- Up-to-date:** Every effort should be made to ensure that information contained in a DAC is current. The date of publication should be clear.
- Substantiable:** The information in a DAC should be capable of substantiation by reference to the medical literature or other authoritative sources.
- Comprehensive:** DACs should cover the key characteristics of the disease.
- Balanced and fair:** DACs should ensure that the impact/implications of the disease are realistically conveyed without being alarmist. Management options should be presented in a balanced and fair manner that does not unduly emphasise particular options or the need to seek treatment.
- Readable /accessible:** The language used should be designed to convey key messages clearly, supported by appropriate design and formatting.
- Source identified:** The source(s) of the DAC should be clearly identified on the publication itself.

Structure

- The most appropriate structure for presenting the information will vary depending on the disease or condition and the medium used. The advice below is not intended to restrict or prescribe the format and content of DACs beyond the legislative requirements but the inclusion of information on the areas outlined below will help to ensure that campaigns communicate appropriate health messages to consumers.

Identification of symptoms or risk factors

An important aspect of any health promotion campaign is to raise awareness of the symptoms or risk factors associated with the disease so that members of the public can seek early diagnosis and treatment, minimise disease progression or avoid complications. The information provided should help the public to be able to recognise the disease, or risk factors for it, in themselves or others and take preventive measures, if appropriate.

General information about the disease

The DAC should provide general background information on the disease including aetiology where appropriate.

Advice for the patient

DACs should point out what the patient needs to do immediately, if necessary, and where to get appropriate advice on management options. Depending on the disease concerned, it may be appropriate to explain the benefit of e.g. lifestyle changes, etc. Nevertheless, the main objective for DACs is to encourage people to take appropriate steps, which may include seeking advice from appropriate health care professionals.

Further information

DACs can include sources for additional advice such as helplines and relevant charities and patient groups. If patients are asked to write in

for further information, their personal details should only be used for educational purposes connected with the initial enquiry.

Further information

9. The Medicines and Healthcare products Regulatory Agency will offer advice on whether proposed DACs fall outside the scope of Title VIII of Directive 2001/83/EC or not. The MHRA also undertakes routine monitoring of advertisements and investigates any complaints received about them. Guidance on the legislative framework governing advertising control is available in an MHRA Guidance Note – Advertising and Promotion of Medicines in the UK also known as *The Blue Guide* – available from the MHRA website or from the Stationery Office.

Annex 4

Particulars to be included in Advertisements to the Public

1. The name of the medicinal product.
2. If the product contains only one active ingredient, the common name of the medicinal product.
3. The information necessary for correct use of the medicinal product, i.e. one or more indications.
4. An express and legible invitation to read carefully the instructions in the leaflet or on the label.
5. For products with a traditional herbal registration only, the statement:

“Traditional herbal medicinal product for use in
[specify one or more indications for the product consistent with the terms of the registration]
exclusively based on long standing use as a
traditional remedy”.

Advertisements are also required to be set out in such a way that it is clear that the material or message is an advertisement and that the product being advertised is a medicine.

Annex 5

Particulars to be included in Advertisements to Persons Qualified to Prescribe or Supply

Identification

1. Licence number.
2. Supply classification: ' POM, P or GSL.
3. Name and address of the marketing authorisation holder or the name and address of that part of their business responsible for the sale or supply of the product.
4. Name of the product and a list of its active ingredient(s) using the common name placed immediately adjacent to the most prominent display of the name of the product.

The particulars in relation to side-effects, precautions and contra-indications, dosage and method of use and warnings should be clearly printed, legible and be placed in such a position in the advertisement to allow the reader to associate the various benefits and risks of using the product without difficulty.

Use of the product

1. Indication(s): one or more of the indications for the product consistent with the terms of the marketing authorisation.
2. Side-effects, precautions and contra-indications: a succinct statement of the appropriate particulars in the summary of product characteristics relating to the indications shown.
3. Dosage and method of use: a succinct statement of the relevant particulars in the summary of product characteristics relating to the indications shown. The method of administration should be shown if this is not obvious.
4. Warnings: any warning issued by the Licensing Authority under Part II of the Medicines Act 1968 which is required to be included in advertisements as a condition of the marketing authorisation.
5. Cost: the cost (excluding VAT) of a specified pack-size, specified quantity or recommended daily dose of the product. There is an exception for audio-visual advertisements and advertisements in journals printed in the UK but with a circulation outside the UK of more than 15% of its total circulation.

Annex 6

Particulars to be contained in Abbreviated Advertisements

1. The name and address of the holder of the product licence which relates to the medicinal product or the business name and address of the part of his business that is responsible for its sale or supply.
2. The supply classification of the medicinal product, specifying whether the product is: a medicinal product for supply by prescription only, a medicinal product on a general sale list, or a pharmacy medicinal product.
3. The name of the product, and a list of the active ingredients using the common name placed immediately adjacent to the most prominent display of the name of the product.
4. A form of words which clearly indicates that further information is available on request to the licence holder or in the summary of product characteristics, or, if there is no summary of product characteristics, the data sheet, relating to the product.
5. Essential information compatible with the SPC – at least one indication for use of the product and any required warning.

Annex 7

Implementation of Title VIII of Directive 2001/83/EC into UK Law

Article 86	Reg 2 of SI 1994/1932	Article 95	Reg 21(2) of SI 1994/1932
Article 87.1	Reg 3 of SI 1994/1932	Article 96.1	Reg 19 & Sch 4 of SI 1994/1932
87.2	Reg 3A of SI 1994/1932 (as amended)	96.2	Inappropriate to UK system
87.3	Reg 3A of SI 1994/1932 (as amended)	Article 97.1	Regs 4 & 13 of, and Schedule to SI 1994/1933
Article 88.1	Reg 7 and 8 of SI 1994/1932	97.2 to 97.4	Regs 6, 7, 8 and 13 of, and Schedule to SI 1994/1933
88.2	Reg 6 & Sch 1 to SI 1994/1932	97.5	Reg 5 of SI 1994/1933
88.3	Inappropriate to UK system	Article 98.1	Reg 4(a) of SI 1994/1932
88.4	Reg 11 of SI 1994/1932	98.2 (i)	Reg 4(c) of SI 1994/1932 (as amended)
88.5	Does not require implementation	(ii)	Reg 23 of SI 1994/1932, Regs 6-8 and 11, and Schedule to SI 1994/1933
88.6	Reg 12 of SI 1994/1932	(iii)	Regs 4(b), 20(2) and (3) of SI 1994/1932
Article 89.1	Reg 10(1) of SI 1994/1932	(iv)	Reg 4(d) of SI 1994/1932 (as amended)
89.2	Reg 10(2) of SI 1994/1932	(v)	Reg 13 of, and Schedule to SI 1994/1933 (as amended)
Article 90	Reg 9 of SI 1994/1932	Article 99	Reg 23 of SI 1994/1932 and Reg 13 of SI 1994/1933
Article 91.1	Reg 14 & Sch 2 of SI 1994/1932	Article 100	Reg 22 of SI 1994/1932
91.2	Reg 17 of SI 1994/1932		
Article 92.1	Reg 18(1) of SI 1994/1932		
92.1	Reg 18(2) of SI 1994/1932		
92.2	Reg 18(3) of SI 1994/1932		
Article 93.1	Reg 4(b) of SI 1994/1932		
93.2	Reg 20(2) of SI 1994/1932		
93.3	Reg 20(3) of SI 1994/1932		
Article 94.1	Reg 21(1) of SI 1994/1932		
94.2	Reg 21(3) of SI 1994/1932		
94.3	Reg 21(5) of SI 1994/1932		
94.4	Reg 21(4) of SI 1994/1932		

Annex 8

Other Regulatory and Self-Regulatory Bodies

Association of the British Pharmaceutical Industry
12 Whitehall
London SW1A 2DY
Tel. 020 7930 3477
www.abpi.org.uk

Advertising Standards Authority
Mid City Place
71 High Holborn
London WC1V 6QT
Tel. 020 7492 2222
www.asa.org.uk

The British Dental Trade Association
Merritt House
Hill Avenue
Amersham
Bucks HP6 5BQ
Tel. 01494 431010
www.bdta.org.uk

Broadcast Advertising Clearance Centre
Franciscan Court
16 Hatfields
London SE1 8DJ
Tel. 020 7633 2935
www.bacc.org.uk

Committee of Advertising Practice and Broadcast
Committee
of Advertising Practice
Mid City Place
71 High Holborn
London WC1V 6QT
Tel. 020 7492 2222
www.cap.org.uk

CAP Copy Advice
Tel. 020 7492 2100
E-mail: copyadvice@cap.org.uk

Health Food Manufacturers' Association
63 Hampton Court Way
Thames Ditton
Surrey KT7 0LT
Tel. 020 8398 1819
www.hfma.co.uk

OFCOM Contact Centre
Riverside House
2a Southwark Bridge Road
London E1 9HA
Tel 020 7981 3040
www.ofcom.org.uk

Proprietary Association of Great Britain
Vernon House
Sicilian Avenue
London WC1A 2QH
Tel. 020 7242 8331
www.pagb.co.uk

Prescription Medicines Code of Practice Authority
12 Whitehall
London SW1A 2DY
Tel. 020 7930 9677
www.pmcpa.org.uk

Radio Advertising Clearance Centre
The Radiocentre
77 Shaftesbury Avenue
London W1D 5DU
Tel. 020 7306 2620
www.racc.co.uk

AA	Advertising Association	GP	General Practitioner
ABPI	Association of the British Pharmaceutical Industry	GSL	General Sale List – medicines available without a prescription in pharmacies or non-pharmacy retail outlets
Advertising Regulations	The Medicines (Advertising) Regulations 1994, SI 1994/1932 as amended.		
ASA	Advertising Standards Authority	HFMA	Health Food Manufacturers' Association
AU	MHRA's Advertising Unit	HMSO	Her Majesty's Stationery Office
AWMSG Group	All Wales Medicines Strategy		
BACC	Broadcast Advertising Clearance Centre	IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
BCAP	Broadcast Committee of Advertising Practice	INN	International Non-proprietary Name
BDTA	British Dental Trades Association	IRP	Independent Review Panel
BMA	British Medical Association		
BNF	British National Formulary	LAPAD	Labelling Authority and Promotional Advice Division
CAP	Committee of Advertising Practice	MA	Marketing Authorisation
Cm	Command Paper	MAH	Marketing Authorisation Holder
Common Name	The international non-proprietary name (INN) or the usual common name.	MALG	Medicines Advertising Liaison Group
CRCA	Commercial Radio Companies Association	MHRA	Medicines and Healthcare products Regulatory Agency
DAC	Disease Awareness Campaign	Monitoring Regulations	The Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 as amended.
DH	Department of Health		
DTI	Department of Trade & Industry	NICE	National Institute for health and Clinical Excellence
ED	European Directive		
EFPIA	European Federation of Pharmaceutical Industries and Associations	OC	Oral Contraceptive
EID	MHRA's Enforcement & Intelligence Division	OFCOM	Office of Communications
EU	European Union	OFT	Office of Fair Trading
		OPSI	Office of Public Sector Information
		OTC	Over-the-Counter – medicines classified as Pharmacy and General Sale List legal categories that are available and can be purchased without a prescription

P	Pharmacy medicine – a medicine which is neither POM nor GSL available only in pharmacy outlets under the supervision of pharmacists	S4C SI SMC SPC	Sianel Pedwar Cymru (Welsh television broadcasting service) Statutory Instrument Scottish Medicines Consortium Summary of Product Characteristics
PAGB	Proprietary Association of Great Britain		
PAR	Public Assessment Report	TSO	The Stationery Office
PGDs	Patient Group Directions	THM	Traditional Herbal Medicine
PIL	Product Information Leaflet (provided in a medicine pack)	THMRS	Traditional Herbal Medicine Registration Scheme
PL	Product Licence		
PLR	Product Licence of Right	VAT	Value Added Tax
PMCPA	Prescription Medicines Code of Practice Authority	Vetting	Review of promotional material prior to issue (sometimes called pre-vetting)
Product Claim	A form of words that highlights the qualities of a medicine		
Promotional Aid	A non-monetary gift made for a promotional purpose by a commercially interested party		
POM	Prescription Only Medicine – a medicine for supply by prescription only		
PQPS	Person Qualified to Prescribe or Supply medicines		
RACC	Radio Advertising Clearance Centre		
RPSGB	Royal Pharmaceutical Society of Great Britain		

- advertisements
 - abbreviated 27, 58
 - definition of 13
 - help and advice on 36–7
 - legal requirements 12
 - misleading 16
 - monitoring 34
 - and pregnancy 20, 49–52
 - regulation of 32
 - statutory procedures 39–40
 - vetting 32, 33–4, 42
 - wording of 26
- advertisers' responsibilities 16
- advertising
 - to children 19
 - for international publication 28
 - on the Internet 21, 25–6
 - to prescribers and suppliers 25–31
 - to the public 19–23, 56
 - through the media 23
 - trade 28
- advertising legislation 13
- Advertising Standards Authority (ASA) 34, 42, 43
- analgesics 22–3
- brand names 22, 23
- British Dental Trade Association (BDTA) 41
- Broadcast Advertising Clearance Centre (BACC) 42
- broadcasting, complaints concerning 34
- 'buy one get one free' advertising 22
- cancer medicines 19
- children 19
- clinical decisions, affecting 19
- co-promotion 31
- Committee of Advertising Practice (CAP) 42
- comparisons of medicines 20
- competitions 30
- complaints organisations 43
- complaints procedure 11, 34–6
 - corrective statements 36
 - determinations 40
 - sanctions 40
- Control of Misleading Advertisements Regulations 1988* 14, 46
- correct usage information 19–20
- corrective statements 36
- cosmetic procedures, advertising of 22
- determinations of complaints 40
- discounts 30
- Disease Awareness Campaigns (DACs) 22, 53–5
- distributors 21, 30
- drugs *see* medicines
- education, supplying for prescribers 31
- endorsements by health professionals 21
- enquiries from the public 23
- European directives 47–8
- General Sale List (GSL) 19
- gifts, promotional 28, 29–30
- glossary 61–2
- health clinics, advertising of 22
- health education 22
- Health Food Manufacturers' Association (HFMA) 41, 42
- health professionals, as prescribers 25–31, 50–1, 57
- herbal medicines 14, 16–17
- homeopathic medicines 17
- hospitality 31
- Independent Review Panel for Advertising 39–40
- inducements 29–30
- 'inexpensive' gifts 30
- instructions leaflets 20
- interactions affecting prescribing 27
- international meetings 28
- international publication advertising 28
- Internet 21, 25–6
- journals, monitoring of 34
- journals on the Internet 26
- legislation 12, 13, 14, 45–8
 - European Directives 47–8

- manufacturers 30
- marketing authorisation holder (MAH) 16, 27–8
- media advertising 23, 34
- media, complaints concerning 34
- media formats 13
- medical representatives 29
- medicinal products, definition of 14
- medicines
 - affecting clinical decisions 19
 - analgesics 22–3
 - cancer 19
 - comparison of 19, 20
 - correct usage information 19–20
 - General Sale List (GSL) 19
 - herbal 14, 16–17
 - homeopathic 17
 - names of 20–21
 - 'placebo-like' 27
 - in pregnancy 20, 49–52
 - prescription only medicines (POM) 19, 23
 - psychotropic or narcotic 19, 29
 - regulation of advertising 32
 - 'safe' 27
 - self-medication 19, 20
 - short-term supplies 29
 - unlicensed 15
- Medicines Act 1968* 13, 45
- Medicines Advertising Liaison Group (MALG) 43
- Medicines (Advertising) Regulations 1994* 13, 45
- Medicines (Monitoring of Advertising) Regulations 1994* 13, 45
- meetings, international 28
- mental health medicines 19, 29
- MHRA (Medicines and Healthcare products Regulatory Agency)
 - role of 33–7
 - and statutory procedures 39–40
- monetary gains for prescribers 30
- monitoring 34

- names of medicines 20–21

- Office of Communications (OFCOM) 41
- organisations, regulatory 41–3, 60
- 'over-the-counter' sales 19, 21, 50

- pack sizes 22
- patients, particular groups of 26–27
- penalties 40
- persons qualified to prescribe or supply (PQPS) 25–31
- pharmaceutical companies, dealing with complaints 11
- pharmaceutical guidance 49–52
- 'placebo-like' medicines 27
- pregnancy, medication affecting 20, 49–52
- prescribers 25–31, 50–1, 57
- prescribing information 26
- Prescription Medicines Code of Practice Authority (PMCPA) 41, 43
- prescription only medicines (POM) 19, 22, 25–6, 50
- press releases 23
- pricing benefits 30
- professional samples 28–9
- promotional gifts 28
- Proprietary Association of Great Britain (PAGB) 41, 42, 43

- quality standards, monitoring of 15–16

- Radio Advertising Clearance Centre (RACC) 42
- recommendations by health professionals 21
- records, maintenance of 16
- regulatory bodies 41–3, 60
- representatives, medical 29
- research posts 31
- responsibilities of advertisers 16

- 'safe' medicines 27
- samples 21, 28–9
- sanctions 40
- self-medication 20
- self-regulation 41–3, 60
- short-term supplies of medicines 29
- side-effects 26
- small-sized packs 21

SPC (summary of product characteristics)
15, 26–7, 51–2

Sponsorship 21

statutory procedures 39–40

summary of product characteristics (SPC) 15, 26–7,
51–2

suppliers 25–31, 57

Title VIII of Directive 2001/83/EC 13, 59

tolerability of medicines 27

trade advertisements 28

Trades Descriptions Act 1968 14, 46

*Traditional Herbal Medicines Registration Scheme
(THMRS)* 14

unlicensed medicines 15

urgent safety restrictions (USR) 27–8

vetting organisations 42

vetting procedures 33–4

websites 21, 25–6

