

truthful

*herbal
medicines*

self-regulation

balanced

responsible

PAGB

Medicines

ADVERTISING CODES

For Traditional Herbal Medicines

	Introduction	
Page 3	1	What is PAGB?
Page 4	2	Introduction to PAGB's Medicines Advertising Codes for Traditional Herbal Medicines
	PAGB Consumer Code for Traditional Herbal Medicines	
Page 5	3.1	Compliance with the PAGB Consumer Code for Traditional Herbal Medicines
Page 5	3.2	What the PAGB Consumer Code for Traditional Herbal Medicines covers
Page 6	3.3	What the PAGB Consumer Code for Traditional Herbal Medicines does not cover
Page 7	3.4	The PAGB approval system for consumer advertising
Page 10	3.5	Rules of the PAGB Consumer Code for Traditional Herbal Medicines
Page 10	3.5.1	- General principles
Page 15	3.5.2	- Misleading advertising
Page 18	3.5.3	- Natural claims
Page 19	3.5.4	- Comparative advertising
Page 22	3.5.5	- Health professionals
Page 24	3.5.6	- Celebrities
Page 26	3.5.7	- Children
Page 27	3.5.8	- Testimonials
Page 28	3.5.9	- Promotions
Page 28	3.5.10	- Essential information for consumer advertising
Page 30	3.6	Submitting advertising for PAGB approval
Page 31	3.7	Consumer advertising checklist
	PAGB Professional Code for Traditional Herbal Medicines	
Page 33	4.1	Compliance with the PAGB Professional Code for Traditional Herbal Medicines
Page 33	4.2	What the PAGB Professional Code for Traditional Herbal Medicines covers
Page 34	4.3	What the PAGB Professional Code for Traditional Herbal Medicines does not cover
Page 36	4.4	PAGB Professional Code for Traditional Herbal Medicines code administration
Page 38	4.5	The PAGB Professional Code for Traditional Herbal Medicines complaints procedure
Page 41	4.6	Rules of the PAGB Professional Code for Traditional Herbal Medicines
Page 41	4.6.1	- General principles
Page 43	4.6.2	- Misleading advertising
Page 46	4.6.3	- Natural claims
Page 46	4.6.4	- Comparative advertising
Page 48	4.6.5	- Testimonials
Page 48	4.6.6	- References
Page 49	4.6.7	- Written material accompanying promotions
Page 49	4.6.8	- Gifts, prizes and inducements
Page 50	4.6.9	- Hospitality and meetings
Page 51	4.6.10	- Training and education
Page 52	4.6.11	- Sampling and free packs
Page 52	4.6.12	- Representatives
Page 53	4.6.13	- Essential information in professional advertising
Page 56	4.7	PAGB Professional Code for Traditional Herbal Medicines glossary
	Information	
Page 58	5	Control of OTC medicines advertising in the UK
Page 61	6	Useful addresses

1 What is PAGB?

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

PAGB's primary aim is to promote responsible self-medication to consumers and professionals. PAGB was set up in 1919 by a group of pharmaceutical manufacturers who wanted to protect the public from misleading medicines advertising by using a system of industry self-regulation. Members of the PAGB agreed to abide by the rules of the original advertising code and their consumer advertising was approved by PAGB prior to publication. The same principle holds true today. Since 1994, PAGB has published codes of practice which detail the requirements for advertising which is aimed at both consumers and professionals. PAGB now provides a pre-publication approval system for consumer advertising of registered traditional herbal medicines (THMs), OTC medicines which are subject to a Marketing Authorisation, and food supplements.

In operating the PAGB Medicines Advertising Codes, PAGB is seeking to ensure that the United Kingdom OTC medicines industry continues to maintain its high standards of promotion. PAGB requires members to uphold the reputation of the OTC medicines industry and to maintain recipients' confidence in the advertisements they receive. The fact that the PAGB Consumer Code has been in operation for over 85 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.

2 Introduction to PAGB's Medicines Advertising Codes for Traditional Herbal Medicines

The PAGB Medicines Advertising Codes are the primary means of self-regulatory control for OTC medicines advertising. To help ensure that this advertising is responsible, PAGB publishes two separate sets of codes. This document applies to advertising for THMs which are registered under the Traditional Herbal Medicines Registration Scheme. The other codes, 'PAGB Medicines Advertising Codes - Codes of Practice for Advertising Over-The-Counter Medicines', apply to advertising for OTC medicines which are subject to a Marketing Authorisation.

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

In 1992, a European Directive on medicines advertising came into force. The Directive was implemented into UK law as the Medicines (Advertising) Regulations 1994. It was later amended in 2005, the Medicines (Advertising Amendments) Regulations 2005, SI No. 2787. The amended regulation applies to the vast majority of medicines advertising, including advertising for THMs which are registered under the Traditional Herbal Medicines Registration Scheme. The Traditional Herbal Medicines Registration Scheme implements Directive 2004/24/EC (the Traditional Herbal Products Directive).

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. (*Please refer to section 3.4.5 and 3.4.6 for further guidance.*) 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. To facilitate the approval process, advertising, design and public relations agencies, employed by member companies, are eligible for associate membership of PAGB.

PAGB does not operate a system of pre-publication approval for advertising which is aimed at persons qualified to prescribe or supply (*please refer to section 4.1*). The PAGB Professional Code for Traditional Herbal Medicines operates through consideration of post-event complaints. It is a condition of PAGB membership that companies ensure that all THMs advertising aimed at persons qualified to prescribe or supply, and those that work for such persons, complies with the relevant sections of the PAGB Professional Code for Traditional Herbal 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 principles of the PAGB Medicines Advertising Codes.

3.1 Compliance with the PAGB Consumer Code for Traditional Herbal Medicines

3.1.1 It is a condition of membership that all THMs advertising which is aimed at consumers must be approved by PAGB prior to its release into the public domain. PAGB will check compliance with the provisions of the PAGB Consumer Code for Traditional Herbal Medicines. Where an advertisement complies with all of the requirements, PAGB will return a copy of the advertisement marked with the PAGB stamp of approval. Where an advertisement does not comply with requirements, PAGB will provide comments to assist member companies in making the required amendments. To enable PAGB to carry out this process, a copy of both the Summary of Product Characteristics (SmPC), and the Traditional Herbal Registration must be submitted. PAGB is unable to provide approvals post-publication.

3.1.2 The main purpose of PAGB's approval of advertising copy is to help ensure that advertising complies with all applicable codes and laws. Advertisers should note that the PAGB Consumer Code for Traditional Herbal Medicines is applied in spirit as well as in principle. Consideration is given not only to the impression created by a careful study of an advertisement, but also to the impression likely to be gained from a brief view, or partial reading, of the advertisement.

3.1.3 It is the responsibility of member companies to ensure that all applicable legal requirements and all requirements of the relevant self-regulatory codes of practice (*please refer to section 5*) are complied with. Whilst PAGB's approval system is intended to assist member companies in discharging this responsibility, the responsibility remains with member companies. It is recommended that all members provide relevant company personnel and advertising agencies with copies of the PAGB Medicines Advertising Codes for Traditional Herbal Medicines and appoint a senior executive to be personally responsible for ensuring compliance. PAGB runs regular advertising workshops to assist companies in applying the principles of the PAGB Medicines Advertising Codes.

3.1.4 PAGB maintains a working relationship with each of the following organisations: the Medicines and Healthcare products Regulatory Agency (MHRA); the Committee of Advertising Practice (CAP); the Advertising Standards Authority (ASA); the Office of Communications (Ofcom); the Broadcast Advertising Clearance Centre (BACC) and the Radio Advertising Clearance Centre (RACC). This allows PAGB to provide a consistent and reliable approval system which takes into account the concerns of both regulators and self-regulators. PAGB may, at its discretion, request the views of any of the above organisations before approving advertising copy. PAGB can offer guidance on the roles of the various bodies involved in the control of medicines advertising.

3.2 What the PAGB Consumer Code for Traditional Herbal Medicines covers

3.2.1 The PAGB Consumer Code for Traditional Herbal Medicines applies to advertising materials which are aimed at consumers and those persons who may legitimately purchase medicines on behalf of another consumer (e.g. parents, who purchase medicines on behalf of their children). The Code covers all branded, promotional materials over which the company has full editorial control. PAGB members should try to ensure that all branded promotional materials over which they do not have editorial control also comply with the spirit of the Code. Materials covered by the PAGB Consumer Code for Traditional Herbal Medicines include:

- advertorials
- aerial promotions, such as hot air balloons
- booklets
- branded materials relating to product sponsorship (limitations of editorial control will be taken into account)
- cinema commercials
- consumer leaflets
- direct mail materials
- on-line advertisements
- outdoor advertising
- point of sale materials
- posters
- print advertisements (for use in newspapers, magazines etc.)
- promotional aids
- promotional scripts for use by telephone helplines
- promotional text messages
- sales promotions
- television and radio commercials
- websites and other Internet materials, including press releases intended for Internet publication which are under the editorial control of the member company.

Please refer to section 3.3.7 for on-pack statements.

3.3 What the PAGB Consumer Code for Traditional Herbal Medicines does not cover

Claims relating to price

3.3.1 The PAGB Consumer Code for Traditional Herbal Medicines does not cover claims related to the price of the product. Member companies are responsible for ensuring that such claims are not misleading.

Public relations

3.3.2 The PAGB Consumer Code for Traditional Herbal Medicines does not cover public relations (PR) materials, where the company does not have full editorial control over resultant printed material. Similarly, it does not cover product launches where the company does not have full control over what is said, or subsequently reported.

3.3.3 The PAGB Consumer Code for Traditional Herbal Medicines does not cover materials which are aimed at third parties e.g. materials sent to journalists, for them to promote to readers.

3.3.4 The only PR materials which require PAGB approval are press releases intended for use on the Internet. These may be accessed directly by consumers and so are considered to be advertising.

3.3.5 Member companies should note that PR is covered by the Medicines (Advertising) Regulations 1994 and so member companies must ensure that all PR materials comply with the law. PAGB produces a separate guideline entitled 'Guidelines on Consumer Promotions and PR Activities.' Further advice can be obtained from PAGB.

Corporate sponsorship

3.3.6 The PAGB Consumer Code for Traditional Herbal Medicines does not cover corporate sponsorship and such schemes do not have to be submitted for PAGB approval. However, materials that carry brand sponsorship must be submitted to PAGB for approval. Please refer to PAGB's 'Guideline on Consumer Promotions and PR Activities'.

Labels and packaging

3.3.7 The PAGB Consumer Code for Traditional Herbal Medicines does not cover product labels, packaging materials and in-pack leaflets. However, PAGB does request that copies of the approved packaging are lodged with PAGB for reference. It is important to note that on-pack statements may not always be acceptable in the context of an advertisement. Therefore, it is recommended that such statements be submitted for approval against the PAGB Consumer Code for Traditional Herbal Medicines if the intention is to use on-pack statements in consumer advertising.

Legal notices and disclaimers included on websites

3.3.8 These materials do not promote brands and hence do not require PAGB approval. Similarly, website registration forms which do not promote brands do not require PAGB approval.

Advertising to health professionals

3.3.9 The provisions of the PAGB Consumer Code for Traditional Herbal Medicines do not apply to advertising aimed at persons qualified to prescribe or supply medicines, or to their employees. Please refer to the PAGB Professional Code for Traditional Herbal Medicines for advertising aimed at these persons.

Advertising of food supplements

3.3.10 The PAGB Consumer Code for Traditional Herbal Medicines only applies to medicines which have been registered under the Traditional Herbal Medicines Registration Scheme and does not cover the advertising of food supplements.

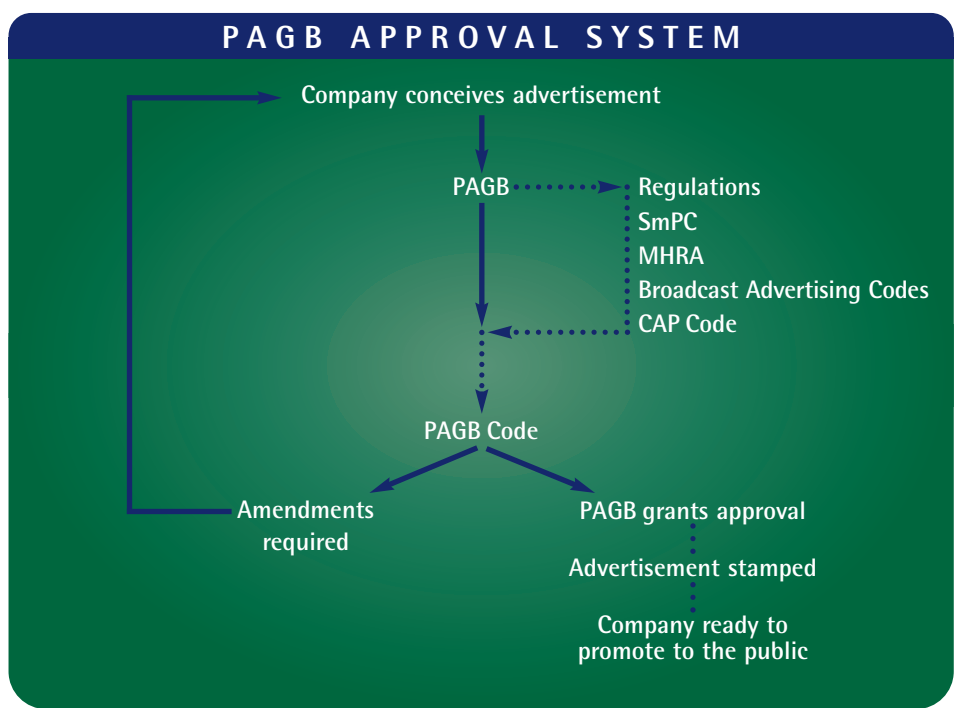
3.4 The PAGB approval system for consumer advertising

Approval process

3.4.1 PAGB's pre-publication approval of advertising materials has helped members achieve a high level of compliance with both statutory and self-regulatory requirements.

3.4.2 Specialist staff carry out the pre-publication approval of advertising materials. PAGB has access to independent legal and medical experts, including experts in herbal medicines to advise on evidence and matters of interpretation under the Code.

3.4.3 The system of pre-publication approval is as follows:



- the member company, or agents working on behalf of the member company, conceive the advertising
- the member company, or agents working on behalf of the member company, submit the advertising to PAGB for approval
- PAGB checks the advertisement against the rules in the PAGB Consumer Code for Traditional Herbal Medicines, the SmPC and any other regulation or code of practice which applies to the specific medium for which the advertisement is intended. Any queries over medical or legal claims are referred to PAGB's medical and/or legal advisers
- PAGB notifies the member company or agents working on behalf of the member company of any changes required, or evidence which is needed, before the advertisement can be approved
- once PAGB is satisfied that the advertisement complies with the PAGB Consumer Code for Traditional Herbal Medicines, it is approved, subject to 'PAGB's Terms of Approval for Advertising' and the company is notified
- the advertisement can now be seen by the public.

Member's responsibilities

3.4.4 Member companies remain obliged to ensure that their advertising complies in all respects with all applicable legal, regulatory and self-regulatory requirements, with the Traditional Herbal Medicine Registration and SmPC. PAGB approval is only one element of member companies' necessary due diligence.

3.4.5 PAGB approval is given based on PAGB's understanding and knowledge of relevant requirements and practice and of the information available to PAGB at the time of approval. This includes any evidence provided to PAGB by the relevant member company or on its behalf. Relevant requirements (and their interpretation) may change from time to time and their application and interpretation are a matter for the appropriate regulatory authorities and/or the Courts. It is member companies' responsibility to respond to, or seek fresh approvals as a result of, changes in relevant requirements (and/or their interpretation by the appropriate regulatory authorities or the Courts) and/or in available evidence. *(Please refer to section 3.4.6, below for further details.)*

3.4.6 Member companies must not continue to use advertising materials which are no longer appropriate. For example:

- any claim that a product is 'new' or 'now available' is only acceptable for one year from when the product was first available for purchase
- where a complaint has been upheld against PAGB-approved copy by a regulatory body, such as the MHRA or the ASA. If a complaint is upheld, the advertising must be amended or discontinued in line with the ruling of the relevant regulatory body. *(Please refer to section 5.)*
- where new information becomes available, such as a change in the law, a change in an applicable code of practice, new guidelines issued by one of the regulatory bodies or new clinical evidence relevant to the product, the category or any other products with which a comparison has been made, the advertising must be reviewed in the light of the new information and, if necessary, changed and resubmitted to PAGB for approval or be discontinued.

Executive Committee

3.4.7 Interpretation of the PAGB Medicines Advertising Codes for Traditional Herbal Medicines is ultimately the responsibility of PAGB's Executive Committee, which can offer views pre- and post-publication. Guidance on Code interpretation can be obtained from PAGB.

Liability

3.4.8 Neither PAGB nor any of its officers, employees, agents or advisers shall have any liability (whether in contract, tort or otherwise) for any loss, damage, liability, cost, claim and/or expense suffered or incurred by any person, firm or company as a result of:

- any approval (or any refusal or failure to give, or delay in giving approval) by or on behalf of PAGB

- any advice, direction, guidance, recommendation or instruction given (whether with or without negligence) by or on behalf of PAGB in connection with any advertising submitted to PAGB for its approval and all such losses (including but not limited to indirect, special, consequential or economic loss and loss of profit) are expressly excluded to the fullest extent permitted by law, but this shall not limit or exclude any liability for fraud, nor for death or personal injury caused by negligence.

3.4.9 Each member company shall indemnify and keep indemnified PAGB and each of its officers, employees, agents and advisers against all and any losses, damages, liabilities, costs (including legal costs on an indemnity basis), claims and/or expenses suffered or incurred by or on behalf of any of them in connection with any advertising (or proposed advertising) by or on behalf of that member company, except where the relevant loss, damage, liability, cost, claim and/or expense is incurred wholly and directly as a result of fraud, wilful default and/or negligence of PAGB, its officers, employees, agents and/or advisers.

3.4.10 The enforcement and interpretation of legislation is a matter for the MHRA (or other applicable regulatory body) and/or the Courts, not PAGB. While PAGB may be willing to provide advice to members on the law, that advice reflects only the opinion of PAGB and PAGB accepts no responsibility for that advice. The legal responsibility for advertising remains with the advertiser.

Review time

3.4.11 PAGB aims to review advertising copy within one working day of receipt, but does not promise or guarantee that it will do so. Advertisers should note that large or complicated pieces of copy, copy relating to new products, or claims which require detailed consideration of supporting evidence, may take longer to assess. PAGB aims to review websites within five working days. The same timescales apply to each subsequent occasion on which advertising is sent in with revisions.

3.4.12 PAGB is willing to offer advice and guidance on promotional concepts at any stage of development to ensure a smooth path towards final approval. As there are various stages involved in the approval process, member companies and their agencies are advised to submit all advertising and supporting evidence as early as possible, to help ensure approval within a reasonable time. By submitting all relevant data together, PAGB is then better placed to provide feedback quickly.

3.4.13 Member companies are reminded to allow for extra time in which PAGB can obtain an expert medical or legal opinion. This is particularly important for new products or where new claims are being submitted. *(Please refer to section 3.4.16-3.4.20 on providing evidence in support of claims.)*

3.4.14 When planning advertising for new products, companies may find it useful to submit a list of proposed claims, together with supporting evidence. Having reviewed the claims, PAGB will then hold a list of agreed claims which can be used in any advertisement for that product. Please note that all advertisements which contain these claims will need to be approved individually and that the acceptability of claims will depend on the context in which they are used.

3.4.15 Please refer to section 3.1 for information on compliance with the PAGB Consumer Code for Traditional Herbal Medicines, to section 3.6 for guidance on submitting advertising for PAGB approval and to section 3.7 for an advertising checklist.

Providing evidence in support of claims

3.4.16 Evidence in support of claims must be submitted to PAGB before approval can be given. Member companies should be aware that evidence is often sent to PAGB's medical adviser and expert in herbal medicines for review. Please build in additional time to allow for this.

3.4.17 The amount of evidence required to support a claim will depend on the type of claim, the magnitude of the claim and the quality of evidence submitted. PAGB does not require

member companies to submit evidence in support of claims which are simply repeating information stated on the SmPC. Evidence will be required to support all other claims. For example, a claim that a laxative product has a unique formulation would require a comprehensive list detailing the active ingredients of all other laxative products. *(Please refer to Rule 36 for guidance on evidence required for superiority claims, including sales claims.)*

3.4.18 All known available evidence, whether or not it supports the claim, must be submitted. For example, if PAGB accepted a claim on the basis of three supportive studies and it was later revealed that there were ten studies that failed to support the claim, it would need to be removed.

3.4.19 All claims will be considered individually, but the following types of evidence are likely to be acceptable:

- published data in a peer reviewed journal, such as the British Medical Journal. The entire paper is requested, rather than merely the abstract
- unpublished company data which has been approved by the company's medical or regulatory departments
- standard textbooks, such as the British Herbal Pharmacopoeia and the British Herbal Compendiums Volumes 1 and 2.

3.4.20 The following are unlikely to be acceptable as supporting evidence:

- editorial material, as this is often anecdotal and not backed by clinical evidence
- claims culled from competitor advertising, as this may be dependent on in-house data
- books which do not reflect available scientific evidence
- information on the Internet which does not reflect available scientific evidence
- evidence which is out-of-date because it has been superseded by more recent studies and a progression in scientific understanding
- reports of poorly designed research giving rise to questionable results
- animal studies, where this is the only evidence submitted.

Further information on the evidence required to substantiate particular claims can be provided by PAGB.

3.5 Rules of the PAGB Consumer Code for Traditional Herbal Medicines

3.5.1 General principles

1 The PAGB Consumer Code for Traditional Herbal Medicines applies to advertising which is aimed directly at consumers and those persons who may purchase medicines on behalf of a consumer (e.g. parents and other carers).

2 A registered traditional herbal medicine must not be promoted to consumers prior to its registration under the Traditional Herbal Medicines Registration Scheme.

3 Advertising shall be true and shall not mislead. It shall not contain any exaggerated claims, either direct or implied. All advertising must be in line with the product's Summary of Product Characteristics.

Advertising for THMs must make it clear that the product is a 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.'

Advertising must comply with the product's Summary of Product Characteristics (SmPC) and not mislead the consumer as to the benefits which can be obtained from using the product. Claims for indications which are not listed in the SmPC are prohibited. While the actual wording of the

claim does not have to be present within the SmPC, the claims must be consistent with the SmPC. Claims for benefits that cannot be expected to be achieved by the majority of users are also prohibited. Subjective claims, such as taste (e.g. 'great tasting throat lozenge') and claims based on market research (e.g. 'seven out of ten people would purchase the product again') are usually not relevant to the SmPC and so no variation to the SmPC is required.

When showing 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 the condition than the product is indicated for. *(Please also refer to Rule 18 on claims of recovery.)*

Advertising for THMs must not mislead consumers regarding the strength of evidence which supports the product's therapeutic benefits *(please refer to Rule 26)*.

Advertisers should consider the overall consumer take-out from the advertisement. Advertising should not communicate unrealistic expectations to the consumer, for example via the visuals.

4 Advertising shall not bring the over-the-counter medicines industry into disrepute, nor shall it undermine or prejudice consumer confidence in medicines.

This rule includes issues such as taste and decency (i.e. avoidance of offence). PAGB holds that certain standards must be upheld, irrespective of the advertising media used. Particular care should be taken to avoid causing offence on the grounds of race, religion, sex, sexual orientation or disability. All materials will be viewed on a case-by-case basis. However, the following examples would not be acceptable:

- portrayal of dangerous behaviour, such as drinking and driving
- full nudity (partial nudity, shot in a tasteful fashion, may be acceptable for example as part of an advertisement for a skin product)
- imagery of an overtly sexual nature
- portrayal of persons (particularly women and children) in vulnerable situations
- cruelty to animals (limited cartoon humour in this area may be acceptable)
- visual portrayals of complaints which the consumer would find tasteless or offensive, such as vaginal thrush, diarrhoea or haemorrhoids
- shocking analogies which consumers may find offensive.

It is felt that shocking or offensive imagery has a knock-on effect and damages the industry as a whole, thus 'undermining or prejudicing consumer confidence in medicines.' The overall tone of the advertisement will have a bearing on how offensive or tasteless it is perceived to be. Each advertisement will be considered on a case-by-case basis, taking into account the overall impression given and the medium used. In the past, the following suggestions have been rejected:

- a head in a vice for an analgesic
- axes, power drills, hammers in the head for an analgesic
- saws embedded in the toes for an antifungal
- a noose round the neck for a sore throat treatment.

The following have been approved:

- nails in a head for an analgesic
- head splitting/cracking for a migraine treatment
- barbed wire round the throat for a sore throat treatment
- brambles around a body for an emollient.

PAGB will consider the medium used. There is a lower threshold of acceptability for the mass-media arena, such as television, billboards or window displays, as parents feel they cannot shield their children from these images. PAGB, in line with other regulators and self-regulators, has adopted a more liberal view on advertising for certain media aimed at specific

Shocking or offensive advertisements

Undermining healthy lifestyles

demographics including magazines such as 'Loaded' and certain radio stations (e.g. 'Kiss FM'). Please note that the guidelines given above still apply to these media and, should they gain a wider audience, the threshold of acceptability would change accordingly.

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

Denigration

The second part of this rule also prohibits any overt or implied criticism of other products. *(For information on unfair denigration, please refer to Rule 30.)*

5 Advertising shall use language which can be understood by the consumer. Although the use of medical terminology is acceptable, care must be taken that this does not confuse or mislead the consumer.

Advertisements must use language which can be easily understood by the average consumer. This will help to prevent any confusion as to what the product is for and the benefits which can be expected from using it.

Although it is acceptable to use less commonplace terminology and medical terms, care must be taken that unfamiliar terminology is not used purely for the sake of confusing consumers or exaggerating the benefits likely to be gained from a particular product.

6 Advertising shall be clearly distinguished from editorial matter.

This rule mainly affects advertorials, where 'advertisement promotion', or words to that effect must be clearly stated, so that the consumer is alerted to the fact that it is advertising and not magazine editorial. PAGB advises that 'advertisement promotion' should appear at the top of each page. Most magazines have a similar stipulation.

This rule also affects materials such as leaflets that give the impression that they have been written by a third party such as a pharmacy chain, health food store or charity. Where member companies are involved in writing such materials, and where brands are mentioned, it must be made clear that this is advertising, rather than purely editorial.

7 Advertising shall not cause consumers unwarranted anxiety with regard to any ailment.

Advertising must not try to induce anxiety among consumers about their condition, for example, by using strong imagery or brutal analogies *(please refer to Rule 4)*.

Advertising should not imply that the condition being treated is of greater severity than that for which the product is indicated.

8 Advertising shall not suggest that health could be adversely affected if the consumer chooses not to use the medicine(s) featured.

Advertising must not suggest that the condition will deteriorate, that it will become more severe, or that the consumer will develop side effects if he or she does not use the brand featured. For example, advertisers must not suggest that, if the consumer does not treat their acute diarrhoeal attack with Brand X, they could develop chronic diarrhoea.

9 Advertising can only refer to the prevention of symptoms and the use of a product in chronic conditions, if this is in line with the Summary of Product Characteristics.

This rule allows advertising for prevention and for long-term use of a product, where this is permitted by the SmPC.

The execution shall make it clear at what point(s) use of the product is appropriate.

Advertisers are advised to stress that consumers should take a responsible approach to self-medication.

10 Advertising shall not contain material which could, either by detailed description or case history, lead to consumers making an erroneous self-diagnosis.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l).

Particular care must be taken when advertising products for conditions which give rise to a range of symptoms that are synonymous with another condition. Care must be taken not to encourage self-diagnosis, but to position the advertising in such a way as to make it clear that the product is aimed at people who have already been diagnosed as having the condition.

11 Advertising shall not discourage consumers from seeking medical or pharmacy advice. Nor shall it suggest that a consultation or surgical operation is unnecessary.

The first part of this rule reflects part of the Medicines (Advertising) Regulations 1994, Part III 9(l)(a).

This rule does not prohibit statements which suggest that people may not always need to consult a doctor for some self-limiting conditions. Statements such as 'It is not usually necessary to consult your doctor when you have a bad cold' may be acceptable. However, advertising should not suggest that it is acceptable to self-medicate when consumers may need GP or specialist help. Where confusion is likely to arise, PAGB recommends the addition of the following statement: 'If you are unsure about your diagnosis, please speak to your doctor or pharmacist.'

This rule prohibits advertising which encourages the long-term use of products, which are indicated for self-limiting conditions. In many cases, if such conditions persist, consumers should seek advice from their pharmacist or GP.

Companies should note that products for use in collaborative care conditions, such as irritable bowel syndrome, eczema, vaginal thrush and arthritic pain, should be targeted at people who have received a doctor's diagnosis. *(For further information, please refer to Rule 10.)*

12 Advertising shall not offer to diagnose, advise, prescribe or treat personally by correspondence.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(a).

'By correspondence' includes communications by letter, telephone, fax, email or Internet.

For example, the following would not be acceptable:

- offers to personally diagnose and advise on treatment
- offers to personally prescribe
- advice on whether a consumer should continue using prescribed medication
- advice on whether a consumer should follow their GP's guidance.

However, this rule does not prohibit the following:

- advice in response to a consumer's request for information in relation to a medicine
- telephone helplines, although care must be taken not to offer a diagnosis of the condition.

13 Care should be taken not to encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any medicine.

PAGB aims to encourage responsible self-medication and this cannot be achieved if the excessive and unnecessary use of medicines is presented as normal in consumer advertising. On this basis, advertising cannot suggest that it is good practice to use medicines for a prolonged period when the condition has been resolved or when further advice needs to be sought.

Advertisements must portray a responsible and cautious use of medicines. People must not be seen to be behaving irresponsibly or out of character due to the knowledge that there is a

Claims which are not considered to be guarantees

product available to treat the symptoms which may result. Similarly, advertising shall not suggest expressly, or by implication, that the consumer can indulge in reckless behaviour, provided they take a preventative treatment.

14 Advertising shall not claim or imply, that a product's effects are guaranteed.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(b).

A 'guarantee' means that the product will work for 100% of the population, 100% of the time. For example 'gets rid of pain' implies that the pain will cease as a result of taking the product and hence it is a guarantee. Similarly 'stops coughing' and 'stops itching' are also guarantees.

PAGB takes the view that the examples listed below are not guarantees, and are therefore acceptable under this rule:

- claims which are preceded by one of the following: 'can', 'to', 'may' or 'helps', for example:
 - 'to' (e.g. 'to relieve pain')
 - 'can' (e.g. 'can be used to treat pain')
 - 'may' (e.g. 'may relieve your symptoms')
 - 'helps' (e.g. 'helps relieve pain')
 - 'could' (e.g. 'could stop the itching').
- claims such as 'relieves' or 'soothes', (e.g. 'relieves pain'). Although these claims indicate an improvement in symptoms, they do not imply that symptoms will be gone completely
- claims which make it clear that the cessation of symptoms applies to one specific episode, usually in the past tense (e.g. 'I used to suffer with headaches, now they have gone')
- claims which make it clear that they refer the process of treating a condition/symptoms, rather than guaranteeing that the condition/symptoms will be removed completely (e.g. 'for clearing congestion'; 'for taking the itch out of insect bites'; 'for stopping diarrhoea'). Please note such claims will be looked at on a case-by-case basis
- in some circumstances, instructional phrases or directions may be viewed as instructions to change behaviour, rather than product guarantees. For example, 'Stop smoking' is healthy lifestyle advice and does not necessarily imply guaranteed efficacy. However, 'Stop coughing', featured next to a cough medicine pack shot would be likely to be seen as a product guarantee.

Advertisers of THMs must make sure that the way in which claims are worded is in line with the therapeutic indications listed on the product's SmPC. (*Please refer to Rule 48.*)

15 Advertising which states that a product is licensed must not imply that the particular medicine has been endorsed by the MHRA or by the Department of Health.

Advertisers may state that a medicine is 'licensed' or 'registered'. However, it is not acceptable to suggest that a medicine has been specifically endorsed or approved by the MHRA or by the Department of Health. Advertisers must not suggest that a particular medicine is superior or 'special', because it has been granted a Traditional Herbal Registration. Advertisers of THMs must not state that the product has been 'authorised' as this term can only be used by those medicines which have a Marketing Authorisation.

The following claims are likely to be acceptable:

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

The following claims would not be acceptable:

- 'approved by the MHRA/Department of Health'
- 'authorised by the MHRA/Department of Health'

3.5.2 Misleading advertising

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

All advertising must make the product indication clear, as stated on the SmPC. It is rare that any confusion does arise, but it could occur in advertorials where other topics, such as lifestyle factors, are discussed, or if a product is featured in a leaflet which references other conditions.

Where advertising is placed in close proximity to a related editorial, the editorial content may be seen to imply benefits which are not in line with the product SmPC. Where the advertiser has prior knowledge of the related editorial, the advertiser should try to ensure that the editorial does not include information which is contrary to the product SmPC. Such implied benefits could confuse the consumer and result in their using the product incorrectly.

In addition, where there is a single active ingredient, this must be stated.

17 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 absorption and speed of action etc., unless they are present in the SmPC. It is unlikely that THMs will have sufficient evidence to support speed of action and duration of action claims. Where sufficient evidence does exist, all such claims must be in line with the SmPC. For example, if the SmPC states that the ingredient is absorbed in 30 minutes, then it would not be acceptable to claim that the product 'gets to work in 15 minutes', despite supporting evidence. Absorption data cannot be extrapolated to claim that a product offers efficacy at a certain point unless there is evidence to substantiate such claims.

Speed of absorption claims (e.g. 'gets to work')

PAGB approves speed of absorption claims (e.g. 'gets to work in ten minutes') on the basis of evidence that a therapeutic level of the active ingredient(s) reaches the site of action at the time stated. Where the product is taken orally, 'gets to work' claims are usually approved on the basis of a therapeutic level of the active ingredient(s) being present in the blood stream at the time indicated. Where there is insufficient evidence to clearly determine the therapeutic level, then it will be assumed that the tablet dosage equates to the therapeutic level. Where sub-therapeutic levels can be identified at an earlier point, advertisers could claim 'starts to get to work in x minutes'.

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

'Starts to work' claims are permitted where sufficient evidence exists to support them. Claims such as 'starts to work' or 'active' are taken to mean that consumers will be starting to feel relief at this point (e.g. the headache is starting to feel better).

PAGB requires advertisements to include an appropriate indication of time lapse between taking the medicine and experiencing the effects. This is particularly important for broadcast advertising and where before-and-after images are used (*please also refer to Rule 18 on claims of recovery*). Commonly used techniques include:

- clocks changing in the background
- characters changing clothing
- change in lighting conditions (e.g. day and night)
- different background sounds to suggest a different time
- different background visuals to suggest a change of location.

Duration of action claims

Duration of action claims are only permitted where sufficient evidence exists to support them. 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. 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.

18 Advertising shall not contain improper, alarming or misleading claims of a recovery.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(j).

This prohibits claims such as 'miracle' and 'wonder product'. It also prohibits visuals which imply a cure, such as sufferers leaping from their sick beds completely rejuvenated; or before-and-after pictures which show a dramatic improvement which most users could not be expected to achieve.

'Before' and 'after' images

The following should be applied when considering the use of before-and-after pictures (*please also refer to Rule 17 for guidance on indicating time change*):

- the 'before' picture must relate to the degree of severity allowed by the SmPC. For example, advertisements for products for the treatment of pain of non-serious arthritic conditions should not show a sufferer with severe arthritis, or show the arthritic joint of a person with severe arthritis
- any 'after' pictures must show a realistic improvement which could be expected by the majority of sufferers when using the product according to its instructions. For example, on using a cough mixture, the majority of people would experience a reduction in coughing but would not experience cessation of all coughing. In a similar way, following the use of a pain reliever, the arthritic joint should not be shown to be similar to that of a person without arthritis because this would imply that the product has a direct effect on the arthritic condition, rather than just relieving the associated pain
- the use of time periods must accurately reflect the length of time it would take to achieve benefit. For example, suggesting that relief of arthritic pain takes place instantly, when benefit actually takes longer, would not be acceptable.

19 Advertising shall not use misleading, alarming or improper visuals to represent changes in the human body.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(k).

Very often advertisements which breach this rule will also fall foul of Rule 4 which covers taste and decency. Care must be taken that all diagrams relate accurately to the product indication. For example, diagrams must be representative of the degree of severity for which the THM is indicated, rather than depicting a more serious or chronic complaint.

20 Advertising shall not mislead about the novelty of a preparation. Claims that a product is 'new' can only be made for one year from the date when the product was first available for consumers to purchase.

'New' claims

This allows companies to say 'new Brand X' or 'now available' for one year from the date when the product was first available. However, care should be taken to avoid confusing consumers by combining 'new' claims with the required 'traditional use statement'. (*Please refer to Rule 48.*) If the product itself is not new, then manufacturers must make it clear which aspect of the product is new.

For example:

- new OTC product launches (e.g. 'new Brand X')
- new registered indications (e.g. 'newly registered for...')
- new format (e.g. 'new Brand X capsule format').

It is advertisers' responsibility to ensure that any packaging or advertising which contains the claim 'new' is revised once the product has reached the one year time limit.

'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 you can treat pain quickly' would not be accepted, as it implies that it is the only product which treats pain quickly.

21 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 which offers the same attribute. A product can claim to be unique within the OTC 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 registered traditional herbal medicine for use in a particular condition (such claims must not imply superiority over medicines which are subject to Marketing Authorisations)
- the only product within the therapeutic category to be available in a once-daily dosage
- the only product within the therapeutic category to have a particular method of delivery
- the only product within the therapeutic category to be available as an infusion
- the only one in the therapeutic category which does not cause drowsiness.

22 Advertising shall not suggest, directly or indirectly, that a product contains an unknown active ingredient.

This prohibits references to 'wonder ingredients' or 'miracle ingredients' etc. This rule is rarely invoked and is a throw back to the days of quack medicines which focused on the mysterious nature of the product in order to entice purchase.

23 Advertising shall not suggest that a medicinal product is a foodstuff, cosmetic or other non-medicinal item.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(g).

This prohibits advertising which states or implies that a product is not a medicine and so misleads the public into assuming that it is a food, cosmetic or other non-medicinal item. Although it is acceptable to indicate that a product is palatable, advertising shall make it clear that it is a medicine. For example, a sore throat lozenge may be able to claim that it tastes pleasant. However, the advertising must make it clear that the product is designed to treat sore throats. It is not acceptable to focus on the taste aspect (either directly or by use of visuals) to the extent that consumers may believe that it is a confectionery item.

24 Advertising shall not suggest that using a medicine can further enhance normal good health.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(c and d).

All advertisements must be clearly targeted towards people who are suffering from the complaint(s) described in section 4.1 of the SmPC (headed 'Therapeutic Indications'). Where the product is indicated for prevention, the advertisement must be clearly aimed at people who are at increased risk of the condition.

This rule prohibits any suggestion that consumers who are not currently suffering from the complaint (or in the case of products indicated for prevention, those who are not at increased risk of developing the complaint) for which the product is intended will also benefit from using the medicine. For example, the following would not be permitted: 'even though you feel good now, use Brand X and notice the difference'.

25 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.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(b).

'Safe' can only be used in certain circumstances with further qualification. To the consumer 'safe' means that there are no side effects or interactions etc. and this is very rarely the case. In those instances where a product's SmPC states 'no known side effects', PAGB would permit this exact phrase to be used in advertising. Similarly, PAGB would approve 'suitable for use...' in certain categories of people e.g. 'suitable for use in children'. However, PAGB would not agree to the claim 'no side effects' as this cannot be certain for any product and it could raise the stakes in terms of product liability. PAGB would allow qualified uses of the word 'safe' (e.g. 'good safety profile'), if there is evidence that this is the case. Please refer to the Consumer Code Glossary for further advice on the use of the word 'safe'.

It is acceptable to highlight the absence of a specific side effect if that side effect is common among other, similar products (e.g. certain allergy treatments can claim to be 'non drowsy' on the basis that some do cause drowsiness).

PAGB does not accept the phrases 'not habit-forming' and 'non-addictive' as, while it may be true that a product will not cause chemical dependency, it is not to say that consumers will not experience a psychological dependency. Product liability should also be considered. 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.

26 Advertising for THMs must not mislead consumers 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 or un-published studies, the advertisement must not give the impression that the product's efficacy is based on scientific studies, rather than on traditional use.

3.5.3 'Natural' claims

27 Advertising shall not claim that a product is 'natural' unless all of its components are naturally occurring. 'Natural' can be used to describe those elements that are naturally occurring (e.g. 'natural active ingredients').

Products can only claim to be natural if the product is 100% natural, i.e. all of the ingredients and excipients are naturally occurring. If, however, only the active ingredient is natural, the claim must be limited to that ingredient (e.g. 'Brand X contains a natural ingredient').

PAGB also accepts phrases such as 'works naturally' and 'acts naturally', for products which have a natural action on the body's physiology.

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

- 'natural remedy', 'natural Brand X', 'natural laxative', 'made from natural ingredients' and 'a natural choice'. These claims are only applicable for products in which both the active ingredients and excipients are naturally occurring.
- 'contains natural ingredient Y'. These claims can be used by all products in which the ingredient referred to is of natural origin.
- 'natural relief for congestion', 'relieves symptoms naturally', 'works naturally' and 'acts naturally'. These claims are only applicable for products which have a natural mode of action i.e. an action which mimics a physiological mechanism of the body.

It is not acceptable to use the term 'nature's remedy' to describe a product.

28 Advertising shall not suggest that the safety of a product is due to the fact that it is natural, or that it is made from herbal ingredients.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(h).

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

3.5.4 Comparative advertising

Unlike many countries, comparative claims are permitted within UK medicines advertising. However, there are limits on the freedom in this area when compared with other consumer goods.

29 All comparisons shall be balanced, fair and supportable.

It is acceptable to make comparative statements, provided they are balanced and fair and do not refer to an identifiable product or treatment (*please refer to Rule 31 and 33 for details*). PAGB does not accept comparisons which denigrate another ingredient, product or product category (*please refer to Rule 30*).

All comparisons must be made on a like-for-like basis. For example, in some circumstances, it may not be acceptable to make a direct comparison between a topical product for relief of congestion and other cold and flu products which also tackle pain and fever. PAGB would allow a comparison based solely on the fact that both treatments relieve congestion. All such comparisons are looked at on a case-by-case basis.

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.

No comparative statement will be accepted if it is likely to mislead the consumer or cause disrepute to the industry.

30 Advertising shall not unfairly denigrate or discredit, either directly or by implication, a competitor product, ingredient or treatment type.

PAGB regards such an approach as 'denigrating' copy and holds that this type of advertising damages public confidence in the safety and efficacy of OTC medicines. This rule applies to all competitor products, ingredients and treatments and not just to identifiable products or treatments.

PAGB can accept copy which compares the different attributes of products, provided this does not stray into denigrating other products. For example, 'some people find that tablets are more convenient than infusions', would be acceptable provided there is sufficient evidence to support the claim. However, PAGB would not accept 'some people find that tablets are better than infusions' as PAGB takes the view that such all-encompassing statements would be denigrating to infusions.

There are circumstances when statements which are technically correct would still be unfairly denigrating. For example, PAGB would not approve advertising which includes the claim 'paracetamol products can be fatal in overdose'. Even though the statement is factually true, it is unfairly denigrating another active ingredient. Nor would PAGB allow, 'Brand X is less likely to be fatal in overdose'.

31 Advertising shall not suggest that a product's effects are better than or equal to another identifiable product or treatment.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(b).

While the laws on comparative advertising permit direct comparisons with other brands, laws that apply to specific industry sectors supersede these. Hence, this rule takes precedence over the general law.

This rule does not allow advertising which highlights any attribute of a competitor's product which would make that product identifiable. Examples of attributes which would make a product identifiable include:

- a unique active ingredient
- a unique mode of application (e.g. if it is the only product in the therapeutic category which is available in a spray format)
- pack livery or colours
- well known straplines
- references to the 'best selling product'.

The following claims would not be acceptable under this rule:

- 'tablets work as well as infusions', where there is only one product for the condition which is available as an infusion
- 'in a recent study, participants indicated that ingredient Y was more soothing than ingredient X', where there is only one product which contains ingredient X
- 'I used to use this (holds up pack which looks similar to competitor pack), but now I prefer Brand X'
- 'I believe it's as good as the brand leader'. There may be many brands which can claim to be 'brand leader', and would argue that such claims are critical of their brand.

If advertisers do wish to show consumers changing from one brand to another, then PAGB advises that the competitor pack is not actually shown, or, if shown, that it cannot be identified. PAGB would agree the use of basic brown bottles or white boxes as representing another brand, except where the bottle is of a distinctive shape and so could be recognised as that of a competitor.

32 Advertising shall not state that a product does not contain an active ingredient or ingredients used in competitor products.

Negative content claims such as 'does not contain manufactured ingredients' are regarded as a form of denigration. The implication of the statement is that products containing manufactured ingredients are inferior. It is, however, acceptable to state that a product does not contain certain excipients (e.g. 'perfume-free', 'preservative-free', 'sugar-free', 'colour free' etc.).

Statements such as 'does not contain aspirin', while not permissible in advertising, may be acceptable on-pack. These are usually only approved by the MHRA where they are relevant to the indications for the product or form part of a specific warning required by the SmPC.

33 Brand names of products of other companies shall not be used without permission of the owner.

Any advertising which wishes to compare or feature other products/brand names must have permission from the owner. This effectively rules out such things as direct price comparisons (e.g. 'Brand X £1.00, Brand Y £1.10'). In theory, it is permissible to price compare when the other brands are not named (e.g. '10% cheaper than the brand leader') but many brands may claim to be the brand leader and this may lead to difficulty in substantiating such a claim.

Where an advertisement depicts other products (e.g. a hand reaching into a medicine cabinet containing other products), care must be taken to ensure that none of the other brands can be identified, unless permission has been obtained from the owner.

Even where an advertiser succeeds in gaining permission to use a competitor's brand name, companies should note that Rule 31 still applies.

34 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:

- 'more' (e.g. 'more natural')
- 'better' (e.g. 'a better treatment for insect bites')
- 'stronger' (e.g. 'a stronger formulation')
- 'quicker' (e.g. 'quicker acting formula')
- 'the difference' (e.g. 'try Brand X and you'll notice the difference').

PAGB will often ask that 'faster', 'better', 'stronger', 'quicker' etc. are amended to 'fast', 'strong', or 'quick'.

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 you have a cold, Brand X helps you to feel better' (i.e. better than not using any treatment)
- 'new improved Brand X now tastes better' (i.e. tastes better than the previous formulation).

35 Supportable top parity claims are acceptable. Such claims will remain valid until another product in the therapeutic category can prove objective superiority.

Top parity is a means of stating that no product has been able to prove superiority in a given area, such as efficacy, speed of action, duration of action etc. It is often the case that several products within a therapeutic category are of equal efficacy and that none of them are able to prove superiority. For example, 'nothing acts faster' and 'nothing is more effective' are comparisons against all other products in that category.

It is unlikely that manufacturers of THMs would have sufficient evidence to support a top parity claim relating to product efficacy.

PAGB produces a separate guideline entitled 'Guidance on the Use and Substantiation of Top Parity Claims'.

36 Superiority claims shall not be used, unless supported by direct comparative tests or other demonstrations

Taste

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, which may be sent to a market research specialist for an opinion. 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 claims

Claims of 'number one' or 'first choice' imply that a product is the best in its field. PAGB requests that these claims be further qualified (e.g. 'number one selling'). Support for such a sales statement requires three months of recent sales data. This data must be volume sales data. Where clear superiority is not demonstrated on the basis of three month's data, PAGB may request data over a longer period. If the sales data shows frequent fluctuations in the leading brands, advertisers will be advised not to run a best selling claim in order to avoid competitor complaints. Opposing sales data produced by a competitor may result in the advertising having to be withdrawn.

On the basis of volume sales data, PAGB can approve the following claims:

- 'no 1 selling travel sickness treatment'
- 'best selling herbal cough lozenge'
- 'nation's favourite natural remedy for insect bites'
- 'market leader for herbal hayfever remedies'
- 'most popular herbal sleep aid'
- 'Brand X - leading sales the treatment skin irritation'

The examples listed below could be viewed as either best selling claims or as claims which imply some other form of superiority. Advertisers would need to qualify these claims and send the appropriate evidence:

- 'no.1 for stress'
- 'brand leader'
- 'leading herbal anti-sickness remedy'.

Clinical superiority

It is unlikely that PAGB would be able to agree a clinical superiority claim, such as 'the best', 'the fastest', 'the strongest', 'the most effective' etc for a THM. Any such claim would require full substantiation, usually direct comparisons with all other products on the market and all available data.

Use of the definitive article

PAGB regards 'the' as a superiority claim. For example, 'The herbal cough treatment' implies that it is the best herbal cough treatment available. PAGB advises that 'the' is amended to 'a' or 'an'.

Subjective superiority claims

Subjective superiority claims relating to efficacy, for example, '90% of people said Brand X relieved faster/better than any other brand' would also need to be supported by direct comparative clinical studies and hence such claims are unlikely to be applicable for THMs.

3.5.5 Health professionals

37 Advertising shall not state or imply that a product is recommended by or used by a health professional or scientist (e.g. a doctor, pharmacist, herbal practitioner, nurse or midwife).

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(f).

While the exact definition of a health professional is not enshrined in law, PAGB and the MHRA regard the following as health professionals (the list is not exhaustive):

- doctors
- dentists
- pharmacists
- pharmacy assistants
- nurses
- herbal practitioners
- midwives
- ophthalmologists
- opticians
- health visitors
- physiotherapists
- dieticians
- chiropractors
- osteopaths
- chiropodists.

Activities which are prohibited under this rule

The following activities would be prohibited under this rule:

- statements that imply a brand is recommended by a health professional. Examples include:
 - 'recommended by doctors/dentists etc.'
 - 'used by herbal practitioners/herbalists etc.'
 - 'Jones's Pharmacy's favourite cough mixture'
 - 'most recommended brand' (consumers would assume that the recommendation is from a health professional)
- the inclusion of a pharmacy or herbal practitioner's stamp in a leaflet where an impression is given that the pharmacists or herbal practitioners at that store recommend the brands featured. For example 'recommended by' followed by a space for pharmacies to place their address stamp would not be acceptable
- advertisers asking health professionals to wear badges that feature the name of a medicinal product
- companies asking health professionals to selectively hand out advertising materials such as leaflets or flyers to individual customers/patients
- having a health centre, G.P. surgery or pharmacy scene in an advertisement may be taken to be endorsement, for example, asking the pharmacist or herbal practitioner for advice beside prominent displays of the product. Such advertisements will be considered on a case-by-case basis. Similarly, a health professional reaching up to pick Brand X off the shelf or a person in a white coat talking about a product can also imply recommendation. If advertisements do feature a person who may be taken to be a health professional, it must be very clear that that person is not endorsing the product.

Activities which are acceptable under this rule

The activities listed below are acceptable under this rule:

- it is acceptable for companies to distribute branded leaflets to health centres, pharmacy stores, dental practices etc. to be placed in a leaflet rack, for patients to help themselves to
- it is acceptable to ask health professionals to hand out leaflets which are of a public health/advisory nature and which merely state that they are sponsored by a particular brand
- companies can provide pharmacists, health food stores and other retailers with information leaflets which can be handed to the consumer at the time of purchase to assist in the appropriate use of the product. Such leaflets must not be promotional
- it is acceptable for companies to place adverts on pharmacy bags or till receipts etc. which are routinely given to all purchasers
- pharmacy chain logos can be used on advertising materials for medicinal products such as point of sale materials and leaflets
- it is acceptable for a pharmacy chain's leaflets or newsletters to include brand mentions as long as it is clear whether the materials are advertising or editorial copy (*please see Rule 6*)
- it is acceptable to include a pharmacy or herbal practitioner's stamp in a leaflet where the impression given is that the products featured are available at the named store and not that the pharmacists at the store recommend the brands featured. For example 'available from' followed by a space for pharmacies to place their address stamp, would be acceptable
- it is acceptable for advertising to include a health professional recommendation of an ingredient, treatment type, formulation or preparation as long as there is more than one product available with this attribute. (Advertising should not contain any health professional endorsement of a product attribute which is unique to one product. This would be an implied endorsement of the brand). The following are likely to be acceptable:

- 'this ingredient, present in Brand X, is recommended by doctors'
- 'this kind of treatment has been recommended by herbal practitioners for 20 years'
- 'doctors/dentists etc. recommend the same formulation/preparation as in Brand X'.

There have been instances where health professionals have been used in advertising and PR activities, although great care should be taken when running similar activities, to ensure that they do not recommend the product.

Printed materials and websites

It is possible to include a section giving general health advice which is written by a health professional. For example, a branded website could include a section entitled 'Dr Smith's Tips for Looking after your Child when he has a cold'. There must not be any references to brands within the section which is identified as having been written by a health professional. It is likely that any mention of 'treatments' in this section would be viewed as implied claims for the products featured elsewhere in the advertisement or website. Any information identified as having been written by a health professional must be clearly separated from the brand advertising. Such information will be judged on a case-by-case basis.

Features about a therapeutic category which are written by a health professional must be unbranded and care must be taken to distance them from any accompanying advertising materials.

Radio and television voice overs

It is possible to have health professionals doing voice-overs as long as they are not identified as health professionals. For example, 'I'm Dr John Smith and I'm here to tell you about Brand X' would not be acceptable.

Consumer videos

Featuring a health professional in a consumer video is acceptable where the video is unbranded, i.e. the video simply refers to the treatment of a condition without referring to, or featuring, any specific product. The video name and packaging must also be unbranded. Although it is permissible to offer such a video via advertising for a product on the grounds of health education, the video cannot be referred to as 'The Brand X guide to eczema', as featuring of a health professional would be an implied recommendation of the brand.

Public relations

The PAGB Code for Traditional Herbal Medicines does not cover public relations, but companies must ensure that their public relations materials comply with the Medicines (Advertising) Regulations. Having a health professional at an event is likely to be acceptable as long as s/he does not endorse the product. The health professional could discuss the clinical aspects of the condition and could also discuss the ingredient(s) or formulation, as long as these features are not unique to the particular product (thereby being an implied brand endorsement). It would not be acceptable to feature a health professional's recommendation of a product in a press release intended for consumer journalists or to advertise to the public that a health professional will be present at an event.

38 Advertising shall not refer to a 'college', 'hospital', 'clinic', 'institute', 'laboratory' or similar establishment, unless the establishment genuinely exists.

PAGB will require substantiation for claims relating to any particular establishments.

Claims that 'Brand X is the hospital favourite' would not be permitted. Such a statement would imply the health professionals working at the hospital are endorsing the product.

3.5.6 Celebrities

39 Advertising shall not include a recommendation by a person who, because of their celebrity, may encourage consumers to use a medicine.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(f).

Any inclusion of a celebrity within advertising materials, even if not overtly endorsing or recommending the product, is likely to be taken to mean celebrity endorsement. The view is that the celebrity has had to be paid and hence is implicitly endorsing the product. If it is not an endorsement, there would be no requirement for a celebrity to be present.

Defining a celebrity is a very grey area. The PAGB stance is that a celebrity is an actual person who is very well-known in public life and who, because of their celebrity status, could encourage the consumption of a medicinal product.

It may be possible to refer to a celebrity without any implication that he/she supports or uses the product. For example, it may be acceptable to encourage people to relax in front their favourite Hugh Grant movie in the context of an advertorial promoting a sleep aid.

There have been instances when fictional characters and deceased celebrities have been used in advertising but this has followed careful consideration of whether the person/character featured would encourage the consumption of medicines. In considering whether this rule is breached, consideration will also be given to the spirit of the PAGB Consumer Code for Traditional Herbal Medicines. The overall impression of the advertisement must not encourage excess use of a medicine. Advertisers should also refer to the CAP Code before undertaking such activities in non-broadcast advertising. Rare instances where such an approach has been permitted are described below.

Fictional characters and 'look alike' celebrities

Biggles and Darth Vader have appeared in advertising as these are not considered to be people. However, many fictional characters would not be acceptable as they would be synonymous with the actor playing the role (e.g. a doctor from a television soap opera). Care should also be taken that the fictional character used does not appeal to children, and so breach Rule 40. The use of a fictional character will be considered on a case-by-case basis.

It may be acceptable to use 'look alike' celebrities. However, the model would need to look sufficiently different to the actual celebrity, so that the public would not assume that a celebrity is endorsing the brand. Such advertising will be considered on a case-by-case basis.

Deceased persons

The only instance where this has been agreed is the use of Laurel and Hardy to promote a hayfever product. Careful consideration was given to the audience, the status of the persons featured and whether it would encourage excessive consumption. Consideration was also given to the 'taste' issue of featuring people who are dead. PAGB would accept the use of dead persons only on the basis that they are long dead and that there is no confusion in the public's mind that the person is deceased. Again, these cases will be determined on a case-by-case basis. Advertisers are advised to ensure they obtain clearance from the dead person's estate before featuring them in advertising.

Public relations

The PAGB Code does not cover public relations, but companies must ensure that their public relations materials comply with the Medicines (Advertising) Regulations. Celebrity endorsement of a product in press releases aimed at consumer journalists is not acceptable. The end recipient of this information is the consumer and so the law would be breached. While it is acceptable to have a celebrity present at an event, care must be taken to ensure that they do not recommend the brand. They can be asked to talk about their experience of the condition, or to recommend the active ingredient. However, celebrities cannot recommend the ingredient/formulation etc., if it is unique to that product. PAGB will not be able to agree advertising relating to the fact that a celebrity is present at an event.

Radio and television voice overs and telephone helplines

It is acceptable to feature celebrities in voice overs, on the basis that it is difficult to define a celebrity by voice alone. However, the celebrity cannot be identified. For example 'I'm David Attenborough and I'm going to tell you about the benefits of Brand X' would not be acceptable. These restrictions also affect actors who specialise in voice overs.

Sponsorship

It may be possible to have brand sponsorship of an event where a celebrity or celebrities are one or some of many people who are involved in the sponsorship, provided no celebrity is directly sponsored and the public are not likely to think that a celebrity is endorsing the product. However, brand sponsorship of individual celebrities or a team which is made up exclusively of celebrities is not acceptable. For example, it may be possible to sponsor an athletics event where some of the competitors are celebrities. In all cases, identifiable celebrities must not be included in associated advertising materials.

3.5.7 Children

40 Advertising shall not be aimed principally or exclusively at children.

This rule reflects the Medicines (Advertising) Regulation 1994, Part III 9(l)(e).

This rule aims to protect children from 'hard-sell' marketing tactics which would encourage them to consume medicines unnecessarily. It also aims to protect parents from the 'pester power' of their child insisting on a certain brand.

There are difficulties in defining when a child becomes an adult, capable of taking over responsibility for their own use of OTC medicines. The various organisations involved in the regulatory and self-regulatory control of medicines advertising set this age at 16 years. It is a requirement for television advertising that all medicines advertising which is aimed at young adults must feature models who are at least 16.

Historically, there have only been two categories of OTC medicines which have been promoted to young adults. These are acne and period pain products. Advertisers must take care not to target teenagers younger than 16 years and should consider the following:

- the readership/audience profile of magazines or radio programmes. PAGB will request evidence that the average readership/audience is over 16 years of age. PAGB is unable to agree advertising in magazines/radio programmes which have a predominantly younger readership/audience age. Where magazines have some readers who are below 16 years of age, PAGB will request that advertising is clearly aimed at the older age group
- the medium used
- the language and style used
- whether the advertisement encourages the cautious use of medicines.

Characters, cartoons and branding

Advertisements and promotional aids which are likely to be widely viewed by children should not feature cartoons, characters and designs which are likely to be particularly appealing to children. If such cartoons, characters and designs are featured in television advertising, the BACC may impose a post-9pm restriction on the advertisement.

Brand names or brand imagery cannot be used on promotional aids or goods which are aimed at children. Examples include books, toys, pencil cases, school bags and children's T-shirts.

Websites

Particular care must be taken when incorporating games onto websites, as computer games are inevitably appealing to children. Companies should either make sure that games do not contain any references to medicinal products, or design the games so as not to be particularly appealing to persons under the age of 16. If the game is unbranded and is likely to be attractive to children, companies should ensure that children do not have to pass through screens containing medicines advertising in order to access the game. One way of doing this may be to have a link which is clearly aimed at adults. Parents could then use the link to access a game which they may wish to show their children (e.g. 'click here for a game to help children understand the importance of emollients').

Sponsorship of children's events

It is not acceptable to have product branding of children's events (e.g. the Brand X Children's Football Championship). However, it is acceptable to have corporate sponsorship of such an event (e.g. the Children's Football Championships sponsored by Company X).

There has been an instance where PAGB has agreed sponsorship of such an event when the corporate sponsor name was the same as a brand (e.g. 'The Brand X Football Championships', on the grounds that Brand X was also the name of a limited company). However, branding of items to give away at such an event must carry the full event name (e.g. Brand X Football Championships, not Brand X alone). These items cannot display the indication. Any promotional items which contain brand names or brand imagery must not be designed to appeal to children (e.g. child-size T-shirts).

41 Advertising shall not show children using, or within reach of, medicines without adult supervision.

The aim of the PAGB is to encourage a responsible attitude towards self-medication. Depicting an unsupervised child handling medicines could encourage other parents to allow their children to do the same, with potentially dangerous consequences.

3.5.8 Testimonials

42 Testimonials shall comply with the other principles of this Code.

Testimonials must comply with all other rules in the PAGB Consumer Code for Traditional Herbal Medicines. Testimonials in themselves are not substantiation of the claim being made. Evidence will be required to support the claim. This prohibits such testimonials as:

- 'I have tried many other products but this is the only one I've found which is any good' (this contravenes Rules 30 and 36)
- 'I find that Brand X is very effective' (this contravenes Rule 26)
- 'Brand X works better' (this contravenes Rule 34)
- 'I also use it on my arthritis' (where the product is not indicated for arthritis).

If an advertiser wishes to use a testimonial such as 'My sore throat felt better in half an hour', the advertiser would need to submit evidence to demonstrate that this is what an average user could expect. In cases where the data is not available, the testimonial would have to be removed.

43 Testimonials shall be less than three years old and be the genuine views of the user.

Advertisers should hold signed and dated proof, including a contact address, for any testimonial they use. This should be no more than three years old and care should be taken in editing that the original meaning is not altered. PAGB will request to see a copy of the testimonial which has been signed and dated by the testimonee.

Advertisers should note that quotation marks around a claim may be taken to imply that the claim is a testimonial. Likewise, any copy which carries the name of the testimonee. However, testimonial-style advertisements, which may give the impression that it is a real consumer, are acceptable, provided no names or addresses are included.

Where photographs are used, care should be taken when using actors' photographs, not to imply that the actor is the testimonee, unless this is the case.

Advertisers should also bear in mind the restrictions on the use of celebrities and health professionals (*please refer to Rules 37 and 39*).

44 A health professional or celebrity shall not be identified as the writer of a testimonial.

This rule reflects the Medicines (Advertising) Regulations 1994, Part III 9(l)(f).

This prohibits testimonials from celebrities, doctors, herbal practitioners, dentists, pharmacists, nurses and midwives etc. For example:

- 'I'm David Attenborough and I swear by Brand X'
- 'It's my first choice treatment for back pain,' Dr Sandra Hobbs.

This rule prohibits companies capitalising on favourable comments from a celebrity or health professional in the media (e.g. 'David Attenborough uses Brand X for insect bites' or 'Dr Smith said in his weekly column that he always recommends Brand X').

3.5.9 Promotions

45 No member shall be involved in promotional schemes which are hazardous to the public or bring the industry into disrepute.

PAGB has produced separate guidelines on this subject. Please refer to PAGB's 'Guidelines on Consumer Promotions and PR Activities' which includes guidance on prize promotions, charity promotions, reader offers, value and volume sales promotions.

46 Medicines shall not be promoted with the offer to refund money to dissatisfied users.

Offers to refund money to dissatisfied users would imply that the product's effects are guaranteed. This would breach Rule 14 of the PAGB Consumer Code for Traditional Herbal Medicines.

It is acceptable to offer to replace damaged goods.

47 No member shall distribute medicine samples to consumers, issue coupons/vouchers relating to the supply of samples from any retail outlet or advertise the availability of samples from any retail outlet.

The amended Medicines (Advertising) Regulations prohibit manufacturers from providing free samples of OTC medicines to consumers, even if the consumer solicits the medicine. Similarly, it also prohibits manufacturers from issuing any coupon/voucher which entitles consumers to receive a free sample of any medicine.

3.5.10 Essential information in consumer advertising

48 All consumer advertising for registered traditional herbal medicines must carry the essential items of information.

Advertisers should note that it is a breach of the law not to include all of the essential information in a clear and legible manner. The following items are required when advertising THMs to consumers:

- the name of the product
- the information necessary for correct use (otherwise known as the indication)
- the single active ingredient (where appropriate)
- an invitation to read the leaflet or label
- the traditional use 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.'

The name of the product

This should be as stated in the SmPC. In rare circumstances a shortened version of the name may be allowed. PAGB does not generally require that companies include the flavour of their product even where this is part of the name. For example 'Brand X Throat Lozenges' would be accepted as the name even where the full name may be 'Brand X Throat Lozenges Lemon Flavour'. However, advertising must clearly refer to a product and not just to an umbrella brand. Therefore, where Brand X is available as a spray and as a cream, the full product name i.e. 'Brand X Cream' or 'Brand X Spray' will be required and not just 'Brand X'.

The information necessary for correct use of the product

The therapeutic indication is described in section 4.1 of the SmPC. The requirement to state the therapeutic indication is usually fulfilled by the inclusion of the traditional use 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.'

Where advertisers include additional wording regarding the product indication, the wording must reflect that used in the SmPC. Where the SmPC states 'Traditionally used for...' or similar, this wording should be used in advertising materials.

Additional statements may be needed in certain circumstances, as a condition of the Traditional Herbal Registration, or as a result of any additional guidance which may be developed for particular types of advertising. Please contact PAGB for further advice.

Advertising does not need to state the full list of indications given in the SmPC, except where a partial indication may be misleading. For example, headache with upset stomach cannot be advertised for upset stomach alone. Companies must make sure that the indication is in line with the SmPC, for example, if a product is for relief of mild arthritic pain, advertising must not imply that it is for treating mild arthritis.

When promoting medicines for use during pregnancy, member companies should refer to the MHRA's guideline 'Medicines which are Promoted for use During Pregnancy'.

The active ingredient, if there is only one

The most common way of including this is simply to state 'Contains ...', or to include a pack shot with the active ingredient placed on the front of the pack. There is no requirement to list the active ingredient separately if it is already present in the brand name.

An instruction to 'always read the label/leaflet'

For products which do not have an in-pack leaflet, all the necessary information is on the label and 'always read the label' will suffice. For products which have an in-pack leaflet, then 'always read the label' can only be used when the label directs the consumer to the information leaflet. If the label does not do this, then the advertising must state 'always read the leaflet'.

Exceptions where not all of the essential information is required

There are some exceptions to the rule, where not all of the essential information is required:

- dummy packs do not have to include 'always read the label/leaflet' as the MHRA agree that this looks out of place on a large pack. The pack must include the name, indication 'traditional use statement' and the single active ingredient, if there is one
- promotional aids which are intended solely as a reminder (e.g. T-shirts, pens, mugs, party balloons etc.), which only state the product name or a reasonable abbreviation thereof, trade mark protection and company name do not have to include the essential information. The umbrella brand name may be used as an alternative to the product name. For example, a pen simply stating 'Brand X' does not need to include any additional information. However, if the pen displays any claim (including a visual representation of a claim), then the essential information would have to be included. If the product name includes a medicinal claim, (e.g. 'Brand X Bruise Treatment'), then simply stating the name does not necessitate the inclusion of the essential information
- shelf edgers and labels which are intended merely to highlight the price of the product or the location of the product on the shelf do not need to include any additional information.

However, if any claim is made (this includes a visual representation of a claim), the essential information must be included. Where the product name includes a medicinal claim (e.g. 'Brand X Pain Reliever'), then simply stating the name does not necessitate the inclusion of the essential information

- coupons which are intended merely to state a price reduction on purchase of a product do not need to include the essential information. However, if a claim is made, (this includes a visual representation of a claim), the essential information must be included. Where the product name includes a medicinal claim (e.g. 'Brand X Pain Reliever'), then simply stating the name does not necessitate the inclusion of the essential information
- point of sale items that highlight an umbrella brand only and do not refer to the name of any medicinal product (either by name, or by use of the pack shot) must not include any claims (such as a product indication) and do not require the essential information.

49 The essential information required in consumer advertising must be clearly legible.

It is the advertiser's responsibility to ensure that all of the essential information is clearly legible. The essential information must be large enough to be clearly legible and prominent enough to be easily noticeable. Companies should note that for ease of reading, the essential items must be placed horizontally and not vertically, or spiralling round the ad. Attention should also be paid to issues such as type style, print quality, contrast between text and background etc. Companies should consider the distance from which a consumer might be viewing the advertisement.

Printed media and point of sale materials

Where items are intended to be read in close proximity, the lower case letter 'a' must be at least 2mm in height. For the majority of fonts, this equates to font size 10.

There is no set font size required for items such as posters, which will be read at a distance. It is recommended that the font size used for the essential information should be at least the same size as the smallest body copy. Careful consideration must be given to the distance from which a consumer might be viewing the advertisement.

Television

Here the emphasis is on duration of hold, rather than font size. BACC's advice is that all supers must be held on screen for at least two seconds, plus an additional time which is calculated pro rata at the rate of five words per second (0.2 seconds per word). For example, a six word text such as 'Contains aspirin. Always read the label' should be held on screen for at least 3.2 seconds. BACC also advises that the text is presented in lower-case, upright typefaces with capitals only where appropriate for punctuation. For further information, please consult the BACC. Where the name of the product is given on the pack shot only, advertisers must ensure that both the visibility and the hold time are long enough for the name of the product to be clear.

3.6 Submitting advertising for PAGB approval

3.6.1 This section explains the procedures which member companies and associate members should follow when submitting advertising to PAGB for approval. *(Please also refer to section 3.4 on the PAGB approval system for consumer advertising.)*

Send advertising to

3.6.2 Please send advertising copy to: Email: copyclearance@pagb.co.uk Fax: 020 7405 7719 Post/courier: Advertising Department, PAGB, Vernon House, Sicilian Avenue, London WC1A 2QS

Format

3.6.3 In general, a faster response can be achieved if advertising copy is sent by email. This enables PAGB to respond electronically and it avoids the problems of legibility associated with faxing. Ideally, advertising should be sent either as a PDF or Microsoft Word attachment.

For websites and online advertisements, PAGB require either a printed copy, or a file such as a PDF or Microsoft Word document which can be viewed offline. This also applies to animated advertisements (e.g. an animated gif or flash).

Review time	3.6.4 Please allow plenty of time for your advertising copy to be assessed. PAGB processes copy in the order in which we receive it. Although we aim to review advertising copy within one working day of receipt, we do not promise or guarantee to do so. PAGB are unable to offer feedback in less than one working day. Large or complicated pieces of copy, or claims which require detailed consideration of supporting evidence, take longer to assess. The same time scales apply to each subsequent occasion on which the advertisement is sent back to PAGB with revisions. <i>(Please refer to section 3.4.11 for further details of review times.)</i>
Contact details	3.6.5 Please make sure you include your contact details including phone number, email address, postal address and fax number. PAGB may wish to contact you to discuss your advertisement before comments or approval are given. Our reply is likely to be delayed if you have not included your contact details in the correspondence.
Highlighting changes	3.6.6 If you are re-submitting copy to PAGB, please highlight the changes made. Highlighting the changes makes it much quicker for PAGB to respond to your enquiry. Highlighting changes is essential when submitting website alterations and updates.
Members and associates only	3.6.7 Please remember that it is only members and associate members who can access PAGB's copy clearance service directly. If member companies are working with PR, advertising or marketing agencies who are not associate members of PAGB, then all materials must be submitted to us by the member company and not by the PR, advertising or marketing agency. (Enquiries about associate membership can be made to PAGB's Company Secretary.)
List of agreed claims	3.6.8 When planning advertising for new products, companies may find it useful to submit a list of proposed claims, together with supporting evidence. Having agreed the claims, PAGB will then hold a list of agreed claims which can be used in any advertisement for that product. Please note that all advertisements which contain these claims will need to be approved individually and that the acceptability of claims will depend on the context in which they are used.

3.7 PAGB Consumer Code advertising checklist

1 Before you submit advertising to PAGB for approval, please check that the following are included in the draft advertisement:

- product name
- indication which reflects the wording used on the SmPC
- single active ingredient (where applicable)
- 'Always read the label/leaflet'
- '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.'
- any other additional information necessary for correct use of the product (e.g. 'Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before using any medicines in pregnancy').

2 Is all of the essential information clearly legible?

3 Check that the advertisement does not breach the PAGB Consumer Code for Traditional Herbal Medicines. The most common things to ask are:

- is it in line with the SmPC?
- does it make claims relating to the product's effectiveness?
- does it contain any guarantees?
- does it claim it be unique?

- does it claim to be new, but has been available for over a year?
- does it make any new claims?
- are the new claims in line with the SmPC?
- does it claim to be free of ingredients present in competitor products?
- does it claim to be 'side effect free' or 'safe'?
- does it make any comparisons other than those which are fair and capable of substantiation?
- does it unfairly denigrate or discredit competitor products?
- does it claim that the product is better than or equal to another identifiable product?
- does it include any competitor brand names?
- does it have any hanging comparisons?
- does it make a superiority claim?
- does it feature a celebrity or health professional in any way?
- does the testimonial comply with the rest of the PAGB Consumer Code for Traditional Herbal Medicines?
- is the advertising aimed at children?

4 Have you submitted the supporting materials which PAGB will need to assess the advertisement? The following will be required:

- if it is a new product, have you sent a copy of the Traditional Herbal Registration, the SmPC, the product packaging and the patient information leaflet (if applicable)?
- have you sent evidence to support the claims made?
- have you forwarded a signed and dated copy of any testimonials?

5 Have you included your contact details?

4.1 Compliance with the PAGB Professional Code for Traditional Herbal Medicines

4.1.1 It is a condition of PAGB membership that companies ensure that all THMs advertising aimed at persons qualified to prescribe or supply, and those that work for such persons, complies with the relevant sections of the PAGB Professional Code for Traditional Herbal 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.

4.1.2 The PAGB Professional Code for Traditional Herbal 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. However, advice on the interpretation of the Code can be sought from PAGB.

4.1.3 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 Traditional Herbal Medicines. The signatory is also responsible for ensuring that any undertakings given as a result of a breach of the Code are carried out.

4.2 What the PAGB Professional Code for Traditional Herbal Medicines covers

4.2.1 This Code applies to the advertising of THMs which is aimed wholly or mainly at persons qualified to prescribe or supply and appropriate administrative staff, where the object of the advertising is to impact sales and/or recommendations to the general public. 'Persons qualified to prescribe or supply' (PQPS), as defined by the Medicines (Advertising) Regulations, include persons who in the course of their profession, or in the course of a business, sell or supply medicinal products. This includes, amongst others, hospitals, health centres, doctors, herbal practitioners, dentists, nurses, pharmacists, pharmacy assistants, optometrists, chiropodists, midwives and other ancillary health workers and retail staff who are legally entitled to supply medicinal products to members of the public. It also includes persons who are legally entitled to choose which medicinal product is supplied in a particular outlet (e.g. buyers). The definition does not include herbal practitioners who do not sell medicines, and who are not qualified to prescribe relevant medicinal products¹. Nor is it interpreted as including wholesale dealers.

4.2.2 Advertising is taken to include:

- printed advertising materials (e.g. journals, advertorials, booklets, posters, direct mail materials, retailer house publications etc.)
- electronic media advertising such as websites, press releases intended for Internet publication, and any other Internet advertising
- audio and audiovisual advertising (e.g. videos)
- 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

¹Relevant medicinal products' includes registered traditional herbal medicines and medicines which are subject to a Marketing Authorisation. Advertising aimed at practitioners who are neither involved in selling, nor prescribing these medicines must comply with the rules for advertising to consumers.

- sponsorship of professional, scientific or promotional meetings and events
- 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 strictly fall under the PAGB Professional Code for Traditional Herbal Medicines, all such materials should comply with the spirit of the Code.)

4.3 What the PAGB Professional Code for Traditional Herbal Medicines does not cover

Pack shots

4.3.1 A genuine photograph of a pack is not in itself subject to the PAGB Professional Code for Traditional Herbal Medicines and does not necessitate the inclusion of essential information. This is despite the fact that there are product claims, including medical claims, on the pack.

4.3.2 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.

Advertisements with no product claims¹

4.3.3 Advertisements which do not contain product claims¹ (other than those on a genuine pack shot) are not subject to the PAGB Professional Code for Traditional Herbal 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 4.6.13.)*

Factual and informative announcements and reference material without medicinal claims²

4.3.4 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 claims². Listings within publications such as the PAGB OTC Directory, Chemist & Druggist Monthly Price List etc. are, therefore, not subject to the PAGB Professional Code for Traditional Herbal 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 would apply to those claims. Essential information would be required. Advertisements within trade catalogues and price lists must comply with Code requirements.

Publications produced by wholesalers for retail pharmacists etc. detailing promotional offers on products stocked by the wholesaler are also outside the scope of this Code.

Public relations

4.3.5 PAGB recognises that the PAGB Professional Code for Traditional Herbal Medicines cannot cover public relations activities (e.g. press releases and product launches). This is because 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 the Medicines (Advertising) Regulations 1994, and ensure that all PR materials comply with the law.

Responses to correspondence and enquiries

4.3.6 Responses to correspondence and enquiries from persons qualified to prescribe or supply and appropriate administrative staff are exempt from the PAGB Professional Code for Traditional Herbal Medicines. Standard letters intended for use in response to enquiries are not subject to the PAGB Professional Code for Traditional Herbal Medicines, provided they are used only when they relate directly and solely to the particular enquiry. Similarly, the Code does not

¹Please refer to the Professional Code for Traditional Herbal Medicines Glossary for a definition of a product claim.

²Please refer to the Professional Code for Traditional Herbal Medicines Glossary for a definition of a medicinal claim.

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 would fall under the Code and require essential information.

Prices, margins and discounts

4.3.7 The Medicines (Advertising) Regulations 1994 excludes trade practices relating to prices, margins or discounts which were in regular use by a significant proportion of the pharmaceutical industry by 1 January 1993 and hence these practices are outside the scope of the PAGB Professional Code for Traditional Herbal Medicines. Other trade practices, such as those introduced after 1 January 1993, are subject to this Code. The terms 'prices', 'margins' and 'discounts' are primarily financial terms and do not include schemes which enable persons qualified to prescribe or supply to obtain personal benefits.

4.3.8 The Royal Pharmaceutical Society of Great Britain 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. would be in breach of the Royal Pharmaceutical Society's Code of Ethics even where these inducements are presented as alternatives to financial discounts.

4.3.9 Bonus schemes based on turnover and accumulated points which can be exchanged for discounts on further orders or free stock (whether exchanged as a 'credit', or 'free goods' shown on the invoice) are considered to be a variation of a 'trade measure or practice relating to prices, margins or discounts' and are, therefore, not subject to the PAGB Professional Code for Traditional Herbal Medicines.

4.3.10 Sections 4.3.11 to 4.3.15, below give examples of measures or trade practices relating to prices, margins and discounts which were in regular use on 1 January 1993.

Stock deals

4.3.11 These include bonus stock, for example offering 14 packs for the price of 12; and the provision of free stock.

4.3.12 It should be noted that where 'free stock' is given, the quantities have to be sufficient for the product to be considered as stock, rather than having the appearance of being a free sample.

Display deals

4.3.13 Display deals are included within discussions on prices, margins and discounts and are, therefore, outside the scope of the Code.

(The display itself would be considered to be advertising and would be subject to either the PAGB Professional Code for Traditional Herbal Medicines or the PAGB Consumer Code for Traditional Herbal Medicines, depending on the intended audience.)

4.3.14 The following are examples of display deals:

- counter displays, which include both permanent and temporary counter display units and under glass counter displays
- gondola ends, which are promotional displays on shelf unit ends
- shelf sites, which are promotional displays along the length of a shelf unit. This type of display may also be known as a hot spot, mid-gondola promotion or blip bay
- back wall features, which are promotional displays usually on the wall space behind the sales counter
- in-store poster sites
- window displays
- retailer consumer leaflets which include medicines advertising.

Listing fees	4.3.15 A listing fee is a lump sum payment covering cost to the retailer of stocking a new product with regard to warehouse space, shelf space, adjusting computerised records, staff training etc. Listing fees are outside the scope of the Code. (A listing fee deal may also include promotional deals and quantity of stock to be purchased.)
Labels and packaging	4.3.16 This Code does not cover product labels, packaging materials and in-pack leaflets. However, PAGB does request that copies of the approved packaging are lodged with PAGB for reference.
Advertising relating to medicines which are subject to a Marketing Authorisation	4.3.17 The PAGB Professional Code for Traditional Herbal Medicines does not cover advertising relating to OTC medicines which are subject to a Marketing Authorisation. The advertising of these medicines falls under the 'PAGB Medicines Advertising Codes - Codes of Practice for Advertising Over-The-Counter Medicines'. Advertising relating to the prescribing of a medicinal product is covered by the 'Association of the British Pharmaceutical Industry (ABPI) Code of Practice', which is administered by the Prescription Medicines Code of Practice Authority.
Corporate activities	4.3.18 The PAGB Professional Code for Traditional Herbal Medicines does not apply to activities carried out by a company where there is no mention of either registered traditional herbal medicines or products which are subject to an application under the Traditional Herbal Medicines Registration Scheme. However, such activities should not conflict with the spirit of the Code.
Non-medicines	4.3.19 This Code does not apply to products, such as food supplements and cosmetics, which may contain herbs, but which are not registered under the Traditional Herbal Medicines Registration Scheme.
Statements relating to human health or disease	4.3.20 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.
Advertising to consumers	4.3.21 The PAGB Professional Code for Traditional Herbal Medicines does not cover the advertising of THMs which is aimed wholly or mainly at the public. This is covered by the PAGB Consumer Code for Traditional Herbal Medicines.

4.4 PAGB Professional Code for Traditional Herbal Medicines code administration

Signatories	4.4.1 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.
	4.4.2 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.
	4.4.3 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.
	4.4.4 The signatories are expected to have a good working knowledge of the PAGB Professional Code for Traditional Herbal Medicines.
Procedures	4.4.5 Companies are expected to have procedures in place to identify professional advertising and to ensure that such advertising complies with the PAGB Professional Code for Traditional Herbal Medicines. The list below is an example of a checklist for professional advertising.

Please note, this list is designed to be an aid and not a complete list of all elements requiring consideration.

1 Decide whether the item falls under the PAGB Professional Code for Traditional Herbal Medicines

The following do not fall under this Code:

- 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
- items that mention a medicine by name but only refer to new labelling, adverse drug reactions, prices etc.
- items promoting a medicine which is subject to a Marketing Authorisation
- items relating to products, such as food supplements and cosmetics, which are not registered under the Traditional Herbal Medicines Registration Scheme
- items that mention a medicine by name but are a response to a specific enquiry or comment by a person qualified to prescribe or supply.

(For further information, on materials which do not fall under the PAGB Professional Code for Traditional Herbal Medicines, please refer to section 4.3.)

2 Ensure the advertising complies with the PAGB Professional Code for Traditional Herbal Medicines

The following items should be checked:

- the medicine should have a Traditional Herbal Registration
- the item should be factual, not misleading and in line with the SmPC
- the activity should respect the status of the recipient, be reputable and all claims should be supportable
- if 'safe' is used, it should be qualified
- if 'new' is used, the medicine should be less than one year old
- no mention should be made of the MHRA or other regulators
- if published studies are referred to, they must be referenced
- if comparisons are used, check they comply with the PAGB Professional Code for Traditional Herbal Medicines
- if the item is over A5 (420cm²), ensure it contains essential information unless it is a promotional aid or dummy pack *(please refer to section 4.6.13)*
- if the item is under A5 (420cm²) and is part of a bound publication, ensure it contains the abbreviated essential information *(please see section 4.6.13)*
- if the item is audio or audio-visual, ensure the essential information is available
- if the promotion involves a gift or prize, ensure it complies with section 4.6.8
- if the promotion involves hospitality ensure it complies with section 4.6.9
- if representatives of the company are involved, ensure it complies with section 4.6.12
- if sampling is involved, this can only be to persons qualified to prescribe (not supply) and must comply with the requirements set out in section 4.6.11
- if the item involves free packs, ensure this complies with section 4.6.11.

3 Training

- companies should ensure that copies of the PAGB Medicines Advertising Codes for Traditional Herbal Medicines are provided to all relevant personnel. This includes agency personnel
- companies should ensure that procedures are in place to disseminate any information that PAGB may provide in relation to the PAGB Professional Code for Traditional Herbal Medicines. For example, personnel involved in ensuring compliance with the Code should be included in PAGB's advertising mailing list

- companies should ensure that personnel who are involved in ensuring compliance with the PAGB Professional Code for Traditional Herbal Medicines have a reasonable working knowledge of the Code
- representatives should be trained to a reasonable level with regard to the products they are promoting
- companies should endeavour to make internal procedures sufficient to ensure compliance with any rulings regarding breaches of the PAGB Professional Code for Traditional Herbal Medicines.

4.5 The PAGB Professional Code for Traditional Herbal Medicines complaints procedure

Introduction

4.5.1 PAGB administers a complaints procedure under the PAGB Professional Code for Traditional Herbal Medicines. The complaints procedure is only applicable to complaints about member companies' advertising materials. In the first instance PAGB will provide informal guidance and advice on the Code and encourage the companies concerned to settle the matters through conciliation.

4.5.2 Complaints will not be pursued if the point at issue is the subject of simultaneous legal action, or if the MHRA, Ofcom, or the ASA is currently investigating it. However, a complaint will be investigated if it is referred back to PAGB, by the MHRA, under the procedures described in the MHRA's 'The Blue Guide Advertising and Promotion of Medicines in the UK'.

4.5.3 The roles of the PAGB Secretariat, the Complaints Committee and the Appeal Board are described below.

PAGB Secretariat

4.5.4 The PAGB Secretariat administers the PAGB Professional Code for Traditional Herbal Medicines and may give advice, guidance and training on the Code. It is also responsible for arranging conciliation between companies, for maintaining a list of signatories and for auditing company procedures when required, to ensure compliance with the Code.

The Complaints Committee

4.5.5 The Complaints Committee administers the PAGB Professional Code for Traditional Herbal Medicines Complaints Procedure. Officers of the PAGB Executive Committee will appoint the Chairperson and members of the Complaints Committee. The Chairperson of the Complaints Committee will be a member of the Executive Committee and the Chairperson has the casting vote on any decision.

4.5.6 The Complaints Committee consists of members drawn from a panel of experts consisting of representatives from the PAGB Executive Committee, independent experts in herbal medicines and other healthcare professionals nominated in consultation with the relevant professional bodies. The PAGB Executive Committee shall approve nominations for appointment to the Complaints Committee Panel.

4.5.7 A Complaints Committee will be constituted as required from members of the panel having no commercial interest in the complaint to be considered. Members of a Complaints Committee will be appointed with regard to their skills, area of expertise and with regard to the intended audience of the advert and the nature of the complaint. The quorum for a Complaints Committee is three members, at least one of whom must be an independent healthcare professional.

4.5.8 The Complaints Committee may obtain additional expert assistance as necessary.

4.5.9 The Secretariat for the Complaints Committee is provided by the Director of Legal and Regulatory Affairs. The Advertising Services Manager may attend meetings to provide factual information about the interpretation of the Code only, but may not take part in the decision making process and does not form part of the Committee.

The Appeal Board

4.5.10 An Appeal Board will be constituted by the Executive Director as required. It shall comprise a Chairperson with legal background or other relevant expertise, ex officio one of the Officers of PAGB Executive Committee (who shall not have any commercial interest in the complaint to be considered), and at least one independent pharmacy and/or medical expert depending on the nature of the complaint. The independent experts will be appointed in consultation with the relevant professional bodies and may be members of the Complaints Committee Panel who have not been involved in any prior consideration of the complaint.

Complaints from pharmaceutical companies

4.5.11 Complaints from pharmaceutical companies must be signed by a Chief Executive Officer, or equivalent and must indicate which rules of the PAGB Professional Code for Traditional Herbal Medicines are alleged to have been breached.

Conciliation

4.5.12 If the complainant is a PAGB member company, the complaint will automatically be subject to conciliation. The PAGB Secretariat will advise and assist in finding a conciliator who would normally be an expert in Code of Practice matters. If conciliation fails to achieve a satisfactory resolution, the complaint will be referred for consideration by the Complaints Committee. Appeals against decisions of the Complaints Committee may be made to the Appeal Board.

4.5.13 Resolution of the complaint will be sought within twenty working days of receipt of the complaint. If the complaint cannot be resolved through conciliation in a manner acceptable to both complainant and respondent, then the complaint will be formally considered under the complaints procedure.

4.5.14 If the outcome of conciliation is acceptable to both the complainant and respondent, the complaint will not formally proceed. Under these circumstances the complaint letter and a brief report of the outcome will be kept on file.

Formal complaints procedure

4.5.15 Complaints for consideration by the Complaints Committee must be received in writing, signed by the Chief Executive Officer, or equivalent, and must indicate which rules of the PAGB Professional Code for Traditional Herbal Medicines are alleged to have been contravened.

4.5.16 The Secretary to the Complaints Committee will detail the alleged breaches to the designated signatory of the respondent company who will be invited to submit written comments in response to the allegations made. The signatory, or a designated deputy, must respond within ten working days of receipt of the complaint. Papers from the informal conciliation process may form part of the evidence considered by the Complaints Committee. The Complaints Committee has the authority to request copies of any relevant material from a member company.

4.5.17 The Chairperson of the Complaints Committee has the casting vote on any decision. All decisions of the Complaints Committee will be provided in writing with reasons to both the complainant and respondent companies.

4.5.18 Where the Complaints Committee decide that a complaint shall not proceed, and the complainant disagrees with this decision, the complaint shall be put to the Appeal Board for a final decision.

4.5.19 If the Complaints Committee decide there is no case to answer upon receipt of the respondent's comments, both the complainant and the respondent will be notified. If the complainant does not accept this decision, the complaint shall be put to the Appeal Board for a final decision.

The appeals procedure

4.5.20 Where the Complaints Committee rule a breach of the PAGB Professional Code for Traditional Herbal Medicines, the respondent is advised and given reasons for the decision. The respondent then has ten working days to provide the Secretariat with a written undertaking that the advertising will be withdrawn or amended. The respondent is required to provide details of the timescale of this undertaking and the actions required to achieve the undertaking. Alternatively, the respondent may lodge an appeal with the Appeal Board within ten working days of receipt of the written reasoned decision of the Complaints Committee.

4.5.21 Where the Complaints Committee rules there is no breach of the PAGB Professional Code for Traditional Herbal Medicines, the respondent and complainant are so advised. The complainant will be sent a report of the complaint and any additional materials provided by the respondent which are not considered to be confidential. All complaints are reported to the Appeal Board Chairperson after the expiration of the appeal period.

4.5.22 The complainant or the respondent may appeal within ten working days of receipt of the Complaints Committee decision in writing. The Appeal Board will only consider written appeals. An appeal must be accompanied by reasons as to why the Complaints Committee's decision is not accepted.

4.5.23 The Appeal Board will consider the Complaints Committee's report on the complaint, in conjunction with any additional formal written materials from the respondent and complainant.

4.5.24 Where an appeal is lodged by the complainant, the respondent company has ten working days to comment on the reasons given by the complainant for the appeal and these comments will be circulated to the Appeal Board.

4.5.25 The complainant has five working days to comment on the respondent's comments, upon the reasons given by the complainant, for the appeal and these comments will also be circulated to the Appeal Board.

4.5.26 Any confidential data, as designated by either the complainant or the respondent, will only be supplied to the independent members of the Appeal Board and these members will be charged with taking the materials into consideration.

4.5.27 Decisions are made by majority voting with the Chairperson having the casting vote. All decisions of the Appeal Board will be provided in writing with reasons to complainant and respondent companies.

4.5.28 Where the Appeal Board decides there is no breach of the PAGB Professional Code for Traditional Herbal Medicines, the complainant and respondent are so advised.

4.5.29 Where the Appeal Board rules there is a breach of the PAGB Professional Code for Traditional Herbal Medicines, the parties are advised in writing and given reasons for the decision.

4.5.30 The respondent company then has five working days to provide the Secretariat with a written undertaking that the advertising will be withdrawn or amended. The respondent is required to provide details of the timescale of this undertaking and the actions to be taken to achieve the undertaking.

4.5.31 The Appeal Board may also call for an audit of the respondent's procedures for ensuring compliance with the PAGB Professional Code for Traditional Herbal Medicines. The audit would be carried out by the PAGB Secretariat or an independent person or persons appointed by the PAGB Secretariat. In the event of an audit, it would be expected that the minimum standards set out in section 4.4.1 to 4.4.5 would be in place.

Complaints Committee case reports

4.5.32 The Appeal Board Chairperson can review the Complaints Committee's decisions relating to any case at report stage. In the event that the Chairperson disagrees with the Complaints Committee's decision, the case may then be reviewed by the Appeal Board under the procedures set out above.

4.5.33 The Complaints Committee may report companies who refuse to comply with the complaints procedure, to the Appeal Board Chairperson. The Appeal Board may decide on sanctions, ranging from a warning letter to expulsion from PAGB membership.

4.5.34 The Chairperson of the Appeal Board must approve any sanction imposed on a company.

4.5.35 At the final determination of a complaint, a draft report is produced by the Complaints Committee or the Appeal Board Chairperson. The report will summarise the details of the complaint, the respondent, the name of the product involved and the reasons for the decision. The complainant will also be named in cases that cannot be attributed to an individual, for example Company X would be named but Dr Y, would not. The draft report is sent to the complainant and respondent who have five working days to comment, following receipt of the document. The Complaints Committee or Appeal Board Chairperson will consider changes and may amend the report as appropriate.

4.5.36 The final report will be sent to the complainant, respondent, the MHRA, the Royal Pharmaceutical Society of Great Britain, the British Medical Association, editors of all major trade press and members of the PAGB Managing Directors mailing list. A report of the outcome of complaints will be published on the PAGB website.

Monitoring

4.5.37 Where a breach of the PAGB Professional Code for Traditional Herbal Medicines is identified by PAGB, the company concerned is requested to comment in writing within ten working days of receipt of notification.

4.5.38 If the company accepts there is a breach of the PAGB Professional Code for Traditional Herbal Medicines, they will be requested to supply an undertaking to comply with the PAGB Professional Code for Traditional Herbal Medicines as set out in 4.5.30. If the company disagrees with the decision then procedures under 4.5.16 onwards will apply.

4.6 Rules of the PAGB Professional Code for Traditional Herbal Medicines

4.6.1 General principles

1 The PAGB Professional Code for Traditional Herbal 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) as defined by the regulations include persons who in the course of their profession, or in the course of a business, sell or supply medicinal products. This includes persons (and their employees), who are legally entitled to choose which medicinal product is supplied, or to supply such a product even if it is chosen by the consumer or by another person legally entitled to make that choice on the consumer's behalf. Persons qualified to prescribe or supply include, amongst others:

- herbal practitioners who are involved in selling medicines to consumers
- doctors
- pharmacists (including pre-registration pharmacists)
- pharmacy assistants
- nurses
- midwives
- dentist
- buyers
- retail staff who have direct contact with the public (this includes all retailers who sell medicines)
- health centres
- health visitors
- hospitals
- chiropodists
- opticians
- optometrists

(For further information, please refer to section 4.2)

Students

Students of the above professions are not considered to be persons qualified to prescribe or supply. Administrative staff and students of the above professions, for example those working in doctors' surgeries or pharmacies, are permitted to see advertisements which are 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 which 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 Traditional Herbal Medicines will apply.

Websites

Websites which 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 registered traditional herbal medicine must not be promoted prior to its registration under the Traditional Herbal Medicines Registration Scheme.

For example, supplying a photograph to a journal to announce a product launch is prohibited, if it is done prior to receipt of the Traditional Herbal Registration and labelling approval. Similarly, teaser advertising is prohibited where it relates to a product which has not yet been granted a Traditional Herbal Registration.

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.

3 Advertising shall be true and shall not mislead. It shall not contain any exaggerated claims, either direct or implied. All advertising must be in line with the product's Summary of Product Characteristics.

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.'

Advertising must be in line with the product's Summary of Product Characteristics (SmPC) and not mislead recipients as to the benefits which can be obtained from the product. Claims for indications which are not listed in the SmPC are prohibited. Claims for benefits that cannot be expected to be achieved by the majority of users are also prohibited.

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 the condition than the product is indicated for.

4 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.

This rule includes issues such as taste and decency (i.e. avoidance of offence). Examples quoted as unacceptable in the PAGB Consumer Code for Traditional Herbal Medicines may be taken as a benchmark for acceptability, but are not necessarily unacceptable for advertising to professionals. On this basis, full or partial nudity would 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.

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. This guidance particularly applies to competition questions.

5 An advertisement must not refer to the Medicines and Healthcare products Regulatory Agency, the Licensing Authority, or any statutory body set up under the Medicines Act 1968, unless required by the Licensing Authority.

4.6.2 Misleading advertising

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

7 All claims concerning the safety, quality or efficacy of a medicine must be fair and capable of substantiation.

The ABPI Code, which relates to advertising for prescribed medicines, requires supporting evidence for any information, claim or comparison to be provided, on request, to health professionals or appropriate administrative staff. Although the PAGB Professional Code for Traditional Herbal Medicines requires all claims to be supportable, it is left to the company's discretion to supply such data to health professionals or to appropriate administrative staff. In the event of a complaint relating to supporting evidence, the complaint would be dealt with under the procedure set out in section 4.5 of this Code. Substantiation would not be required to support indications stated on the SmPC.

Advertising for THMs must not mislead consumers regarding the strength of evidence which supports the product's therapeutic benefits (*please refer to Rule 13*).

8 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 absorption and speed of action etc., unless they are present in the SmPC. It is unlikely that THMs will have sufficient evidence to support speed of action and duration of action claims. Where sufficient evidence does exist, all such claims must be in line with the SmPC. For example, if the SmPC states that the ingredient is absorbed in 30 minutes, then it would not be acceptable to claim that the product 'gets to work in 15 minutes', despite supporting evidence. Absorption data cannot be extrapolated to claim that a product offers efficacy at a certain point unless there is evidence to substantiate such claims.

Speed of absorption claims (e.g. 'gets to work')

PAGB interprets speed of absorption claims (e.g. 'gets to work in ten minutes') on the basis of evidence that a therapeutic level of the active ingredient(s) reaches the site of action at the time stated. Where the product is taken orally, 'gets to work' claims are acceptable on the basis of a therapeutic level of the active ingredient(s) being present in the blood stream at the time indicated. Where there is insufficient evidence to clearly determine the therapeutic level then it will be assumed that the tablet dosage equates to the therapeutic level. Where sub-therapeutic levels can be identified at an earlier point, advertisers could claim 'starts to get to work in x minutes'.

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

Speed of action claims are permitted where sufficient evidence exists to support them. Claims such as 'starts to work' or 'active' are taken to mean that consumers will be starting to feel relief at this point.

Duration of action claims

Duration of action claims are permitted where sufficient evidence exists to support them. 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. 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.

'New' claims

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

This allows companies to say 'new Brand X' or 'now available' for one year from the date when the product is first available for purchase OTC. If the product itself is not new, then manufacturers must make it clear which aspect of the product is new. For example:

- new product launches (e.g. 'New Brand X')
- new registered indications (e.g. 'new for skin irritation')
- new format (e.g. 'new Brand X tablet format').

Advertisers of THMs need to avoid causing confusion when combining 'new' claims with the required 'traditional use statement'. (*Please refer to Rule 33.*)

It is advertisers' responsibility to ensure that any packaging or advertising which contains the claim 'new' is revised once the product has reached the one year time limit.

'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. Such claims are not acceptable where there are other products available with the same characteristic. For example, 'Use Brand X - now you can treat pain fast' would not be acceptable, as it implies that it is the only fast acting pain reliever.

10 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 treatment'). 'Unique' claims can only be used until another product becomes available which offers the same attributes. A product can claim to be unique within the OTC 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 class which contains a particular active ingredient
- the only product within the therapeutic category to be available in a once-daily dosage
- the only product within the therapeutic category to be available as an infusion

- the only registered traditional herbal medicine for use in eczema (such claims must not imply superiority over medicines which are subject to Marketing Authorisations)
- the only one in the therapeutic category which does not cause drowsiness.

11 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.

Where a SmPC states 'no known side effects', PAGB would accept that this exact phrase could be used in advertising. However, 'no side effects' should not be used, as this cannot be guaranteed for any product. Furthermore, such claims could raise the stakes in terms of liability if a consumer does experience a side effect.

For similar reasons, PAGB advises advertisers that 'safe' should 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.

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

It would not be acceptable to use phrases such as 'not habit forming' and 'non-addictive' as, while it may be true that a product does not cause chemical dependency, it 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.

12 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 etc. Graphs and tables should be adequately labelled so that 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. *(Please also refer to Rule 23.)*

13 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.

4.6.3 'Natural' claims

14 Advertising shall not claim that a product is 'natural' unless all of its components are naturally occurring. 'Natural' can be used to describe those elements that are naturally occurring (e.g. 'natural active ingredients').

Products can only claim to be 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 natural active ingredients').

Phrases such as 'works naturally' and 'acts naturally' can be used for products which have a natural mode of action i.e. an action which mimics a physiological mechanism of the body. Claims such as 'natural relief for constipation' and 'relieves constipation naturally', are also generally viewed as implying that the product has a natural mode of action.

It is not acceptable to use the term 'nature's remedy' to describe a product.

15 Advertising shall not suggest that the safety or efficacy of a product is due to the fact that it is natural, or that it is made from herbal ingredients.

This does not prohibit advertising claiming that a product is natural or that it contains natural ingredients, but it does prohibit claims such as 'have confidence in Brand X because it is made from natural ingredients' or 'It's made from herbs so you can be sure that it is safe'.

4.6.4 Comparative advertising

16 All comparisons shall be balanced, fair and supportable.

All comparative statements must be balanced and fair and all comparisons must be made on a like-for like basis. For example, in some circumstances, it may not be acceptable to make a direct comparison between a topical product for relief of congestion with other cold and flu products which also treat pain. Comparisons based solely on the fact that both treatments relieve congestion would be acceptable.

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.

Comparative statements should not be misleading and must not cause disrepute to the industry.

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

This rule applies to all competitor products, ingredients and treatments and not just to identifiable products or treatments. PAGB regards such an approach as 'denigrating' copy and holds that this type of advertising damages confidence in the OTC industry.

Copy which compares the different attributes of products, treatments or ingredients, is acceptable, provided this does not stray into denigration. For example, 'some people find that tablets are more convenient than infusions', would be acceptable provided there is sufficient evidence. However, PAGB would not accept 'some people find that tablets are better than infusions' as PAGB takes the view that such all encompassing statements would be denigrating to infusions.

Identifiable products

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 cause disrepute to the industry.

Where a comparison is made to a product which 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.

18 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:

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

Words such as 'faster', 'better', 'stronger', 'quicker' etc. can be amended to 'fast', 'strong', 'long', or 'quick'.

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 tastes better' (i.e. tastes better than the previous formulation).

19 Supportable top parity claims are acceptable. Such claims would remain valid until another product in the therapeutic category can prove objective superiority.

Top parity is a means of stating that no product has been able to prove superiority in a given area, such as efficacy, speed of action, duration of action etc. It is often the case that several products within a therapeutic category, are of equal efficacy. For example, 'nothing acts faster' and 'nothing is more effective' are comparisons against all other products in that category.

It is unlikely that manufacturers of THMs would have sufficient evidence to enable them to make a top parity claim relating to product efficacy.

PAGB produces a separate guideline entitled 'Guidance on the Use and Substantiation of Top Parity Claims'.

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

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 claims

Claims that a product is 'number one' also imply that it is the best in its field. PAGB advises that these claims should be further qualified (e.g. 'number one selling'). Support for such a sales statement requires three months of recent sales data. 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.

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

- 'no 1 selling travel sickness treatment'
- 'best selling herbal cough lozenge'
- 'nation's favourite natural remedy for insect bites'
- 'market leader for herbal hayfever remedies'
- 'most popular herbal sleep aid'
- 'first choice decongestant rub'
- 'Brand X - leading sales in the treatment skin irritation'.

The examples listed below could be viewed as either best selling claims or as claims which imply some other form of superiority. Advertisers would need to qualify these claims and send the appropriate evidence:

- 'no.1 for stress'
- 'brand leader'
- 'Brand X is the leading herbal anti-sickness remedy'.

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 products on the market and all available data. It is unlikely that THMs would have sufficient evidence to support a clinical superiority claim.

Use of the definitive article

Advertisers should note the word 'the' may be regarded as a superiority claim. For example, 'The herbal cough treatment' implies that it is the best herbal cough treatment. PAGB advises that 'the' is amended to 'a' or 'an'.

Subjective superiority claims

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

4.6.5 Testimonials

21 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 Traditional Herbal Medicines. Testimonials and quotes in themselves are not substantiation of the claim being made. Member companies must hold evidence to support the claims made. Companies must also make certain that the views ascribed to an individual or organisation accurately represent the current views of those persons. Care should be taken in editing that the original meaning is not altered.

4.6.6 References

22 When promotional material refers to published studies, the studies must be referenced.

However, where published studies are referred to, advertisers should bear in mind that the advertisement must not give the impression that the product's efficacy is based on clinical trials, rather than on traditional use.

23 Graphs, tables, quotations and other illustrative matter, taken from a medical journal or other scientific work, must be accurately reproduced and the precise source(s) indicated. This includes materials such as 'before-and-after' photographs.

Please also refer to Rule 22.

4.6.7 Written material accompanying promotions

24 Written material accompanying promotions is defined as any advertising material which is not bound into a dated publication, such as loose inserts and detail aids. All such materials shall be accurate, up to date, verifiable or 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.

25 Written material accompanying promotions shall include the essential information required in advertising and the date the information was last drawn up or revised.

4.6.8 Gifts, prizes and inducements

26 No gift, pecuniary advantage 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.

An inexpensive gift is considered to have cost the donor company no more than £6 excluding VAT. Acceptable gifts may include:

- pens
- notepads
- diaries
- desk tidies
- calendars
- desk clocks
- inexpensive computer accessories such as mouse mats
- nail brushes
- surgical gloves
- first aid kits
- calculators
- relevant books or vouchers towards such books
- mugs
- tissues
- umbrellas
- phone cards
- stress toys etc.

Prizes

An inexpensive prize is considered to 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. 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 the previous section:

- relevant books and journal subscriptions (e.g. British Medical Journal, Chemist and Druggist etc.)
- training courses (or a contribution towards the cost of attending such a course)
- training software
- health education videos
- free stock (to a maximum of £130, calculated as manufacturers selling price)
- advertising space (e.g. advertising in a local newspaper for a community pharmacy)
- panic buttons (e.g. for use in a doctor's surgery/pharmacy)

- high visibility jackets (e.g. for doctors doing night time home visits)
- work wear (e.g. white coats etc.)
- briefcases/Gladstone bags
- electronic organisers
- business card holders
- coffee/tea making equipment.

Gifts and prizes which are likely to be taken home are likely to be unacceptable. Items which have been found to be unacceptable include: microwave ovens, television sets, watches, cordless phones, leisure bags, vouchers, health farm weekends, music compact disks.

All prize promotions must comply with the relevant laws and industry codes, including the British Code of Advertising, Sales Promotion and Direct Marketing (please refer to section 5.3). Competitions related to window displays, or similar are subject to the provisions of the PAGB Professional Code for Traditional Herbal Medicines and hence any prizes would need to be in line with this rule.

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 is required to purchase or supply a stated amount of product in order to receive a planogram, then this would be treated as an inducement.

Corporate activities

This rule does not prevent companies providing medical and educational goods and services which 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.

4.6.9 Hospitality and meetings

27 Companies may provide hospitality to persons qualified to prescribe or supply and those who work for such persons in association with professional, scientific and promotional meetings/events and other such meetings/events, provided that it is reasonable in level and subordinate to the main purpose of the meeting or event.

Pharmaceutical companies may appropriately sponsor a wide range of meetings. These include small lunch time audio-visual presentations in a group practice, hospital meetings, meetings at postgraduate education centres, product launches, management training courses, meetings of clinical trialists, patient support group meetings, satellite symposia and large international meetings, organised by independent bodies with sponsorship from pharmaceutical companies (*please refer to section 4.6.10 on training*).

When meetings are sponsored by pharmaceutical companies, this must be disclosed in the papers relating to the meeting and in any published proceedings.

The impression that is created by the arrangements for any meeting must be kept in mind. A useful criterion in determining whether the arrangements for a meeting are acceptable is 'would you and your company be willing to have these arrangements generally known?' The aspects described below should be considered.

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 relates to practice administration. Pharmacy assistants may be invited to a meeting on pharmacy management where health education is discussed.

Food and drink	<p>Hospitality must not extend beyond persons qualified to prescribe or supply, other health professionals and appropriate administrative staff.</p> <p>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.</p>
Expenses	<p>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.</p> <p>Payments may not be made directly or indirectly for room rental for such meetings.</p>
Trade shows and exhibitions	<p>Trade shows and exhibitions are outside the scope of the PAGB Professional Code for Traditional Herbal Medicines unless they are promoting, or are sponsored by a medicinal product. Any promotional activities which are run in association with medicinal products would be subject to the PAGB Professional Code for Traditional Herbal Medicines.</p> <p>Meetings of a commercial nature are also outside the scope of the PAGB Professional Code for Traditional Herbal Medicines where discussion is predominantly related to prices, margins and discounts.</p>
Corporate activities	<p>Corporate activities are outside the scope of the PAGB Professional Code for Traditional Herbal Medicines provided they do not constitute an inducement to supply, administer or buy any medicine. However, it should be noted that the British Medical Association Code recommends that doctors only attend meetings where the purpose of the event is educational.</p>

4.6.10 Training and education

28 Member companies may provide training or education for persons qualified to prescribe or supply, and may also sponsor training provided by other organisations. Such materials should offer accurate, balanced information on the subject area and include a clear indication of which company has produced or sponsored the material.

Training materials which are not within the editorial control of a member company are not strictly within the scope of the PAGB Professional Code for Traditional Herbal Medicines. However, a company should try to ensure that such materials comply with the spirit of the PAGB Professional Code for Traditional Herbal Medicines. Brand mentions in these materials would not automatically bring the material within the scope of the Code, provided such brand mentions are limited. Advertisements could be included within the materials. The advertisements would be subject to the Code.

Where training or educational materials are significantly brand biased or where they may be considered to be advertising, they would be required to comply with the PAGB Professional Code for Traditional Herbal Medicines. Examples include excessive mentions of one product over comparable products, use of well established straplines etc.

Where a training or educational event is entirely within the control of a member company and is linked to a medicinal product, then provision of hospitality or inducements is subject to the PAGB Professional Code for Traditional Herbal Medicines. Any materials provided should be acceptable under the Code.

4.6.11 Sampling and free packs

29 Under certain circumstances a free sample of a medicinal product can be given to persons qualified to prescribe for the purpose of their becoming familiar with the product.

These requirements are set out in the Medicines (Advertising) Regulations 1994.

The circumstances under which a free sample of a medicine can be supplied are as follows:

- a free sample of a medicine can only be given to a health professional who is qualified to prescribe
- any free medicinal sample must be relevant to the responsibilities of the particular health professional
- member companies must ensure that samples are only given for the purpose of the recipient gaining experience in dealing with such a product
- free samples must only be supplied on an exceptional basis and not for promotional purposes
- a free sample can only be supplied in response to a written request, signed and dated
- the free sample provided must be no larger than the smallest available pack which has been approved by the MHRA
- the free sample must be marked with 'free medical sample - not for resale' (or similar)
- a copy of the SmPC must be provided with the free sample
- suppliers of samples must maintain an adequate system of control and accountability.

This rule does not extend to supplying free samples to persons qualified to supply but not to prescribe (i.e. persons who sell medicines to consumers but who are not qualified to prescribe them). Nor is it acceptable to send samples of medicinal products to journalists, for PR purposes etc.

It should be noted that where 'free stock' is given, the quantities have to be sufficient for the product to be considered as stock, rather than having the appearance of being a free sample.

It is acceptable, however, to give mock-ups of packaging to health professionals to enable them to become familiar with the product.

4.6.12 Representatives

Training

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

Member companies should note that, although training materials do not strictly fall under the PAGB Professional Code for Traditional Herbal Medicines, all such materials should comply with the spirit of the Code. *(Please refer to Rule 28.)*

Summary of product characteristics

31 Representatives are required to have available a copy of the Summary of Product Characteristics for any medicine which they promote. This should be given to persons covered by this Code on request.

Reporting of information

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

4.6.13 Essential information in professional advertising

33 Essential information is required to be provided in all advertising materials directed wholly or mainly at persons qualified to prescribe or supply.

Identification

The Medicines (Advertising) Regulations 1994 require that essential information is included in all advertisements aimed at an audience made up wholly or mainly of persons qualified to prescribe or supply. This essential information consists of:

- name of the product and a list of the active ingredients, which must be placed immediately adjacent to the most prominent display of the product name. The list of active ingredients should either use the same amount of space as the name of the product, or use a font size in which the lower case letter 'a' measures at least 2 mm in height. (This equates to font size 10 for the majority of fonts.) *(Please refer to Rule 35, 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 or GSL.

Traditional Use Statement

The following statement must be included in advertisements for THMs:

- '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.' This statement must be sufficiently prominent to ensure that recipients of the advertisement understand that the product is a THM.

Use of the product

- indications: one or more of the indications for the use of the product. The indication must be included in the 'traditional use statement' above. Any additional information regarding the indication must reflect the wording in the SmPC. Where the SmPC states 'Traditionally used for...' or similar, this information should be used in advertising materials. (This excludes references to the indication made on pack shots.)
- 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 the 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 Traditional Herbal Registration
- 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.

Examples of where essential information is required³

Essential information must be included in the following circumstances:

- where product claims⁴ are made. (This does not include those which can be seen on a genuine pack shot)
- where direct or implied product claims⁴ are included in the form of artwork. (This does not include the artwork on a genuine pack shot)
- where direct or implied product claims⁴ are included in the form of questions and answers, such as in a competition
- where advertisements or promotional items are used at exhibitions. (The essential information may be available either on the items themselves or at the stand)

³ Please refer to Rule 34 for details of when abbreviated essential information is acceptable.

⁴ Please refer to the Professional Code glossary for a definition of a product claim.

- where 'post-it notes' or calendars bear product claims⁴. (The essential information does not need to be included on every page, provided it is supplied on the cover or back page)
- in factual and informative announcements which include medicinal claims⁵. This does not include those which can be seen on a true representation of a pack, or as a straightforward representation of the indications (*please refer to section 4.3.4*). Factual and informative announcements include documents such as trade catalogues, price lists and planned list order forms (PLOFs).

Buyers and shopkeepers

Note: Advertisements which are aimed at buyers and shopkeepers, who do not have a healthcare qualification, only require essential information when medicinal claims⁵ are included, rather than where other types of product claims⁴ are used.

Examples of where essential information is not required

Essential information is not required in the following circumstances:

- in advertisements which do not contain product claims⁴ (other than those which can be seen on a genuine pack shot). (*For further information, please refer to section 4.3.3.*)
- on items which are intended wholly or mainly for consumers. These may be shown to persons qualified to prescribe or supply without triggering the requirement for essential information
- on promotional aids, provided they feature no more than the product name or a reasonable abbreviation thereof, trade mark protection and company name. (*Please refer to Rule 38 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 or supply.)
- in factual and informative announcements which do not include medicinal claims⁵ other than those which can be seen on a true representation of a pack, or as a straightforward representation of the indications (*please refer to section 4.3.4*). Factual and informative announcements include documents such as trade catalogues, price lists and planned list order forms (PLOFs)
- in advertisements, which do not include any medicinal claims⁵, and which are aimed at buyers and shopkeepers, who do not have a health care qualification.

Note: When promoting medicines for use during pregnancy, member companies should refer to the MHRA's guideline 'Medicines which are Promoted for use During Pregnancy'.

34 Advertisements which appear in bound publications and which do not exceed an area of 420cm² are exempt from the requirement to include full essential information but must include abbreviated essential information.

Abbreviated information may be provided where an advertisement appears in a bound publication and does not exceed an area of 420cm². 420cm² equates to A5. Journals, calendars, diaries, wall-planners and desk pads bearing advertisements are also included in the definition of 'a bound publication'.

There are no limitations on the types of claims that can be made in an advertisement displaying abbreviated information, over and above those rules that apply to all advertisements aimed at PQPS.

Advertisements eligible for the inclusion of abbreviated essential information must include the following:

- name of the product and a list of the active ingredients, which must be placed immediately adjacent to the most prominent display of the product name. The list of active ingredients should either use the same amount of space as the name of the product or use a font size in which the lower case letter 'a' measures at least 2mm in height. (This equates to font size 10 for the majority of fonts.) (*Please refer to Rule 35, on legibility.*)
- supply classification, P or GSL.

⁵ Please refer to the Professional Code glossary for a definition of a medicinal claim.

Identification

- Traditional Use Statement**
- 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.
- Use of the product**
- indications: one or more of the indications for the use of the product. The indication must be included in the 'traditional use statement' above. Any additional information regarding the indication must reflect the wording in the SmPC. Where the SmPC states 'Traditionally used for...' or similar, this information should be used in advertising materials. (This excludes references to the indication made on pack shots.)
 - warnings: any warning statements required for advertisements as a condition of the Traditional Herbal Registration.
- Further information**
- a statement that 'further information is available from', followed by the name and address of the product licence holder or the part of the product licence holder's business responsible for the supply.

35 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 which affect legibility. Attention should 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.

Active ingredients

The Medicines (Advertising) Regulations 1994 require 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 either occupy a total area which is no less than that which is taken up by the brand name, or should be stated in a bold type 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.)

There is no set font size required for essential information on items such as posters, which 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.

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, it is acceptable to have the information on a facing page, provided there is no intervening editorial or pictorial etc.

In the case of multiple page advertisements, information is not required on each page, provided there is a clear reference on the outer edge of each page referring the reader to where the information can be found. This is only applicable where the advertisement is

consecutive with no intervening editorial. The reference should be 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.

36 In the case of audio visual material such as films, video recordings etc. and interactive data systems, the essential information may be provided either by way of a document which is made available to all persons to whom the material is shown or sent, or by inclusion in the audio-visual recording or interactive data system itself.

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.

37 In the case of audio material consisting of sound only, the essential information must be provided by way of a document which 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 the inclusion of abbreviated essential information.

38 Promotional aids are not required to comply with the requirements to include essential information, provided they feature no more than the product name, trade mark protection and company name.

Items such as pens, letter openers, mugs etc. bearing only a product name, a reasonable abbreviation thereof or an umbrella brand name are considered to be promotional aids. As such, they are exempt from the requirement to include essential information, as set out in Rule 33. Promotional aids may also feature the trade mark protection and company name. However, if any additional information is included, such as a strapline or a visual representation of a claim, the item would need to carry essential information.

The list of acceptable gifts in Rule 26, 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, provided they bear no more than the product name, company name and trademark protection.

4.7 PAGB Professional Code for Traditional Herbal Medicines glossary

Medicinal claims

4.7.1 Medicinal claims are defined as claims relating to the medicinal benefits of the product. They do not include claims solely relating to the product format, packaging, ease of use, sensory aspects such as taste, availability, price, claims that the product is new, or claims relating to sales, either actual or projected. Examples of medicinal claims include:

- descriptions of the product's benefits e.g. relieves, treats, soothes, prevents etc.
- comparisons with the effects of other products
- duration of action claims
- speed of action/absorption claims
- claims that the product 'works naturally'.

Product claims

4.7.2 Product claims are defined as any claims relating to the attributes of the product. They include medicinal claims. They do not include claims relating to price, availability, claims that the product is new, or claims related to sales, either actual or projected. For example:

- great flavour
- easy to use spray
- available in handy sachets
- non-greasy cream
- new compact pack size
- easy to swallow
- contains natural ingredients
- all medicinal claims.

5 Control of OTC medicines advertising in the UK

The roles of the regulatory and self-regulatory organisations that are involved in the control of OTC medicines advertising are described below. The sanctions are also listed for those organisations that deal with complaints and/or breaches of the codes/regulations.

The Medicines and Healthcare Products Regulatory Agency (MHRA)

5.1 The 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 the Medicines (Advertising) Regulations 1994 (as amended) on behalf of the health ministers. The MHRA is responsible for deciding if legal action will be taken against any advertiser under the Medicines (Advertising) Regulations. The key principle is that advertising should not mislead and should reflect the terms of the product's Traditional Herbal Registration or Marketing Authorisation. The regulations specifically allow complaints, under Regulation 9, to be referred by the MHRA into the self-regulatory system, if those involved in the complaint agree.

MHRA sanctions

5.2 The MHRA monitors advertising and also acts on complaints received concerning possible breaches of the Medicines Act and Regulations. Breaches of the Medicines Act 1968 and Regulations invoke separate and distinct sanctions which can be civil sanctions (e.g. withdrawal or amendment of advertising before issue or re-issue, or injunctive powers to prevent issue or re-issue) 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 can appeal to the Independent Review Panel regarding MHRA rulings.

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

5.3 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 British Code of 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.

5.4 CAP's Broadcast Committee is contracted by the broadcast regulator, Ofcom, to write and enforce the codes of practice that govern TV and radio advertising, the Radio Advertising Standards Code, the TV 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.

5.5 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 TV Advertising Standards Code, the Radio Advertising Standards Code, or the Advertising Standards Code for Text Services as applicable.

ASA sanctions

5.6 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 cooperate with the self-regulatory 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.

5.7 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 that persistently breach the Code jeopardise their membership of trade organisations.

5.8 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)

5.9 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.

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

The Broadcast Advertising Clearance Centre (BACC)

5.11 The BACC is funded by television companies operating within the UK. All television advertising to be broadcast by these television companies must be cleared by the BACC before transmission. The BACC uses the TV Advertising Standard Code as the basis for its approvals. It also produces comprehensive guidelines on all aspects of the TV Advertising Standards Code. It is usual for the BACC to refer to their medical panel for advice on medicines. PAGB member companies are required to submit television advertising materials to both the BACC and PAGB.

The Radio Advertising Clearance Centre (RACC)

5.12 The 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 Radio Advertising Standards Code. The RACC is funded by all licensed radio broadcasters. All radio advertising for medicines and food supplements must be cleared by the RACC before transmission. PAGB member companies are required to submit radio advertising materials to both the RACC and PAGB. The RACC has access to independent medical and nutrition advisors.

The Proprietary Association of Great Britain (PAGB)

5.13 The PAGB is the self-regulatory body for OTC medicines advertising. It offers a pre-publication approval service for consumer advertising in relation to OTC medicines, (including THMs) and food supplements; together with advice on advertising which is aimed at professionals. Details of these services are given in sections 3.4 and 4.1 of this document, respectively. PAGB also runs a post-publication complaints system for advertising to persons qualified to prescribe and supply. The details of this are set out in section 4.5 of this document.

PAGB sanctions – advertising to consumers

5.14 The PAGB Consumer Code for Traditional Herbal Medicines operates through pre-publication advertising approval. Failure by a company to comply with this Code will result in a request for an advertisement to be amended or withdrawn. Failure to comply could result in the company being expelled from PAGB membership.

5.15 The purpose of this system is to prevent misleading advertising and so avoid complaints being upheld against PAGB member companies. While we can liaise informally between members, the PAGB itself does not handle complaints against consumer advertisements. Any complaints against PAGB-approved advertising must be addressed to the MHRA, or the ASA, as appropriate. However, members can request that matters of Secretariat interpretation of the PAGB Consumer Code for Traditional Herbal Medicines be reviewed.

PAGB sanctions – advertising to persons qualified to prescribe or supply

5.16 Where the Complaints Committee finds a company's professional advertising to be in breach of the PAGB Professional Code for Traditional Herbal Medicines, the company will be requested to either amend or withdraw the advertising. Failure to comply with such a sanction could result in the company being expelled from PAGB membership. Full details can be found in section 4.5.

PAGB review process

5.17 The PAGB Secretariat is responsible to the PAGB Executive Committee. The Executive Committee delegates matters of day-to-day interpretation of the PAGB Medicines Advertising Codes for Traditional Herbal Medicines to the Secretariat. The Executive Committee are entitled to review any decisions of the Secretariat, or to give general or specific guidance to the Secretariat on the interpretation of the Codes.

5.18 Any PAGB member company can request a review by the Secretariat, or by the Executive Committee, of a Secretariat decision, or point of interpretation. A request for a formal review should be made to the PAGB's Executive Director. A report will then be developed which details the complainant's case and the reasons behind the approval or non-approval. This report is put before the Executive Committee for a decision. Any change in the interpretation of the PAGB Consumer Code for Traditional Herbal Medicines will be communicated to all members and reflected in the decisions of the Secretariat. The Executive Committee may ask all current advertising to be altered to reflect the decision. However, generally, changes will only affect future decisions of the Secretariat. All members affected by such a review will be notified as soon as possible following the review.

Legislation

5.19 It is an offence under the Medicines Act 1968 to issue a false or misleading advertisement for any medicinal product.

5.20 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 are:

- The Medicines Act 1968 (Parts V and VI)(as amended)
- The Medicines (Advertising) Regulations 1994 SI 1994/1932 (as amended)
- The Medicines (Monitoring of Advertising) Regulations 1994 SI 1994/1933
- The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 SI 1994/3144
- The Medicines (Advertising) Amendment Regulations 1996 SI 1996/1552
- The Control of Misleading Advertising Regulations 1988 SI 1998/915
- The Medicines (Advertising and Monitoring of Advertising) Amendment Regulations 1999 SI 1999/267
- The Medicines (Codification of Amendments Etc.) Regulations 2002 SI 2002/236
- The Medicines (Advertising) Amendment Regulations 2004 SI 2004/1480
- Council Directive 2004/24/EC - The Traditional Herbal Medicinal Products Directive
- The Medicines (Advertising Amendments) Regulations 2005 SI 2005/2787.

Guidance notes on all of these statutes are available from the MHRA. The MHRA also produce additional guidelines on certain types of advertising e.g. advertising medicines for use in pregnancy.

6 Useful addresses

The Proprietary Association of Great Britain

Vernon House, Sicilian Avenue, London WC1A 2QS

Tel 020 7242 8331

Fax 020 7405 7719

Advertising approval email address: copyclearance@pagb.co.uk

General email address: info@pagb.co.uk

The Advertising Standards Authority

Mid City Place, 71 High Holborn, London WC1V 6QT

Tel 020 7492 2222

The Association of the British Pharmaceutical Industry

12 Whitehall, London SW1A 2DY

Tel 020 7930 3477

The British Medical Association

BMA House, Tavistock Square, London WC1H 9JP

Tel 020 7387 4499

The Broadcast Advertising Clearance Centre

4 Roger Street, 2nd Floor, London WC1N 2JX

Tel 020 339 4700

The Committee of Advertising Practice

Mid City Place, 71 High Holborn, London WC1V 6QT

Tel 020 7492 2222

The Medicines and Healthcare Products Regulatory Agency

Market Towers, 1 Nine Elms Lane, London SW8 5NQ

Tel 020 7084 2000

Office of Communications

Riverside House, 2A Southwark Bridge Road, London SE1 9HA

Tel 020 7981 3000

The Prescription Medicines Code of Practice Authority

12 Whitehall, London SW1A 2DY

Tel 020 7930 9677

The Radio Advertising Clearance Centre

The Radiocentre, 77 Shaftesbury Avenue, London W1D 5DU

Tel 020 7306 2620

The Royal Pharmaceutical Society of Great Britain

1 Lambeth High Street, London SE1 7JN

Tel 020 7735 9141

Further information about the OTC medicine industry and the work of the PAGB is available from PAGB's Communications Department, Vernon House, Sicilian Avenue, London WC1A 2QS. Tel 020 7242 8331. Fax: 020 7405 7719. Email: info@pagb.co.uk.



Proprietary Association of Great Britain
Vernon House, Sicilian Avenue,
London WC1A 2QS
Tel 020 7242 8331
Fax 020 7405 7719
General email info@pagb.co.uk
Advertising email copyclearance@pagb.co.uk