THE BLUE GUIDE

ADVERTISING AND PROMOTION OF MEDICINES IN THE UK

Medicines and Healthcare products Regulatory Agency

Third Edition
August 2012

MHRA CONTACT POINTS FOR ADVICE ON ADVERTISING AND PROMOTION OF MEDICINES

The Advertising Standards Unit
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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.

For general enquiries about advertising of licensed medicines and legislation	Email: advertising@mhra.gsi.gov.uk Tel: 020 3080 6689/7523/6658
For enquiries about advertising policy	Email: advertising@mhra.gsi.gov.uk Tel: 020 3080 6765/6039

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Customer Services	E-mail: info@mhra.gsi.gov.uk Tel: 020 3080 6000

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Chapter 1

GENERAL INTRODUCTION

1.1 Introduction

This chapter introduces the controls on medicines advertising in the UK and provides background information on the development of the Blue Guide. It also provides a general introduction to the regulation of medicines in the UK.

1.2 Medicines regulation

Medicines have the potential for benefit to individuals who use them and to the public health. But all effective medicines may be associated with adverse effects. The law recognises that medicines should not be treated as an ordinary general commodity by placing specific restrictions on them.

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

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

The basis of the licence for any medicine is the Summary of Product Characteristics (SPC). This sets out the details of what the product is licensed for, how it should be administered and warnings and side effects. The SPC sets the boundaries for what can be claimed in advertising for the product.

The licence also determines how the product may be supplied. This may be on prescription only or non-prescription, either through pharmacies under the supervision of a pharmacist or on general sale. This in turn determines to whom the product may be advertised.

1.3 Regulation of advertising

Advertising of medicines is acceptable provided it is in line with legislation and agreed standards of good practice. Society demands that advertising of any commodity, service or anything that may be of interest to the consumer, should be of a high standard. It should not include anything that could cause serious

or widespread offence, create unrealistic expectations in the consumer or be misleading. In other words, there are rules and regulations that apply to advertising in general. These need to be taken into account when advertising a medicine, to ensure required standards are met and that consumer protection is not compromised.

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

All means and media used in the promotional marketing of medicines are subject to the legislation controlling advertising. This includes evolving digital communications channels as well as more conventional communications.

Medicines advertising in the UK is regulated by a combination of European and national legislation. Full descriptions of the legislation on medicines advertising and what this requires are provided in chapters 3 to 7 of this guidance.

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

The control of medicines advertising in the UK is based on a long established system of self-regulation supported by the statutory role of the 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 MHRA works closely with other statutory regulators and self-regulatory bodies to ensure a consistent approach so that public health and safety is not compromised in any way. A description of the MHRA's activities and functions in regulating medicines advertising and those of the other regulatory bodies is provided in chapters 8 to 10 of this guidance.

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

The MHRA aims to be transparent about its activities and performance. The MHRA publishes on its website the outcome of the complaints it investigates. Statistics on advertising cases are provided in the MHRA Annual Report and a

separate report on advertising is published each year providing more detailed information and an overall review of the activities of the MHRA Advertising Standards Unit in the year. These are available on the MHRA website.

1.4 **Development of the Blue Guide**

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

The second edition was published in 2005. This reflected the 2005 changes in legislation governing the advertising of medicines and other developments that had taken place in the MHRA's policy and procedures.

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

The Blue Guide should be read alongside the Human Medicines Regulations 2012 (SI 2012/1916). The MHRA assesses complaints about medicines advertising in relation to their compliance with this legislation.

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. It does not add any legal requirements to the law.

1.5 **Further information**

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

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

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

Chapter 2

HOW TO COMPLAIN

2.1 Introduction

This chapter describes how to complain about advertising 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 advertising 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 advertising was seen should be provided, if possible with a copy of the advertisement, together with details of the concerns about the advertising. The MHRA is particularly keen to investigate complaints where the advertising 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 10 which regulates the type of advertising 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 6.

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. If a complaint is being or has already been investigated by another body, the MHRA will not generally conduct a second investigation unless a clear risk to public health is identified.

2.3 What will happen next?

The MHRA 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 8 of this guidance. During correspondence with the advertiser the MHRA will not disclose the identity of the complainant.

We will endeavour to complete the investigation within 30 days. This time may be extended where there is detailed discussion between the MHRA 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 MHRA 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 legislation the first consideration and point of contact for companies should be the licence 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 for medicines promoted for prescribing. 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 advertising, 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 advertising@mhra.gsi.gov.uk or by post to MHRA Advertising Standards Unit, Area 3-M MHRA, 151 Buckingham Palace Road, LONDON SW1W 9SZ.

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 – those granted a marketing authorisation, traditional herbal registration or homeopathic registration. Products covered include 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 homeopathic remedies.

UK legislation sets 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. It also sets 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 licence holder, a private individual or any third party such as journalists, publishers or public relations agencies, to ensure compliance with the legislation.

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 Titles VIII and VIIIa of European Directive 2001/83/EC as amended ("the Community Code relating to medicinal products for human use"). Title VIII contains rules on the content of advertising and promotions and requirements for national monitoring.

From August 2012, the relevant **UK legislation** is Part 14 of the Human Medicines Regulations 2012 ("the Regulations" – SI 2012/1916). This codifies and has replaced the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994. Part 14 implements Title VIII of the Directive, as amended.

Chapter 1 of Part 14 sets out general definitions relevant to advertising. These supplement the general definitions in Part 1 of the Regulations. Chapter 2 of Part 14 contains rules on the contents of advertisements and promotions. Chapter 3 contains provisions for enforcing the requirements in Chapter 2, 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 Regulations have been breached.

A full listing of all the relevant legislation and details of the legislation in force before August 2012 are given in Annex 1.

3.3 Scope of the Regulations

The Regulations apply to "advertisements" for "medicinal products".

"Advertisement" is defined in regulation 7 of the Regulations (advertisements relating to medicinal products). It is a broad definition. It reflects the definition of "advertising of medicinal products" at article 86 of Directive 2001/83/EC, which introduces the important concept of activities "designed to promote the prescription, supply, sale or consumption of medicinal products".

This definition replaces the meaning given to advertisement in regulation 2(2) of the Medicines (Advertising) Regulations 1994 by reference to section 92 of the Medicines Act 1968.

For the purposes of the Regulations, an advertisement is any thing or any activity which is intended to encourage prescription or supply by healthcare professionals and use of medicines by the general public, generally by means of highlighting qualities of the medicine ("product claims").

The definition of “advertisement” in the Regulations gives a non-exhaustive list of examples of activities that are classed as an advertisement, including:

- visits by medical sales representatives,
- the supply of samples,
- the provision of inducements to prescribe or supply medicines. And
- sponsorship of meetings.

An advertisement is not limited to specific media. It includes articles published in journals, magazines and newspapers, displays 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 advertisement as is the spoken word.

The following are <u>not</u> advertisements for the purposes of the Regulations:

- reference material, factual informative statements or announcements, trade catalogues and price lists, provided that they do not make a product claim;
- information relating to human health or diseases where there is no reference to medicinal products;
- correspondence, possibly accompanied by material of a non-promotional nature, to answer a specific unsolicited question about a medicinal product.

Generally speaking, the labelling and package leaflet of a product which comply fully with the requirements of the Regulations and Title V of European Directive 2001/83/EC would not fall to be considered here. This definition is also understood to exclude independent reference sources which list details of the range of medicines available, for example the British National Formulary.

A ‘medicinal product’ is defined at regulation 2 of the Regulations. The term ‘medicinal product’ covers the vast majority of medicines[1] from advanced

[1] 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

therapy medicinal products (ATMPs) to homeopathic medicines authorised under the UK National Rules Scheme. It includes both nationally licensed products and those with an EU-wide authorisation from the European Commission. Separate provisions apply to homeopathic medicines covered by product licences of right[2]. These are set out in schedule 32 to the Regulations.

The UK definition of a medicinal product also includes traditional herbal medicinal products (THM) with a "traditional herbal registration" under the Traditional Herbal Medicines Registration Scheme which implements Directive 2004/24/EC (the Traditional Herbal Medicinal Products Directive). This Directive applies the requirements of Title VIII of Directive 2001/83/EC to advertisements for herbal medicines registered under Directive 2004/24/EC.

Not all the provisions of the Regulations apply to all advertisements or to all medicinal products. Some only apply to advertisements to the public, others only to advertisements to healthcare professionals and some sections only apply to registered homeopathic medicines.

3.4 **Other legislation relevant to medicines advertising**

The Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008 (SI 2008/1277), regulate consumer advertising generally, including the advertising of medicines. The Business Protection from Misleading Marketing Regulations 2008 (SI 2008/1276) perform a similar function for advertising to businesses. This legislation is administered by the Office of Fair Trading and the Advertising Standards Authority on behalf of the Department for Business Innovation & Skills. The regulations above implement relevant aspects of the EU Directives on misleading and comparative advertising (Directives 2005/29/EC and 2006/114/EC).

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). It implements the UK's obligations under the EU Audiovisual Media Services Directive (1989/552/EEC).

The definition of advertisement includes product placement, the inclusion of a product (or reference to a product) in an otherwise non-promotional communication in return for money or other valuable consideration. In the UK, product placement for any medicine in a television programme is prohibited under the terms of the Communications Act 2003.

The Bribery Act 2010 provides a legal framework to combat bribery in the public or private sectors. It includes offences covering the offering, promising or giving

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information on the definition of a medicinal product is available in MHRA Guidance Note No. 8 (A Guide to what is a Medicinal Product)

[2] The advertising of homeopathic medicines with a product licence of right remains subject to the Medicines (Advertising of Medicinal Products) (No. 2) Regulations 1975 [SI 1975/1326] and the Medicines (Labelling and Advertising to the Public) Regulations 1978 [SI 1978/41]

of an advantage, and requesting, agreeing to receive or accepting of an advantage. It is enforced by the Serious Fraud Office (SFO). The SFO has advised that this does not prevent proportionate promotional expenditure. They will not seek to prosecute unless it considers this is in the public interest and in reaching such a decision the SFO will take into account relevant action taken by the PMCPA and the MHRA.

3.5 **Where to get the legislation**

The Regulations are available for downloading at www.legislation.gov.uk. Hard copies of the Regulations can be purchased from The Stationery Office (TSO), telephone 0870 600 55 22, or through the TSO online book shop at www.tsoshop.co.uk or from TSO agents and distributors. The relevant SI numbers for the 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

Chapter 4

GENERAL RULES

4.1 Introduction

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

4.2 Prohibition on advertising unlicensed medicines

By regulation 279 of the Regulations, medicinal products which do not have a valid licence - a marketing authorisation, traditional herbal registration or homeopathic registration - may not be advertised for medicinal purposes. The MHRA 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 licence has been granted. Exceptionally for new treatments which are expected to give rise to significant changes in costs from those for currently available treatments, 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. The information should focus on the cost implications and 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 or horizon scanning bodies such as the Scottish Medicines Consortium, All Wales Medicines Strategy Group or the National Institute for health and Clinical Excellence.

For innovative over-the-counter medicines being reclassified for the first time from prescription only to pharmacy sale or from pharmacy to general sale, limited factual information for the sole purpose of enabling listing for the product may be provided to potential trade buyers. The content of such material should not be promotional.

This prohibition on advertising unlicensed medicines does not prevent a factual answer to an unsolicited question about an unlicensed medicine, or about use of a licensed medicine outside the terms of its licence (‘off label’ use). Any activity that appeared to be designed to solicit such questions would be likely to be considered promotional and in breach of this prohibition.

Licensed manufacturers and suppliers of unlicensed medicines (‘specials’) must not advertise specific unlicensed products but this does not preclude them from sending out price lists to healthcare professionals to whom the price of specials may be relevant, such as potential customers and budget managers. Price lists can be sent out at reasonable intervals or in response to an enquiry and must

not include product claims. A price list would typically include the active ingredient, strength, dosage form, pack size and price for each product listed. Companies may promote the service they provide but any proactive display of information about their products, for example at a conference stand, is likely to be seen as promotional. A medicine may only be supplied as a 'special' if, amongst other things, it is supplied in response to an unsolicited request. Any question as to whether a medicine may be supplied as a 'special' would be considered separately from any consideration of promotion.

In each of the above cases, the licensing status of the product should be clear.

4.3 Quality standards

By regulation 280 of the Regulations, an advertisement must:

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

(2) encourage the rational use of the product by presenting it objectively and without exaggerating its qualities; and

(3) not be misleading.

The provisions are not mutually exclusive and each one must be complied with.

(1) Compliance with the SPC

An advertisement must not promote a medicine outside the therapeutic indications listed in the 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 and are not inconsistent with the SPC information. A claim that went beyond specific information included in the SPC would be likely to breach this provision. For example, if the SPC makes no mention of any comparative study then a comparative claim would be permitted in advertising, provided it related to the licensed use of the product and was supported by robust evidence. But where the current SPC reports that a comparative study shows non-inferiority and a new study becomes available showing superiority, the SPC would need to be amended before a superiority claim could be made in advertising.

Including information about planned or ongoing trials in unlicensed indications in materials that advertise medicines is likely to be seen as promoting the unlicensed indications.

(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.

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. Where a relative change is quoted, the absolute values should also be given to enable the reader to fully assess the magnitude of the claimed benefit.

A claim that presented findings from *in vitro* or animal studies as directly relevant to the clinical use of the product may also be considered to exaggerate the benefits of the product, unless data are available to demonstrate the relevance and significance of the findings. See section 6.6 for more information on safety claims.

(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 280(1) or (2). A factually accurate advertisement may also be misleading due to the overall impression given. Unrealistic or inappropriate images can give rise to misleading expectations about the product or the indicated patient population. 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 licence 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 *Medicines Advertising Codes*. Companies are asked also to inform the MHRA of such appointments and of any subsequent changes. Notifications should be made by email to signatories.advertising@mhra.gsi.gov.uk.

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

4.5 Updating advertising

The law requires all advertising to be consistent with the current SPC for the product. This includes the essential information (see section 6.4). All advertising materials should be reviewed promptly each time the SPC changes to determine whether any changes are required and if materials need to be withdrawn from use. This is particularly important when the changes relate to safety.

4.6 Keeping records

A licence holder 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 licence holders 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.

The MHRA maintains records of complaint cases for a period of seven years from completion of any action.

4.7 Special requirements for traditional herbal medicinal products (THMs)

In addition to the requirements set out in chapters 4 to 7, all advertisements for herbal medicinal products with a traditional herbal registration under Part 7 of the Regulations 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.

Claims that a product is "organic" may only be made for products that have been certified by an approved Certification Body as meeting organic standards applicable to the production of herbal medicines.

The MHRA has developed specific guidance for the advertising of products given a traditional herbal registration. A copy of the guidance can be found at Appendix 1.

4.8 Special requirements for homeopathic medicines

Advertising for homeopathic medicinal products is also subject to the requirements set out in this Guide. The MHRA has developed specific guidance for the advertising of homeopathic medicinal products. A copy of the guidance can be found at Appendix 2.

There are two current licensing schemes under which homeopathic medicines may be licensed in the UK and the requirements for advertising are specific to the licensing scheme used.

For products granted a certificate of registration under Part 6 of the Regulations (the Simplified Scheme), only the information specified on the labelling may be used in advertising. No mention of a specific indication may be made.

For products granted a marketing authorisation under Part 5 of the Regulations read with schedule 10 (the National Rules Scheme), the indication is based

upon UK homeopathic practitioners' traditional homeopathic use of the product, and product claims and advertising must be clearly set in the context of traditional homeopathic use. Advertising that implies that a product's efficacy is based on clinical trial data or the use of wording to imply that efficacy has been demonstrated, such as 'effective for' or 'works fast to relieve', is not acceptable.

In addition some homeopathic products may be licensed via Product Licences of Right under a previous licensing scheme. These products are not subject to the requirements of Part 14 of the Regulations.

General guidance on registered homeopathic medicines is provided in a separate guidance note (Guidance Note 17) available from the MHRA website. This also includes advice on advertising.

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.

Regulations 282 to 293 of the Human Medicines Regulations 2012 set out the provisions for advertising aimed at the general public. In addition the general rules set out in chapter 4 of this guidance 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 the 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) (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, electronic communication 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 3 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.

The MHRA advises caution for advertising 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 mislead as to the nature and use of an individual product. This is particularly important when other products available are not classed as medicines. Where an advertisement promotes more than one product with similar branding, 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.

Safe use of some medicines depends on compliance with certain conditions, which should be clearly indicated in advertising material. For example, a medical diagnosis is necessary before self-treatment with certain products such as those indicated for irritable bowel syndrome and advertising material should clearly reflect this.

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.

Advertisements relating to products which act as a reminder 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.

Where the name for a product listed in the SPC includes technical information describing the dosage form, a suitable abbreviation may be used in advertising provided this uniquely identifies the product(s) being advertised.

5.6 **Advice on claims**

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 Appendix 3.

Comparative claims for a medicine against another named product such as “works faster than XXX” are prohibited. This does not prevent a category claim such as “works faster than standard tablets”, provided it is supported by evidence. 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 mislead 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. It is unlikely that a time to onset of relief of more than 30 minutes would be considered to be ‘fast’ for a product for relief of an acute condition.

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 considers that it is not appropriate to refer to any medicine as "essential" in advertising. Medicines are indicated for people suffering from a specific condition, rather than the general population, and they may not be suitable for everyone.

5.7 **Recommendations and endorsements**

Advertisements to the general public should not contain material which refers to recommendations by scientists or healthcare professionals, or which refers to recommendations by celebrities 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. A simple statement of sponsorship by 'Brand X' would be classed as a reminder advertisement and would not attract the need for the statutory particulars listed in Annex 3, provided no product claims are made.

5.9 **Samples for promotional purposes**

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

- holders of a marketing authorisation or registration 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 Regulations on the sale of small-sized packs of medicines for supply through normal trade outlets on normal business terms provided the necessary authorisation or registration has been obtained to market the product.

5.10 **Advertising using digital communications media and the internet**

The Regulations also apply to digital communications channels such as social networking sites, blogs and discussion forums when these are used to communicate about medicines. This includes provision of statutory information in accordance with the requirements set out in Annex 3.

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 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 using the internet or other digital channels is prohibited.

5.11 **Multiple purchase promotions for analgesics**

The Government introduced legal restrictions on pack sizes for aspirin and paracetamol in 1998 to reduce the risk of toxicity in overdose particularly related to impulsive gestures which may be associated with stocks of medicines in the home. The sale and supply of large quantities of analgesic medicines or volume-based price promotions of them undermines 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 such as "3 for the price of 2" and “buy one get one free”. All persons responsible for approving proposals for price promotions for medicinal products should take into consideration consumer safety.

In association with stakeholders representing large and small retailers, pharmacists, trading standards officers and the pharmaceutical industry, the MHRA has developed guidance to encourage “best practice” in this area and ensure that there is a level playing field. The guidance outlines that no more than two packs should be sold in one transaction and discourages retailers from promoting offers that encourage the sale of more than one pack at a time. It is available at Appendix 4.

Chapter 6

ADVERTISING TO PERSONS QUALIFIED TO PRESCRIBE OR SUPPLY MEDICINES

6.1 Introduction

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

Regulations 294 to 300 of the Human Medicines Regulations 2012 set 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 of this guidance apply.

6.2 Scope of "persons qualified to prescribe or supply" medicines

The scope of PQPS is interpreted as including persons 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. The definition of PQPS used for the purposes of Part 14 of the Regulations is given in regulation 277. It also includes employees of PQPS who are not themselves qualified to prescribe or supply medicines.

Persons qualified to prescribe or supply 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 healthcare 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.

A number of professionals are qualified to supply medicines under Patient Group Directions (PGDs). This category includes Dietitians, Occupational Therapists, Speech and Language Therapists, Prosthetists and Orthotists. These occupations are 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, such as wholesalers.

6.3 **Advertising on the Internet**

Internet advertising of medicines is acceptable provided it complies with the Regulations. The MHRA considers that advertisements for POMs are acceptable only on websites whose nature and content are directed at healthcare professionals. Sections of a website aimed at healthcare 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 healthcare 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 should be provided in public areas so that individuals do not need to access sections for healthcare 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 Sections 7.5 and 7.6 for further advice.

A journal which is published or posted on the Internet and which is expressly stated to be for healthcare professionals is considered to be directed at persons qualified to prescribe or supply medicines and the advertising contained within the journal should comply with the requirements for advertising to PQPS. Each page of an advertisement for a prescription only medicine (POM) should be clearly labelled as intended for healthcare 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 294 and schedule 30 to the Regulations lay down the particulars to be contained in advertisements to PQPS. In any case all the particulars referred to in Annex 4 must be given. Annex 4 clarifies the particulars set out in schedule 30 to the 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. Where the information is presented as a linked page on an internet website, the link should be clearly visible. It is good practice for the link to appear on each 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 healthcare 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 30 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 a journal 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, those listed in the SPC for certain products may be quite extensive. As a minimum, the information 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 recommended that advertisements should include a reminder giving information on reporting of suspected 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.

For products subject to intensive surveillance by the MHRA under the additional monitoring scheme, it is good practice to include the identifying symbol (currently an inverted black triangle ▼) on all promotional material to alert prescribers to the need for special reporting in relation to adverse reactions.

6.5 **Provision of information - abbreviated advertisements**

Abbreviated advertisements, defined under regulation 295, 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.

Abbreviated advertisements must include a reference to at least one of the SPC indications for the use of the product.

Abbreviated advertisements must contain essential information compatible with the product SPC, as set out in schedule 30. tThey differ from full advertisements in that the detailed prescribing information is provided on a specified website rather than in the actual advertisement itself. The location of the information should be obvious when the website is accessed. A link to the current SPC for the product on the MHRA website (http://www.mhra.gov.uk/Safetyinformation/Medicinesinformation/SPCandPILs/index.htm) or on the electronic Medicines Compendium (eMC - www.medicines.org.uk/emc/) would be considered to fulfil this requirement. A company address from where this information is available should also be provided in the advertisement.

The particulars to be contained in abbreviated advertisements are given in regulation 295 and schedule 30 of the Regulations. In any case all the particulars referred to in Annex 5 must be given.

6.6 **Safety 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 medicine is generally well tolerated, 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. Claims that a product has a well established safety profile are only possible once there has been extensive post-marketing experience. ‘Well established’ should not be confused with ‘good’.

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.

It is helpful to refer to risk management materials in advertising where relevant, for example to highlight the availability of a patient alert card. Where factual safety messages given in advertising are based on advice given in the MHRA Drug Safety Update, the messages may be referenced to this publication.

6.7 **Urgent safety restrictions or safety variations**

It is the responsibility of the licence holder 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 essential information of an advertisement (see section 6.4 above) 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. This should be continued for a suitable period until it is reasonable to assume the majority of readers will have become aware of the change.

6.8 **Trade advertisements**

The Regulations provide that “reference material and announcements of a factual and informative nature, including … trade catalogues, and price lists” shall not be taken to be an advertisement, provided that no product claim is made. Materials relating to 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 appropriate when advertising GSL medicines to purchasers who may not have specialist medicines expertise.

6.9 Promotional aids

Advertisements relating to products which act as a reminder 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.

A "promotional aid" is a form of reminder advertisement. It 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). 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 300. 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 licence 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

Advertising material relating to products or indications that are not licenced in the UK may be displayed or made available on request at international symposia, conferences and other meetings of high scientific standing provided that a significant proportion of the attendees are from countries outside the UK where the product or indication 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 298 applies to the supply of a free sample of a licensed 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 (this may be an electronic signature);

(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 SPC.

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

The supply of samples of medicines containing psychotropic or narcotic substances which are controlled under the Narcotic Drugs Convention or the Psychotropic Substances Convention is prohibited except for those listed under schedule III or paragraphs 2 and 3 of Article 2 of the respective Conventions.

Guidance on the interpretation of 'limited' in the context of regulation 298 is given in self regulatory codes of practice. See chapter 10 of this Guide for details.

Department of Health policy is that there is no role for short-term supplies provided by pharmaceutical companies on request to medical practitioners for use in emergency situations, e.g. out-of-hours and in the patient's home (so-called "starter packs")[3]. The MHRA considers these free "starter packs" to be samples for promotional or advertising purposes under the Regulations. Consequently they are required to comply with the requirements above for professional samples.

[3] Department of Health. 2004. 'Securing proper access to medicines in the out-of-hours period' available at: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4134236.

6.13 **Medical sales representatives**

Anyone who promotes a medicine, for example a medical sales representative, 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. The Association of the British Pharmaceutical Industry (ABPI) provides training programmes for representatives. Further details are available from them at the address given in Annex 6.

Representatives should, during each visit, give to all persons whom they visit, or have available for them at the time of the visit, the current SPC for each product which they promote at that visit. This is to enable the healthcare professional to check any statements made against the licensed product particulars covering the use of product. The SPC can be provided electronically.

Representatives must also report all information relating to the safety of a product which they receive from healthcare professionals directly to scientific services set up by the licence holder under the Regulations.

6.14 **Gifts, inducements and other benefits**

Regulation 300(1) of the Regulations provides that "a person may not, in connection with the promotion of medicinal products to persons qualified to prescribe or supply them, supply, offer or promise to such persons any gift, pecuniary advantage or benefit unless it is- (a) inexpensive; and (b) relevant to the practice of medicine or pharmacy".

Regulation 300(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 medicinal product by PQPS will be caught by regulation 300(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 300(6).

Regulation 300(6) provides an exemption to the prohibition in regulation 300(1) for promotional activity in the form of "measures or trade practices relating to prices, margins or discounts which were in existence on 1st 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 300(6).

Any “person” promoting medicines to PQPS will be subject to regulation 300(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 300(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 300(1) is a criminal offence. It is also 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 300(1) of the 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. The criterion of "relevance" is only 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 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 UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing)*.

6.16 **Hospitality**

The restrictions of regulation 300(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 300(2) and (3) 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 healthcare professionals e.g. partners.

Regulation 300(3) provides that hospitality can also be offered to healthcare 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 licence holder and one or more companies nominated by him is not prohibited in the UK.

Chapter 7

PROVIDING NON-PROMOTIONAL INFORMATION ABOUT PRESCRIPTION ONLY MEDICINES TO THE PUBLIC

7.1 Introduction

This chapter provides guidance on how pharmaceutical companies and others can provide factual information about prescription only medicines without breaching the Human Medicines Regulations 2012 (the Regulations). General guidance on preparing health information for the public is available from various sources, including the Department of Health Information Standard and the Pharmaceutical Forum.

7.2 Independent information sources

The Regulations apply to 'any person' who promotes a medicine, not just pharmaceutical companies. Journalists and patient organisations can have an important role in informing patients and the public about medicines; the MHRA has issued guidance to help ensure that they can provide information to help people make informed choices, while keeping out of the advertising controls. This can be found at Appendix 5. Materials should be balanced and factual, independently authored and designed to inform rather than to promote specific medicines.

7.3 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 highlight the qualities of a specific prescription only medicine since this is likely to breach the Regulations by encouraging individuals to request a particular treatment. 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 materials such as magazine advertisements and flyers distributed to the public must not mention product names such as "Botox" or "botulinum toxin".

The MHRA has developed specific guidance for consumer websites offering medicinal treatment services. This can be found at Appendix 6.

7.4 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 Appendix 7.

7.5 Company internet sites

Companies may include the following information in a website aimed at the public:

- disease-related information in accordance with the guidance provided in Section 7.4 above,
- patient information leaflets (PILs), SPCs and public assessment reports (PARs) for their POM products
- other non-promotional reference information about the product that fairly reflects the current body of evidence about the product and its benefit risk profile.

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.

7.6 Materials for patients

Companies may also provide non-promotional information and other items to support patients who have been prescribed a particular medicine. This is sometimes required as part of a risk management plan. Any such materials should provide a demonstrable benefit to the patient. Materials are usually provided to health professionals to give to their patients.

Patient materials may include alert cards for patients to carry, leaflets about the disease and the treatment or additional advice on how to take the medicine, for example a video showing how the product is prepared and administered. The materials should be factual and promotional claims must not be included. Consideration should always be given to whether this information can be included in the patient information leaflet which accompanies all medicines.

Copies of appropriate materials may also be made available on a company internet site for reference purposes. If a website provides both information for the general public and copies of materials aimed at patients prescribed the product, the sections for each target audience should be clearly separated and clearly marked for the target audience. Adequate non-promotional information must be provided for general members of the public so that individuals do not need to access sections designed for patients 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.

7.7 **Press releases and other information to the media**

Press releases e.g. at the time of launch of an innovative product 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 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.

7.8 **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.

REGULATION OF MEDICINES ADVERTISING IN THE UK

Under European legislation, regulation of advertising for all medicines is a national responsibility. 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 MHRA also carries out monitoring of medicines advertising and investigates complaints about advertising from any source, including healthcare 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 8

THE ROLE OF THE MHRA

8.1 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.

8.2 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 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 authorised product, subject to additional 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 active substances.

The period of vetting of all advertising for a product will normally be one to three months and would normally not extend for longer than six months. The marketing authorisation holder 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, the time period over which materials are received 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. The MHRA also expects non-promotional items, such as press releases and risk management materials, to be submitted for review to ensure that these are not promotional. All materials to be vetted 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. The company should keep the MHRA informed of when they are likely to submit advertising for review.

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 MHRA's ability to perform this function.

8.3 **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 healthcare professional and consumer journals and other types of media for advertisements relating to any medicinal product, which are then checked against the Regulations for compliance. A company may also be asked to submit copies of current advertising materials for checking if a safety concern has been identified.

Should there be a cause for concern the MHRA will contact the company for supporting evidence, comment or clarification on advertising and will initiate action as for a complaint if necessary (see below for further details).

8.4 **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 regulations 286 to 290 or regulations 294 to 300, the 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 MHRA 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 314 of the 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 MHRA 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 regulation 304 of the Regulations formally requesting a copy of the advertisement in question.

Complaints are considered by the MHRA's Advertising Standards Unit as a whole at its regular meetings. Accelerated action is taken on any case that is judged to pose a serious risk to public health. In these cases, the MHRA may

provide a view indicating the reasons for such a view at this initial stage and ask for immediate withdrawal of the advertisement.

The MHRA 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 MHRA, 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 Standards Unit also calls on an Advertising Action Group, consisting of senior professional assessors and other MHRA staff with experience of advertising regulation, for advice if needed.

Many cases are resolved at an early stage, either because the MHRA decides there is no case to answer or the company recognises the concerns of the complainant and the MHRA 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 MHRA'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, the MHRA may request that any revised material 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 MHRA will review the case again and then consider what further steps are appropriate. The MHRA, 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 Regulations. Details of the statutory procedures are provided in the next chapter. Cases may also be referred, at any stage, to the MHRA Enforcement Group 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 MHRA 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 MHRA and the company, or when statutory action is taken.

8.5 **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 that a corrective statement 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 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 MHRA 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.

Particularly for an OTC product, it may be appropriate to issue the correction in the form of a statement in future advertising that corrects the misleading impression given.

In addition, where a corrective statement has been required for misleading advertising, the MHRA may request 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.

8.6 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 Regulations, enforcement action will be considered. 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 10 and at Annex 6.

Chapter 9

STATUTORY ACTION

9.1 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.

9.2 Taking statutory action

Although the Human Medicines Regulations 2012 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 regulations 305 to 307. 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 licence holder.

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 person may be issued with a notice under regulation 305 advising him that:

(i) the MHRA is "minded to" determine that the advertisement, if published, would be in breach of the 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.

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 MHRA 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.

Cases may also be referred, at any stage, to the MHRA Enforcement Group for consideration of enforcement action. Once a case is referred, any further contact or correspondence about the case will only be with the Enforcement Group. 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.

9.3 **Independent Review Panel (IRP)**

The 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 the Independent Review Panel for Advertising (IRP) for consideration. The IRP's view on whether the advertisement breaches the 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 at Appendix 8 and on the MHRA website.

9.4 **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 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 Regulations. In this case, a notice under regulation 306 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.

9.5 **Sanctions**

A breach of any of the provisions of the Regulations listed in regulation 303 of those Regulations is a criminal offence. This covers the vast majority of requirements set down by the 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 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 Regulations, for example, requiring publication of a corrective statement where Health Ministers have prohibited publication of an advertisement for breaching the Regulations. Further guidance on the format of corrective statements is provided in Section 8.5.

Chapter 10

SELF-REGULATION

10.1 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.

10.2 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 6.

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 for prescribing, to members of UK healthcare professions and to appropriate administrative staff, and to certain non-promotional materials and activities including information made available to the public about prescription only medicines. The Code also applies to a number of areas which are non-promotional, including the provision of information to patients and the public about prescription only medicines.

The Code is drawn up in consultation with the British Medical Association (BMA), the Royal College of Nursing (RCN), the Royal Pharmaceutical Society (RPS) 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 also sets out 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 6). Details of the ABPI Representatives Examination may be obtained directly from that body (contact details appear in Annex 6).

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 *Medicines Advertising Codes* include a Consumer Code of Practice that lays down standards for the advertising of

authorised OTC medicines to the general public. They also include a Professional Code of Practice for advertising directed at persons qualified to prescribe or supply medicines. These Codes are drawn up in consultation with the MHRA, ASA, Ofcom and the bodies responsible for clearance of TV and radio advertisements (Clearcast and RACC – see section 10.3 for details).. Separate *Medicines Advertising Codes* cover traditional herbal medicines.

PAGB provides training programmes on its Advertising Codes. (Further details about these training programmes are available from the PAGB – see contact details in Annex 6.)

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.

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 contracting out responsibility for broadcast advertising. It retains responsibility for programme sponsorship and product placement.

Advertising Standards Authority (ASA) and Committees of Advertising Practice

The ASA ensures that advertising in all media is legal, decent, honest and truthful. For more than fifty years, the ASA has been responsible for administering the UK non-broadcast advertising Code, now the *UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing* (the CAP Code).

The Committee of Advertising Practice (CAP) is responsible for authoring and maintaining the CAP Code. The Broadcast Committee of Advertising Practice (BCAP) performs a similar function for the *UK Code of Broadcast Advertising* (the BCAP Code). As well as authoring the Codes, CAP and BCAP are the industry facing side of the self-regulatory system. They provide guidance and advice on compliance with the Code as well as working to enforce ASA decisions.

The self-regulatory system has developed significantly in recent years. In 2004, the ASA and the newly constituted BCAP assumed responsibility for television and radio advertisements, in a co-regulatory partnership with Ofcom, creating a 'one-stop shop' for all advertising content complaints.

The ASA has also assumed new responsibilities for digital marketing. In 2010, Ofcom designated CAP as the regulator of advertising content associated with

video-on-demand services. In March 2011, the remit of the CAP Code was extended to include marketing communications appearing on marketers' own websites and in other non-paid-for space under their control, such as social networking sites like Facebook and Twitter. The ASA is now the comprehensive regulator of marketing communications in the UK across traditional and new media.

The ASA is the established means for consumer protection in non-broadcast media, recognised by Government and the Courts. The Office of Fair Trading acts as a legal backstop in cases of repeated non-compliance. For broadcast advertising, under the co-regulatory partnership the ASA is able to refer particularly serious cases to Ofcom. Ofcom is able to levy fines and revoke licences.

The contact details of the ASA, CAP and BCAP can be found in Annex 6.

10.3 **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 *UK Code of Broadcast Advertising*.

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 before use.

Clearcast

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

Radio Advertising Clearance Centre (RACC)

RACC is part of RadioCentre, the industry body for UK commercial radio. RACC is responsible for ensuring that medicines advertising on radio complies with the *UK Code of Broadcast Advertising*. The Code requires that all national and special category advertisements and commercial references, including all

advertisements featuring health claims and for medicines, medical devices and treatments, are cleared before broadcast.

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 *UK Code of Non-broadcast 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.

10.4 **Investigation of complaints**

In addition to the statutory regime established by the 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 patients and the general public about prescription only 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 ASA investigates complaints about marketing communications for medicines and ensures compliance with the *UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing* and the *UK Code of Broadcast Advertising*. Both 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 6.

10.5 **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, Clearcast, RACC, PMCPA, PAGB, ASA, CAP, HFMA, BHMA (the British Herbal Medicine Association) and the MHRA. The MHRA liaises with these groups to develop guidance and a common understanding of Part 14 of the Regulations, providing clarification of the law where necessary and raising current issues for discussion and dissemination. Minutes of meetings are published on the MHRA website.

Annex 1

RELEVANT LEGISLATION

THE PRINCIPAL UK LEGISLATION FOR THE ADVERTISING AND MONITORING OF MEDICINES

Human Medicines Regulations 2012, SI No. 1916

In August 2012, the Human Medicines Regulations 2012 (the Regulations) brought together most of the legislation relating to medicines in the UK, excluding the regulation of clinical trials and fees. These Regulations simplify and replace most of the Medicines Act 1968 and around 160 statutory instruments relating to medicines.

Part 14 of the Regulations codifies all the UK legislation on the advertising of medicines that implements Title VIII of Codified Council Directive 2001/83/EC (previously Directive 92/28/EEC).

Part 14 is divided into three Chapters. The first provides definitions relevant to advertising to supplement the general definitions given in Part 1 of the Regulations. Chapter 2 covers the legal requirements for advertising to the public and to healthcare professionals and the responsibilities of licence holders. Chapter 3 sets out the legal framework for enforcement of these requirements.

Previous legislation in force before August 2012:

Medicines Act 1968

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 made provisions for promotion of medicines (most of which have been superseded by subsequent legislation) and section 92 used to define the meaning of “advertisement”. Many of the provisions relating to medicines, including Part VI, were repealed by the Human Medicines Regulations in August 2012.

Medicines (Advertising) Regulations 1994, SI No. 1932

The Medicines (Advertising) Regulations 1994 (the Advertising Regulations) implemented Directive 92/28/EEC, later codified as Title VIII of Directive 2001/83/EC) in the UK. The Advertising Regulations set out the provisions for advertising, including homeopathic medicines and advertising directed at the public and healthcare professionals. The Advertising Regulations made provisions for breaches that constituted a criminal offence and specified the penalties.

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

The Medicines (Monitoring of Advertising) Regulations 1994 (the Monitoring Regulations) implemented Articles 97 98 (part) and 99 of Directive 2001/83/EC by specifying procedures whereby advertisements which were considered to be inconsistent with the Advertising Regulations could be acted upon, either by reference to an administrative body established for that purpose or by civil proceedings.

The Advertising Regulations and the Monitoring Regulations came into force on 9 August 1994 and reinforced existing controls on advertising under the Medicines Act 1968. Both these Regulations were amended a number of times.They were both revoked by the Human Medicines Regulations in August 2012.

OTHER UK LEGISLATION THAT AFFECTS MEDICINES ADVERTISING

Cancer Act 1939

The Cancer Act 1939 makes provision for, amongst other things, the prohibition of certain advertisements relating to treatments for cancer. Section 5.2 of this Guide provides further information.

Trade Descriptions Act 1968 and Consumer Protection from Unfair Trading Regulations 2008, SI No. 1277

The Trade Descriptions Act 1968 and the Consumer Protection from Unfair Trading Regulations 2008 regulate consumer advertising generally, including the advertising of medicines. This legislation is administered by the Department for Business, Innovation & Skills. The 2008 Regulations implement relevant aspects of the European Directives on misleading and comparative advertising (Directives 2005/29/EC and 2006/114/EC) 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.

Broadcasting Acts 1990 & 1996 and Communications Act 2003

The Broadcasting Acts 1990 and 1996 and the 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, amongst other things, confers on Ofcom regulatory functions for broadcast advertising, programme sponsorship and product placement including powers to regulate advertising standards.

Ofcom, the regulator for the communications industry, has used its powers to contract out some of its functions to a self-regulatory body for broadcast advertising. The day-to-day responsibility for TV and radio advertising standards rests with the ASA.

The Enterprise Act 2002

Regulations made under the Enterprise Act 2002 designate the Secretary of State for Health (in effect the MHRA) as an enforcer under the terms of the European Consumer Protection Cooperation Regulation. The powers are exercisable in relation to a “Community infringement” which includes an infringement of Title VIII of Directive 2001/83/EC. This applies not only to an infringement covered by Part 14 of the Human Medicines Regulations but also infringement of the national laws of other Member States which implement articles 86 to 100.

The Bribery Act 2010

The Bribery Act 2010 provides a legal framework to combat bribery in the public or private sectors. It includes offences covering the offering, promising or giving of an advantage, and requesting, agreeing to receive or accepting of an advantage. It is enforced by the Serious Fraud Office (SFO).

UK LEGISLATION FOR HOMEOPATHIC MEDICINES WITH PRODUCT LICENCES OF RIGHT

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

The 1975 Regulations apply to homeopathic products with Product Licences of Right (PLRs). 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 1978 Regulations apply to homeopathic products with PLRs. These 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. They also contain 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 Directive 2001/83/EC 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 were 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 in the UK 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 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

Directive 2004/27/EC amends Directive 2001/83/EC and introduces further changes following the review of European medicines legislation. The changes were implemented in the UK through amendments to existing legislation with effect from 30 October 2005.

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

Directive 2004/24/EC 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 in the UK on 30 October 2005.

Directive 2004/24/EC provided a seven-year transitional period for herbal medicines already on the market on 30 April 2004 when it came into force. The

period for manufacturers of traditional herbal medicines to register their products under the traditional Herbal Medicines Registration Scheme expired on 30 April 2011, although pre-existing stocks of products already in the supply chain before that date could continue to be sold.

Council Directive 2005/29/EC – The Unfair Commercial Practices Directive.
Council Directive 2006/114/EC – The Misleading and Comparative Advertising Directive.

Directives 2005/29/EC and 2006/114/EC concern unfair commercial practices and misleading and comparative advertising, including the advertising of medicines to the public. The second codifies and repeals the previous Directive on Misleading Advertising (Directive 84/450/EEC). The provisions have been implemented in the UK by the Consumer Protection from Unfair Trading Regulations 2008 and the Business Protection from Misleading Marketing Regulations 2008.

Council Directive 1989/552/EEC – The Audiovisual Media Services Directive.

Directive 1989/552/EEC makes provisions for medicines advertising, in particular the prohibition on the promotion of prescription only medicines to the public. It has been amended several times and now also covers product placement and sponsorship of programming.

EC Regulation 2006/2004 - The Consumer Protection Cooperation (CPC) Regulation

Regulation (EC) No. 2006/2004 concerns unfair business-to-consumer commercial practices in the internal EU market. It provides for cross-border co-operation between national authorities responsible for the enforcement of EC consumer protection laws.

Annex 2

IMPLEMENTATION OF TITLE VIII OF DIRECTIVE 2001/83/EC INTO UK LAW

Directive article	Proposed new UK regulation under the Human Medicines Regulations 2012	Previous UK regulation
86	Reg 7	Reg 2 of SI 1994/1932
87.1	Reg 279	Reg 3 of SI 1994/1932
87.2	Reg 280	Reg 3A of SI 1994/1932
87.3	Reg 280	Reg 3A of SI 1994/1932
88.1	Regs 284 and 285	Reg 7 and 8 of SI 1994/1932
88.2		Reg 6 & schedule 1 to SI 1994/1932
88.3		Inappropriate to UK system
88.4	Reg 292	Reg 11 of SI 1994/1932
88.5		Does not require implementation
88.6	Reg 293	Reg 12 of SI 1994/1932
89.1	Reg 291	Reg 10(1) of SI 1994/1932
89.2	Reg 296	Reg 10(2) of SI 1994/1932
90	Regs 286 to 290	Reg 9 of SI 1994/1932
91.1	Regs 294 and 295 and schedule 30	Reg 14 & schedule 2 of SI 1994/1932
91.2	Reg 296	Reg 17 of SI 1994/1932
92.1	Reg 297(1)	Reg 18(1) of SI 1994/1932
92.2	Reg 297(2)	Reg 18(2) of SI 1994/1932
92.3	Reg 297(3)	Reg 18(3) of SI 1994/1932
93.1	Reg 281(3)	Reg 4(b) of SI 1994/1932
93.2	Reg 299(2)	Reg 20(2) of SI 1994/1932
93.3	Reg 299(3)	Reg 20(3) of SI 1994/1932
94.1	Reg 300(1)	Reg 21(1) of SI 1994/1932
94.2	Reg 300(2)	Reg 21(3) of SI 1994/1932
94.3	Reg 300(4)	Reg 21(5) of SI 1994/1932
94.4	Reg 300(6)	Reg 21(4) of SI 1994/1932

95	Reg 300(3)	Reg 21(2) of SI 1994/1932
96.1	Reg 298	Reg 19 & schedule 4 of SI 1994/1932
96.2		Inappropriate to UK system
97.1	Regs 304 to 309	Regs 4 & 13 of, and Schedule to SI 19941933
97.2 to 97.4	Regs 304 to 309 and 311 to 314	Regs 6, 7, 8 and 13 of, and schedule to SI 1994/1933
97.5	Reg 310	Reg 5 of SI 1994/1933
98.1	Reg 281(2)	Reg 4(a) of SI 1994/1932
98.2 (i)	Reg 281(4) and (5)	Reg 4I of SI 1994/1932 (as amended)
(ii)	Reg 303	Reg 23 of SI 1994/1932, regs 6-8 and 11, and schedule to SI 1994/1933
(iii)	Reg 281(3) and 299	Regs 4(b), 20(2) and (3) of SI 1994/1932
(iv)	Reg 281(5)	Reg 4(d) of SI 1994/1932 (as amended)
(v)	Reg 308	Reg 13 of, and schedule to SI 1994/1933
99	Regs 303 and 308	Reg 23 of SI 1994/1932 and reg 13 of SI 1994/1933
100	Reg 301	Reg 22 of SI 1994/1932

Annex 3

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.

Homeopathic medicines granted certificates of registration have separate requirements. Please refer to the Guidance at Appendix 2 of this Guide.

Annex 4

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 or registration 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.

Use of the product

1. Indication(s): one or more of the therapeutic indications for the product consistent with the terms of the licence. For products with a traditional herbal registration, the following statement must be included:

   "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".

2. Side-effects, special warnings and precautions for use 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. 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.

The particulars in relation to side-effects, warnings and 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.

Annex 5

PARTICULARS TO BE CONTAINED IN ABBREVIATED ADVERTISEMENTS

1. The name and address of the holder of the marketing authorisation or registration 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 (see also point 4 below, the information only needs to be given once).

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 a specified website or on request to the licence holder as follows:

   "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at:"

   This should be followed by a website address that corresponds to that statement and the information given in point 1 above. The specified website must include the particulars listed in Annex 4 and/or a copy of the SPC for the product.

5. At least one indication for use of the product. For products with a traditional herbal registration, the following statement must be included:

   "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".

Annex 6

OTHER REGULATORY AND SELF-REGULATORY BODIES

Association of the British Pharmaceutical Industry 7th Floor Southside 105 Victoria Street London SW1E 6QT Tel. 0870 890 4333 www.abpi.org.uk	Advertising Standards Authority and Committee of Advertising Practice and Broadcast Committee of Advertising Practice Mid City Place 71 High Holborn London WC1V 6QT Tel. 020 7492 2222 www.asa.org.uk www.cap.org.uk CAP Copy Advice Tel. 020 7492 2100 E-mail: copyadvice@cap.org.uk
Clearcast 2nd & 3rd Floor 4 Roger Street London WC1N 2JX Tel. 020 7339 4700 www.clearcast.co.uk	Health Food Manufacturers' Association 1 Wolsey Road East Molesey Surrey KT8 9EL Tel. 020 8481 7100 www.hfma.co.uk
Ofcom 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 2QS Tel. 020 7242 8331 www.pagb.co.uk
Prescription Medicines Code of Practice Authority 7th Floor Southside 105 Victoria Street London SW1E 6QT Tel. 020 7747 8880 www.pmcpa.org.uk	Radio Advertising Clearance Centre The RadioCentre 6th Floor 55 New Oxford Street London WC1A 1BS Tel. 020 7010 0608 www.racc.co.uk

GUIDES

These guides are designed to provide detailed advice on the legislation relating to a particular area in an easily accessible form.

List

1. Registered traditional herbal medicines: Guidance for consumer advertising

2. Homeopathic medicines: Guidance on advertising

3. Best practice guidance on the sale of medicines for pain relief

4. Medicines which are promoted for use during pregnancy: Guidance for the pharmaceutical industry

5. Reporting to the public on medicines: Advice for journalists and patient organisations

6. Advertising of medicines: Guidance for consumer websites offering medicinal treatment services

7. Disease Awareness Campaign Guidelines

8. Guidance on review of advertising by an Independent Review Panel

Appendix 1

Registered Traditional Herbal Medicines: Guidance on consumer advertising

1. Purpose of this guideline

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) in consultation with the herbal medicines sector and advertising regulatory bodies.

The guidance is supplementary to the regulatory framework as set out in Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916 – the Regulations), which implement Title VIII of European Directive 2001/83/EC in the UK.

The guidance is intended for advertisers of traditional herbal medicinal products (THMs) holding a registration certificate granted by the MHRA under the Traditional Herbal Medicines Registration Scheme provided for in Part 7 of the Regulations. This Scheme implements the requirements of the Traditional Herbal Medicines Directive (Directive 2004/24/EC).

Products registered under this Scheme must meet established standards of safety and quality for medicines but, instead of the recognised efficacy standards required for a marketing authorisation, the product must have been used for at least 30 years (at least 15 of which must normally have been within the EU) to demonstrate long-standing traditional use in the specified conditions of use.

This guidance interprets the legal requirements for advertising to the public and recommends best practice for advertisers to ensure safe and responsible advertising of these medicines. It reflects the general principles to be adopted so that advertising does not convey misleading messages that could lead to inappropriate use of these medicinal products.

Further information and general advice on compliance with the medicines advertising legislation is available in the MHRA Blue Guide, *Advertising and Promotion of medicines in the UK*, available on the MHRA website.

On investigation, the decision on whether a particular advertisement complies with the Regulations would be taken by the MHRA on a case by case basis, having regard to the facts of the particular case.

2. Scope of guidance

All advertising of traditional herbal medicinal products or treatment services is subject to the general rules on misleading advertising administered by the

Advertising Standards Authority. Further information is available at www.asa.org.uk.

This guidance covers the specific requirements under the Regulations for consumer advertising for registered traditional herbal medicines in the UK.

Although some of the requirements and restrictions may also apply to advertising aimed at healthcare professionals, this guidance does not cover advertising directed at healthcare professionals. Requirements are set out in chapter 6 of the MHRA Blue Guide.

3. General statement

It is a central feature of the traditional herbal medicine registration scheme that the products concerned do not fulfil the requirement to demonstrate efficacy for a marketing authorisation. In particular, such products will not fulfil the efficacy requirements for a marketing authorisation based on well-established medicinal use. If a product fulfils the criteria for a marketing authorisation, then it is not usually appropriate to grant that product a traditional herbal registration.

THMs are generally registered for use in minor self-limiting conditions that are suitable for self-management and do not require the intervention of a medical practitioner.

All of the general rules about medicines advertising in the Regulations apply to traditional herbal medicinal products. There is one additional requirement for advertising of these products, which is to include a specified form of wording to inform the consumer that the efficacy of the product for the stated indications is not scientifically supported but is based exclusively on evidence of long-standing use.

4. Specific requirements for advertising THMs to the public

4.1 THM statement

All advertising for THMs, to the public or to healthcare professionals, must include 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 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 take the product.

The exact wording above must be used (with the italic section completed with appropriate indication(s) for use of the product).

If placed clearly in the body of the advertisement rather than as a footnote, this text meets the requirement to include an indication for use of the product in advertising to the public.

Where the advertisement is restricted in terms of permitted characters, for example on Twitter, the MHRA would not object to a reasonable abbreviation of this statement, provided the meaning is conveyed.

Advertising a range of products: Where a range of products is being advertised, it may not be practical to include an individual statement for each product in a brief advertisement. In this situation, a single statement to cover all the products that meets the requirements above may be appropriate.

4.2 Indication statement

Advertisements must include at least one indication for use of the product.

THMs are generally registered with an indication such as “A traditional herbal medicinal product used for the temporary relief of symptoms of [*a specific condition*] based on traditional use only”. All advertising must reflect the approved indication accurately and in its entirety. Text does not need to use the exact wording in the Summary of Product Characteristics (SPC) but the meaning should be clear. As an example for the indication above, it should be clear that the product is:

- a traditional remedy/traditionally used or similar wording
- for relief of symptoms (i.e. not for curing or preventing the condition)
- for treatment of the specified condition
- where the condition includes a reference to its severity, e.g. mild or moderate, this should be included. Words or illustrations should not suggest that a more serious degree of the condition can be treated.
- additionally for products indicated for short term use, the advertising should not suggest it may be taken for a longer period.

For maximum clarity it is recommended that the full indication is included prominently in one place in the body of the advertisement.

4.3 Making other claims for the product

Additional claims must be clearly set in the context that the indications for the product are based exclusively on longstanding use.

As an example, wordings such as “traditionally used as a remedy/treatment for …” or “XXX has been marketed for many years as a traditional remedy for …” would be likely to be acceptable.

Wordings that imply efficacy has been demonstrated such as “clinically proven”, “effective for …” or “works fast to relieve …” are unlikely to be acceptable.

References to clinical studies

The required THM statement is clearly intended to inform the consumer that the efficacy of the product for the stated indications is based exclusively on long-standing use, i.e. that there were insufficient clinical data to demonstrate the efficacy of the product. There is therefore an obvious risk of exaggerating the benefits of the product and misleading the consumer if the advertisement then goes on to explain the results of a clinical trial apparently demonstrating efficacy.

In order to ensure that consumers are not misled when presenting the results of limited clinical studies, it is important to make clear the basis on which the product was registered, i.e. that there were insufficient clinical data to demonstrate the efficacy of the product. In practice, given the nature of the traditional herbal scheme, it would be particularly difficult, in brief advertisements, to make reference to clinical trial data without misleading consumers. In principle it may be more feasible that compliance with the regulatory requirements may be achievable in a longer, more narrative type of advertisement (‘advertorial’), but the practicalities of this would need careful consideration.

There are also specific problems with including clinical evidence. It would be misleading for an advertisement selectively to refer to the results of particular studies which showed the efficacy of the product in a particular light, when there were also other less favourable studies available that cast doubt on the efficacy of that product. A further issue is that, historically, there will have been numerous clinical studies of various herbal ingredients, but MHRA experience suggests that many of them are likely to have had flaws, sometimes fundamental ones, in design and/or control, which seriously limit their value in providing information useful to the consumer.

Testimonials

These may be used in advertising but any statements must be in line with the indication for traditional use and must not suggest that the product has proven efficacy. Similar concerns arise as for references to clinical studies above and it would be very difficult to include testimonials that make personal efficacy claims for a THM product in brief advertisements because of the potential to mislead. In a more detailed piece such as a website, MHRA takes the view that it may be possible to include a genuine factual testimonial based on personal use. Any testimonial must be clearly set in the context that the product is a traditional remedy and it must be explicitly stated that this represents one person’s experience and the efficacy of the product has not been proven.

‘Organic’ claims

Claims that a product is ‘organic’ may only be made for products that have been certified by an approved Certification Body as meeting organic standards applicable to the production of herbal medicines.

4.4 Other requirements

For ease of reference, Annex 1 provides a summary list of the other legal restrictions on advertising medicines to the public that apply to all OTC medicines, including registered THMs.

4.5 Certification mark

The MHRA has registered a certification mark that companies may, if they wish, include in their advertising and/or on pack labelling to help the public to identify that the product holds a THM registration. Details of the mark and how it may be used are available from:

http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalmedicines/PlacingaherbalmedicineontheUKmarket/TraditionalHerbalMedicinesRegistrationScheme/TraditionalHerbalRegistrationcertificationmark/index.htm.

5. Self regulation in the UK

A system of self regulation for medicines advertising has been long established in the UK. This includes Codes of Practice and advice and vetting services for consumer advertising prior to publication. For over the counter medicines and THMs, these services are provided by the following organisations:

British Herbal Medicine Association	www.bhma.info
Health Food Manufacturers' Association	www.hfma.co.uk
Proprietary Association of Great Britain	www.pagb.co.uk

As a condition of membership, these organisations require their members to submit all advertising to the public for vetting prior to issue. The MHRA supports self regulation as it sets high standards and promotes good practice. Its effectiveness is demonstrated by the very low numbers of complaints about advertising to the public received by the MHRA. The MHRA encourages all advertisers of traditional herbal medicines to join one of these associations to provide external assurance that proposed advertising to the public complies with the legislation. Where complaints are upheld about advertising, the MHRA will consider the need to require vetting of future materials to ensure compliance if this is not already provided for through self regulation.

Advertisements for medicines must also comply with the general controls on advertising operated by the Advertising Standards Authority. Further information is available at www.asa.org.uk.

6. Further information and guidance

Further information and general advice on compliance with the advertising legislation is available from the self regulatory bodies listed above and in their Codes of Practice.

Advice is also available from the MHRA Advertising Standards Unit at advertising@mhra.gsi.gov.uk and in the Blue Guide, *Advertising and Promotion of medicines in the UK*, on the MHRA website at:

http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf

General information about herbal medicines and the THM Registration Scheme is available on the MHRA website at:

http://www.mhra.gov.uk/Howweregulate/Medicines/Herbalandhomoeopathicmedicines/Herbalmedicines/index.htm

MHRA
July 2012

Annex 1

This Annex briefly summarises the general requirements under the legislation on advertising THMs to the public.

A. Statutory requirements for advertising to the public

All advertising of THMs to the public must include:

- the name of the product,
- the common name of the product, if the product contains only one active ingredient,
- at least one indication for use consistent with the terms in the SPC,
- a clear and legible invitation to “Always read the label” or leaflet,
- 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 upon long-standing use as a traditional remedy”.

Exceptions are made for promotional aids (e.g. pens) which may only contain the name of the product, trademark or its international non-proprietary name and for factual announcements which include no product claims.

B. Summary of other key statutory requirements

All advertising must:

- comply with the particulars listed in the SPC;
- encourage the rational use of the product by presenting it objectively and without exaggerating its properties;
- not be misleading.

Manufacturers and suppliers must not provide a free sample of a THM product to any member of the public.

A THM product must not be promoted before a registration is granted.

All promotional material must be clearly identified as an advertisement.

C. What advertising must not include

Advertising to the public must not:

- give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, telephone or other electronic communication;

- suggest that the effects of taking the medicinal product are guaranteed, are not accompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product;
- suggest that health can be enhanced by taking the medicinal product;
- suggest that health could be affected by not taking the medicinal product;
- be directed exclusively or principally at children;
- refer to a recommendation by scientists, healthcare professionals or persons who because of their celebrity, could encourage the consumption of medicinal products;
- suggest that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggest that the safety or efficacy of the product is due to the fact that it is natural;
- might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refer, in improper, alarming or misleading terms, to claims of recovery;
- use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts of it.

For further information, consult the Blue Guide, *Advertising and Promotion of medicines in the UK*, available on the MHRA website at:

http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf

Appendix 2

Homeopathic Medicines: Guidance on advertising

1. Purpose of this guideline

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) in consultation with the homeopathic medicines sector and advertising regulatory bodies. It is intended for advertisers and suppliers of homeopathic medicinal products.

This guidance explains the legal requirements for advertising of homeopathic medicines to the public and to homeopathic practitioners and recommends best practice to ensure responsible advertising. It is supplementary to the regulatory framework in Part 14 of and schedule 32 to the Human Medicines Regulations 2012 (SI 2012/1916 – the Regulations), which implement Title VIII of European Directive 2001/83/EC.

Further information and general advice on compliance with the Regulations is available in the MHRA Blue Guide, *Advertising and Promotion of medicines in the UK*, available on the MHRA website.

On investigation, the decision on whether a particular advertisement complies with the Regulations would be taken by the MHRA on a case by case basis, having regard to the facts of the particular case.

2. Scope of guidance

All advertising of homeopathic products or services is subject to the general rules on misleading advertising administered by the Advertising Standards Authority. Further information is available at www.asa.org.uk.

This guidance covers the specific requirements under the medicines legislation for advertising of homeopathic medicines for human use in the UK. Advice is also provided to help ensure that advertising for services which involve the supply of homeopathic products, to practitioners or to the public, does not promote unlicensed homeopathic medicines.

Advertising of medicinal products has a broad definition under the Regulations and is considered to be anything which is designed to promote the prescription, supply, sale or consumption of medicinal products.

3. Regulation of homeopathic products

There are currently three licensing schemes for homeopathic products. Under each scheme, products must meet established standards of safety and quality but are not required to demonstrate efficacy.

- Product Licences of Right (PLRs) were issued to all medicinal products on the market at the time that the Medicines Act 1968 was implemented in 1971. Homeopathic products covered by PLRs may include indications.

- The Simplified Registration Scheme was introduced in 1992 under Article 14(1) of European Directive 2001/83/EC. Registered products are not allowed to include indications.

- The National Rules Scheme was introduced in 2006 under article 16(2) of European Directive 2001/83/EC to regularise the inconsistencies between these two schemes. It allows homeopathic products to be granted a marketing authorisation for the relief or treatment of mild, self-limiting conditions (those that can ordinarily be relieved or treated without the supervision or intervention of a doctor).

All homeopathic products must be licensed in one of the schemes and, where possible, companies are encouraged to re-register their existing PLR products in one of the two newer Schemes.

4. Specific requirements for advertising homeopathic medicines to the public

i. Homeopathic Products with Product Licences of Right

Schedule 32 of the Regulations provides that advertising of homeopathic products covered by product licences of right is subject to the provisions of the Medicines (Labelling and Advertising to the Public) Regulations 1978 (SI 1978/41). These products are not covered by Part 14 of the Human Medicines Regulations 2012.

Under the 1978 regulations, the following are not acceptable:

- Promotion of a product for any disease listed in the relevant schedules to the regulations unless the specific requirements are complied with; and

- Advertising for a product which makes reference to the Advisory Board on the Registration of Homeopathic Products, the Commission on Human Medicines, the MHRA or the Licensing Authority.

ii. Homeopathic Products registered under the Simplified Scheme

Advertising for homeopathic products granted a certificate of registration under Part 6 of the Regulations (the Simplified Scheme) is regulated under Part 14 of the Regulations. Regulation 301 governs advertising of registered homeopathic products. Only the information listed in schedule 28 to the Regulations, and included on the product labelling registered with the MHRA, , may be included

in advertisements for the product. No mention of a specific indication or therapeutic claims may be made. Advice on permitted labelling is available at:

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007550&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB

Company or product-specific leaflets available at the point of sale are subject to the same restrictions. This does not prohibit the availability at the point of sale of general homeopathic reference materials such as books and independently authored periodicals (e.g. a Materia Medica) describing the uses of a wide range of homeopathic substances.

iii. Homeopathic Products authorised under the National Rules Scheme

Advertising of homeopathic products granted a marketing authorisation under Part 5 and schedule 10 of the Regulations (the National Rules Scheme) is also regulated under Part 14 of the Regulations. Companies may include the homeopathic use of the product in their advertising. Promotional claims must be consistent with the authorised indication for the product and clearly state that the product is a homeopathic medicinal product used within the UK homeopathic tradition for that indication.

The indication is based upon UK homoeopathic practitioners' traditional homeopathic use of the product, and product claims and advertising must be clearly set in the context of traditional use. Advertising that implies that a product's efficacy is based on clinical trial data, or the use of wording to imply that efficacy has been demonstrated, such as 'effective for', or 'works fast to relieve', is not acceptable.

There is an obvious risk of exaggerating the benefits of the product and misleading the consumer if an advertisement presents the results of a clinical trial apparently demonstrating efficacy if information is not clearly set within this context and related to the homeopathic tradition.

Other requirements for Simplified and National Rules products: All of the general rules about medicines advertising as set out in Part 14 of the Regulations apply to these homeopathic medicinal products. For ease of reference, Annex 1 provides a summary list of the other legal restrictions on advertising medicines to the public that apply to these homeopathic medicines. As for all medicines, homeopathic medicinal products should not be described in any advertising or promotional material as "essential" for a general population including people not suffering from any condition.

iv. Homeopathic products not registered or authorised by the MHRA

Advertising of unlicensed medicines in the UK is prohibited. Therefore homeopathic products which do not hold a current registration or authorisation under one of the above schemes must not be advertised.

v. Remedy kits

Remedy kits advertised for specific purposes, e.g. “Childbirth Kit”, may only contain products that are licensed by the MHRA and that have indications (or usage within the homeopathic tradition for Simplified Scheme products) that are relevant to the condition. No product claims may be made for any other kit.

5. Advertising homeopathy services

Homeopathic practitioners may promote the service they provide for the public, e.g. the availability of a homeopathic consultation service. Details of products in any advertising must be limited to those licensed by the MHRA and must comply with the requirements set out in section 4 above.

These restrictions apply equally to advertising on the **internet**. Product information, including sales material and any online purchase facility, may only be provided for licensed products.

Any service that offers advice about treatment options based on answers to questions online should ensure that it does not suggest that a medical consultation is unnecessary. Only licensed products for minor, self limiting conditions may be offered without an individual consultation with a homeopathic practitioner.

For more information, the Borderline Unit has provided specific guidance on how a company can give customers information on websites without making medicinal claims. This is available at:

“The Medicines Borderline Section and the Internet”
http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON2023338&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB

Companies holding a ‘specials’ manufacturing licence may advertise that they make up individualised remedies to order for healthcare professionals[1], e.g. “We can make to order remedies for your patients”. It should be clear that these remedies are not available for supply directly to the public.

It is only appropriate to advertise this facility to healthcare professionals who are authorised to have specials supplied to them[2].

‘Specials’ manufacturers must not advertise or otherwise solicit orders for specific unlicensed products. This does not preclude them from sending out simple price lists to healthcare professionals to whom the price of specials may be relevant, such as potential customers and budget managers. Price lists can

[1] Healthcare professional is defined in regulation 8 of the Human Medicines Regulations 2012, SI 2012/1916. Healthcare professionals are subject to statutory regulation by a body such as the General Medical Council or Health and Care Professions Council.
[2] For more information on the type of healthcare professionals to whom specials may be supplied, see regulations 167 and 168 of the Human Medicines Regulations 2012.

be sent out at reasonable intervals or in response to an enquiry and must not include product claims.

Registered pharmacies may also advertise that they offer a service to provide individualised remedies to the customer's specification. In this case the customer does not have to be a healthcare professional.

In each case, details of individualised remedies that may be made up specifically for a patient's condition should not be provided as this may promote a homeopathic product which is not registered or authorised. For example. "Hayfever Mix" or "An individualised remedy containing XXX and YYY to help relieve stress" would not be acceptable.

All these requirements apply equally to advertising on the **internet**. A factual list of homeopathic ingredients and prices may be provided such as an A-Z list of ingredients and potencies available. The list must not link to any product claims since this is likely to be seen as making claims for and promoting the products. Information and links on the home page should refer to the service being offered and not to products.

Alternatively, a list of generic homeopathic substances and their general use within the homeopathic tradition can be included for general information. Usage information can only be provided if specific unlicensed homeopathic products and product claims are not made and sales information, for example a purchase facility, is not provided on the website. See the advice referred to above on "The Medicines Borderline Section and the Internet" for further guidance.

6. Further information and guidance

Advice on advertising medicinal products is available from the MHRA Advertising Standards Unit at advertising@mhra.gsi.gov.uk and in the Blue Guide, *Advertising and Promotion of medicines in the UK*, on the MHRA website at:

http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf

General information about homeopathic medicines and the licensing schemes is available on the MHRA website at:

http://www.mhra.gov.uk/Howweregulate/Medicines/Homeopathicmedicines/index.htm

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Annex 1

This annex briefly summarises the general requirements under the legislation on advertising to the public for homeopathic medicines authorised under the National Rules and Simplified Schemes.

A. Statutory requirements for advertising to the public

All advertising to the public of homeopathic medicines authorised under the National Rules Scheme must include:

- the name of the product or a reasonable abbreviation thereof,
- the scientific name(s) of the stocks,
- at least one indication for use consistent with the terms in the SPC,
- a clear and legible invitation to “Always read the label” or leaflet,

The only exception is for promotional aids which may only contain the brand name of the product, trademark or the scientific name(s) of the stocks.

For homeopathic medicines under the Simplified Scheme the information that may be contained in advertising is limited to the items permitted for inclusion on the labelling of the product. No other information may be included.

B. Summary of other key statutory requirements

A homeopathic medicinal product must not be promoted before a registration/marketing authorisation is granted.

All advertising must:

- comply with the particulars listed in the summary of product characteristics (SPC);
- encourage the rational use of the product by presenting it objectively and without exaggerating its properties;
- not be misleading.

All promotional material must be clearly identified as an advertisement.

Manufacturers and suppliers must not provide free sample(s) of a homeopathic product to any member of the public.

C. What advertising must not include

Advertising to the public must not:

- give the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, telephone or other electronic communication;

- suggest that the effects of taking the medicinal product are guaranteed, are not accompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product;
- suggest that health can be enhanced by taking the medicinal product;
- suggest that health could be affected by not taking the medicinal product;
- be directed exclusively or principally at children;
- refer to a recommendation by scientists, healthcare professionals or persons who because of their celebrity, could encourage the consumption of medicinal products;
- suggest that the medicinal product is a foodstuff, cosmetic or other consumer product;
- suggest that the safety or efficacy of the product is due to the fact that it is natural;
- be such that it might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;
- refer, in improper, alarming or misleading terms, to claims of recovery;
- use, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts of it.

D. Further information

For further information, consult the Blue Guide, *Advertising and Promotion of medicines* available on the MHRA website at:

http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf

Appendix 3

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 Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916).

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 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. The *Prescribing in pregnancy* section 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 humans but no drug is safe beyond all doubt in early pregnancy. Screening procedures are available where there is a known risk of certain defects.
>
> **Absence of information does not imply safety.**

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

Regulations 282 to 293 of the Human Medicines Regulations 2012 lay down the requirements and restrictions for 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 healthcare professionals includes promotion of prescription only medicines and over-the-counter products. Regulations 294 to 300 of the Human Medicines Regulations 2012 lay 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 Part 14 of the 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 states that in the overall assessment, all available knowledge should be taken into account, including clinical studies and post-marketing surveillance, pharmacological activity, results from non-clinical studies, and knowledge about compounds within the same class.

In the section on pregnancy, it states that the following should be mentioned:

- Recommendations on the use of the medicinal product during the different periods of gestation, including the reason(s) for these recommendations.

- Recommendations for the management of exposure during pregnancy when appropriate.

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Appendix 4

Best practice guidance on the sale of medicines for pain relief

- **Don't sell more than two packs in any one transaction**
- **Don't use offers that encourage the sale of more than one pack**

What is best practice?

Sales:
Sales of medicines for pain relief should be restricted to a maximum of two packs in any one transaction.

Explanation:
This limit is a reasonable balance between meeting a customer's immediate need for pain relief while helping to minimise stockpiling and accidental or impulsive overdose.

Tools to implement this best practice include:

- Till bars to prevent purchase of more than two packs.

- Regular training for staff on the restrictions, the reason for them, and how to respond to customers who want to buy larger quantities.

- Notices on shelving for customers and in the payment area for staff to raise awareness.

Offers:
Promotional offers on medicines for pain relief should not directly encourage the purchase of more than one pack.

Explanation:
Multi-buy offers such as 'buy one get one free' or 'buy 2 for £xx' may encourage consumers to purchase more packs than they currently need. The customer may stockpile excess packs, which pose a danger for accidental or impulsive overdose.

Please note: This guidance does not prevent reduced price offers on single packs.

Why are these restrictions needed?

Medicines for pain relief on general sale are effective and acceptably safe when used according to the label instructions. But there is evidence to show that people sometimes use large quantities of these medicines impulsively. Restricting the availability of pain relief medicines for purchase and in the home is effective in reducing the number of hospital admissions and deaths from accidental or impulsive overdose.

What does the law say?

The maximum pack size for pain relief medicines in a general sale outlet is 16 tablets or capsules. A pharmacy may sell larger packs containing up to 32 tablets or capsules under the supervision of a pharmacist. It is illegal to sell more than 100 tablets or capsules of either paracetamol or aspirin in any one retail transaction.

Where can I get further advice and information?

The Medicines and Healthcare products Regulatory Agency (MHRA) has developed this guidance with stakeholders representing large and small retailers, pharmacists, trading standards offices and the pharmaceutical industry. It applies to all solid dose (oral tablet or capsule) medicines for pain relief sold without pharmacist supervision. Additional restrictions apply to certain products available only from pharmacies.

Further advice on these voluntary restrictions is available from your trade association, local trading standards office or from MHRA Customer Services at info@mhra.gsi.gov.uk.

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Appendix 5

Reporting to the public on medicines: Advice for journalists and patient organisations

Health issues always hit the headlines and access to health information is important in empowering people to make informed decisions about their health care. Articles often draw attention to a prescription only medicine (POM) or results from trials on new products still in research. Yet the advertising legislation prevents these medicines being advertised to the public and the law applies to 'any person' - not just pharmaceutical companies. So what do journalists and patient organisations need to do to ensure they stay within the law when writing about medicines? Reporting information fairly and accurately while ensuring a balanced view is represented is paramount. Paying attention to these will help ensure the ban on advertising prescription medicines does not become an issue. The bottom line is - keep it factual and balanced to keep out of the advertising controls.

Background – what the law says

There are a number of legal safeguards on advertising medicines intended to protect public health. These apply to materials which fall within the definition of an 'advertisement', which broadly speaking is anything "designed to promote the prescription, supply, sale or consumption" of a medicine.

The safeguards include a ban on advertising medicines which have not been granted a marketing authorisation and on advertising prescription only medicines to the public. They also state that advertisements must present medicines objectively, without exaggerating their properties and that advertisements must not be misleading.

The key point is that these controls (and the penalties for breaches) apply to **any person** who promotes a medicine - not just the manufacturer. This can potentially include newspaper or magazine articles or information disseminated by a patient organisation.

How is the advertising law interpreted

A judgment from the **European Court of Justice**[1] has provided clarification of the advertising law. The Court held that under European law "dissemination by a third party of information about a medicinal product, including its therapeutic or prophylactic properties, may be regarded as advertising …, even though the third party in question is acting on his own initiative and completely

[1] Details of Case C421/07 (Reference for a preliminary ruling from the Vestre Landsret, Denmark: Criminal proceedings against Frede Damgaard) are available at: http://curia.europa.eu/jurisp/cgi-bin/form.pl?lang=en&alljur=alljur&jurcdj=jurcdj&jurtpi=jurtpi&jurtfp=jurtfp&numaff=&nomusuel=damgaard&docnodecision=docnodecision&allcommjo=allcommjo&affint=affint&affclose=affclose&alldocrec=alldocrec&docor=docor&docav=docav&docsom=docsom&docinf=docinf&alldocnorec=alldocnorec&docnoor=docnoor&radtypeord=on&newform=newform&docj=docj&docop=docop&docnoj=docnoj&typeord=ALL&domaine=&mots=&resmax=100&Submit=Rechercher

independently, *de jure* and *de facto*, of the manufacturer and the seller of such a medicinal product".

The Court reaffirmed that any person could be viewed as promoting a medicine and proof of a commercial link to the sale of the product was not required. The Court went on to advise that the national courts were best placed to decide on individual cases, balancing the right to free speech against the potential for damage to public health that the law is designed to protect.

So what does this mean in practice?

Implications for journalists

Provided they are intended to inform rather than promote medicines, articles discussing potential treatments won't fall within the scope of the legislation on advertising medicines[2] – the legal restrictions don't prevent balanced factual reporting. But articles should not actively encourage readers to seek a particular product from their healthcare provider and must take care not to exaggerate the potential benefits. It can be hard for a healthcare provider to explain to a patient who has read about the latest 'wonder drug' that it is not in fact suitable for them or not yet available.

Articles discussing healthcare issues, particularly medicines, ought to be factual, well balanced and accurate. Readers who may be suffering from a distressing and disabling condition are entitled to balanced and accurate information that does not raise false hopes or unnecessary worries about their treatment.

Implications for patient organisations

Patient organisations have a clear and important role in providing information on medical conditions and advice on the therapeutic and other management options available. Most have robust procedures to ensure they retain their independence from pharmaceutical companies who may contribute to their support. Even if information provided about treatment is supported by an educational grant from a pharmaceutical company, if editorial control is with the charity and it can demonstrate independent procedures, the material would not be deemed to be promotional. As explained above, patient organisations should not actively encourage people to seek a particular product from their healthcare provider.

Charities take great care to ensure the advice they issue is in line with current clinical evidence and best medical practice, and of course they always have the best interests of members at heart. They often have a reference group including healthcare professionals who are specialists in the area to ensure materials are factual and balanced, and will be able in future to demonstrate quality by certification under the Information Standard[3].

[2] Part 14 of the Human Medicines Regulations 2012 (SI 2012/1916).
[3] For further information see http://www.theinformationstandard.org/.

Implications for other information providers
If you are an independent provider of information about medicines, the principles are the same. Keep the information factual and balanced, and do not directly encourage readers to seek a particular product.

Further information on regulation of the promotion of medicines in the UK is available in the MHRA Blue Guide[4] or from the MHRA Advertising Standards Unit, email advertising@mhra.gsi.gov.uk.

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[4] The MHRA Blue Guide, *Advertising and promotion of medicines in the UK*, available at:

http://www.mhra.gov.uk/home/idcplg?IdcService=GET_FILE&dDocName=CON007552&RevisionSelectionMethod=Latest&noSaveAs=0&Rendition=WEB

Appendix 6

Advertising of medicines: Guidance for consumer websites offering medicinal treatment services

1. Purpose

This guidance has been developed by the Medicines and Healthcare products Regulatory Agency (MHRA) and is supplementary to the regulatory framework as set out in Part 14 of Human Medicines Regulations 2012 (SI 2012/1916) which implement Titles VIII and VIIIa of European Directive 2001/83/EC. General advice on compliance with the Regulations is given in the MHRA Blue Guide.

The internet is used widely to provide information to consumers and to promote products and services. This guidance is intended primarily for companies and organisations which do not hold marketing authorisations for medicines but which provide services that may lead to the prescription and supply of a prescription only medicine (POM). The guidance seeks to ensure that the content of such websites does not contravene the Regulations. In particular, it highlights the prohibition by regulation 284 of the Regulations of advertisements to the public likely to lead to the use of a POM. It is designed to help advertisers to promote their services without promoting specific POM medicines and thereby coming within the scope of the Regulations.

If a complaint is received, the decision on whether a particular website complies with the Regulations will be taken by the MHRA on a case by case basis, having regard to the circumstances of the particular case.

2. Scope of guidance

This guidance covers all websites for consumers, registered in the UK or aimed at the UK audience, which provide services that may lead to the prescription and supply of a POM. Such sites must not promote POMs to the public as this is in breach of UK medicines advertising legislation.

The guidance does not cover websites directed at healthcare professionals.

3. General principles

Online services such as online clinics or pharmacies may promote the service they provide (e.g. medical consultation for individuals with erectile dysfunction or treatments for lines and wrinkles). They may give information on a certain condition and its management, which may include a balanced overview of the range of therapeutic options. Such material should not draw attention to

specific prescription only medicines (POMs) since this is likely to breach the Regulations by encouraging individuals to request a particular treatment and this may result in the prescription and use of a POM. 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. Prescribers have a responsibility to provide information about the products they prescribe.

4. Guidance on ensuring website content does not promote medicines

Information on a particular condition or disease may be provided on websites. Care must be taken when providing information relating to POMs. This should be presented in the context of a balanced overview of all treatment options and relevant disease information. Further specific advice is available in the MHRA Disease Awareness Guidelines in the Blue Guide.

The Home page should focus on medical conditions and the service the website provides and should not include any reference to named POMs, including price information (see below). Links and navigation aids may be given for particular conditions and diseases but not to specific POMs. Hover text and any small print at the bottom of the home page should also not refer to specific POMs. This provision is designed to ensure that casual browsers are not presented with advertising for specific POMs.

Further pages about the condition, which the consumer chooses to access, may contain information on specific medicines provided this is presented in the context of a fair overview of the treatment options.

It should be clear that the customer is being offered a medical consultation and that this may or may not lead to the provision of a prescription.

Prices

On the homepage, only indicative prices for a particular medical condition may be provided, for example, “Erectile dysfunction treatment - £20 for a medical consultation, £50 for an initial course of 4 tablets.” Any mention of prescription only medicines on the home page is likely to be considered as advertising of prescription only medicines to the public. A factual list of prices for available treatments and/or pack sizes may be provided on pages other than the home page. The price list should not include product claims or actively encourage viewers to choose a product based on the price.

Special offers on prices of medicines should not be highlighted on the website as they are likely to promote the specific prescription only medicine.

The information associated with price lists should make it clear that the viewer’s preferred option will not be prescribed if it is not suitable. Decisions about treatment are for the prescriber and patient to jointly consider during consultation and are not based solely on the price.

Icons
It is permissible to use icons to encourage people to undertake a medical consultation. Icons or other features encouraging the purchase of POMs for example, “Buy Now”, “Buy XXX”, “Add to Basket”, etc. should not be used on websites offering POM treatments. These invite consumers to purchase POMs and are intended to promote sales.

Promotional claims
Specific POMs should not be promoted as this is likely to encourage the purchase of a POM and contravene the Regulations. All information about medicines should be balanced and factual, for example “XXX is used to treat …” rather than “XXX, the best/fastest/strongest/etc. treatment for …”. Suitable sources of non-promotional material may include the patient information leaflet or summary of product characteristics for the product, often available on the UK website of the company marketing the product.

Unlicensed medicines should not be mentioned, to comply with regulation 279 of the Regulations which prohibits advertising of medicines for which no marketing authorisation or registration is in force.

Competitive Tools (Meta-tags/ Meta-descriptions/ Meta-Keywords)
Our main focus is the content of the website, rather than the competitive tools used to increase awareness of the website which are not usually prominent in customer views.

Website addresses
Website addresses should not name specific POMs in their core URL (e.g. www.wesellXXX.co.uk). Website addresses like this may be considered to promote a POM to the public.

Sponsored links
The text may promote the service provided but should not mention specific prescription only medicines.

5. Prescription dispensing services

Where a website dispensing service is aimed specifically at patients who already have a prescription, provided no product claims are made beyond a simple disease category, the MHRA would not object to a list of products and dispensing prices.

Where a dispensing service is promoted in association with an online consultation service, the restrictions in section 4 above will apply.

6. Enforcement priorities

Our enforcement approach for web-based treatment services takes the potential risk to public health into account. We focus primarily on material on

the home pages of clinic websites. The aim is to ensure that customers who are seeking general information on the internet about a clinic or potential treatments are not presented with overt advertising for POMs. This is similar to our approach for other forms of advertising for services, e.g. in magazines, where mention of POMs is not permitted.

To target our resources, we have chosen not to focus on information that is found by the browser who chooses to access information about specific treatment options for their condition on a clinic website. The MHRA will not routinely review material on website pages other than the home page unless we consider that the information poses a risk to public health.

The MHRA takes robust enforcement action where a significant risk to public health has been identified from advertising to the public for unlicensed or prescription only medicines.

Failure to comply with the Regulations will result in a request for the website to be amended or withdrawn. Cases may also be referred to the Inspection, Enforcement and Standards Division for consideration of legal action. Clinics and individual healthcare professionals may also be referred to their professional regulators if compliance is not achieved in a timely fashion.

7. Further information

Further information and advice is available from the MHRA Advertising Standards Unit at advertising@mhra.gsi.gov.uk and in the Blue Guide[5], *Advertising and Promotion of medicines in the UK*, available on the MHRA website.

Registered pharmacies are also encouraged to display the Internet Pharmacy logo of the General Pharmaceutical Council (GPhC) on their website home page to assure consumers that medicines are supplied by a registered pharmacy. Details of this scheme and how to join are available on the GPhC website at: http://www.pharmacyregulation.org/regulatingpharmacy/registration/internetpharmacy/index.aspx.

The websites of pharmaceutical companies are covered by self regulatory codes of practice operated by the Prescription Medicines Code of Practice Authority[6] and the Proprietary Association of Great Britain[7].

The Advertising Standards Authority has a general remit to ensure that advertising, including advertising on companies' own websites, complies with

[5] The MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK,* is available on the MHRA website at www.mhra.gov.uk.
[6] The ABPI Code of Practice for the Pharmaceutical Industry covers prescription medicines and is available on the PMCPA website at www.pmcpa.org.uk.
[7] The PAGB Medicines Advertising Codes cover over-the-counter medicines and a summary is available on the PAGB website at www.pagb.org.uk.

the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing. Details of their work are available at www.asa.org.uk.

Clinics may also be regulated by the Care Quality Commission (www.cqc.org.uk) and individual prescribers by their own professional body (e.g. the General Medical Council for doctors).

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Appendix 7

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; Part 14 of the Human Medicines Regulations 2012 (S.I. 2012/1916). 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 healthcare 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

8. 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 healthcare 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 the MHRA Blue Guide, *Advertising and Promotion of Medicines in the UK*, available from the MHRA website at http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf or from the Stationery Office.

MHRA
July 2012

Appendix 8

Guidance on review of advertising by an Independent Review Panel

1. Introduction

1.1 The MHRA on behalf of Health Ministers may serve a "minded to" notice on a company advising it that it is minded to determine that an advertisement, if published, would be in breach of the legislation on advertising medicines (see regulation (305 of the Human Medicines Regulations 2012 (SI 2012/1916)). This note outlines the procedure for requesting a review of such a notice by the Independent Review Panel for Advertising (IRP).

1.2 The MHRA will normally contact a company informally to advise them that there are some concerns about a particular advertisement. This may be a result of routine monitoring by the Advertising Standards Unit or as a result of a complaint received by the MHRA. The company will be asked for comments and may be asked to supply other promotional material for the product before being given the MHRA's opinion on the acceptability of the original advertisement. There are in the advertising legislation powers to require copies of advertisements, including advance copies, to be supplied to the MHRA.

1.3 This guidance provides advice on what steps you need to take if your company receives a "minded to" notice and explains the review procedure.

2. When to ask for a review

2.1 If the MHRA has raised concerns with you that cannot be resolved informally, the MHRA may issue a "minded to" notice under regulation 305 of the Regulations. The notice will set out the reasons for MHRA's position and will be supplemented by any relevant supporting evidence and assessment reports. You will be informed in the notice of your right to make written representations prior to the making of a final determination by the MHRA (acting on behalf of Health Ministers), provided these are made within 21 days.

2.2 Any representations made will be referred to an Independent Review Panel in order for them to give advice to the MHRA as to the determination which should be made. The Panel is designed to provide a rapid and independent review of the matters at issue, should you request it, prior to a decision being made by the MHRA on an advertisement. It does not replace or substitute the legal right to apply for a judicial review.

The Independent Review Panel does not have the remit to consider any other advertising issues.

2.3 The panel will normally consist of three persons, a legally qualified Chairman, a medically or pharmaceutically qualified person and a person with experience in consumer affairs. The members will not represent any particular organisation but will use their experience in giving advice to the MHRA. If the case concerns advertising for a traditional herbal medicine, an additional member with relevant specialist expertise may be chosen by the Chairman. The Panel will be served by a Secretariat provided by MHRA and made up of officers who have no involvement in the assessment of advertising material.

2.4 Panel members will be required to follow the Code of Practice on Relations within the Pharmaceutical Industry and accordingly declare any interest in any matter before the Panel and withdraw from any matter in which they have a conflict of interest.

3. What to do

3.1 Where the "minded to" notice includes a requirement that the advertisement should not be published pending the withdrawal of the notice, you must comply with the requirement until the review is completed or the earlier withdrawal of the notice.

3.2 If you wish for a review, you must reply to the notice within 21 days of the date of the notice setting out in a written representation why you consider that the advertisement would not be in breach. The letter should be addressed to the Secretary to the Independent Review Panel at the address given in section 6 of this guidance. The MHRA will require six copies of the representation.

3.3 You should provide full details of why you believe the advertisement would not be in breach and include all additional information which you consider will support your views. This submission should be limited to addressing the specific issues raised in the notice only but should include all the points you wish to raise before the Panel. There will be no automatic right to an oral hearing but if you feel that an oral hearing would help you to present your case, you may include a request with your written representation giving reasons.

4. What happens next?

4.1 Your written representations will be forwarded to the MHRA Advertising Standards Unit for review. If you have included in your written representation any relevant information which was not available to the MHRA during earlier negotiations, and which could have materially affected the "minded to" notice, the advertisement will be reconsidered.

If appropriate, a revised "minded to" notice will be served, restarting the process. Alternatively the MHRA may notify you that one or more of the grounds set out in the notice are withdrawn and no longer at issue before the Panel. The MHRA will also consider whether, in the light of representations made, the "minded to" notice should be withdrawn without referring the matter to the Panel.

4.2 Your written representations, together with the MHRA papers, will also be provided to the Independent Review Panel (through the Secretariat). The MHRA papers will consist of the notice and supplementary evidence and assessment reports referred to in point 2.1, a copy of the advertising material and supporting references, details of the original complaint and copies of all correspondence with the company relating to the assessment of the complaint.

4.3 If you have requested an oral hearing, the Panel will decide, taking into account any MHRA views, whether an oral hearing is required in order to ensure fairness, having particular regard to the complexity of the issues in the case. The MHRA may also request an oral hearing but has stated, as a matter of policy, that it will not normally do so. When an oral hearing is to take place the hearing will be set for a time and place as notified by the Panel (taking into account any representations made by the parties). Where an oral hearing is not to take place, the Panel will inform the parties of the date on which it will settle its advice. The date of the Panel meeting will normally be within 4 to 6 weeks of the date of receipt of your written representations.

4.4 With the notification of the Panel date you will also receive any MHRA response to the points raised in your representations (see point 4.1 above) and copies of any additional MHRA papers not provided with the original “minded to” letter. The MHRA will either copy to you any of this material which did not accompany the original "minded to" letter, or (where you already have the material) will inform you of the fact that it is relying on it.

4.5 The Panel may also call for further information from either party or from an independent expert. Any material lodged with the Panel will be made available to both parties.

4.6 If an oral hearing is held, both you and the MHRA may attend to answer questions from the Panel. The MHRA will first be given the opportunity to answer any questions from the Panel. You will then be given the opportunity to answer the Panel’s questions and respond to MHRA's points at issue. Both the company and the MHRA representatives will then withdraw when the Panel begins their detailed discussion of the case leaving only the Panel members themselves and the Secretariat members.

4.7 At an oral hearing, a party may only call witnesses if the Panel, on application, considers that this is necessary in order to clarify any matter

or otherwise ensure fairness. The normal procedure of the Panel will be to consider written submissions and supporting evidence and you should include any witness statements in your written evidence, assuming that oral evidence from witnesses will not be required. The Panel may request witnesses to attend of its own motion. Either party may present all or part of its case through an in-house lawyer. However, a party may only be represented by independent Counsel in exceptional circumstances and the Panel will only accede to a request to be so represented if it concludes that, without Counsel, a party would not be able to present its case to the Panel with sufficient clarity, or otherwise so as to ensure fairness. The Panel may settle its advice without an oral hearing if you fail to appear at the date and time set for the hearing.

4.8 An oral hearing will be in private with support from the Panel Secretariat. The Panel may adjourn an oral hearing date or the date on which it will settle its advice (as the case may be) on application or on its own initiative.

4.9 The Panel will consider the advertisement for compliance with the Regulations, taking into account the papers submitted by the MHRA, the written representations received from the company, and any oral representations made by the parties. The Panel will settle its advice, if necessary, by majority verdict. The Panel's advice will be put in writing, giving full reasons, and forwarded to the Advertising Standards Unit.

4.10 Following the sitting of the Panel, the MHRA (acting on behalf of Health Ministers) will make a final determination on the advertisement taking into account the advice of the Panel. You will normally be advised of the final decision within 21 days of the Panel sitting, and will be informed of any delay and the reasons for it, if this deadline is not met.

4.11 The MHRA will notify the company of the final determination and the reasons for any determination that the advertisement would be in breach. It will include a copy of the Panel’s advice and will specifically point out any divergence between a determination that the advertisement would be in breach and the Panel's advice, and give the reasons for this.

4.12 At the close of the case, a report including the advice of the Panel and the final determination of Health Ministers will be published on the MHRA website (subject to the exclusion of any confidential material). This will also include copies of all representations to the Panel unless these have been identified as confidential by the company concerned.

5. What if I still disagree?

5.1 There is no right of appeal against the final determination that the advertisement would breach the Regulations, but you may apply for it to be judicially reviewed. If the notice of final determination requires you to refrain from publishing the advertisement and you decide to disregard the notice and re-issue the advertisement without amendment, the

MHRA may take further action. This may take the form of injunctive action to prevent the publication of the advertisement or a prosecution for an offence under the Human Medicines Regulations.

6. Further information

6.1 Further advice about advertising policy can be obtained from:

Advertising Standards Unit
Area 3-M MHRA
151 Buckingham Palace Road
LONDON SW1W 9SZ
Tel: 020 3080 6765/6039
Email: advertising@mhra.gsi.gov.uk

6.2 Further advice about the Independent Review Panel and its processes can be obtained from the Secretariat:

Independent Review Panel Secretariat
Area 4-T MHRA
151 Buckingham Palace Road
LONDON SW1W 9SZ
Tel: 020 3080 6959
Email: expertcommittee@mhra.gsi.gov.uk

MHRA
July 2012

GLOSSARY

AA	Advertising Association
ABPI	Association of the British Pharmaceutical Industry
Advertising Regulations	The Medicines (Advertising) Regulations 1994, SI 1994/1932 as amended.
ASA	Advertising Standards Authority
ATMP	Advanced Therapy Medicinal Product
AWMSG	All Wales Medicines Strategy Group
BCAP	Broadcast Committee of Advertising Practice
BHMA	British Herbal Medicine Association
BMA	British Medical Association
BNF	British National Formulary
CAP	Committee of Advertising Practice
Cm	Command Paper
Common Name	The international non-proprietary name (INN) or the usual common name.
DAC	Disease Awareness Campaign
DH	Department of Health
eMC	Electronic Medicines Compendium – a database of SPCs and PILs for licensed medicines, see http://www.medicines.org.uk/emc/
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EU	European Union

GP	General Practitioner
GPhC	General Pharmaceutical Council
GSL	General Sale List – medicines available without a prescription in pharmacies or non-pharmacy retail outlets
Healthcare professional	As defined in regulation 8 of the Human Medicines Regulations 2012. Healthcare professionals are subject to statutory regulation by a body such as the General Medical Council or Health and Care Professions Council.
HFMA	Health Food Manufacturers' Association
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
INN	International Non-proprietary Name
IRP	Independent Review Panel
MA	Marketing Authorisation
MALG	Medicines Advertising Liaison Group
MHRA	Medicines and Healthcare products Regulatory Agency
Monitoring Regulations	The Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 as amended.
NICE	National Institute for health and Clinical Excellence
Ofcom	Office of Communications
OFT	Office of Fair Trading
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

PAGB	Proprietary Association of Great Britain
PAR	Public Assessment Report
PGD	Patient Group Direction
PIL	Patient Information Leaflet (provided in a medicine pack)
PL	Product Licence
PLR	Product Licence of Right
PMCPA	Prescription Medicines Code of Practice Authority
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
RCN	Royal College of Nursing
RPS	Royal Pharmaceutical Society
S4C	Sianel Pedwar Cymru (Welsh television broadcasting service)
SFO	Serious Fraud Office
SI	Statutory Instrument
SMC	Scottish Medicines Consortium
SPC	Summary of Product Characteristics
‘Special’	An unlicensed medicine supplied to meet the special need of a patient
TSO	The Stationery Office

THM	Traditional Herbal Medicine
USR	Urgent Safety Restriction
VAT	Value Added Tax
Vetting	Review of promotional material prior to issue (sometimes called pre-vetting)