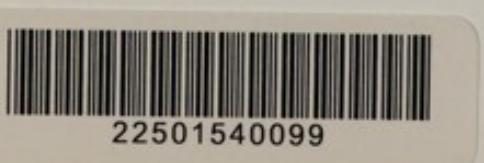
Advertising and promotion of medicines in the UK : guidance notes on the medicines (advertising) : regulations 1994 (as amended) / [Medicines Control Agency].

MCA

MEDICINES CONTROL AGENCY

Advertising and Promotion of Medicines in the UK



Advertising and

MEDICINES CONTROL AGENCY

Promotion of Medicines in the UK

Guidance notes on the Medicines (Advertising) Regulations 1994 (as amended)

London : The Stationery Office

MCA Guidance Note No. 23

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Contact for information:
Ms Elizabeth M Hopkins
Rm 926A Market Towers
Medicines Control Agency
1 Nine Elms Lane
London SW8 5NQ

Telephone: 020 7273 0281
Fax: 020 7273 0109

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Introduction

The guidance explains the provisions and requirements laid down in the Regulations and provides additional clarification, where necessary, on the interpretation of the Regulations and their application to certain commonly found situations.

It should be read alongside the Medicines Act 1968, the Medicines (Advertising) Regulations 1994, SI No. 1932, the Medicines (Monitoring of Advertising) Regulations 1994, SI No. 1933, the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, SI No. 3144, the Medicines (Advertising) Amendment Regulations 1996, SI No. 1552 and the Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999, SI No. 267. The Regulations implement Directive 92/28/EC in the United Kingdom and are to be interpreted accordingly.

References in the guidance to the 'Advertising Regulations' and to the 'Monitoring Regulations' are to the principal Regulations as amended. Similarly, where numbered regulations are quoted, the reference is to the principal Regulations.

Further guidance can be found in the codes of practice of self-regulatory and regulatory bodies concerned with the advertising and promotion of medicines referred to in Section 2.

The guidance does not replace, or constitute, formal decisions of the Licensing Authority or the Secretary of State and should not be taken as a complete or definitive statement of the law. Further advice can be obtained as necessary from the Advertising Unit, Post Licensing Division, MCA.

A list of references to statutory and non-statutory documents to which these guidelines refer is provided as Annex 1.

SECTION 1

Background

1.1 The legal basis for MCA control of medicines advertising

The legal basis for the control of advertising is contained in the Medicines (Advertising) Regulations 1994 and the Medicines (Monitoring of Advertising) Regulations 1994, both as amended. A detailed explanation is given in Annex 1.

The Advertising Regulations contain rules on the contents of advertisements and promotions. The Monitoring of Advertising Regulations contain rules on the making of complaints about advertisements, on applications to court by the Health Ministers and on the making of determinations by the Health Ministers as to whether the Advertising Regulations have been breached.

1.2 The role of self-regulation

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

1.3 Scope of the Regulations

The Regulations apply to promotional and advertising materials for all relevant medicinal products, which include proprietary and generic medicines, both for supply by prescription only and over the counter. Where regulations apply only to particular categories of products this is clearly stated, for example, registered homoeopathic remedies.

Under normal circumstances all advertising of relevant medicinal products will now be assessed for acceptability for issue by reference to the Advertising Regulations, which now fully implement Directive 92/28/EC, and not by reference to the Medicines Act.

Homoeopathic medicines covered by product licences of right (PLRs) remain subject to the Medicines Act and the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI No. 41.

1.4 Other legislation relevant to medicines advertising

The above Regulations relate specifically to medicines. Other consumer legislation which covers provisions for medicines, includes the Trade Description Act 1968 and supporting Regulations and the Broadcasting Acts 1990 and 1996, which are enforced by the Independent Television Commission, the Radio Authority and the Welsh Authority. The MCA is not responsible for administering this legislation and non-compliance is subject to enforcement by others.

1.5 Where to obtain the Regulations

Copies of the Regulations can be purchased from the Stationery Office (TSO), Books Publications Centre, PO Box 276, London SW8 5DT, through TSO book shops or from official agents for government publications and some are available on the TSO web site: http://www.hmso.gov.uk.
The relevant SI numbers for the Advertising and Monitoring Regulations are SI 1994/1932, SI 1994/1933, SI 1996/1552, SI 1999/267 and SI 1999/784.

1.6 Definitions used in the Regulations

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

The definition of advertising applied to medicines is not limited to specific media and includes articles in published journals, magazines and newspapers, display on posters and notices, photographs, film, broadcast

material, video recording, electronic transmissions and material posted on the Internet. Point of sale materials, informative leaflets, booklets and other promotional materials which include specific product claims and which are supplied separately from the product may also be considered 'advertisements'. Words forming part of a sound track or video recording are within the definition of advertising as is the spoken word.

Generally speaking, the labelling and package leaflet of a product which comply fully with the requirements of SI 1994/3144 and Directive 92/27/EC would not fall to be considered here.

A **'medicinal product'** is defined by European law (Article 1 of Directive 65/65/EC) as:

'Any substance or substances presented for treating or preventing disease in human beings or animals.'

(That is, in broad terms, a substance that is claimed to treat or prevent disease in human beings or animals.)

'Any substance or combination of substances which may be administered to human beings or animals with a view to making a diagnosis or to restoring, correcting or modifying physiological functions in human beings or animals is likewise considered a medicinal product.'

(That is, in broad terms, a substance which has an actual function of treating or preventing a disease, or otherwise altering bodily functions in human beings or animals.)

Further information on the definition of a medicinal product is available in MCA Guidance Note No. 8 *A guide to what is a medicinal product*.

A **'relevant medicinal product'** as defined in regulation 2 of the Advertising Regulations means:

'(a) a medicinal product for human use to which Chapters II to V of the 1965 Directive apply and accordingly includes products to which Title II of Council Regulation (EEC) No. 2309/93 applies,

(b) a substance or article for human use -

(i) to which Chapters II to V of the 1965 Directive apply, and

(ii) specified in an order made under section 104 or 105 of the Act or in regulations made under section 2(2) of the European Communities Act 1972, which direct that Part VI or any section of that Part of the Act has

effect in relation to such substance or article as that Part or section has effect in relation to medicinal products within the meaning of the Act, or

(c) a registered homoeopathic medicinal product, ...'

This definition was extended by the 1999 Amendment Regulations to make it clearer that products authorised under the centralised system are also subject to the Advertising Regulations and the Monitoring Regulations.

"'**Persons qualified to prescribe or supply**' includes persons and employees of such persons, who in the course of their profession or in the course of a business may lawfully prescribe, sell by retail or supply in circumstances corresponding to retail sale relevant medicinal products."

A '**promotional aid**' is a non-monetary gift made for a promotional purpose by a commercially interested party and is subject to the requirements of the Advertising and Monitoring Regulations.

1.7 Contact points

A list of useful contact points for information and advice about the advertising and promotion of medicines is given in Annex 2.

SECTION 2

General Principles and Responsibility for Compliance

2.1 General rules

In order to protect public health it is essential that advertising and promotion of medicines should be subject to effective monitoring and control at all times.

By regulation 3 of the Advertising Regulations, products which do not have a valid marketing authorisation may not be advertised for medicinal purposes (with the exception of products registered under the homoeopathic registration scheme). It is therefore in breach of the Regulations to issue any promotional material until the marketing authorisation has been granted. Companies can disseminate limited factual information to persons such as Health Authorities or trust hospital budget holders where that information may be significant to the planning of their expenditure over future years, for example, for novel medicines or new means of administration where the changes may have significant cost implications. The information should be targeted at those who need to make budgetary decisions rather than to prescribers.

By regulation 3A of the Advertising Regulations, an advertisement must comply with the particulars listed in the summary of product characteristics (SPC). Further it must encourage rational use (i.e. the correct and proper use) of the product by presenting it objectively and without exaggeration as to its safety, quality or efficacy.

The MCA considers that, in order for an advertisement to be 'objective' it must, in the first place, be accurate and factually verifiable. For instance, an advertisement would not be objective where it implied a cure for a condition when it provided merely short-term relief of symptoms. An advertisement would also not be 'objective' where it relies solely on the feelings or opinions of the advertiser. An advertisement would fail to encourage rational use where it tended to lead to inappropriate or incorrect use.

In the above example, rational use would not be encouraged because the advertisement would tend to encourage overuse of the product, with consequent risk.

All parts of an advertisement must be consistent with the approved SPC. The indications for use shown must be those approved on the marketing authorisation and should not be extended or extrapolated to include unauthorised uses. Advertising a licensed product for an unlicensed indication is prohibited. An advertisement should not give the impression that the product is particularly suitable for the elderly, young children or those with specific diseases or conditions unless the marketing authorisation clearly allows such use.

2.2 Advertising on the Internet

The definition of an advertisement under the Advertising Regulations incorporates that given under Section 92 of the Act, which is very broad and encompasses the Internet. In questions relating to the advertising and promotion of medicines a consistent approach should be taken to all media. The requirements and restrictions which apply to advertising directed at either the general public or to health professionals apply equally to material posted on the Internet.

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

Open access web sites of marketing authorisation (MA) holders can contain only approved SPCs, European public assessment reports (EPARs) and patient information leaflets (PILs) for POMs as it is considered that these sites have not been set up solely for health professionals.

There is an ongoing debate in Europe on the acceptability of Internet advertising of medicines. Therefore, until this is concluded, the MCA considers that advertisements for POMs are acceptable only on web sites whose nature and content is directed at health professionals.

2.3 Responsibility for advertising compliance

The primary responsibility for the content and dissemination of all advertising and promotion of a medicine lies with the MA holder, who is

also responsible for the training and conduct of medical representatives. A company will normally delegate final approval of all material to qualified signatories who will certify that the material meets the regulatory requirements. The appointment of qualified signatories for advertising purposes is a requirement of both the ABPI Code of Practice and, more recently, of the PAGB Code of Practice for Health Professionals. Companies are asked also to inform the MCA Advertising Unit of such appointments and of any subsequent changes.

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

The MA 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 MCA may request for consideration and to comply with any decisions taken by the MCA in respect of advertising and promotional material. Failure to do so is a criminal offence under the Regulations.

2.4 Pre-vetting of advertising material by other regulatory bodies representing the pharmaceutical industry and the media

Several trade associations for the pharmaceutical industry provide, as a condition of membership, that advertising material should be submitted to them for pre-vetting against their codes of practice before issue. Material which is intended for broadcast must also be approved as complying with the Independent Television Commission's Code of Advertising Standards and Practice for television advertising.

Bodies which pre-vet advertising for medicines include:

1 The Broadcast Advertising Clearance Centre (BACC)

The BACC approves advertising for television against the Independent Television Commission Code of Practice (see above) and provides advice on television advertising, producing comprehensive guidelines on all aspects of the code.

2 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 Consumer Code lays down standards for the advertising of OTC medicines to the general public. As a condition of membership, all advertising material directed to consumers must be submitted for approval against the Consumer Code before issue.

3 The Radio Advertising Clearance Centre (RACC)

The RACC is responsible for ensuring that medicines advertising on radio complies with the Radio Authority's Code (see below). All radio advertising must comply with the Code of Practice.

4 The Committee of Advertising Practice (CAP)

Although there is no compulsory pre-vetting of advertising of non-broadcast (including Internet) media, CAP offers, on request, to advertisers and publishers a free copy advice service concerning the British Codes of Advertising and Sales Promotion. Advertising Standards Authority (ASA) adjudication under these Codes frequently asks that the advertiser seeks CAP copy advice for future advertising.

2.5 Complaints about medicines advertising

Where a complaint is made directly to it, the MCA (as Licensing Authority) has a general duty under the legislation to consider that complaint. If the complaint refers to an alleged breach of regulation 9 or Part IV of the Advertising Regulations, the complaint is passed to a suitable self-regulatory body where both the MCA and the complainant agree. However, where the complaint has not been dealt with in a satisfactory manner within a reasonable timescale by the designated regulatory body the MCA is required to investigate the complaint.

Complaints about broadcast advertising which are received solely by the MCA are the Agency's responsibility and will be investigated or referred in the way described above. Where a complaint about a broadcast advertisement is received by both the Agency and the relevant statutory body (Independent Television Commission, Radio Authority or the Welsh Authority for S4C) or by the statutory authority alone, it is the responsibility of that body to investigate the complaint. These bodies were established under the Broadcasting Act 1990 and investigate complaints by reference to their individual codes of conduct. Their enforcement powers are contained in regulation 11 of the Monitoring Regulations and enable them to prevent

the publication or further publication of the advertisement, subject to an obligation to give reasons and review by the courts.

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

1 Advertising Standards Authority (ASA)

The Advertising Standards Authority investigates complaints about published medicines advertisements and ensures compliance with the British Codes of Advertising and Sales Promotion which include a section on medicines advertising. It also monitors advertising in the press, direct marketing and sales promotion and the Internet. Advertisements directed at health professionals are exempt from the British Codes of Advertising and Sales Promotion.

2 The Prescription Medicines Code of Practice Authority (PMCPA)

Complaints about the advertising of medicines supplied on prescription 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 promotional 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*.

3 The Proprietary Association of Great Britain (PAGB)

In addition to its Consumer Code the PAGB also operates a Professional Code of Practice for advertising directed at persons qualified to prescribe or supply medicines. However, the PAGB does not pre-vet advertising directed at professional or trade audiences. Complaints under the PAGB Professional Code of Practice are considered by the PAGB Secretariat and can be appealed to the Code of Practice Committee. Case reports are published in the *PAGB Bulletin*. 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 the above bodies are given in Annex 2.

SECTION 3

Advertising to the Public

3.1 Medicines suitable for advertising to the public

Advertising to the public is permitted for medicines legally classified pharmacy sale (P) or general sale list (GSL), subject to compliance with Part III of the Advertising Regulations. The Regulations prohibit the issue of any advertisement to the general public which is likely to lead to the use of a prescription only medicine (POM). Government controlled vaccination campaigns are exempt from this prohibition.

The Regulations prohibit advertising to the general public of medicinal products for the treatment, prevention or diagnosis of certain diseases or conditions which are specified in Annex 3. A specific exemption is provided for advertisements likely to lead to the use of medicinal products for the purpose of prevention of neural tube defects or for the purpose of the treatment of the symptoms of sprains or strains or the relief of pain or stiffness of rheumatic or non-serious arthritic conditions.

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 (Cmnd 2631, published by the Her Majesty's Stationery Office) or exempted under paragraphs 2 and 3 of Article 3 of the Psychotropic Drugs Convention 1971 (Cmnd 7330, published by HMSO) (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.

3.2 Prescription only medicines: press releases and other information to the media

Information on prescription medicines which is provided to the lay press, television or radio or by press releases must be factual and non-promotional

and should not encourage the general public to ask their GP to prescribe 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 medicines to the general public.

3.3 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.

3.4 Information necessary for the correct use of a medicine

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 lay down further rules for the timing of broadcast advertisements and the clarity and discernibility of statutory particulars.

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

3.5 Recommendations and endorsements

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

An advertisement should not refer to the fact that a medicine is licensed, either directly or indirectly, and should not infer that a product has MCA or DoH 'approval'. Similarly references to PL numbers in advertising to the general public, which are intended to promote a specific product as superior to competitive products, are not allowed.

3.6 Children

Advertising of medicines should not be directed exclusively or principally at children (under 16s).

3.7 Disease awareness and health education campaigns

Campaigns directed at the general public with a view to providing information, promoting awareness or educating the public on a particular condition or disease are encouraged. However, 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 medicine can all lead to a potential breach of the Regulations.

3.8 Samples for promotional purposes

The Advertising Regulations prohibit the sale or supply of samples of relevant medicinal products for promotional purposes to any member of the public. The prohibition encompasses not only marketing authorisation holders and persons acting on their behalf (such as distributors) but also all commercial undertakings including registered pharmacies, doctors, dentists, 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.

There is no prohibition under the Advertising Regulations on the provision of small sized packs of medicines for supply through normal trade outlets on normal business terms provided the necessary authorisation has been obtained to market the product. These smaller packs enable professionals and consumers to assess the benefits of a particular product at a reasonable cost.

SECTION 4

Advertising to Persons Qualified to Prescribe or Supply

4.1 Scope of 'persons qualified to prescribe or supply'

Part IV of the Regulations (with the exception of regulations 19, 20 and 21) applies to advertisements wholly or mainly directed at persons qualified to prescribe or supply relevant medicinal products. 'Persons qualified to prescribe or supply' (PQPS) as defined in the Regulations, includes persons who in the course of their profession or in the course of a business sell or supply medicinal products but does not include veterinary surgeons or veterinary practitioners.

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

This will include, *inter alia*, hospitals, health centres, doctors, dentists, nurses, pharmacists, pharmacy assistants, optometrists, chiropodists, midwives and other ancillary health workers and retail staff who are legally entitled to supply medicinal products directly to members of the public.

The Regulations require such advertising to include standard 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 particular requirements for 'abbreviated advertisements' (see page 26).

4.2 Provision of information for PQPS

Essential information compatible with the summary of product characteristics (SPC) 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. In any case all the particulars referred to in Annex 4 must be given.

The essential 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.

A copy of the approved SPC or data sheet must be sent or delivered with free samples supplied to prescribers and be available from medical representatives at visits where a particular product is promoted.

4.3 Abbreviated advertisements

Abbreviated advertisements 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.

4.4 Promotional aids

Advertisements relating to products which are on a promotional aid (e.g. the supply of an item such as a pen, notepad, mug) and which consist solely of the name of the product and the name of the company involved are exempt from the need to include other essential information. The value of such items should be around £5 or less (excluding VAT) to the donor, represent a similar value to the recipient and must comply with the requirements of regulation 21. Items used as promotional aids must be relevant to the practice of medicine or pharmacy.

4.5 Advertising intended for international publication

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

Material relating to products which do not hold UK marketing

authorisations which is displayed or available on request at international symposia, conferences and other meetings is permitted, provided that a significant proportion of the attendees are from outside the UK and the material is relevant, proportional to the purpose of the meeting and clearly and prominently indicates that the product is unlicensed in the UK.

4.6 Professional samples

Regulation 19 applies to the supply of a free sample of a medicinal product to a person who receives it for the purpose of acquiring experience in dealing with the product. Such a sample may only be supplied to a person qualified to prescribe medicinal products, and on the following conditions:

(i) they shall be supplied on an exceptional basis only;

(ii) a limited number only of samples of each product may be supplied in any one year to any one recipient;

(iii) they should be supplied only in response to a written request, signed and dated, from the recipient;

(iv) suppliers shall maintain an adequate system of control and accountability;

(v) they shall be no larger than the smallest presentation available for sale in the UK;

(vi) they must be appropriately labelled and be marked 'free medical sample - not for resale' (or similar);

(vii) every sample shall be accompanied by a copy of the approved SPC.

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

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

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

4.7 Medical sales representatives

Medical sales representatives must be given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and complete as possible about the products they are promoting. Both the Association of the British Pharmaceutical Industry (ABPI) and the Proprietary Association of Great Britain (PAGB) provide training programmes for representatives. (Further details are available from the addresses in Annex 2.)

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

4.8 Gifts, inducements and other benefits

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

Any promotional activity which is intended to encourage the purchase or sale of a relevant medicinal product by PQPS is encompassed by regulation 21. This includes advertising, loyalty schemes, bonus schemes, linked share offers, public relations exercises and merchandising offers.

Any scheme launched by a medicines manufacturer or distributor whose business is linked with the sale or supply of medicines to PQPS may be considered to be promotional. It is not interpreted as including wholesale dealers who have no interface with the public.

'Measures or trade practices relating to prices, margins or discounts which were in existence on 1 January 1993' are exempt from the prohibition by virtue of regulation 21(4). These are primarily financial terms and normally cover cash discounts or equivalent business discount schemes on purchases of medicinal products, including volume discounts. Such practices are considered exempt under regulation 21(4) if they were in regular use by a significant proportion of the industry prior to 1 January 1993 and provided they are clearly identifiable and invoiced.

Cash returns to individuals and other personal benefits 'in lieu' of discounts such as preferential loans, share options, gifts or special prices for travel, insurance deals, office equipment or computer software are not exempt under regulation 21(4) and are therefore considered under regulation 21(1).

4.9 Interpretation of 'inexpensive' and 'relevant to the practice of medicine or pharmacy'

The item or benefit offered must be both inexpensive and relevant to the practice of medicine or pharmacy for it to fall outside the prohibition in regulation 21(1) of the Advertising Regulations. Both conditions must be satisfied in all cases. Inexpensive items are considered to be those which do not cost a company more than £5 (excluding VAT).

The criteria of 'relevance' is met by items which have a general business use such as pens, notepads, calculators, inexpensive computer accessories, diaries, calendars, surgical gloves, surgery clocks, tissues and coffee mugs.

An equivalent approach applies to membership schemes and cumulative points schemes which have the effect of conferring personal benefits in the form of free or reduced price goods or services.

The prizes in competitions which are open to PQPS and which are linked to the promotion of a relevant medicinal product must be both inexpensive and relevant to the practice of medicine or pharmacy. The maximum prize figure considered appropriate for a competition is £100 (excl. VAT). The number of prizes should be restricted to a few only.

4.10 Hospitality provided to PQPS

Where products are being promoted to PQPS the restrictions of regulation 21(1) do not prevent the offer of hospitality to them at events purely for professional or scientific purposes under the conditions laid down under regulation 21(2) which include the condition that the hospitality should not be offered to persons who are not health professionals.

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

4.11 Provision of medical or pharmaceutical education, goods and services

Schemes which are launched by the pharmaceutical industry offering sponsorship of research posts, study visits etc. 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.

SECTION 5

Medicines Control Agency Role and Procedures

5.1 The role of the Medicines Control Agency (MCA)

The MCA acts on behalf of Health Ministers. Its key function is 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 MCA works with other statutory regulators and self-regulatory bodies, (including those shown in Section 2).

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

(i) checking advertising for compliance with the law prior to publication 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 complying with the Regulations.

5.2 Scrutiny of advertising material prior to issue

In order to perform its supervisory functions under the Regulations, the MCA is obliged to monitor not only published advertisements but also advertisements prior to publication. As part of that task, advertising material for certain products may be required to be submitted for scrutiny prior to issue. Circumstances where this may be required include:

(i) where a newly licensed product, subject to intensive monitoring, is placed on the market;

(ii) where a product is reclassified, such as from POM to P; or

(iii) where previous advertising for a product has breached the Regulations.

The MCA Advertising Unit will undertake to give its opinion on the advertising material within a given timescale 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 MCA 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 MCA of the form of the advertisement, the intended audience and the intended date and duration of issue for each piece of copy submitted.

The period of prior scrutiny of all advertising for a product will normally be at least six months. The marketing authorisation (MA) holder will be advised of the requirement for prior scrutiny and of the reasons for, and duration of, the requirement in each case.

Where an MA holder, or an agency or trade association acting on his behalf, submits advertising copy to the MCA voluntarily and asks for advice on its suitability for issue, the Advertising Unit will assess the advertising in the normal way and provide suggested amendments where appropriate. If the material is issued without amendment, and the MCA considers that it is potentially in breach of Regulations, consideration of enforcement will be initiated.

Where advertising material is assessed prior to issue, the opinion of the MCA is based upon the information provided at the time and the current state of scientific knowledge. However, the MCA has a statutory function to monitor advertisements on a continuing basis and to consider complaints made in the future. The above opinions will therefore be given without prejudice to our ability to perform this function.

5.3 Monitoring of advertising material

All advertising material for new medicines under intensive surveillance (those identified by ▼ on all product information and advertising) is routinely monitored by the Agency. Sampling of advertising for other medicinal products in a variety of media is also carried out.

5.4 Investigation of complaints

A complainant can choose to refer directly to any self-regulatory or regulatory body which deals with complaints (see Section 2 page 19). This section explains the procedure for complaints made directly to the Agency. All complaints are acknowledged by the Advertising Unit on receipt and investigated. As part of its investigation the Advertising Unit will notify the MA holder of the complaint and include an anonymised copy. This will offer the MA holder an opportunity to comment and provide any information which he considers appropriate to answer the complaint. If appropriate, the MCA 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 MCA may issue a notice under paragraph 1(a) of the Schedule to the Monitoring Regulations formally requesting a copy of the advertisement in question. Both the complainant and the MA holder will be advised of the outcome of the investigation.

5.5 Referral to a self-regulatory body

Complaints involving a potential breach of regulation 9 of, or Part IV of, the Medicines (Advertising) Regulations 1994 may, under the Monitoring Regulations, and with the agreement of both the MCA and the complainant, be passed to a suitable self-regulatory body for investigation. However, where the complaint has not been dealt with in a satisfactory manner or within a reasonable timescale by the designated regulatory body, the MCA is required to investigate the complaint.

Where a complaint does not involve a breach of legislation the MCA may suggest referral to a self-regulatory body for consideration of a breach of the relevant codes of practice.

5.6 Breach of Advertising Regulations

Where the assessment of advertising material identified under paragraphs 2, 3 or 4 above indicates a potential breach of the Advertising Regulations, the person responsible for the advertisement will be advised that the MCA considers that the advertisement is potentially in breach of the Advertising Regulations.

Although the Regulations clearly set out the powers available to the MCA, the Agency is not intending to extend its role. It is expected that, in the majority of cases, companies will work with the MCA to issue acceptable advertising without the need to resort to the formal procedures laid down under the Schedule to the Monitoring Regulations. However, once the

formal procedures have been invoked they will continue until the matter is resolved.

In the small minority of cases where we are unable to reach a satisfactory result by negotiation the advertiser may be issued with a notice under paragraph 3 of the Schedule to the Monitoring Regulations advising him that:

(i) the MCA is 'minded to' determine that the advertisement, if published, would be in breach of the Advertising Regulations and the reasons why they are minded to make such a determination;

(ii) if such a determination is made, that person may be required to refrain from publishing that advertisement by a notice served under paragraph 5 of the Schedule; and

(iii) the person on whom the notice is served has 21 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 the notice has been withdrawn by Health Ministers. In deciding whether to include such a requirement, the MCA will take into account all the interests involved and, in particular, the public interest.

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

If the advertiser considers that the advertising is not in breach of the Advertising Regulations, he may submit a written representation that the proposed determination should not be made. The representation will be passed to an Independent Review Panel for advice before a final decision is made by the Licensing Authority. Full details of the operation of the Review Panel are available from the MCA.

5.7 Issue of decisions and determinations

If an advertiser has provided written representations in response to a notice under paragraph 3 of the Schedule to the Monitoring Regulations, the advertisements in question will be reconsidered in the light of that representation. The MCA will refer the advertisement and written representation to an Independent Review Panel for advice before making a final determination. If, following consideration of that advice, the MCA decides that the advertisement would not be in breach of the Regulations,

a notice under paragraph 4 of the Schedule will be issued informing the advertiser of that decision and withdrawing the notice served under paragraph 3.

Alternatively, the MCA may, in the light of advice received from the Independent Review Panel, make a determination that the advertisement, if published, would be in breach of the Advertising Regulations. In this case, a notice under paragraph 5 of the Schedule will be issued stating the reasons for the determination, withdrawing the notice served under paragraph 3 and which may require the advertiser to refrain from publishing the advertisement.

Where the publication of an advertisement has been prohibited under paragraph 5, and that advertisement has previously been published, the person may be required to publish the reasons for the determination (as notified to him by the notice under paragraph 5a in full or in part) and a corrective statement within a specified time and in an appropriate form (paragraph 6 of the Schedule refers).

Once the Licensing Authority's final decision has been given, any further disagreement must be settled in the Courts. A company which is unhappy about the decision will continue to have the opportunity to request a judicial review of the Authority's executive decision.

5.8 Sanctions

Paragraph 7 of the Schedule creates offences where the addressees of notices under paragraphs 1, 3 or 5 of the Schedule fail to comply with the requirements imposed. Paragraph 8 makes it an offence for a person to fail to comply with any requirement imposed on him under paragraph 6 of the Schedule. The provisions of the Monitoring Regulations make it an offence to fail to comply with the MCA's determination of the matter and the MCA will consider enforcement action where any breach of the Regulations has taken place and where the legislation makes that breach a criminal offence. In addition, the MCA is entitled to seek an injunction in the courts as part of its investigation of a complaint or of its own motion.

ANNEX 1

Relevant Legislation and Codes of Practice

UK Legislation

The Medicines Act 1968

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

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

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

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

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

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

The Medicines (Monitoring of Advertising) Amendment Regulations 1999, SI No. 784 (This SI amends the Monitoring Regulations Schedule inserted by SI 1999/267 to correct a technical error.)

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

The Control of Misleading Advertising Regulations 1988, SI No. 915

The Broadcasting Acts 1990 and 1996

The Trade Description Act 1968

European Directives:

92/28/EC on the advertising of medicinal products for human use, 65/65/EC (as amended) on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and 92/73/EC extending the scope of 65/65/EC in relation to homoeopathic medicines.

The Principal Regulations for the Advertising and Monitoring of Medicines

The Medicines (Advertising) Regulations 1994, SI No. 1932 ('the Advertising Regulations'), together with the Medicines (Monitoring of Advertising) Regulations 1994, SI No. 1933 ('the Monitoring Regulations') implemented Directive 92/28/EC into UK law and, by so doing, reinforced existing controls of advertising under the Medicines Act 1968.

The Advertising Regulations revoked the Medicines (Advertising to Dental and Medical Practitioners) Regulations 1978, SI No. 1020. The Medicines (Labelling and Advertising to the Public) Regulations 1978, SI No. 41 were amended by the Advertising Regulations so that they do not apply to 'relevant medicinal products'.

The Monitoring Regulations implemented Articles 12, 13 (part) and 14 of Directive 92/28/EC by specifying procedures whereby advertisements which are considered to be inconsistent with the Advertising Regulations can be acted upon, either by reference to an administrative body established for that purpose or by civil proceedings.

The Advertising and Monitoring Regulations came into force on 9 August 1994. The Advertising Regulations were amended by the Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994, SI No. 3144 and by the Medicines (Advertising) Amendment Regulations 1996, SI No. 1552. The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999, SI No. 267 amend both the Advertising Regulations and the Monitoring Regulations.

Codes of Practice

The ABPI Code of Practice for the Pharmaceutical Industry

The PAGB Codes of Practice for Consumer Advertising and for Advertising to the Trade and Health Professionals

The Committee on Advertising Practice's British Codes of Advertising and Sales Promotion

The Independent Television Code

The Radio Authority Code

ANNEX 2

MCA Contact Points for Advice on Advertising and Promotion of Medicines

The Advertising Unit
Post Licensing Division
Medicines Control Agency
Room 926, Market Towers
1 Nine Elms Lane
London SW8 5NQ

For general enquiries about licensed medicines	Tel: 020 7273 0689/0664 Fax: 020 7273 0109
For enquiries about advertising policy and legislation	Tel: 020 7273 0281 Fax: 020 7273 0109
For enquiries about borderline substances	Tel: 020 7273 0602

Other regulatory and self-regulatory bodies mentioned in the guidance notes

ABPI/PMCPA
12 Whitehall
London SW1A 2DY

Tel: 020 7930 9677

PAGB
Vernon House
Sicilian Avenue
London WC1A 2QH

Tel: 020 7242 8331

Advertising Standards Authority
2 Torrington Place
London WC1E 7HW

Tel: 020 7580 5555

Radio Advertising Clearance Centre
46 Westbourne Grove
London W2 5SH

Tel: 020 7727 2646

Broadcast Advertising Clearance Centre
200 Gray's Inn Road
London WC1X 8HF

Tel: 020 7843 8265

Radio Authority
Holbrook House
14 Great Queen Street
Holborn
London WC2B 5DG

Tel: 020 7430 2724

The British Dental Trade Association
Merritt House, Hill Avenue
Amersham
Bucks HP6 5BQ

Tel: 01494 431010

Copy Advice Service
Committee of Advertising Practice
2 Torrington Place
London WC1E 7HW

Tel: 020 7580 4100

ANNEX 3

Diseases and Conditions for which Medicines cannot be Advertised to the Public

Bone diseases

Cardiovascular diseases

Chronic insomnia

Diabetes and other metabolic diseases

Diseases of the liver, biliary system and pancreas

Endocrine diseases

Genetic disorders

Joint, rheumatic and collagen diseases*

Malignant diseases

Psychiatric diseases

Serious disorders of the eye and ear

Serious gastrointestinal diseases

Serious infectious diseases including HIV-related diseases and tuberculosis

Serious neurological and muscular diseases*

Serious renal diseases

Serious respiratory diseases

Serious skin disorders

Sexually transmitted diseases

* Specific exemptions are provided for advertisements likely to lead to the use of medicinal products for the purpose of the treatment of the symptoms of sprains or strains or the relief of pain or stiffness of rheumatic or non-serious arthritic conditions or for the purpose of prevention of neural tube defects.

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 (MA) holder** or the name and address of that part of his 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 indications for the product consistent with the terms of the MA.

2 **Side effects, precautions and contra-indications**: a succinct statement of the appropriate particulars in the summary of product characteristics relating to the indications shown.

3 **Dosage and method of use**: details of how and when the product should be used for the indications shown in a succinct statement from the particulars in the summary of product characteristics.

4 **Warnings**: any warning issued by the Licensing Authority under Part II of the Medicines Act which is required to be included in advertisements as a condition of the MA.

5 **Cost**: the cost (excluding VAT) of a specified pack size, specified quantity or recommended daily dose of the product.

The particulars 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

Activities undertaken by the MCA and the Statutory Powers used

1 **Scrutiny of published and pre-published adverts** - Regulation 13 of, and para 1 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

2 **Advice to marketing authorisation holder that a potential breach has been identified** - Regulation 13 of, and para 3 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

3 **Request for copies of other related material** - Regulation 4(d) of the Medicines (Advertising) Regulations 1994, as amended and regulation 13 of, and para 1 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

4 **Request for an advert to be withdrawn/amended** - Regulation 13 of, and paras 2, 3 and 5 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

5 **Prevention of publication following decision that there has been a breach** - Regulation 13 of, and para 5 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

6 **Refer to the MCA's enforcement section or bring injunction proceedings** - Regulations 6 of, and paras 7 and 8 of the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

7 **Consideration of complaints about adverts where the complaint concerns breaches of Part IV of the Advertising Regulations or regulation 9 of the Monitoring Regulations.** (In these referral to appropriate regulatory body is considered.) - Regulation 5(1) of the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

8 **Subject to agreement of both the complainant and the MCA, the complaint is referred to appropriate regulatory body** - Regulation 5(2) of the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

9 **Refer broadcast complaints to the Independent Television Commission or Radio Authority or to the Welsh Authority as appropriate** - Regulations 5(1), 9(1) and 10(1) of the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

10 **Complainant or the MCA does not agree to referral** - the complaint is taken forward under MCA procedures - Regulations 5, 6 and 13 of, and the Schedule to, the Medicines (Monitoring of Advertising) Regulations 1994 (as amended).

ANNEX 6

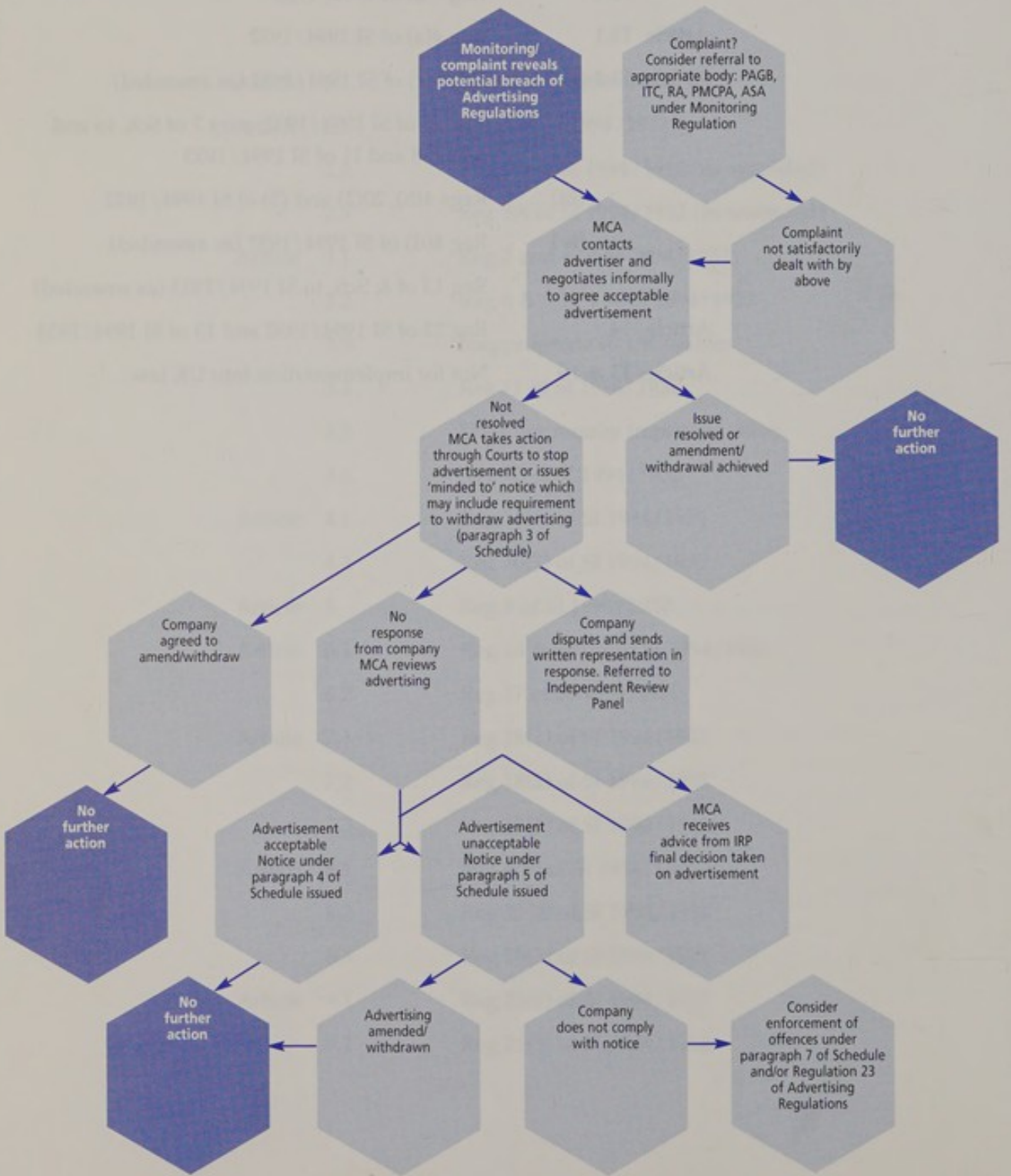
Implementation of Directive 92/28/EC into UK Law

Article	1	Reg 2 of SI 1994/1932
Article	2.1	Reg 3 of SI 1994/1932
	2.2	Reg 3A of SI 1994/1932 (as amended)
	2.3	Reg 3A of SI 1994/1932 (as amended)
Article	3.1	Reg 7 and 8 of SI 1994/1932
	3.2	Reg 6 & Sch. 1 to SI 1994/1932
	3.3	Inappropriate to UK system
	3.4	Reg 11 of SI 1994/1932
	3.5	Does not require implementation
	3.6	Reg 12 of SI 1994/1932
Article	4.1	Reg 10(1) of SI 1994/1932
	4.2	Reg 10(2) of SI 1994/1932
Article	5	Reg 9 of SI 1994/1932
Article	6.1	Reg 14 & Sch. 2 of SI 1994/1932
	6.2	Reg 17 of SI 1994/1932
Article	7.1	Reg 18(1) of SI 1994/1932
	7.2	Reg 18(2) of SI 1994/1932
	7.3	Reg 18(3) of SI 1994/1932
Article	8.1	Reg 4(b) of SI 1994/1932
	8.2	Reg 20(2) of SI 1994/1932
	8.3	Reg 20(3) of SI 1994/1932
Article	9.1	Reg 21(1) of SI 1994/1932
	9.2	Reg 21(3) of SI 1994/1932

	9.3	Reg 21(5) of SI 1994/1932
	9.4	Reg 21(4) of SI 1994/1932
Article	10	Reg 21(2) of SI 1994/1932
Article	11.1	Reg 19 & Sch. 4 of SI 1994/1932
	11.2	Inappropriate to UK system
Article	12.1	Regs 4 & 13 of, & Sch. to SI 1994/1933
	12.2	Regs 6, 7 & 8 of SI 1994/1933
	12.3	Reg 13 of, & Sch. to SI 1994/1933
	12.4	Reg 5 of SI 1994/1933
Article	13.1	Reg 4(a) of SI 1994/1932
Article	13.2 (i)	Reg 4(c) of SI 1994/1932 (as amended)
	(ii)	Reg 23 of SI 1994/1932, para 7 of Sch. to and regs 6-8 and 11 of SI 1994/1933
	(iii)	Regs 4(b), 20(2) and (3) of SI 1994/1932
	(iv)	Reg 4(d) of SI 1994/1932 (as amended)
	(v)	Reg 13 of & Sch. to SI 1994/1933 (as amended)
Article	14	Reg 23 of SI 1994/1932 and 13 of SI 1994/1933
Articles	15 & 16	Not for implementation into UK law

ANNEX 7

Key Steps in the Consideration of Advertising



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