

Medicines Advertising Codes

Professional Code

Including
traditional
herbal medicines

CODES OF PRACTICE FOR ADVERTISING OVER-THE-COUNTER
MEDICINES WHICH ARE SUBJECT TO A MARKETING AUTHORISATION
OR TRADITIONAL HERBAL MEDICINES REGISTRATION.

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What is PAGB?

PAGB (the Proprietary Association of Great Britain) is the national trade association that represents manufacturers of branded over-the-counter (OTC) medicines and food supplements.

PAGB was founded in 1919 with the aim of promoting responsible consumer healthcare. The organisation was set up by a group of pharmaceutical manufacturers who wanted to protect the public from misleading medicines advertising. They devised a system of self-regulation to ensure that their advertising was balanced and responsible. The system required member companies to submit all of their advertising to the association for checking, before publication, and to abide by the rulings made.

The same principle holds true today. PAGB publishes codes of practice detailing the requirements for advertising aimed at consumers and professionals. PAGB provides a pre-publication approval system for consumer advertising of over-the-counter medicines that are subject to a Marketing Authorisation, registered traditional herbal medicines (THMs) and food supplements.

In addition to advertising, PAGB offers a comprehensive range of services to support its members. These include regulatory and legal affairs, health policy and public affairs, training and information services and a pack design approval service for over-the-counter medicines. PAGB publishes a separate code on pack design, the 'PAGB Code of Practice for Pack Design for Over-the-Counter Medicines'. Further details of PAGB's services may be found in 'PAGB Services Guide for Members'.

Introduction to the PAGB Medicines Advertising Codes

The PAGB Medicines Advertising Codes are the primary means of self-regulation for over-the-counter medicines advertising. To help ensure that this advertising is responsible, PAGB publishes two Codes of Advertising Practice. One focuses on advertising directed at consumers while the other relates to advertising aimed at persons qualified to prescribe and supply (PQPS), and people working for them. The PAGB Medicines Advertising Codes apply to advertising for all over-the-counter medicines regardless of their route to market approval (marketing authorisation (MA) or traditional herbal medicines registration). Advertisers should be aware that where marketing authorisation is stated in the text this should be interpreted as also applying to products holding a traditional herbal medicines registration. In addition to the general requirements of the Codes, there are specific requirements applying to registered traditional herbal medicines (THMs); these are shown in green text throughout the Codes.

In operating the PAGB Medicines Advertising Codes, PAGB is seeking to ensure that the United Kingdom over-the-counter medicines industry continues to maintain its high standards of promotion. PAGB requires members to uphold the reputation of the over-the-counter medicines industry and to maintain recipients' confidence in the advertisements they receive. The fact that the PAGB Consumer Code has been in operation for 90 years testifies to its success. Throughout its history, government officials and professional associations have repeatedly endorsed its effectiveness. Recognition of its success by the European Commission has ensured that the self-regulation of advertising is built into European law.

The PAGB Medicines Advertising Codes reflect the law and provide an interpretation of the law. In some areas they go beyond the law and consider other aspects of advertising, such as taste and decency and sponsorship. It is a condition of PAGB membership that all members comply with the PAGB Medicines Advertising Codes in both the letter and the spirit.

PAGB operates a pre-publication approval system for member companies' consumer advertising. It is a condition of membership that all advertising aimed at consumers must be submitted to PAGB for screening and PAGB approval must have been given prior to its release into the public domain. It is the responsibility of each member company to seek fresh approvals when this is necessary. Whilst member companies are legally responsible for their advertising, the pre-publication approval system aims to help members ensure that their consumer advertising complies with the legal and self-regulatory requirements and that the messages portrayed are legal, balanced, truthful and responsible.

PAGB does not operate a system of pre-publication approval for advertising that is aimed at persons qualified to prescribe or supply (PQPS). The PAGB Professional Code operates through consideration of post-event complaints. It is a condition of PAGB membership that companies must ensure that all over-the-counter medicines advertising aimed at persons qualified to prescribe or supply, and those that work for such persons, complies with the PAGB Professional Code, in both the letter and the spirit. Companies must also ensure that all such advertising complies with the law.

PAGB runs regular advertising workshops to assist companies in applying the PAGB Medicines Advertising Codes.

1. PAGB Professional Code

1.1 Compliance with the PAGB Professional Code for Medicines

1.1.1 It is a condition of PAGB membership that companies ensure that all over-the-counter medicines advertising aimed at persons qualified to prescribe or supply, and those who work for such persons, complies with the relevant sections of the PAGB Professional Code for Medicines in both the letter and the spirit. Companies must also ensure that all such advertising complies with the law. PAGB runs regular advertising workshops to assist companies in applying the rules of the PAGB Medicines Advertising Codes. Advice on the interpretation of the Code can be sought from PAGB.

1.1.2 The PAGB Professional Code for Medicines operates through consideration of post-event complaints. PAGB does not operate a system of approval for advertising aimed at persons qualified to prescribe or supply. The details of this are set out in 'PAGB's Standard Operating Procedure for Member Companies' Informal Queries and Complaints Regarding Competitors' Over-the-Counter Medicines Advertising'.

1.1.3 Members are required to provide details of a signatory who is responsible for ensuring that the company's advertising complies with the PAGB Professional Code for Medicines. The signatory is also responsible for ensuring that any undertakings given as a result of a breach of the Code are carried out.

1.2 What the PAGB Professional Code for Medicines covers

1.2.1 This code applies to advertising involving over-the-counter medicines that is aimed wholly or mainly at persons qualified to prescribe or supply and appropriate administrative staff, where the object of the advertising is to influence sales and/or recommendations to the general public.

N.B. Advertising intended to influence the writing of prescriptions is covered by the ABPI Code of Practice, not by this code (See 1.3.1).

1.2.2 Advertising under the Professional Code is aimed at Persons Qualified to Prescribe (PQPS), and can be regarded as any advertisement primarily intended to promote sale or recommendation of an OTC medicine to a consumer/patient.

The PAGB Professional Code for Medicines does not cover the advertising of over-the-counter medicines aimed wholly or mainly at the public. This is covered by the PAGB Consumer Code.

A full definition of Persons Qualified to Prescribe or supply can be found in section 6.2 of the MHRA Blue Guide which is available online at <http://www.mhra.gov.uk/home/groups/pl-a/documents/publication/con2022589.pdf>

1.2.3 Persons qualified to prescribe or supply includes those persons who are legally entitled to choose which medicinal product is supplied in a particular outlet, such as buyers. It is not, however, interpreted as including wholesale dealers.

1.2.4 The PAGB Professional Code for Medicines applies to advertising materials over which members have editorial control. Part 14 of the Human Medicines Regulations 2012 lists a number of

promotional activities, such as advertisements with no product claims (please refer to section 2.1 for a definition of 'product claims') and factual and informative announcements, that are not regarded as advertising under that regulation. These activities are listed in section 1.3 and do not fall under the PAGB Professional Code for Medicines.

1.2.5 Advertising is taken to include:

- printed advertising materials e.g. journals, advertorials, booklets, posters, direct mail materials, retailer house publications
- envelopes addressed to persons qualified to prescribe or supply
- electronic media advertising, such as websites, press releases intended for Internet publication, and any other Internet advertising
- audio and audio-visual advertising e.g. DVDs
- promotional aids
- the supply, offer or promise, of any gift, pecuniary advantage or benefit in kind
- hospitality at professional, scientific or promotional meetings/events attended by persons qualified to prescribe or supply
- sponsorship of professional, scientific or promotional meetings and events
- sponsorship of written materials produced by third parties
- samples and free packs
- representations, i.e. any oral communication in order to promote a brand, including the activities of company representatives. (Member companies are reminded that, although training materials do not fall under the PAGB Professional Code for Medicines, all such materials should comply with the principles of the Code.) (Please refer to section 1.5.13 and rule 34.)

1.3 What the PAGB Professional Code for Medicines does not cover

Prescription medicines

1.3.1 The PAGB Professional Code for Medicines does not cover advertising relating to the prescribing of a medicinal product. These activities are covered by the Association of the British Pharmaceutical Industry (ABPI) Code of Practice, which is administered by the Prescription Medicines Code of Practice Authority. The ABPI Code also applies to advertising designed to encourage the issue of a prescription for a medicine where the medicine is available both for purchase and for prescription.

Advertising to consumers

1.3.2 The PAGB Professional Code for Medicines does not cover the advertising of over-the-counter medicines aimed wholly or mainly at the public. This is covered by the PAGB Consumer Code.

Packshots

1.3.3 A genuine photograph of a pack is not in itself subject to the PAGB Professional Code for Medicines and does not necessitate the inclusion of essential information. This is despite the fact that there are product claims, including medicinal claims, on the pack. (Please refer to section 5 for definitions.)

Advertisements with no product claims

1.3.4 Similarly, the Code does not apply to the provision of a pack shot for purely editorial purposes where the company has no control over the final text used. This applies even where payment is made to the journal for the incorporation of the pack shot.

Factual and informative announcements and reference material without medicinal claims

1.3.5 Advertisements that do not contain product claims (other than those on a genuine pack shot) are not subject to the PAGB Professional Code for Medicines and do not require the inclusion of essential information. A therapeutic category may be mentioned without necessitating the inclusion of essential information. (Please refer to section 1.5.14.)

1.3.6 Informative announcements and reference materials such as details of pack changes, adverse reaction warnings, trade catalogues and price lists are not considered to be advertisements, provided they do not include medicinal claims. (Please refer to section 2.1.1) Listings within publications such as PAGB's 'OTC Directory', 'Chemist & Druggist Monthly Price List' etc. are, therefore, not subject to the PAGB Professional Code for Medicines. If medicinal claims are made other than those appearing on a true representation of a pack or as a straightforward representation of the indications the Code will apply to those claims and essential information will be required. Advertisements within trade catalogues and price lists must comply with Code requirements.

Publications produced by wholesalers

1.3.7 Publications produced by wholesalers for retail pharmacists, etc. are outside the scope of this Code.

Public relations

1.3.8 PAGB recognises that the PAGB Professional Code for Medicines cannot cover public relations activities (e.g. press releases and product launches) once the material is passed to a journalist. It is unlikely that such activities will be completely under the company's control or that materials such as press releases will not be changed by journalists who use the material. However, member companies should note that PR is covered by Part 14 of the Human Medicines Regulations 2012, and ensure that all PR materials comply with the Professional Code and the law at the point when the company relinquishes editorial control.

Responses to correspondence and enquiries

1.3.9 Responses to correspondence and enquiries from persons qualified to prescribe or supply and appropriate administrative staff are exempt from the PAGB Professional Code for Medicines. Standard letters intended for use in response to enquiries are not subject to the PAGB Professional Code for Medicines, provided they are used only when they relate directly and solely to the particular enquiry. Similarly, the Code does not apply to responses made to specific communications, such as letters or articles published in professional journals. All such responses should be accurate, should not mislead and should stick to the subject of the original enquiry or comment. Care must be taken that such replies do not have the appearance of advertising; otherwise they will fall under the Code and require essential information.

Note: Please refer to section 2.1, for definitions of 'product claims' and 'medicinal claims'.

Labels and packaging

1.3.10 This Code does not cover product labels, packaging materials and in-pack leaflets. PAGB has a separate code covering pack design, the 'PAGB Code of Practice for Pack Design for Over-the-Counter Medicines'.

Statements relating to human health or disease

1.3.11 Statements relating to human health or disease are not covered by this Code provided there is no reference, either directly or indirectly, to specific medicines.

1.4 PAGB Professional Code for Medicines administration

1.4.1 In the event that an audit of a member company's procedures is required, it would be expected that the minimum standards outlined below would be in place. (Please also refer to 'PAGB's Standard Operating Procedure for Member Companies' Informal Queries and Complaints Regarding Competitors' Over-the-Counter Medicines Adverts.)

Signatories

1.4.2 Member companies are required to notify PAGB of a signatory who is responsible for ensuring that the company's advertising to persons qualified to prescribe or supply is produced in compliance with this Code.

1.4.3 Companies should ensure that the details notified to PAGB are accurate and up to date. Companies may wish to notify PAGB of one or more deputy signatory or signatories. Deputy signatories should be appointed to cover holiday periods, etc.

1.4.4 The signatories are expected to have a good working knowledge of the PAGB Professional Code for Medicines.

Procedures

1.4.5 Companies are expected to have robust procedures in place to ensure that all advertising aimed at persons qualified to prescribe or supply complies with the PAGB Professional Code for Medicines. Companies may wish to use the checklist provided in section 1.6 as a reminder. Please note, the checklist is not a complete list of all elements requiring consideration.

1.5 Rules of the PAGB Professional Code for Medicines

1.5.1 General principles

1 The PAGB Professional Code for Medicines applies to advertising directed wholly or mainly at persons qualified to prescribe or supply and those that work for such persons.

Persons qualified to prescribe or supply (PQPS)

This Code applies to the advertising of over-the-counter medicines wholly or mainly to persons qualified to prescribe or supply (and appropriate administrative staff) and where the object of the advertising is to influence sales and/or recommendations to the general public.

For THMs, this includes herbal practitioners involved in selling medicines to the public.

N.B. Advertising intended to influence the writing of prescriptions is covered by the ABPI Code of Practice, not by this code (See 1.3.1).

Advertising under the Professional Code is aimed at Persons Qualified to Prescribe (PQPS), and can be regarded as any advertisement primarily intended to promote sale or recommendation of an OTC medicine to a consumer/patient.

The PAGB Professional Code for Medicines does not cover the advertising of over-the-counter medicines aimed wholly or mainly at the public. This is covered by the PAGB Consumer Code.

A full definition of Persons Qualified to Prescribe or supply can be found in section 6.2 of the MHRA Blue Guide which is available online at https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/376398/Blue_Guide.pdf.

Students

Students of the above professions are not considered to be persons qualified to prescribe or supply.

Administrative staff

Administrative staff and students of the above professions, for example those working in doctors' surgeries or pharmacies, are permitted to see advertisements aimed at persons qualified to prescribe or supply.

Mixed readership

Where advertising is placed in journals with a mixed readership, it is the main audience that determines the status of the readership, and hence which Code applies. For example, the British Medical Journal may be read by consumers. However, the majority of the readership will be doctors and, therefore, the PAGB Professional Code for Medicines will apply.

Websites that contain advertisements/information aimed at professionals should make it very clear that the site is for professionals only. Where websites contain materials both for professionals and consumers, there must be a clear differentiation between what is aimed at consumers and what is aimed at professionals.

2 A medicine must not be promoted prior to the granting of the Marketing Authorisation or registration under the THMR Scheme.

For example it is not acceptable to supply a photograph to a journal to announce a product launch prior to receipt of the Marketing Authorisation or registration under the THMR Scheme and labelling approval. Similarly, teaser advertising is prohibited where it relates to a product that has not yet been granted a Marketing Authorisation.

The legitimate exchange of medical and scientific information during the development of a medicine is permitted, provided that any such information does not constitute advertising.

Where lead times are particularly long, it may be acceptable to provide retailers with limited, factual, information and a pack shot or mock-up clearly labelled 'draft' to enable them to plan stock. Such information should be provided on a one-to-one basis and not, for example, as an article in a journal.

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.

3 All advertising must be in line with the product's Summary of Product Characteristics.

Advertising must comply with the product's Marketing Authorisation (which includes the Summary of Product Characteristics (SmPC)).

While the actual wording of the claim does not have to be present within the SmPC, all claims must be consistent with the SmPC. For example, if the SmPC states that relief is obtained at 30 minutes, then a claim that the product relieves in 15 minutes would be unacceptable, despite supporting evidence. In order for the claim to be made, a variation to the SmPC would need to be agreed by the MHRA. If the SmPC does not mention speed of action, then the claim may be made as long as it is supported by appropriate evidence.

Subjective claims, such as taste (e.g. 'great tasting throat lozenge') and claims based on market research (e.g. 'seven out of ten people found Brand X relieved their symptoms') are usually not relevant to the SmPC and so no variation to the SmPC is required.

4 Advertising shall be true and shall not mislead. It shall not contain any exaggerated claims, either direct or implied.

Both the claims used and the overall impression given by the advertisement must be in line with the degree of improvement the average user should expect. Claims for benefits that cannot be expected to be achieved by the majority of users are prohibited.

Advertising for THMs must make it clear that the product is a registered traditional herbal medicine. All advertisements 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 on long-standing use as a traditional herbal remedy.'

When using before-and-after pictures of a sufferer using a product, the visuals should not imply or show complete eradication of the condition, nor can the visuals imply that a product can be used to treat more serious forms of disease than the Marketing Authorisation would allow.

Claims such as '90% of users felt better with Brand X' are only permitted when backed with substantiation relating to normal over-the-counter usage. For example, it would not be acceptable to imply that 90% felt better after one dose if the research is based on continued use.

5 Advertising shall not bring the over-the-counter medicines industry into disrepute, nor should it undermine or prejudice the confidence of recipients. All activities must acknowledge the status of the recipient.

Shocking or offensive advertisements

This rule includes issues such as taste and decency (i.e. avoidance of offence). Examples quoted as unacceptable in the PAGB Consumer Code may be taken as a benchmark, but are not necessarily unacceptable for advertising to professionals. On this basis, full or partial nudity may be acceptable if related to the use of the product. However, it would not be acceptable if used purely for attracting attention to an advertisement. In the case of a complaint, copy would be considered on a case-by-case basis.

Tailored to the audience

Advertising should be tailored to the audience to whom it is directed. For example, advertising devised for general practitioners may not be appropriate for GSL retailers.

6 Advertising shall not undermine current healthy-lifestyle advice.

It is not acceptable for advertisers to undermine evidence-based healthy lifestyles or health-promoting behaviour, such as exercise, healthy eating or smoking cessation. Similarly, advertising must not promote behaviour that could be damaging to health (e.g. smoking, dietary practices known to be detrimental to health, excessive drinking or a sedentary lifestyle).

7 An advertisement may only refer to the Medicines and Healthcare products Regulatory Agency, the Department of Health, the European Medicines Agency or any other MHRA advisory committees in order to state that the product is licensed. No other reference to these bodies is acceptable unless specifically required by the Licensing Authority.

Advertisers may state that a medicine is 'licensed' or 'authorised', or for THMs, 'registered'. However, it is not acceptable to suggest that a medicine has been specifically endorsed or approved by the Department of Health, the MHRA, the European Medicines Agency (EMA), the Commission on Human Medicines (CHM) or any other MHRA advisory committees. Advertisers must not suggest that a particular medicine is superior or 'special', because it has been granted a Marketing Authorisation.

Acceptable claims

The following claims are likely to be acceptable:

- 'Brand X is a licensed medicine'
- 'licensed/authorised for the treatment of...'
- 'licensed/authorised by the MHRA/Department of Health'
- 'licensed/authorised by the MHRA/Department of Health for the treatment of...'
- 'the only product licensed/authorised by the MHRA/Department of Health for the treatment of...'
(where applicable to the product).

For THMs the following claims are likely to be acceptable:

- 'Brand X is a registered traditional herbal medicine'
- 'Brand X is an authorised traditional herbal medicine'
- 'authorised by the MHRA/Department of Health as a traditional remedy for the treatment of...'

Unacceptable claims

The following claims would not be acceptable:

- 'approved by the MHRA/Department of Health'
- 'approved by MHRA/Department of Health for the treatment of...'

1.5.2 Potentially misleading advertising

8 Advertising shall not mislead as to the nature of the product, its ingredients or indications.

Advertising must be in line with the product's SmPC (please see rule 3) and all claims must be supported by evidence (please see rule 9). In addition, claims that a product/ingredient is 'prescription strength' are only permitted where the product/ingredient is the same strength as a prescription-only variant and is the highest strength available over-the-counter.

9 Advertisers must hold evidence for all claims made in advertising.

Part 14 of the Human Medicines Regulations 2012 requires that all advertising claims are verifiable. Companies may receive requests from health professionals or appropriate administrative staff to provide data in support of statements made in advertising. Whilst it is good practice to respond to such requests, it is left to the company's discretion to supply such data. (Please also refer to section 1.5.7 on including references for claims made in advertising.)

In the event of a complaint, substantiation would be required to support any statement not included in the SmPC.

Further information on the evidence required to substantiate particular types of claims can be found in the rules relating to those claims.

10 Advertising claims relating to speed of action, absorption, dissolution, distribution or other pharmacokinetic particulars, are only acceptable if supported by evidence and if in line with the product's Summary of Product Characteristics.

Member companies must hold evidence to support claims relating to speed of action, duration of action, speed of absorption and dissolution, etc., unless they are present in the SmPC.

All speed of absorption and speed of action claims must be in line with the SmPC. For example, if the SmPC states that relief is obtained within 30 minutes, advertising should not claim that the product relieves within 15 minutes, despite supporting evidence. In order for the claim to be made, data would have to be developed and a variation to the SmPC would need to be agreed by the MHRA.

Speed of absorption claims

PAGB accepts absorption claims on the basis of evidence that a therapeutic level of each active ingredient reaches the site of action within the time stated. Advertisers must ensure that the wording of the claim is in line with their data. Where sub-therapeutic levels can be identified at an earlier point, advertisers could claim that the product 'starts to be absorbed within x minutes' or words to that effect. Where the product has more than one active ingredient, and where only one of them 'starts to be absorbed' in the time stated, advertisers should make it clear which ingredient is being

referred to.

The phrases 'gets into the system' or 'gets to work' are sometimes used to describe the rate of absorption of the active ingredient(s). Where 'gets to work' is used, the advertiser must specify that the claim relates to the speed of absorption. (PAGB is of the opinion that 'gets into the system' is less likely to be misinterpreted and further qualification is not needed.) The criteria for 'gets into the system', 'starts to get into the system', and any qualified uses of 'gets to work' and 'starts to get to work' are as described in the paragraph on absorption claims above.

Clinical effect claims (e.g. 'starts to work')

Claims such as 'starts to work', 'active' or any unqualified uses of 'gets to work' are taken to mean that consumers will be starting to feel relief at this point (e.g. 'Brand X starts to work within 30 minutes'). Such claims must be supported by efficacy data demonstrating that the average user could expect to experience relief within the time stated. Absorption data is not appropriate to support this type of claim.

'Fast' claims

For most indications such as relief of pain, fever, cold and flu symptoms, allergy symptoms, indigestion, travel sickness and sleeplessness, 'fast' is currently taken to mean 'within 30 minutes'.

'Immediate' and 'instant' claims

In order to claim that a product has an 'immediate' or 'instant' benefit, advertisers must be able to demonstrate that the product has the advertised effect within 10 seconds.

11 Advertising claims relating to duration of action are only acceptable if supported by evidence and if in line with the product's Summary of Product Characteristics.

Duration of action claims

Member companies must hold evidence to support of duration of action claims, unless the duration is stated on the SmPC. Please note that dosage instructions to take the product once a day do not necessarily mean that a claim of 24-hour relief would be acceptable. Where a claim is closely defined, it is usual for a qualifier of 'up to' to be used to take account of any variability of response (e.g. 'relieves pain for up to ten hours'). Qualifiers are often unnecessary for more general claims such as 'lasts for hours'. The requirement for such a qualifier will depend on the actual claim used and the data provided.

PAGB interprets claims of 'all day' or 'all night' as follows:

- 'all-day relief' - the product should work for at least 10 hours
- 'all-night relief' - the product should work for at least 8 hours.

12 Advertising for THMs must not mislead recipients regarding the strength of evidence which supports the product's therapeutic benefits.

The Traditional Herbal Medicines Registration Scheme is based on a demonstration that the product (or a comparable product) has been used as a medicine for at least thirty years; normally fifteen of which have to have been within the European Union. The Registration Scheme is only open to herbal medicines which are not able to obtain a Marketing Authorisation due to there being insufficient scientific evidence of the product's effectiveness. For this reason, the following claims would be unacceptable for THMs:

- 'effective cough mixture'
- 'clinically proven travel sickness remedy'
- 'scientifically proven...'
- 'medically proven...'

Where advertising for a THM refers to published studies, the advertisement must not give the impression that the product's efficacy is based on scientific studies, rather than on traditional use.

13 Advertisers shall not mislead about the novelty of a product. Claims that a product is 'new' can only be made for one year from the date of the national launch.

'New' claims

Advertisers may say 'new', 'or 'now available' for one year from the date when the active ingredient (or the combination of active ingredients) was first available for purchase over the counter. Where the product, active ingredient, or combination of active ingredients was previously only available on prescription, advertisers may say 'newly available for consumers to purchase' or 'now available without prescription'.

If the active ingredient (or the combination of active ingredients) has previously been available over the counter, then advertisers must make clear which aspect of the product is new. For example:

- 'new format' - the format is new but the formulation has been previously available
- 'new Brand X formulation' - the formulation is new to Brand X, but may also be available from other brands
- 'new for pain relief of common arthritic conditions' - the product has been licensed for an additional indication
- 'new orange flavour' - this is acceptable whether or not competing brands are available in orange.

In some cases it may be possible to use a 'new' flash and to explain which aspect of the product is new elsewhere in the advertisement. For example, where the product is the first product in the range to have a particular active ingredient, it may be possible to include a 'New*' flash and to say in a sufficiently visible place elsewhere in the advertisement '*New to Brand X'. Such qualifying statements should be positioned close to the original claim. The acceptability of the qualifier will depend on which aspect of the product is 'new'. For example, it would not be acceptable to use a 'New*' flash and to add '*New tablet size' as a qualifier.

Advertisers of THMs need to avoid causing confusion when combining 'new' claims with the required 'traditional use' statement. Please refer to Rule 41.

It is the advertiser's responsibility to ensure that all advertising containing the claim 'new' is revised once the product has reached the one-year time limit and that no such advertising is distributed after this period.

'Now' claims

'Now' often implies that a product is 'new' (e.g. 'now available') and so the same time restrictions apply. However, 'now' can also imply that the product brings something new to a sector. For example, 'Use Brand X - now your customers can treat pain quickly' would not be accepted, as it implies that Brand X is the only product that treats pain quickly.

Advertisers should bear in mind that the above guidance is not exhaustive. 'New' and 'now' claims must be considered on a case by case basis.

14 A product, or any of its attributes, shall not claim to be unique unless it differs significantly from others on the market.

Where advertising claims that a product is unique, it must make it clear which aspect is unique (e.g. 'unique once-daily dose' or 'unique formulation'). 'Unique' claims can only be used until another product becomes available that offers the same attributes. A product can claim to be unique within

the over-the-counter sector, even if there are prescription-only medicines available with the same attributes. For example, products with the following attributes could claim to be unique for the reasons stated:

- the only product in its therapeutic category that contains a particular active ingredient
- the only product within the therapeutic category to be available in a once-daily dose
- the only product within the therapeutic category to have a particular method of delivery
- the only product that has a licence for a specific indication
- the only one in the therapeutic category that does not cause drowsiness.

15 Information and claims about side-effects must reflect available evidence. It must not be stated that a product is side-effect free. The word 'safe' must not be used without qualification.

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

'Safe' can only be used with further qualification. Qualified uses of the word 'safe' (e.g. 'good safety profile') can be used if there is evidence that this is the case and it is relevant to use.

It is acceptable to highlight the absence of a specific side effect if that side effect is common among the therapeutic category and it is relevant to use (e.g. certain allergy treatments can claim to be 'non-drowsy' on the basis that some allergy treatments do cause drowsiness).

PAGB would not accept phrases such as 'not habit-forming' and 'non-addictive' as, while it may be true that a product does not cause chemical dependency, that is not to say that consumers will not experience a psychological dependency. For this reason, PAGB advises advertisers to say 'not known to be habit-forming' or 'not known to be addictive', provided there is evidence to support this.

16 Sales claims must be supported by evidence. Best-selling claims must be carefully worded to avoid implying superior efficacy.

Sales claims must be supported by three months of most recent sales data. The data may be either volume-sales data or value-sales data. All sales claims used in advertising to persons qualified to prescribe or supply should be referenced. The reference should make clear whether volume or value data has been used. Where the sales data shows frequent fluctuations in the leading brands, advertisers are advised not to run a best-selling claim. Opposing sales data produced by a competitor may result in a complaint being upheld.

Claims that a product is 'number one' also imply that it is the best in its field. PAGB requires that these claims should be further qualified (e.g. 'number one selling').

On the basis of sales data the following would be acceptable:

- 'no.1 selling children's painkiller'
- 'best-selling antacid'
- 'nation's favourite decongestant spray'
- 'market leader for hayfever'
- 'most popular choice for athlete's foot'
- 'Brand X - leading sales for allergies'.

The following examples could be viewed as either best-selling claims or as claims that imply some other form of superiority. Advertisers are required to qualify such claims:

- 'no.1 children's painkiller'
- 'first choice decongestant spray'
- 'leading hayfever product'.

17 Artwork, graphs, tables and pictorial representations must be relevant to the claims made and give a true and fair view.

Care should be taken with graphs and tables to ensure that they do not mislead, for example, by being incomplete or having unusual scales. Graphs and tables should be adequately labelled so that the information presented is easily understood. If a graph or table is not reproduced in its entirety, adaptations must be clearly demonstrated and should not mislead.

1.5.3 Advertising medicines for use in pregnancy

18 Advertisements that promote the use of a medicine during pregnancy are only acceptable where a positive statement in section 1.1 or 1.6 of the Summary of Product Characteristics supports the use of the product in pregnancy. All such advertisements must encourage a cautious approach to the use of medicines in pregnancy.

Where there is a specific indication for use in pregnancy in section 1.1 of the SmPC, medicines may be promoted for use in pregnancy.

Where there is not a specific indication for use in pregnancy in section 1.1, the advertisement may include textual information regarding the use of the product during pregnancy. This information must reflect section 1.6 of the SmPC. The MHRA considers that the use of images of pregnant women is not appropriate in this situation.

Advertising should not convey that it is routine practice for pregnant women to take medicines. It must not suggest that the advertised product, or any other medicine, cannot harm the developing fetus. Claims that a product is 'safe for use in pregnancy' are prohibited. It is generally not acceptable to use ultrasound scans or images of a fetus in advertising.

Advertising should reflect any warning statements on the SmPC concerning use at particular times during pregnancy. For example, some medicines should not be used close to the expected date of delivery.

All advertisements referring to the use of a medicine during pregnancy must include a statement that women should consult their doctor or pharmacist before using any medicine during pregnancy. MHRA's suggested wording for the warning statement is:

'Care should be taken when recommending medicines for use in pregnancy as medicines can cross the placenta and may affect the fetus'.

All of the information contained in section 1.6 of the SmPC should be included in the prescribing information.

The MHRA have issued guidelines entitled 'Medicines which are promoted for use during pregnancy'. Members are advised to refer to these guidelines, which can be downloaded from MHRA's website. (Please refer to section 8 for the website address.)

1.5.4 Natural and herbal claims

19 Advertisers shall not suggest that a medicine is herbal unless it complies with the definition of ‘herbal medicinal products’ as set out in EU Directive 2004/24 EC (as amended).

Advertisers may claim that a product, substance or preparation is herbal if it meets one of the following criteria:

- ‘Herbal medicinal product: any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more such herbal preparations.’
- ‘Herbal substances: all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried, form, but sometimes fresh. Certain exudates that have not been subjected to a specific treatment are also considered to be herbal substances.’
- ‘Herbal preparations: preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation. These include comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates.’

Where the active ingredients are of plant origin but do not comply with the criteria set out above, advertisers may state that the active ingredients are ‘of plant origin’ or words to that effect.

20 Advertisers shall not claim that a product is ‘natural’ unless all of its components are naturally occurring. ‘Natural’ can also be used to describe the particular elements of a product that are naturally occurring (e.g. ‘natural ingredient’).

Advertisers may only claim that a product is natural if the product is 100% natural, i.e. all of the ingredients and excipients are naturally occurring. If, however, only the active ingredients are natural, the claim must be limited to those ingredients (e.g. ‘Brand X contains [name of ingredient], a natural active ingredient’ or ‘Brand X contains the natural active ingredients [name of ingredient] and [name of ingredient]’).

The majority of ‘natural’ claims fall into one of three categories:

- products in which all of the ingredients and excipients are naturally occurring, e.g. ‘natural remedy’, ‘natural Brand X’, ‘natural laxative’, ‘made from natural ingredients’, ‘a natural choice’
- products in which the ingredient referred to is of natural origin, e.g. ‘contains natural ingredient Y’
- products which have a natural mode of action i.e. an action which mimics a physiological mechanism of the body e.g. ‘works naturally’ and ‘acts naturally’. A bulk forming laxative could claim to ‘act naturally’ even if the product is not made from natural active ingredients.

21 Advertising shall not suggest that the safety or efficacy of a product is due to the fact that it is natural or herbal.

This does not prohibit advertising claiming that a product is natural or herbal or that it contains natural or herbal ingredients, but it does prohibit claims such as ‘have confidence in Brand X because it is made from natural/herbal ingredients’ or ‘as it’s natural/herbal, you can be assured that it is safe’.

1.5.5 Comparative advertising

22 All comparisons shall be balanced, fair and supportable.

The most common comparisons are those relating to product palatability, speed of action, onset of action or duration of action. Very often these relate to the product's underlying mode of action.

Acceptable claims

For example, the following may be acceptable, provided there is sufficient evidence to support them:

- 'antacids can offer faster relief of the pain of excess acid, compared with H2 antagonists'
- 'some people find traditional treatments for vaginal thrush are less convenient than oral remedies'
- 'a topical nasal spray gets straight to work while tablets need to get into the system before they start to work'
- 'emollients need to be applied liberally and frequently, unlike steroid creams, which should be applied sparingly'.

When using comparisons, advertisers must ensure that the point of difference is sufficiently significant to be meaningful. For example, the following claim would not be acceptable:

- 'the only pain relief tablet that works for up to 6 hours', where there is a capsule that has a similar duration of action.

The claim below would be acceptable:

- 'the only soluble pain reliever that works for up to 6 hours', where the only other products with this duration of action are solid-dose capsules and tablets.

For THMs, advertising should not suggest that the efficacy of a THM is comparable to that of a medicine which has a Marketing Authorisation. The Traditional Herbal Medicines Registration Scheme is only open to herbal medicines which are not able to obtain a Marketing Authorisation due to there being insufficient scientific evidence of the product's effectiveness.

23 Comparisons shall not denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type, nor shall they mislead the recipient.

This rule applies to all competitor products, ingredients and treatments and not just to identifiable products or treatments. PAGB holds that this type of advertising damages confidence in the over-the-counter medicines industry.

Copy that compares the different attributes of products, treatments or ingredients, is acceptable provided it does not stray into denigration. For example, 'H2 antagonists have a longer duration of action than antacids', would be acceptable provided there is sufficient evidence. However, PAGB would not accept 'H2 antagonists are better than antacids' as PAGB takes the view that such all-encompassing statements would be denigrating to antacids.

In the case of a complaint relating to a comparison, the overall tone of the piece would play a significant role in influencing the acceptability. No comparative statement would be acceptable if intended to mislead the recipient or to denigrate another product or products.

Naming competitor products

Whilst it is acceptable to name competitor products in advertising aimed at persons qualified to prescribe or supply, advertisers should be very careful to avoid denigrating other products. Companies should also ensure that they comply with relevant trade mark laws.

Identifiable products

Where a comparison is made to a product that is identifiable through the pack livery, market position, etc., care should be taken to ensure that the identifiable product will not be confused with another product. A complaint may be upheld if the comparison could be related to another product where the comparison would be invalid.

Alteration of a competitor's materials to highlight a benefit to your product would turn those materials into advertising for your product. For example, if sections of a competitor's SmPC favour your own product, highlighting those sections would turn this into advertising for your product and so would require essential information to be included.

24 Hanging comparisons shall not be used.

A hanging comparison is a comparison which begs the question 'compared to what?' Such phrases imply superiority over other products. The most common hanging comparisons are words or phrases such as:

- 'faster' (e.g. 'faster pain relief')
- 'better' (e.g. 'a better treatment for insect bites')
- 'stronger' (e.g. 'a stronger painkiller')
- 'longer' (e.g. 'longer-lasting relief')
- 'quicker' (e.g. 'quicker-acting formula')
- 'more relief' (e.g. 'provides more relief')
- 'extra relief' (e.g. 'provides extra relief')
- 'the difference' (e.g. 'try Brand X and you'll notice the difference').

Words such as 'faster', 'better', 'stronger', 'longer', 'quicker' can be amended to 'fast', 'strong', 'long', or 'quick', and 'more' or 'extra' should be removed, unless they are qualified.

Words commonly used as part of hanging comparisons may be acceptable where the comparator is clear from the context. The most common examples are where the effects of the product are being compared to the effects of not using any treatment, or where the product is being compared to its previous formulation. Examples include:

- 'when your customers have a cold, Brand X helps them to feel better' (i.e. better than not using any treatment)
- 'new improved Brand X now works faster' (i.e. faster than the previous formulation).

25 Top parity claims are only acceptable when they are supported by positive evidence. Top parity claims are permitted where studies have been carried out which show that no other product within the same therapeutic category is superior to the one being advertised.

Top parity claims imply that no one product has superiority in a given area, such as efficacy, speed of action, duration of action, etc. It is often the case that several products within the category are of equal efficacy and that no single product can prove superiority.

Top parity claims are effectively comparisons made with all other products within the category, including medical devices. Examples include:

- 'nothing is proven to work better/faster/longer'
- 'nothing acts faster/better/longer'
- 'unbeaten relief/strength/power'
- 'there's nothing stronger available without prescription'
- 'there's nothing more effective/powerful'.

In order to make a top parity claim, advertisers must ensure that they consider all similar over-the-counter products, both branded and generic. Advertisers must ensure they have reviewed all published evidence relating to the proposed claim for each product/ingredient. Advertisers should be able to demonstrate that they have taken a systematic approach to reviewing the available evidence relating to competitor products.

Evidence for top parity claims typically consists of comparative studies or meta analysis. It should be noted that whilst head-to-head comparative studies are preferable to single ingredient (or single product) data there may be occasions when single ingredient studies and/or the pharmacological properties are sufficient to determine whether or not a claim is acceptable.

Companies who are using top parity claims must ensure that they proactively maintain an awareness of new products and ingredients and new evidence so that previously approved advertising does not continue to be used once new evidence and/or new products mean that the top parity claim has become invalid.

For further information on top parity claims, please refer to PAGB's 'Guideline on the Use and Substantiation of Top Parity Claims'.

26 Superiority claims are not acceptable unless supported by direct comparative tests or other demonstrations.

Care must be taken when making superiority claims as products within a therapeutic category are often licensed as offering the same degree of relief (e.g. 'mild to moderate pain').

Clinical superiority

Clinical superiority claims, such as 'the best', 'the fastest', 'the strongest', 'the most effective', require full substantiation, usually direct comparisons with all other formulations on the market and all available data. In practice, it is unusual for over-the-counter medicines to be able to prove clinical superiority and hence such claims are fairly uncommon.

Use of the definite article

Advertisers should note the word 'the' may be regarded as a superiority claim (e.g. 'the painkiller' implies that it is the best painkiller available). PAGB advises that 'the' is amended to 'a' or 'an'.

Subjective superiority

Subjective superiority claims relating to efficacy (e.g. '90% of people said Brand X gave faster/ better relief than any other formulation') also need to be supported by direct comparative clinical studies.

Taste

Subjective superiority claims relating to taste or other non-efficacy parameters, such as '90% of those asked said they preferred the taste of Brand X', are acceptable. However, such claims require robust consumer research. This type of claim requires comparisons against all other similar products in the category. Advertisers should note that the likelihood of competitor complaints is high. There is also the risk that should competitors run similar trials and reach an opposing conclusion the claim may have to be withdrawn.

Superiority vs. no.1 selling claim

Claims based on sales data must be carefully worded to avoid implying clinical superiority. Please refer to rule 16 for guidance on sales claims.

1.5.6 Testimonials

27 Quotations and testimonials shall comply with the other principles of this Code and must reflect the genuine views of the author.

Testimonials and quotes must comply with all other rules in the PAGB Professional Code for Medicines. Testimonials and quotes in themselves are not substantiation of the claim being made. Member companies must hold evidence to support the claims and the views expressed must be in line with current medical opinion. Companies must also make certain that the views ascribed to an individual or organisation accurately represent their current views. Care should be taken in editing that the original meaning is not altered.

1.5.7 References

28 All product claims used in promotional materials must be referenced unless the information is included in the Summary of Product Characteristics.

Please refer to section 1.1, for a definition of 'product claims'.

Whilst it is not a Code requirement, it is also good practice to reference background information relating to the therapeutic area.

'Data on file' can be used as a suitable reference where no published information or more specific reference can be quoted.

29 All graphs, tables, quotations and other illustrative matter must be accurately reproduced and the precise source(s) indicated. This includes materials such as 'before-and-after' photographs.

30 All sales claims used in advertising to persons qualified to prescribe or supply must be referenced.

Please refer to rule 16 for further information.

1.5.8 Promotional materials that are not part of a bound publication

31 All written materials shall be accurate, up to date, verifiable and sufficiently complete to enable the recipient to form his or her own opinion of the therapeutic value of the product to which the documentation relates.

32 All promotional materials that are not part of a bound publication must include the date of when the essential information was last drawn up or revised.

Please refer to rule 41 for further information, including details as to when the essential information may be omitted.

1.5.9 Gifts, prizes and inducements

33 No gift or benefit in kind shall be supplied, offered or promised to persons qualified to prescribe or supply unless it is inexpensive and relevant to the recipient's work.

Gifts

To be considered inexpensive a gift should have cost the donor company no more than £6 excluding VAT. Advertisers should also take into account the perceived value, which is the price at which recipients could purchase the item themselves. Acceptable gifts may include:

- pens
- notepads
- diaries
- desk tidies
- calendars
- desk clocks
- inexpensive computer accessories, such as mouse mats and data sticks
- relevant books
- surgical gloves
- first aid kits
- calculators
- nail brushes
- mugs
- tissues
- umbrellas
- stress toys.

Prizes

To be considered inexpensive a prize should have cost the donor company no more than £130 per prize, excluding VAT. No more than six prizes of £130 may be provided per national competition. Advertisers should also take into account the perceived value, which is the price at which recipients could purchase the item themselves.

For smaller competitions there should be no more than three prizes to the value of £130. Should companies wish to provide a larger number of small prizes, the total value of prizes awarded must amount to no more than £780 (i.e. 6 x £130) for a national competition and no more than £390 (i.e. 3 x £130) for a smaller competition.

Acceptable prizes may include the following, together with those items listed under gifts:

- relevant books and journal subscriptions (e.g. British Medical Journal, Chemist and Druggist)
- training courses (or a contribution towards the cost of attending such courses)
- training software
- test kits (e.g. cholesterol test kits, smokerlyzers, pregnancy test kits, blood glucose monitors, blood pressure monitors)
- health education DVDs
- free stock (to a maximum of £130, calculated at manufacturer's selling price)
- advertising space (e.g. advertising in a local newspaper for a community pharmacy)
- high-visibility jackets (e.g. for doctors doing night-time home visits)
- work wear (e.g. white coats)
- briefcases
- desk fans
- electronic organisers
- business card holders
- water coolers
- coffee/tea making equipment.

Gifts and prizes that are likely to be taken home are likely to be unacceptable. Items that have been found to be unacceptable include microwave ovens, television sets, watches, cordless phones, leisure bags, book vouchers, health farm weekends, music CDs, iPods, digital cameras and donations to charities.

Planograms

Provision of planograms by companies to persons qualified to prescribe or supply is acceptable provided it is not connected to the supply of any medicine. If a person qualified to prescribe or supply were to be required to purchase or supply a stated amount of product in order to receive a planogram, it would be treated as an inducement and, as such, subject to the provisions of the PAGB Professional Code for Medicines. In this instance, the planogram would need to be inexpensive. This guidance would also apply to other similar activities, such as provision of marketing advice.

Royal Pharmaceutical Society

The Royal Pharmaceutical Society has issued guidance in relation to the acceptance of gifts and inducements to prescribe or supply. Pharmacists who accept items such as gift vouchers, bonus points, discount holidays, sports equipment, etc. are in breach Part 14 of the Human Medicines Regulations 2012, as well as not complying with the guidance from Royal Pharmaceutical Society. This applies even where the inducements are presented as alternatives to financial discounts.

Corporate activities

This rule does not prevent companies providing medical and educational goods and services that will enhance customer care, benefit pharmacy or grocery services or benefit the National Health Service. However, they must not bear the name of, or be related to, any medicine but may bear a corporate name. For example, donation of the Company X fridge or Company Y hospital bench would be acceptable, so long as it is not linked to any medicine. Similarly, Company X may sponsor awards of greater value than £130, provided there are no links to any medicinal products.

1.5.10 Hospitality and meetings

34 Companies may offer hospitality to persons qualified to prescribe or supply and those who work for such persons, in association with professional, scientific, training and promotional meetings or events, provided that it is reasonable in level and strictly limited to the main purpose or scientific objective of the meeting or event.

SPONSORSHIP OF MEETINGS AND EVENTS

Member companies may sponsor a range of meetings, including small lunch time presentations in a group practice, hospital meetings, meetings at postgraduate education centres, management training courses, meetings of clinical trial sponsors or administrators, satellite symposia and large international meetings, organised by independent bodies (please refer to rule 35 on training).

The level of sponsorship provided must be proportionate to the event. For example, it may be acceptable to provide a greater level of sponsorship for an international seminar than for a local post-graduate training event.

Brand sponsorship

It is acceptable for brands to sponsor educational, scientific and training meetings or events. (It may be possible for a brand to sponsor a promotional event, although in most cases a brand is more likely to be hosting, than truly sponsoring, a promotional event.) Where meetings are sponsored by a brand, the provisions for that meeting must comply with 'Provisions for meetings', below.

It is not acceptable for brands to sponsor social events, such as award ceremonies.

Corporate sponsorship

Pharmaceutical companies may sponsor a wider range of meetings and events, including scientific, educational, training and promotional events.

It is acceptable for a pharmaceutical company to sponsor industry award ceremonies/dinners provided there is no mention of the company's medicinal products (apart from any mentions resulting from the awards).

Where a company is sponsoring a scientific, educational or training event, the provisions for the meeting must comply with 'Provisions for meetings', below.

Events hosted by pharmaceutical companies

Where a pharmaceutical company hosts an event such as a product launch, training or educational event, the hospitality provided must follow the guidelines below. These requirements must be followed whether or not any references are made to brands.

PROVISIONS FOR MEETINGS

The impression that is created by the meeting arrangements must be kept in mind. A useful criterion is 'Would you and your company be willing to have these arrangements generally known?'

Attendees

Retail/administrative/support staff may be invited to meetings where appropriate. For example, receptionists might be invited to a meeting in a general practice when the subject matter includes practice administration; pharmacy assistants might be invited to a meeting on pharmacy management where health education is discussed.

It should be noted that the British Medical Association Code recommends that doctors only attend meetings where the purpose of the event is educational.

Food and drink

Hospitality must not extend beyond persons qualified to prescribe or supply, other health professionals and appropriate administrative staff.

Hospitality must be secondary to the purpose of the meeting. The level of hospitality offered must be appropriate and not out of proportion to the occasion. The costs should not exceed the level which the recipients would normally pay for themselves.

Expenses

Hospitality includes the payment of reasonable, actual, travel costs for a delegate to attend a meeting. The payment of travel expenses and the like for persons accompanying the delegate are not permitted. The payment of reasonable honoraria and reimbursement of out-of-pocket expenses, including travel, for speakers is permissible.

Payments may not be made to doctors, other prescribers or pharmacists for use of their meeting rooms.

Venues

Venues must be appropriate for the purpose of the meeting. Companies should avoid using venues that are overly extravagant or renowned for their entertainment facilities.

Member companies should only host or sponsor meetings outside of the UK where it makes greater logistical sense to do so, for example, where most of the attendees are from outside the UK and travel arrangements mean that holding the meeting elsewhere would be more convenient. Similarly, if the resource or expertise that is the subject matter of the meeting is outside the UK, then it may be more appropriate to hold the meeting overseas.

TRADE SHOWS AND EXHIBITIONS

Trade shows and exhibitions are outside the scope of the PAGB Professional Code for Medicines unless they are promoting, or are sponsored by, a medicinal product. Any promotional activities run in association with medicinal products are subject to the PAGB Professional Code for Medicines.

MEETINGS OF A COMMERCIAL NATURE

Meetings of a commercial nature, where discussion is predominantly related to prices, margins and discounts, are outside the scope of the PAGB Professional Code for Medicines.

MEETING PAPERS AND PUBLISHED PROCEEDINGS

When meetings or events are sponsored or arranged by pharmaceutical companies or brands, the company sponsoring or arranging the event must be disclosed in the meeting papers and in any published proceedings (please refer to rule 34).

1.5.11 Training and education

35 Pharmaceutical companies or brands may provide training or education for persons qualified to prescribe or supply. They may also sponsor training or education provided by third parties. All materials must give a clear and concise indication of the exact involvement of the company/brand producing or sponsoring the materials.

Company-produced materials

Company-produced materials must be clearly identified as such, to ensure the recipient does not mistakenly interpret the materials as being independent. If brand mentions are included, the materials are likely to fall under the PAGB Professional Code for Medicines (depending on the content of the materials). Sponsorship statements must not be made on such materials, as this implies a degree of independence, and as such would be disguised promotion.

Third-party-produced materials that have been paid for by a pharmaceutical company

Member-company paid-for materials that have been produced by a third party and that discuss brands are viewed as promotional and are subject to the Code. Should a complaint be made against such materials, limitations of editorial control will be taken into account. Such materials must give a clear and concise indication of the exact involvement of the company/brand producing or sponsoring the materials, for example 'Developed in partnership with Company X'. The statement must not imply independence.

Companies should note that materials written by a third party and which mention the company's brands are regarded as advertisements, and it is the responsibility of the member company to ensure that such materials are factually accurate, consistent with the relevant SmPC(s) and fully compliant with this Code.

Member-company paid-for materials that have been produced by a third party and that do not discuss brands must explicitly declare the nature of their sponsorship. Such materials should offer unbiased, accurate and balanced information on the subject area. Examples of sponsorship statements include:

- 'Supported by an educational grant by Company X' (where Company X has provided money and had no further involvement)
- 'Article and printing costs sponsored by Company X' (where Company X has provided money and had no further involvement)
- 'Developed in partnership with Company X' (where Company X has had the opportunity to comment on/make amendments to the text).

Advertisements can be included within these materials, but they cannot be directly linked to the educational content. The advertisements would be subject to the Code.

1.5.12 Provision of samples for promotional purposes

36 The provision of samples is not permitted under the PAGB Professional Code for Medicines.

These requirements are set out in Part 14 of the Human Medicines Regulations 2012. Samples to prescribers are, under certain circumstances, allowed under the Association of the British Pharmaceutical Industry (ABPI) Code of Practice.

1.5.13 Representatives

37 Members should ensure that representatives have adequate training to ensure sufficient scientific knowledge of the medicines they promote to enable the provision of precise and complete information about such medicines.

38 Members should also ensure that representatives have sufficient knowledge of the PAGB Professional Code for Medicines.

PAGB runs regular advertising workshops to assist companies in applying the principles of the PAGB Medicines Advertising Codes.

39 Representatives are required to have available a copy of the SmPC for any medicine that they promote. This should be given to persons covered by this Code on request. The SmPC can be provided electronically (e.g. by CD.DVD, memory stick, weblink etc). Companies are advised that should a representative be asked for hard copy having offered an electronic copy, this may be provided later.

40 Representatives must notify the scientific service of their company regarding any information received in relation to the use of the medicines they promote, particularly any information relating to adverse reaction reports.

1.5.14 Essential information in professional advertising

41 Essential information is required to be provided in all advertising materials directed wholly or mainly at persons qualified to prescribe or supply except for those materials that are specifically exempt from this requirement.

There are two forms of essential information that can be used in different circumstances: long form and short form.

The long form essential information must be included for:

- Training material for P medicines (for GSL products essential information is required, the long form is recommended)
- Advertisements for innovative pharmacy only medicines exceeding 420cm² (NB. 310.8cm² equates to A5) and all loose inserts for these medicines during the first two years after launch and where mandated by the MHRA (eg. through a requirement in the Risk Management Plan (RMP) of the product).

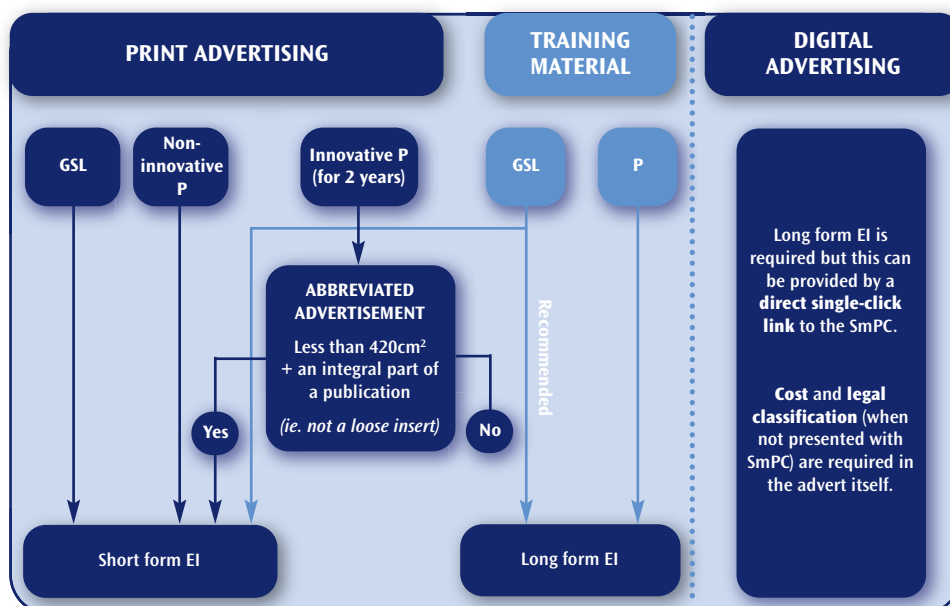
NB. For advertisements for innovative pharmacy only medicines that are less than 420cm² that are an integral part of a larger publication (not issued in the form of a loose insert), the short form essential information is still acceptable.

The short form essential information must be included in:

- Abbreviated advertisements (no larger than 420cm² and an integral part of a larger publication ie. not issued in the form of a loose insert)
- Advertisements for non-innovative pharmacy only medicines and medicines classified as general sales including advertisements for products with traditional herbal registrations. NB If preferred the long form essential information can be included instead of the short form

Long form

Short form



Long form requirements:

Identification

- name of the product
- a list of the active ingredients, which must be placed immediately adjacent to the most prominent display of the product name. (The font size must be such that the lower case letter 'a' measures at least 2 mm in height, which equates to font size 10 for the majority of fonts. Where the name on pack is the most prominent product name in the advertisement, front facing pack shots (not oblique) may satisfy this requirement provided they meet the required font size (please refer to rule 42, on legibility)
- product licence number
- name and address of the product licence holder, or the part of the product licence holder's business responsible for the supply of the product
- supply classification (P, GSL)

Use of the product

- indications: one or more of the indications for the use of the product (including the traditional use statement when required)
- side effects, precautions and relevant contra-indications: a succinct statement describing the side effects, precautions and contra-indications related to the indications shown
- dosage and method of use: a succinct statement describing how and when the product should be used. The method of administration should be included if it is not obvious
- warnings: any warning statements required for advertisements as a condition of the Marketing Authorisation
- cost: the cost (excluding VAT) of a specified pack size, specified quantity or recommended daily dose of the product. It should be clear whether the quoted price refers to trade or retail (both are acceptable)*
- date: the date when the essential information was drawn up or revised should be included if the advertisement is not bound into a dated publication.

*There is an exception 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.

Identification

Short form requirements:

- name of the product
- a list of the active ingredients, which must be placed immediately adjacent to the most prominent

¹ Please refer to section 5.1, for a definition of 'product claims' and 'medicinal claims'.

display of the product name. The font size must be such that the lower case letter 'a' measures at least 2 mm in height, which equates to font size 10 for the majority of fonts. Front facing pack shots (not oblique) may satisfy this requirement provided they meet the required font size (please refer to rule 42, on legibility)

- name and address of the product licence holder, or the part of the product licence holder's business responsible for the supply of the product
- supply classification (P, GSL)

Use of the product

- indications: one or more of the indications for the use of the product (including the traditional use statement when required)
- "Information about this product, including adverse reactions, precautions, contra-indications, and method of use can be found at: [direct single-click website link]"

Digital advertisements requirements:

For advertisements on digital platforms the long form essential information should be included however, these requirements can be met by the inclusion of a direct single-click link to information listed above. Cost and legal classification are not included in the SmPC but must still be included in the advertisement or linked information.

Traditional Use Statement

For Traditional Herbal Medicines (THMs), the statement 'Traditional herbal medicinal product for use in [specify one or more of the indications for the product consistent with the terms of the registration] exclusively based on long-standing use as a traditional herbal remedy.' This statement must be sufficiently prominent to ensure that recipients of the advertisement understand that the product is a THM.

Adverse Event Reporting

Whilst there is no requirement to include information on adverse event reporting within advertising materials, it may be helpful to do so. Advertisers who choose to include this information may wish to use wording similar to: 'Adverse events should be reported. Reporting forms and information can be found at yellowcard.mhra.gov.uk. Adverse events should also be reported to [relevant pharmaceutical company]'.

NB. Advertising for use during pregnancy

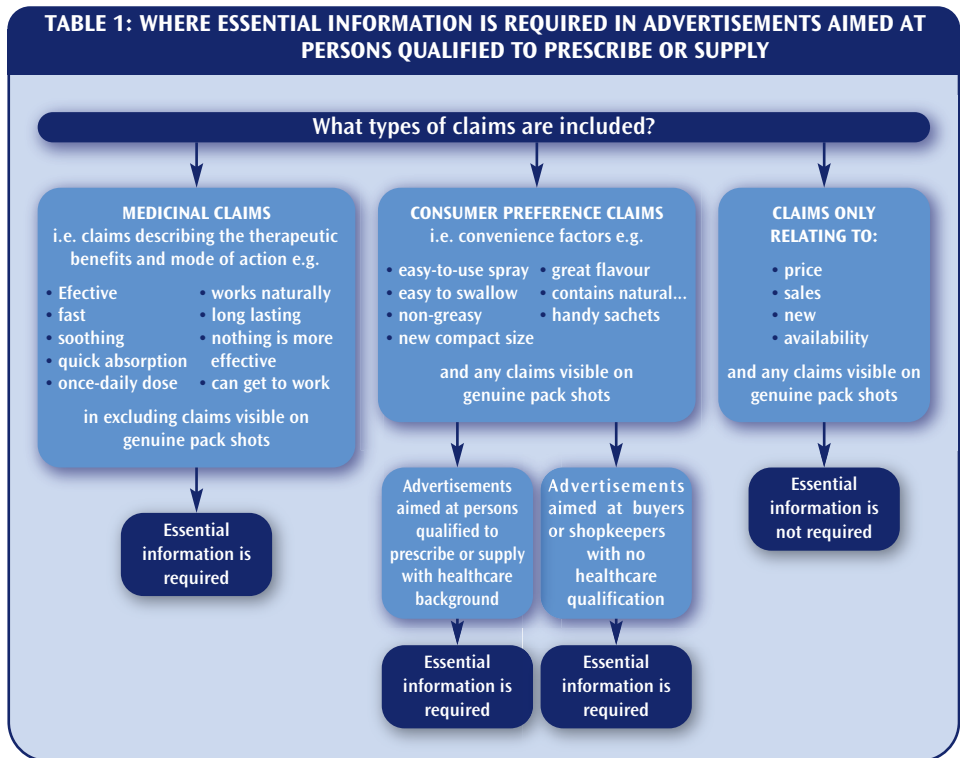
When promoting medicines for use during pregnancy, member companies should refer to rule 18 and to the MHRA's guideline 'Medicines which are promoted for use during pregnancy'

Circumstances in which essential information is required

Essential information must be included in the following circumstances (please also refer to 'Buyers and shopkeepers' below):

- where product claims¹ are made. (This does not include those which can be seen on a genuine pack shot)
- where direct or implied product claims¹ are included in the form of artwork. (This does not include the artwork on a genuine pack shot)
- where direct or implied product claims¹ are included in the form of questions and answers, such as in a competition
- where promotional items used at exhibitions include product claims¹. (The essential information may be available either on the items themselves or at the stand.)
- where 'post-it notes' or notes¹ or calendars bear product claims¹. (The essential information does not need to be included on every page, provided it is supplied on the cover or back page.)

- on envelopes addressed to persons qualified to prescribe or supply. (Envelopes may have a claim or a brand name without necessitating the inclusion of essential information. If both a claim and a brand name are included the essential information must be present.)
- in factual and informative announcements that include product claims¹. This does not include those that can be seen on a true representation of a pack, or as a straightforward representation of the indications (please refer to section 1.3.4). Factual and informative announcements include documents such as trade catalogues, price lists and planned-list order forms (PLOFs)



Circumstances in which essential information is not required

Essential information is not required in the following circumstances:

- in advertisements that do not contain product claims¹ (other than those that can be seen on a genuine pack shot). (For further information, please refer to section 1.3.3.)
- on items intended wholly or mainly for consumers. These may be shown to persons qualified to prescribe or supply without triggering the requirement for professional essential information
- on promotional aids, provided they feature no more than the product name or a reasonable abbreviation thereof, and trade mark protection. (Please refer to rule 45 for further information.)
- on dummy packs used for display purposes. (However, essential information may be required where additional advertising claims are added and where such claims are aimed at persons qualified to prescribe and supply.)
- in factual and informative announcements that do not include product claims¹ other than those that can be seen on a true representation of a pack, or as a straightforward representation of the indications (please refer to section 1.3.4). Factual and informative announcements include documents such as trade catalogues, price lists and planned-list order forms (PLOFs)

Note on planned-list order forms (PLOFs)

Whether the essential information is needed on a PLOF will depend on who the target audience is (persons with or without a healthcare qualification) and on what claims are included. The flow chart above can be used as a guide to whether essential information should be included.

¹ Please refer to section 5.1, for a definition of 'product claims'.

42 The essential information required in professional advertising must be prominent and clearly legible.

Advertisers are responsible for ensuring that the essential information is clearly legible. The information below describes the minimum requirements in terms of font size. However, there are several additional factors that affect legibility; attention should also be paid to issues such as number of characters in a line, line spacing, type style, print quality, contrast between text and background and identification of headings.

Font size of active ingredients

Part 14 of the Human Medicines Regulations 2012 requires that the active ingredients are listed immediately next to the most prominent display of the product name. The most prominent display of the product name is subjective. However, where a pack shot is featured, this is generally considered to be the most prominent display and a list of all actives should be placed adjacent to this.

The list of active ingredients should be stated in a font in which the lower case letter 'a' measures at least 2mm in height. (This equates to font size 10 for the majority of fonts.)

Other items of essential information

For all other items of essential information, where an advertisement is intended to be read in close proximity a lower case letter 'a' must measure at least 1mm in height. For the majority of fonts, this equates to font size 8. (This guidance does not apply to active ingredients.)

No set font size is required for essential information on items, such as posters, that will be read at a distance. It is the advertiser's responsibility to ensure that all of the essential information is clearly legible. Careful consideration must be given to the distance from which the advertisement will be viewed.

Positioning of essential information

The essential information must be horizontal.

It is not acceptable to have the information upside down in relation to the advertisement, printed in a spiral fashion, around the outside of the advertisement or in any manner that makes reading the information difficult.

Essential information should be contained within the advertisement or, in the case of a full A4 advertisement or similar, on a facing page, provided there is no intervening editorial or pictorial, etc. With regard to website banner advertising, the essential information may be provided by adding a direct and prominent link to the necessary information.

In the case of multiple-page advertisements, information is not required on each page provided there is a clear reference on the front page referring the reader to where the information can be found. This is only applicable where the advertisement is on consecutive pages with no intervening editorial. The reference must measure at least 1mm in height. For the majority of fonts, this equates to font size 8.

Essential information needs to appear only once. For example, if a pack shot includes the name and indications in a legible manner there is no requirement to repeat the name and indications elsewhere.

43 In the case of audio-visual material, such as films, video recordings, etc., and interactive data systems, the essential information must be provided in written form. This may be

provided either by way of a document that is made available to all persons to whom the material is shown or sent, or by inclusion in the audio-visual recording or the interactive data system.

Audio-visual advertisements and advertisements on interactive systems require the full essential information to be included and are not eligible for the inclusion of abbreviated essential information.

It is acceptable to provide the essential information audibly as an addition to the written form, but not instead of the written form.

44 In the case of audio material consisting of sound only, the essential information must be provided by way of a document that is made available to all persons to whom the material is played or sent.

Audio advertisements require the full essential information to be included. They are not eligible for exemption from the requirement to include full essential information. It is acceptable to provide the essential information audibly as an addition to the written form, but not instead of the written form.

45 Promotional aids are not required to comply with the requirements to include essential information, provided they feature no more than the product name or reasonable abbreviation thereof and the trade mark protection.

Promotional aids are items that have a purpose other than to promote a medicine but which display a product name as a reminder. Examples include pens, mugs, coasters, note pads and mouse mats. Promotional aids are exempt from the requirement to include essential information, as set out in rule 41, if they bear no more than a product name, a reasonable abbreviation thereof or an umbrella brand name and a trade mark protection. However, if any additional information is included, such as a strap line or a visual representation of a claim, the item will need to carry essential information.

The list of acceptable gifts in rule 33 may also be used as guidance on the provision of promotional aids. However, items not considered to be relevant to the practice of medicine or pharmacy are not excluded. For example, depending upon the circumstances balloons may be used as promotional aids. Promotional aids intended for persons qualified to prescribe or supply should cost no more than £6 excluding VAT. Advertisers should also take into account the perceived value, which is the price at which recipients could purchase the item themselves.

1.6 PAGB Professional Code for Medicines advertising checklist

The list below is intended as a reminder of some of the elements you should consider when reviewing professional advertising. It is not a complete list of all aspects to be considered.

1 Does the item fall under the PAGB Professional Code for Medicines?

The following do not fall under the PAGB Professional Code for Medicines:

- items that do not mention a medicine by name
- items that mention a medicine by name but contain no product claims other than those featured on a genuine pack shot (sections 1.3.1 and 2.1)
- factual and informative announcements that only refer to prices, adverse drug reactions, new labelling and new pack sizes, etc.

- items promoting the prescribing of a medicine
- items relating to products, such as medical devices, food supplements and cosmetics, that are not subject to a Marketing Authorisation
- items that are a response to a specific enquiry or comment by a person qualified to prescribe or supply.

(For further information on materials that do and do not fall under the PAGB Professional Code for Medicines please refer to sections 1.2 and 1.3.)

2 Ensure the advertising complies with the PAGB Professional Code for Medicines.

The following items should be checked:

- the medicine should not be advertised prior to the issue of the Marketing Authorisation (rule 2)
- the item should be factual, not misleading and in line with the SmPC (rules 3 and 4)
- the material should encourage the responsible use of medicines and should not undermine current healthy-lifestyle advice (rules 5 and 6)
- the activity should respect the status of the recipient and be reputable, and all claims should be supportable (rules 5 and 9)
- the material may only refer to the MHRA, EMA or to the Licensing Authority in order to state that the product is licensed (rule 7)
- if 'new' is used, the medicine should have been launched within the UK for no longer than one year (rule 13)
- if the product is said to be unique, there should be an explanation as to why it is unique (rule 14)
- if 'safe' is used, it should be qualified (rule 15)
- if use in pregnancy is mentioned, rule 18 must be complied with
- if the product is said to be 'herbal' or 'natural', rules 19 to 21 must be complied with,
- if comparisons are used, they must comply with rules 22 to 26
- any quotations must be up to date, must comply with all other rules of the Code and must be in line with current medical opinion (rule 27)
- references must be included for all graphs, tables, sales claims and all product claims that are not in the SmPC (section 1.5.7)
- if the item is for an innovative P product and over 420cm² ensure it contains the long form essential information (rule 41)
- if the item is under 420cm² and is part of a bound publication, ensure it contains the short form essential information (rule 41)
- if the item is under 420cm² but not part of a bound publication, ensure it contains the full essential information (rule 41)
- if the item is audio or audio-visual, ensure the essential information is available in written form (rules 43 and 44)
- if the promotion involves a gift or prize, ensure it complies with rule 33
- if the promotion involves hospitality, ensure it complies with rule 34
- if representatives of the company are involved, ensure it complies with rules 37 to 40,
- if sampling is involved, ensure it complies with rule 36
- if the item involves free packs, ensure this complies with sections 1.3.10, 1.3.12 - 1.3.14 and 1.5.12 as applicable.

3 Training

- Training materials require essential information. In all cases the long form essential information is recommended, for innovative P it is mandatory. (Rule 41)
- companies should ensure that those involved in ensuring compliance with the PAGB Professional Code for Medicines have a thorough working knowledge of the Code

- companies should ensure that copies of the PAGB Medicines Advertising Codes are provided to all relevant personnel and that these personnel are encouraged to attend a PAGB Medicines Advertising Workshop. This includes company representatives and agency staff
- representatives should be trained to a reasonable level with regard to the products they are promoting and with regard to the relevant aspects of the PAGB Professional Code for Medicines
- companies must endeavour to make internal procedures sufficient to ensure compliance with any rulings regarding breaches of the PAGB Professional Code for Medicines
- companies should ensure that procedures are in place to disseminate any information that PAGB may provide in relation to the Code. For example, personnel involved in ensuring compliance with the PAGB Professional Code for Medicines should be included on PAGB's advertising mailing list
- brand specific training materials for P medicines must include the long form essential information (for GSL products short form essential information is required, however the long form is recommended).

Advertising case studies

A4 Professional Journal Advertisement A

1. Essential information

Comment: This advertisement is over 420cm², in most cases for OTC medicines the short form essential information should be included. However, for innovative P products in advertisements larger than 420 cm² the long form essential information is required (Rule 41). For short form essential information the following should be considered:

- the active ingredient must be stated immediately adjacent to the most prominent display of the product name. Arguably, this would be the product name in pink at the top of the advertisement
- this advertisement will be published in a journal, so the date when the essential information was last updated is not required
- the font is very pale which makes the text difficult to read. It would also be helpful to put the subheadings in bold. (Rules 41 and 42)



2. New Unique Formulation

Comment: The formulation has been available in the UK for more than one year. Therefore, the claim needs to be amended to 'New to the PAGB range', or similar. (Rule 12)

Where advertising claims that a product is 'unique', it must make clear what aspect of the product is unique.

3. Dual action – helps to soothe colds

Comment: This claim is misleading. Section 5.1 of the SmPC indicates that the product has one mode of action. Looking at section 4.1 of the SmPC, it is clear that product is not indicated to treat

colds. (Rules 3 and 4)

4. Faster relief

Comment: This is a hanging comparison. The claim could be changed to 'fast relief' if the advertiser has evidence that the product relieves symptoms within 30 minutes. (Rule 23). The claim would need to be referenced as the speed of action is not stated on the SmPC. (Rule 27)

5. Better than Brand X

Comment: The PAGB Professional Code for Medicines does not prohibit advertisers from mentioning a competitor's brand name. However, the term 'better than' is unfairly denigrating to the competitor product. (Rules 21 and 22) If the claim is amended to something more suitable, it will need to be referenced. (Rule 27)

6. Recently approved by the Department of Health

Comment: MHRA have advised that this wording would not be acceptable. The claim could be changed to 'Authorised by the Department of Health'. (Rule 7)

7. Natural

Comment: In order to make this claim, all of the actives and excipients would need to be natural. Looking at sections 2 and 6.1 of the SmPC, we can see that the claim is not supportable. (Rule 19)

8. Nothing lasts longer

Comment: Top parity claims are only acceptable when supported by evidence (Rule 24). Under the PAGB Professional Code for Medicines, product claims must be referenced, unless the information appears on the SmPC. (Rule 27)

9. No 1

Comment: This claim must be supported by three months of recent sales data and needs to be referenced (Rules 15 and 29). In addition, the claim needs to be reworded to clarify that it relates to sales data. (Rule 15)

10. Enter our competition to win a training course on children's medicines worth £250. See www.pagbcomp.com for details.

Comment: Under the PAGB Professional Code for Medicines, prize promotions are only acceptable if the value does not exceed a maximum of £130. (Rule 32) The terms and conditions must also be stated.

A5 Professional Journal Advertisement A

1. Essential information

Comment: This advertisement is less than 420cm² and is printed in a bound journal. Therefore, it may include the short form essential information (Rule 41), rather than the long form essential information (Rule 41). It must also comply with guidance on prominence and legibility. (Rule 42) The following should be considered:

- the active ingredient must be stated immediately adjacent to the most prominent display of the product name. The most prominent display of the product name is the product name in pink at the top of the advertisement
- the supply classification, P or GSL must be stated
- any warning statements required by the Marketing Authorisation should be stated
- The following form of words to indicate that further information is available on a specified website: "Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at: [direct single-click website link]" (Rules 41 and 42)



2. Helps with all types of cough

Comment: Section 4.1 of the SmPC states that the product is indicated for dry, tickly cough only. (Rules 3 and 4)

3. Guaranteed to soothe tickly cough in children of all ages

Comment: There is no specific prohibition on the use of guarantees in advertising to professionals and trade. However, claims must not be misleading and should reflect the degree of change that an average user could expect. (Rule 4) 'Children of all ages' is misleading as the product is indicated for children of 3 months and over. (Rules 3 and 4)

4. No 1 best-selling medicine

Comment: This claim must be supported by three months of most recent sales data and needs to be referenced. (Rules 15 and 29)

5. Can work in 10 minutes

Comment: The wording of this claim is not ideal as it may imply that the product can result in a cessation of symptoms in ten minutes. 'Can relieve symptoms in 10 minutes' would be preferable, as long as the advertiser has evidence to support the claim. The claim would need to be referenced as this information is not stated in the SmPC. (Rules 10 and 27)

6. PAGB Children's Ticky Cough is sponsoring Jones' Awards Dinner in November.

Comment: Brands are not permitted to sponsor social events such as award dinners. It would, however, be acceptable for the pharmaceutical company to sponsor the event. (Rule 34)

7. Call 0800 123 456 for free samples

Comment: The provision of samples is not permitted under the PAGB Professional Code for Medicines. (Rule 36)

8. 'Always read the label.'

This warning is not required in advertising aimed at persons qualified to prescribe or supply.

A5 Professional Journal Advertisement B

1. Essential information

Comment: This advertisement is less than 420cm² and is printed in a bound journal. Therefore, it may include the abbreviated essential information, rather than the full essential information (Rule 41). It must also comply with guidance on prominence and legibility. (Rule 42) The following should be considered:

- the active ingredient must be stated immediately adjacent to the most prominent display of the product name. The most prominent display of the product name is the product name in pink at the top of the advertisement
- the supply classification, P or GSL must be stated
- any warning statements required by the Marketing Authorisation should be stated
- The following form of words to indicate that further information is available on a specified website: "Information about this product, including adverse reactions, precautions, contraindications, and method of use can be found at: [direct single-click website link]". (Rules 41 and 42)

2. New Flavour

Comment: This claim is acceptable as long as the flavour has only been available for less than one year. (Rule 12)

3. This product is about to be licensed and will soon be available to order

Comment: It is not acceptable to advertise a product before the Marketing Authorisation is granted. (Rule 2)

4. No 1 best-selling children's cough syrup

Comment: This claim must be supported by three months of most recent sales data and needs to be referenced. (Rules 15 and 29)

5. Can get to work in 10 minutes

Comment: This claim must be supported by evidence. If the advertiser has evidence that the product offers relief in 10 minutes, the claim would be acceptable. In cases where the claim is based on absorption data, the advertiser would need to add "*refers to absorption data" or similar. The claim needs to be referenced. (Rules 10 and 27)



A5 Professional Journal Advertisement C

1. Essential information

This advertisement does not contain any product claims (other than those appearing on the pack shot) and hence the essential information is not required. (Rule 41)



2. Glossary

2.1 Product Claims

Product claims are defined as any claims relating to the therapeutic benefits or user-friendly nature of the product. They include both 'medicinal claims' and 'consumer preference claims'. They do not include claims relating to price or availability, claims that the product is new, claims related to sales or commercial claims.

Medicinal claims

2.1.1 Medicinal claims are defined as claims relating to the therapeutic or medicinal benefits of the product. Medicinal claims include claims relating to the product's mode of action, such as 'works naturally'. Examples of medicinal claims include:

- 'effective'
- 'soothing'
- 'fast'
- 'works naturally'
- 'long lasting'
- 'can get to work in...'
- 'lasts for up to 4 hours'
- 'nothing is more effective than...'
- 'fast absorption'
- 'once-daily dose'.

Consumer preference claims

2.1.2 Consumer preference claims are defined as any claims relating to the sensory attributes or user-friendly nature of the product. These are non-medicinal claims that relate to consumer preferences and not to the product's therapeutic benefits. They include claims relating to the product format, packaging and ease of use, together with sensory aspects, such as taste. (They do not include claims relating to availability or price, claims that the product is new, or sales claims.)

Examples include:

- 'easy to swallow'
- 'made from natural ingredients'
- 'great flavour'
- 'compact pack'
- 'handy sachets'
- 'non-greasy'.

2.2 Advanced

An efficacy advance

When using the term 'advanced', advertisers should make it clear which aspect of the product they are referring to as 'advanced'. As a rule of thumb, PAGB has devised three criteria for the use of the word 'advanced'.

2.2.1 For example, if Brand X has data to show that it offers better dandruff removal compared to all other products on the market, it can use the claim 'advanced dandruff removal'.

2.2.2 Where it is the only product that has become available over the counter and can demonstrate a superior level of efficacy, then the product can continue to use the 'advanced' claim indefinitely. However, where more than one product has become available that can demonstrate the same level of efficacy (for example, when two or more products with the same

active ingredient have recently switched from POM to P), then each product can make the claim for one year from the date that the first product with that level of efficacy became available over the counter.

A formulation advance

2.2.3 For example, if a product contains the ingredient perceived as being the most state-of-the-art ingredient in this sector, it can claim to have an 'advanced formulation'. Such claims are likely to be very similar to advanced efficacy claims.

Product reformulation advance

2.2.4 Where it is the only product that has become available over the counter and that contains this ingredient, it can continue to use the 'advanced' claim for as long as the ingredient continues to be perceived as being the most advanced ingredient in its sector. However, where more than one product has become available, each of which contains the said ingredient, all such products can make the claim for one year from the date when the ingredient was first available for purchase.

A format advance

2.2.5 Where a brand is reformulated to deliver improved benefits to consumers, it can claim to be advanced for this reason. For example, if Brand X is reformulated to incorporate faster dissolution it can then claim to be 'Advanced Brand X'. In such cases, the advertising must specify in what way the product has advanced. This claim could be used for one year from the date when the reformulated product became available.

2.2.6 Where a treatment first becomes available in a particular format, and can demonstrate that this offers a benefit to consumers, it can claim to be advanced for this reason.

2.2.7 Where a product is the only over-the-counter product in its category that has this particular format, and where that format offers a tangible benefit to consumers, the product can continue to use an 'advanced' claim until it is superseded by other format advances. However, when more than one product can demonstrate the same format advance, each product can make the claim for one year from the date that the first product with the particular format became available over the counter.

2.3 Breakthrough

The claim 'breakthrough' would only be acceptable where a product offers a significant, tangible benefit for consumers, compared to previously available products. In other words, where 'advanced' is a step forward, 'breakthrough' would be a leap forward.

2.3.1 A 'breakthrough' claim may be acceptable in the following circumstances:

- with formulations that have recently switched from POM to P
- where the product is the first in a therapeutic category to be available over the counter
- where the product is the first one in the therapeutic category to contain a particular active ingredient offering a significant clinical improvement on the active ingredients that were previously available.

For example, when statins switched from POM to P, they offered a breakthrough in self-medication for the treatment of raised cholesterol.

2.3.2 'Breakthrough' claims can be used for one year from the date when the first product with that particular attribute became available over the counter.

2.4 Revolutionary

The same criteria would apply as for breakthrough. Please refer to section 2.3.

3. Summary of differences between the PAGB Consumer Code and the PAGB Professional Code for Medicines

The table on the next page is intended as a useful reminder as to the organisations from which members are required to obtain pre-publication approval for consumer advertising, along with the relevant complaint bodies. Please note, in certain circumstances MHRA may also require Marketing Authorisation holders to submit their advertising for pre-vetting.

TABLE 2: SUMMARY OF THE KEY DIFFERENCES BETWEEN THE PAGB CONSUMER CODE AND THE PAGB PROFESSIONAL CODE

	PAGB CONSUMER CODE	PAGB PROFESSIONAL CODE
PAGB pre-publication approval of advertising?	Yes	No
PAGB complaints process?	Informal conciliation	PAGB considers formal complaints
General principles	Additional rules relating to: <ul style="list-style-type: none"> • use of medicinal terminology • not causing unnecessary anxiety • not suggesting health could be adversely affected if the consumer chooses not to use the medicine featured • not providing information that could lead to the consumer making an erroneous self-diagnosis • not discouraging consumers from seeking advice from a health professional • not offering to diagnose or advise by correspondence • not encouraging unnecessary use of medicines • prohibition on implying that the product's effects are guaranteed 	Additional rules relating to: <ul style="list-style-type: none"> • use of graphs and tables
Misleading advertising	Additional guidance relating to: <ul style="list-style-type: none"> • basing no.1 selling claims on volume-sales data • indicators of time change, particularly for TV advertising 	Additional guidance relating to: <ul style="list-style-type: none"> • no.1 selling claims - may be based on value-sales data but must be referenced
Pregnancy	A positive statement in section 1.1 or 1.6 of the SmPC is required	Images of pregnant women are only permitted where the product is indicated for use in pregnancy (1.1 of the SmPC)
Natural and herbal claims	No significant differences	No significant differences
Flavour claims	Additional rules relating to the use of flavour claims	
Advertising including medicines and non-medicines	Additional guidance relating to materials promoting medicines and non-medicines together	
Comparisons	Additional rules relating to: <ul style="list-style-type: none"> • prohibition on implying that the product's effects are better than or equal to another identifiable product • prohibition on the use of a competitor's brand name, unless permission is given • prohibition on stating that a product does not contain an active present in a competitor product where this would be denigrating 	
Endorsement	Additional rules relating to: <ul style="list-style-type: none"> • prohibition on health-professional endorsement • prohibition on celebrity endorsement • prohibition on advertising stating that a product is, or has been available on prescription 	
Testimonials	Rules are similar in both Codes	Rules are similar in both Codes
References		Additional rules relating to: <ul style="list-style-type: none"> • sales claims, graphs, tables and product claims that are not present on the SmPC
Gifts, prizes and inducements	Further guidance can be found in 'PAGB's Guideline on Consumer Promotions	Specific rules regarding gifts and prizes
Hospitality and meetings		Specific rules regarding hospitality and meetings
Training and educational materials	Sponsored materials must give a clear indication of the involvement of the sponsoring company/brand	Sponsored materials must give a clear indication of the involvement of the sponsoring company/brand
Sampling	Prohibited for Marketing Authorisation holders	Possible in very limited circumstances
Company representative activities		Specific rules
Essential information	Refer to Codes for information	Refer to Codes for information

4. Control of over-the-counter medicines advertising in the UK

4.1 Organisations involved in the regulation and self-regulation of over-the-counter medicines advertising

Medicines and Healthcare Products Regulatory Agency (MHRA)

The roles of the regulatory and self-regulatory organisations involved in the control of over-the-counter medicines advertising are described below. Also listed are the sanctions available to the organisations that deal with complaints and/or breaches of the codes/regulations.

Please refer to table 3 summarising the codes that apply to various consumer promotional activities and to table 4 summarising the organisations from which advertisers are required to obtain pre-publication approval for consumer advertising.

MHRA sanctions

4.1.1 MHRA is an executive agency of the Department of Health whose role it is to safeguard public health by ensuring that medicines and medical devices are effective and acceptably safe. Part of MHRA's role is to monitor and enforce Part 14 of the Human Medicines Regulations 2012 on behalf of the health ministers. MHRA is responsible for deciding if legal action will be taken against any advertiser under Part 14 of the Human Medicines Regulations 2012. The key principle is that advertising should not mislead and should reflect the terms of the product's Marketing Authorisation. The regulations specifically allow complaints under Regulation 9 to be referred by MHRA into the self-regulatory system.

The Committee of Advertising Practice (CAP) and the Advertising Standards Authority (ASA)

4.1.2 MHRA monitors advertising and also acts on complaints received concerning possible breaches of Part 14 of the Human Medicines Regulations 2012. Breaches of the Medicines Act 1968 and Regulations invoke separate and distinct sanctions that may be civil sanctions (e.g. withdrawal or amendment of advertising, injunctive powers to prevent issue of an advertisement, requirement to publish a corrective statement) or criminal sanctions (e.g. a fine of up to £5,000 on summary conviction, a fine of up to £5,000 or imprisonment for up to two years, or both, on conviction or indictment). Companies may appeal to the Independent Review Panel regarding MHRA rulings.

4.1.3 The Committee of Advertising Practice is the industry body responsible for the UK's advertising codes. Its non-broadcast Committee, CAP, writes and enforces the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code), which applies to non-broadcast advertising. The Committee comprises representatives of advertisers, agencies, media owners and other industry groups (including PAGB), all of which are committed to upholding the highest standards in advertising. CAP offers a free, pre-publication copy-advice service. The CAP Code does not apply to health claims in materials aimed at health professionals.

4.1.4 CAP's Broadcast Committee is contracted by the broadcast regulator, Ofcom, to write and enforce the codes of practice that govern television and radio advertising, the BCAP Broadcast Advertising Standards Code and the Advertising Standards Code for Text Services. The Broadcast Committee of Advertising Practice, BCAP, comprises representatives of broadcasters licensed by Ofcom, advertisers, agencies and direct marketers.

ASA Sanctions

4.1.5 The ASA is the independent body that is responsible for ensuring that the system operates in the public interest. Each year the ASA receives approximately 25,000 complaints about UK advertisements. Complaints are assessed against the CAP Code, the BCAP Broadcast Advertising Standards Code, or the Advertising Standards Code for Text Services, as applicable.

4.1.6 If a complaint is upheld, the ASA asks the advertiser to withdraw or amend the advertising. Broadcasters are obliged, by a condition of their Ofcom licences, to enforce ASA rulings and not to run advertisements that have been found to breach the codes. Similarly, if non-broadcast advertisers do not comply with adjudications, CAP can issue an 'Ad Alert'. Ad Alerts ask those responsible for accepting ads for publication to consult CAP's Copy Advice team before accepting any ads from the advertiser named in the alert. If advertisers do not co-operate with the selfregulatory system, the ASA can refer the advertiser to the Office of Fair Trading.

The ASA publishes adjudications on investigated complaints each week on its website (www.asa.org.uk). This generates a high volume of adverse publicity for advertisers who breach the codes.

4.1.7 Advertisements that break the codes are disqualified from industry awards, denying them and the agencies that created the ads the opportunity to showcase their work. Advertisers and agencies who persistently breach the Code jeopardise their membership of trade organisations.

4.1.8 In exceptional circumstances, an advertiser may apply to have an ASA adjudication reviewed if new evidence can be provided in defence of claims or if the advertiser can demonstrate a significant flaw in the adjudication or in the decision process.

Ofcom (Office of Communications)

4.1.9 Ofcom is a statutory body set up under the Communications Act 2003. Amongst a broad range of roles as communications regulator, Ofcom must ensure that the content of programmes and advertising on television and radio meets appropriate standards. Ofcom has contracted out the regulation of broadcast advertising to the ASA and BCAP.

Ofcom has retained responsibility for sponsorship on television and radio. The sponsorship rules can be found in the Ofcom Broadcasting Code.

Clearcast

4.1.10 Clearcast is the company responsible for the pre-transmission examination and clearance of television advertisements. As part of their licensing agreements with Ofcom, broadcasters are required to ensure that the advertising they broadcast is not misleading or harmful to viewers. Broadcasters choose to do this by pre-clearing advertising before it is broadcast. Clearcast is owned and funded by eight commercial broadcasters, all of whom are represented on Clearcast's board and all of whom use Clearcast for clearing advertising. Other broadcasters using Clearcast for clearance pay individually for Clearcast's services. Advertising is cleared in accordance with the BCAP Broadcast Advertising Standards Code and Clearcast's own Notes of Guidance. PAGB member companies are required to submit television advertising material to both Clearcast and PAGB.

Radio Advertising Clearance Centre (RACC)

4.1.11 The Radio Advertising Clearance Centre (RACC) is the self-regulatory body responsible for pre-vetting radio advertising copy. It is required and authorised by the regulator of commercial radio, Ofcom, to approve advertising copy in advance of broadcast. It therefore translates practically the requirements of the BCAP Broadcast Advertising Standards Code. RACC is funded by all licensed radio broadcasters. All radio advertising for medicines must be cleared by RACC before transmission. PAGB member companies are required to submit radio advertising materials to both RACC and PAGB. RACC has access to independent medical and nutrition advisers.

Cinema Advertising Association (CAA)

4.1.12 The primary function of CAA is to promote, monitor and maintain standards of cinema advertising. This includes pre-vetting all cinema commercials to ensure conformity with the UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code). CAA Copy Panel clears commercials for exhibition in cinemas in the UK and the Republic of Ireland. No commercial may be exhibited in a cinema unless it has been cleared by CAA.

4.1.13 PAGB is the self-regulatory body for over-the-counter medicines advertising. It offers a pre-publication approval service for consumer advertising in relation to over-the-counter medicines and food supplements, and advice on advertising aimed at professionals. Details of these services are given in sections 3.4 and 1.1.1 respectively, p7-10, p39.

4.1.14 PAGB runs a post-publication complaints system for advertising aimed at persons qualified to prescribe and supply. PAGB is unable to adjudicate on formal complaints about member companies' consumer advertising as it will have approved the advertising prior to publication. Details of how PAGB deals with complaints regarding professional advertising and informal queries regarding consumer advertising are set out in 'PAGB's Standard Operating Procedure for Member Companies' Informal Queries and Complaints Regarding Competitors' Over-the-Counter Medicines Advertising'.

4.1.15 The PAGB Secretariat is responsible to the PAGB Board. The Board delegates matters of day-to-day interpretation of the PAGB Medicines Advertising Codes to the Secretariat. The Board are entitled to review any decisions of the Secretariat and to give general or specific guidance to the Secretariat on the interpretation of the Codes. Any PAGB member company can request a review, by the Secretariat, or the Board, of a Secretariat decision or point of interpretation. The process for requesting a review by the Board is set out in 'PAGB's Standard Operating Procedure for Member Companies' Informal Queries and Complaints Regarding Competitors' Over-the-Counter Medicines Advertising'.

The table below is intended as a useful reminder as to the organisations from which members are required to obtain pre-publication approval for consumer advertising, along with the relevant complaint bodies. Please note, in certain circumstances MHRA may also require Marketing Authorisation holders to submit their advertising for pre-vetting.

TABLE 3: SUMMARY OF THE ORGANISATIONS FROM WHICH PAGB MEMBERS ARE REQUIRED TO OBTAIN PRE-PUBLICATION APPROVAL FOR CONSUMER ADVERTISING, TOGETHER WITH INFORMATION ON THE RELEVANT COMPLAINT BODIES

CONSUMER PROMOTIONAL ACTIVITY	APPROVAL NEEDED	COMPLAINT BODIES
Print advertisements and direct marketing	PAGB	MHRA and ASA
Point-of-sale materials (not including promotions)	PAGB	MHRA
Sales promotions	The advertising material requires approval by PAGB	MHRA and ASA
Radio advertising	PAGB and RACC	MHRA and ASA
TV commercials	PAGB and Clearcast	MHRA and ASA
Cinema commercials	PAGB and the Cinema Advertising Association	MHRA and ASA
TV sponsorship	PAGB	MHRA and Ofcom
Radio sponsorship	PAGB	MHRA and Ofcom
Sponsorship, non-broadcast	PAGB	MHRA
Internet advertising	PAGB	MHRA and ASA
Internet home page	PAGB	MHRA and ASA

4.2 Regulations and codes of practice that apply to over-the-counter medicines advertising

Legislation

4.2.1 It is an offence under the Human Medicines Regulations 2012 to issue a false or misleading advertisement for any medicinal product.

4.2.2 Member companies and their agents are responsible for ensuring they are fully acquainted with, and conform to, the legal requirements in force at any time. Since such requirements are continually evolving, it is not possible to provide a definitive list of the relevant statutory instruments. However, the principal legal requirements which apply specifically to medicines advertising are the Human Medicines Regulations 2012.

4.2.3 MHRA produces guidance in the form of the Blue Guide – Advertising and Promotion of Medicines in the UK and additional guidelines on certain types of advertising e.g. advertising medicines for use in pregnancy. These may be found on MHRA's website (www.mhra.gov.uk).

Codes of Advertising Practice

4.2.4 The table below is intended as a useful reminder as to the different codes that apply to various consumer promotional activities. Please note that this is not an exhaustive list and there may be additional codes and/or guidelines depending on the type of promotional activity. Each of the codes referred to can be downloaded from the code-owning bodies' websites. Please refer to section 8 for details.

TABLE 4: SUMMARY OF THE MAIN CODES AND REGULATIONS THAT APPLY TO VARIOUS CONSUMER PROMOTIONAL ACTIVITIES

Consumer Promotional Activity	Codes and Regulations	Part 14 of the Human Medicines Regulations 2012	PAGB Consumer Code	The CAP Code (The UK Code of Non-broadcast Advertising, Sales Promotion and Direct Marketing)	BCAP Broadcast Advertising Standards Code	Ofcom Broadcasting Code
Print advertisements and direct marketing		Y	Y	Y		
Point-of-sale materials (not including promotions)		Y	Y			
Sales promotions		Y	Y	Y		
Radio advertising		Y	Y		Y	
TV commercials		Y	Y		Y	
Cinema commercials		Y	Y	Y		
TV sponsorship		Y	Y		Y	Y
Radio sponsorship		Y	Y		Y	Y
Sponsorship, non-broadcast		Y	Y			
Internet advertising		Y	Y	Y		
Internet home page		Y	Y	Y ¹		

¹The CAP Code applies to marketing communication on companies own websites. Please refer to the CAP Code for details.

5. External contacts

The Advertising Standards Authority

Mid City Place, 71 High Holborn, London WC1V 6QT
Tel: 020 7492 2222
Website: www.asa.org.uk

The Association of the British Pharmaceutical Industry

7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 0870 890 4333
Website: www.abpi.org.uk

Cinema Advertising Association

Corinthian House, 279 Tottenham Court Road, London W1T 7RJ
Tel: 0207 199 2433
Website: www.cinemaadvertisingassociation.co.uk

Clearcast

4 Roger Street, 2nd Floor, London WC1N 2JX
Tel 020 7339 4700
Website: www.clearcast.co.uk

The Committee of Advertising Practice

Mid City Place, 71 High Holborn, London WC1V 6QT
Tel: 020 7492 2222
Website: www.cap.org.uk

The Medicines and Healthcare Products Regulatory Agency

151 Buckingham Palace Road, Victoria, London SW1W 9SZ
Tel: 0203 080 6000
Website: www.mhra.gov.uk

Office of Communications

Riverside House, 2A Southwark Bridge Road, London SE1 9HA
Tel: 020 7981 3000
Website: www.ofcom.org.uk

The Prescription Medicines Code of Practice Authority

7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 020 7747 8880
Website: www.pmcpa.org.uk

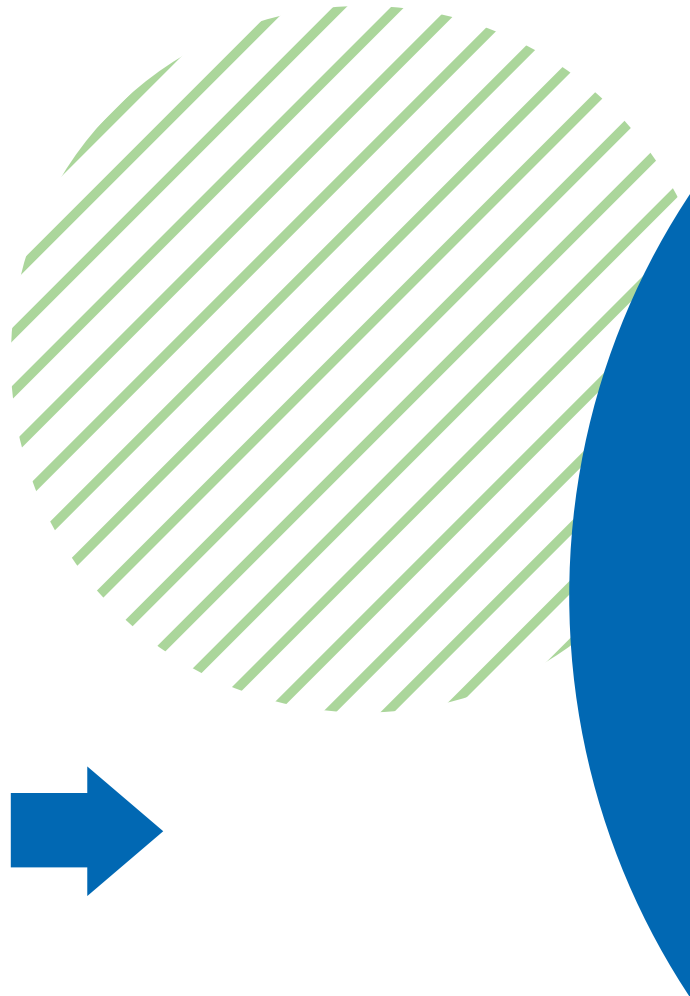
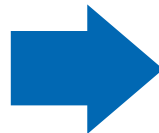
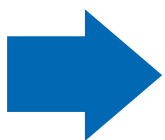
The Radio Advertising Clearance Centre

The Radiocentre, 6th Floor, 55 New Oxford Street, London WC1A 1BS
Tel: 0207 010 0608
Website: www.racc.co.uk

The Royal Pharmaceutical Society of Great Britain

1 Lambeth High Street, London SE1 7JN
Tel: 020 7735 9141
Website: www.rpsgb.org

Further information about the over-the-counter medicines industry and the work of the PAGB is available from: PAGB, Vernon House, Sicilian Avenue, London WC1A 2QS.
Tel: 020 7242 8331. Fax: 020 7405 7719. Email: copyclearance@pagb.co.uk.



Proprietary Association of Great Britain

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