

# Medicines Advertising Codes

## Consumer Code

Including  
traditional  
herbal medicines

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

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## What is PAGB?

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

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

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

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

## Introduction to the PAGB Medicines Advertising Codes

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

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

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

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

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

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

# 1. Consumer Code

## 1.1 Compliance with the PAGB Consumer Code for Medicines

**1.1.1** It is a condition of membership that all over-the-counter medicines advertising that is aimed at consumers must be approved by PAGB prior to its release into the public domain. Once the advertising has been received, PAGB will check compliance with the provisions of the PAGB Consumer Code for 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 Marketing Authorisation and the Summary of Product Characteristics (SmPC) must be submitted. A new copy must be supplied each time these documents are updated.

**1.1.2** The main purpose of PAGB's approval of advertising copy is to help ensure that over-the-counter medicines advertising complies with all applicable codes and laws. Advertisers should note that the PAGB Consumer Code for 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.

**1.1.3** 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 4) 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 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.

**1.1.4** 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); Clearcast and the Radio Advertising Clearance Centre (RACC). This allows PAGB to provide a consistent and reliable approval system that 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 and when dealing with queries or complaints. PAGB can offer guidance on the roles of the various bodies involved in the control of over-the-counter medicines advertising.

## 1.2 What the PAGB Consumer Code for Medicines covers

**1.2.1** The PAGB Code applies to advertising materials 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 editorial control including public relations material released by a company. (Please also refer to sections 1.3.2 to 1.3.4)

Materials covered by the PAGB Consumer Code for Medicines include:

- advertorials
- aerial promotions, such as hot air balloons
- branded materials relating to product sponsorship (limitations of editorial control will be taken into account)
- cinema commercials
- clam shell advertising (please refer to rule 57)
- consumer leaflets

- direct mail materials
- display packs, including dummy P packs (please refer to rule 57)
- online advertisements (please refer to rule 53)
- outdoor advertising
- pay-per-click advertising, such as that used on internet search engines (please refer to rule 57)
- point-of-sale materials
- posters
- print advertisements (for use in newspapers, magazines etc.)
- promotional aids (please refer to rule 57)
- promotional scripts for use by telephone help lines
- sales promotions
- shelf-ready packaging (please refer to rule 57)
- social media - refer to guidance documents
- television and radio commercials
- text messages (please refer to rule 57)
- websites and other Internet materials, including brand home pages, banner advertising and press releases intended for Internet publication which are under the editorial control of the member company (please refer to rule 53)
- materials that have been written by a third party but regarding which members have the opportunity to comment and to request amends (issues of final editorial control will be taken into account).

**1.2.2** Most PR materials do not require PAGB pre-approval. The only PR materials that require PAGB approval are press releases which are hosted in the consumer facing section of a member's website. These may be accessed directly by consumers and so are considered to be advertising. Press releases hosted in a dedicated press section of the website do not require PAGB approval.

### 1.3 What the PAGB Consumer Code for Medicines does not cover

#### Claims relating to price

**1.3.1** The PAGB Consumer Code for Medicines does not cover simple price claims. Member companies are responsible for ensuring that such claims are not misleading.

#### Public relations

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

#### Materials intended for third parties

**1.3.3** The Code does not cover materials aimed at organisations, such as hotel chains, pubs or sports clubs, where the intention is to encourage the organisation(s) to support an advertising campaign or promotion that is aimed at their customers/patrons. (All materials for which the intention is to encourage the staff to purchase the product for their own use do come under the PAGB Consumer Code for Medicines. All materials intended to be passed directly to potential consumers, and over which PAGB members have editorial control, do come under the PAGB Consumer Code for Medicines.)

#### Corporate sponsorship

**1.3.4** The PAGB Consumer Code for 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 rule 56.)

#### Labels and packaging

**1.3.5** This Code does not cover product labels, packaging materials and in-pack leaflets. PAGB has a separate code covering pack design, the 'PAGB Code of Practice for Pack Design for Over-the-Counter Medicines'. (Companies should note that that shelf-ready packaging is viewed as advertising, rather than labelling.) However, PAGB does request that copies of the approved packaging are lodged with PAGB for reference.

For Traditional Herbal Medicines (THMs), 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 Medicines if the intention is to use on-pack statements in consumer advertising.

**Legal notices and disclaimers included on websites**

**1.3.6** These materials are not intended to promote brands and hence do not require PAGB approval. Similarly, website registration forms that do not promote brands do not require PAGB approval.

**Advertising to health professionals**

**1.3.7** The PAGB Consumer Code for Medicines does 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 advertising aimed at these persons.

**Food supplements**

**1.3.8** The PAGB Consumer Code for Medicines does not cover the advertising of food supplements. Please contact PAGB for advice on food supplement advertising.

**Medical devices**

**1.3.9** The PAGB Consumer Code for Medicines does not cover medical devices.

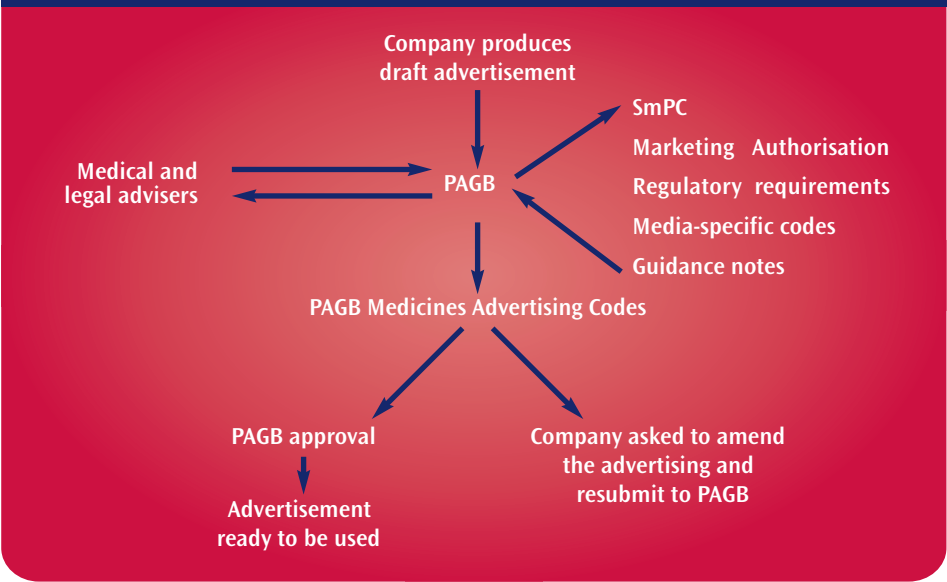
**1.4 The PAGB Approval System for Consumer Advertising**

**1.4.1** Specialist staff at PAGB carry out the pre-publication approval of advertising materials. PAGB has access to independent medical and legal expertise to advise on evidence and matters of interpretation under the PAGB Consumer Code for Medicines and Traditional Herbal Medicines.

**1.4.2** The system of pre-publication approval is as follows:

- the member company, or associate member agents working on behalf of the member company, produces the draft advertisement and submits it to PAGB for approval
- PAGB checks the advertisement against the rules of the PAGB Consumer Code for Medicines for Medicines and Traditional Herbal Medicines, the Marketing Authorisation and any other regulation or code of practice that applies to the specific medium for which the advertisement is intended. Any claim-substantiation or legal queries 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 needed before the advertisement can be approved
- once PAGB is satisfied that the advertisement complies with the PAGB Consumer Code for Medicines, it is approved, subject to 'PAGB's Terms of Approval for Advertising' and the company is notified
- the advertisement can now be published/broadcast. (Depending on the intended advertising

**TABLE 1: PAGB'S APPROVAL SYSTEM FOR CONSUMER ADVERTISING**



media, the advertisement may also need to be approved by organisations such as Clearcast (for television advertising), the Radio Advertising Clearance Centre (RACC) or the Cinema Advertising Association (CAA). (Please refer to section 4.1 for further information.)

## SUBMITTING ADVERTISING FOR PAGB APPROVAL

**1.4.3** It is a condition of membership that all over-the-counter medicines advertising aimed at consumers must be approved by PAGB prior to its release into the public domain. PAGB is also willing to offer informal advice on promotional concepts in order to help avoid major changes being required later in the review process. Please note that once the final draft advertisement is ready for submission, it should undergo internal compliance checks and sign-off before it is submitted to PAGB for approval. PAGB is unable to provide approvals post-publication. The section below explains the procedures that member companies and associate members should follow when submitting advertising to PAGB for approval.

### Posters and point-of-sale advertising

**1.4.4** For posters and point-of-sale advertising the final artwork must be submitted for approval. PAGB recommends that members also submit the text to PAGB before the artwork is produced.

### Press advertising

**1.4.5** For press advertisements consisting of text with the addition of a photograph or pack shot, members may submit the text and photograph without needing to resubmit the final layout. If there are any changes to the text during layout stage, the item must be resubmitted for approval. Please note that rule 58 on the positioning and legibility of essential information must be complied with.

### Television commercials

**1.4.6** For television commercials, the script and preferably the storyboard, must be submitted to PAGB for approval. The final film must also be submitted for approval, preferably in Mpeg format.

### Radio advertising

**1.4.7** Radio scripts must be submitted for approval. Should there be any concerns about how the script is finally executed, PAGB may also request that an audio file is supplied for approval.

### Websites and online advertisements

**1.4.8** For Internet materials, PAGB requires a file that can be viewed offline. This enables PAGB to add comments and to keep an accurate record of what has been reviewed and subsequently approved. PAGB prefers to receive offline versions as PDF or Word documents. Where the offline version does not include the final visuals, members are asked to supply a link to the development site. This also applies to animated advertisements, such as banner ads (e.g. animated gif or flash files).

### Other items

**1.4.9** For all other items, if in doubt as to what should be submitted, please contact PAGB for advice.

## HOW TO SUBMIT ADVERTISING

### Email submissions

Please send advertising copy to [copyclearance@pagb.co.uk](mailto:copyclearance@pagb.co.uk). In exceptional circumstances (e.g. internet problems), it is acceptable to send copy by fax or via courier or mail: (fax) 020 7405 7719; (post/courier) Copy Clearance, PAGB, Vernon House, Sicilian Avenue, London WC1A 2QS.

### Contact details

**1.4.11** Please make sure you include your contact details, including phone number, email address and postal address. PAGB may wish to contact you to discuss your advertisement before making comments or giving approval.

### Members and associates only

**1.4.12** Please remember that it is only members and associate members who can access PAGB's copy clearance service. 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 PAGB 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.)



## REVIEW TIME

**1.4.13** Please allow plenty of time for your advertising copy to be assessed. PAGB processes copy in the order in which it is received. Although we aim to review advertising copy within one working day of receipt, we do not promise or guarantee to do so. Advertisers should note that large or complicated pieces of copy, or claims requiring detailed consideration of supporting evidence, take longer to assess. PAGB aims to review websites within five working days. The same timescales apply to each subsequent occasion on which the advertisement is sent back to PAGB with revisions.

**1.4.14** 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. If all relevant data are submitted together, PAGB is better placed to provide feedback quickly.

### Medical and legal opinion

**1.4.15** 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. In such cases, please allow five working days for PAGB to obtain an opinion on the proposed claims. (Please refer to rule 5 on providing evidence in support of claims.)

## TIPS ON SPEEDING UP THE PROCESS

### Evidence

**1.4.16** Please submit the evidence with the advertisement (Please refer to rule 5, for details) and remember to check the proposed advertisement against the consumer checklist before submitting. (Please refer to the Consumer Code checklist. Companies should also refer to section 1.5.15 for details of essential information in consumer advertising.)

### Highlight changes

**1.4.17** If you are re-submitting advertising to PAGB, please highlight the changes. This makes it much quicker for PAGB to respond to your enquiry. Highlighting changes is essential when submitting website alterations and updates.

### List of agreed claims

**1.4.18** When planning advertising for new products, companies may find it useful to submit a list of proposed claims, together with supporting evidence. Agreeing the claims in advance will make it quicker for PAGB to review subsequent advertising copy. Please note that the acceptability of individual claims will depend on the context in which they are used.

## MEMBERS' RESPONSIBILITIES

**1.4.19** Member companies remain obliged to ensure that their advertising complies in all respects with all applicable legal, regulatory and self-regulatory requirements and any relevant product authorisation. PAGB approval is only one element of member companies' necessary due diligence.

**1.4.20** PAGB approval is given on the basis of PAGB's understanding and knowledge of relevant requirements and practice and on 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 1.4.21, below for further details.)

**1.4.21** Member companies must not continue to use advertising materials that are no longer appropriate, for example:

- any claim that a product is 'new' or 'now available' is only acceptable for one year from the date when the medicine is first available for consumers to 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 regulatory body. (Please refer to section 4.1.)
- 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 discontinued.

## LIABILITY

**1.4.22** 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 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.

**1.4.23** 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.

**1.4.24** 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.

## 1.5 Rules of the PAGB Consumer Code

### 1.5.1 General principles

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

**2 Medicines must not be promoted to consumers prior to the granting of the Marketing Authorisation.**

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

Advertising must comply with the product's Marketing Authorisation (which includes the Summary of Product Characteristics (SmPC)). Claims for indications which are not listed on the SmPC are prohibited.

Where the indication states "traditionally used for..." or similar wording, this information should be stated in advertising materials. Claims such as "clinically proven" or "effective in ..." are not acceptable for THMs since the registration is based exclusively on long-standing use.

For claims relating to the speed of action, duration of action, absorption etc., whilst the actual wording of the claim does not have to be present in the SmPC, all claims must be consistent with the SmPC. For example, if the SmPC states that relief is obtained at 30 minutes, then PAGB would be unable to agree a claim that the product offers relief in 15 minutes, despite supporting evidence. In order for the claim to be made, a variation to the SmPC would need to be agreed by the MHRA. If the SmPC does not mention speed of action, PAGB will assess the claim on the basis of the evidence provided.

Subjective claims, such as taste (e.g. 'great tasting throat lozenge') and claims based on market research are usually not included on the SmPC. PAGB assesses such claims based on the evidence provided. (Please also refer to rule 5 on evidence.)

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

All advertisements for medicinal products must encourage the rational use of medicines by presenting them objectively and without exaggerating their properties.

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

Advertisers should consider the overall consumer take-out from the advertisement. Even if the claims are supported with evidence, there may still be concerns that the advertisement communicates unrealistic expectations to the consumer, for example via the visuals.

Further advice is available from CAP, who offer a free advice service. Advertisers are advised to consult the advice on the CAP website, and also that which is provided in the Consumer Protection regulations (Department for Business, Innovation and Skills).

**Before and after pictures**

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 may the visuals imply that a product can be used to treat more serious forms of disease than the Marketing Authorisation would allow. (Please also refer to rule 23 on claims of recovery.)

Claims such as '90% of users felt better with Brand X' are only permitted when backed with substantiation that relates to normal over-the-counter usage. For example, it would not be acceptable to imply that 90% felt better if the research is based on a higher dosage than that recommended for the over-the-counter product.

**Use of asterisks to qualify claims**

Asterisks may be used to qualify or expand claims that are in essence correct. Asterisks must not be used to contradict claims that would otherwise be false or misleading. Qualifying statements should be positioned close to the original claim. When judging whether a qualifying statement is sufficient, PAGB will take the following into account: the significance of the qualification, the positioning of the qualifying statement, the prominence of the original claim, legibility issues such as font size and clarity, together with the content and layout of the rest of the advertisement.

**Traditional Herbal Medicines (THMs)**

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

Advertising for THMs must not mislead consumers regarding the strength of evidence which supports the product's therapeutic benefits (*please refer to Rule 20*)

## 5 Advertisers must hold evidence for all claims made in advertising.

Evidence must be submitted to PAGB before approval can be given.

Advertisers should be able to demonstrate that they have taken a systematic approach to reviewing the available evidence. Full papers should be submitted, rather than just the abstracts. All known available evidence, whether or not it supports the claim, must be submitted. For example, if PAGB accepted a claim such as 'relieves in 15 minutes' on the basis of supportive studies and it was later revealed that there were other, better conducted, trials that failed to support it, the claim would need to be removed.

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. 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 28 on unique claims.) Comparisons relating to efficacy, such as 'Brand X offers the fastest pain relief available', would require considerably more data, including comparisons with all over-the-counter analgesic formulations. (Please refer to rule 44 for guidance on evidence required for superiority claims.)

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

- published data in a peer-reviewed journal
- standard textbooks, such as 'Martindale: The Complete Drug Reference' and 'British National Formulary'
- unpublished company data that has been approved by the company's medical or regulatory departments.

The following are unlikely to be acceptable as supporting 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
- books and information on the Internet that do not reflect available scientific evidence
- editorial material such as newspaper reports, as this is often anecdotal and not backed by clinical evidence
- animal studies where this is the only evidence submitted.

Member companies should be aware that evidence is often sent to PAGB's medical adviser for review. Please allow five working days for PAGB to obtain a medical opinion on the proposed claims.

Member companies are not required to submit evidence in support of claims stated in the SmPC as this information has already been assessed by the MHRA. PAGB may ask to see supporting evidence in order to provide a clearer picture of the likely benefits of a product, and thus assist staff in reviewing the advertising.

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

## 6 Advertising shall not bring the over-the-counter medicines industry into disrepute, neither shall it undermine nor prejudice consumer confidence in medicines.

This rule includes issues such as taste and decency (i.e. avoidance of offence). 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

### Shocking or offensive advertisements

- full nudity (partial nudity, shot in a tasteful fashion, may be acceptable in 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 that the consumer would find tasteless or offensive, such as vaginal thrush, diarrhoea or haemorrhoids
- shocking analogies that consumers may find offensive.

The overall tone and context of the advertisement will have a bearing on how offensive or tasteless it is perceived to be. In the past, the following suggestions have been rejected:

- a head shattering for a pain killer
- a noose round the neck for a sore throat treatment.

The following have been approved:

- 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.

Advertisers should be particularly careful about any advertisements placed near to schools, nurseries and places of worship. PAGB, in line with other regulators and self-regulators, has adopted a more liberal view on advertising for certain media aimed at specific demographics, including magazines such as 'FHM,' 'Viz' and 'Nuts'.

CAP offers a free advice service which advertisers are advised to use if any issues arise relating to taste and decency.

## Denigration

The second part of this rule also prohibits any overt or implied criticism of other products. Medicines are licensed on the basis of safety, quality and efficacy. Therefore it is not acceptable to suggest that another medicine is unsafe, of poor quality or ineffective. (For further information on denigration, please refer to rule 38.)

### **7 Advertising shall not undermine current healthy-lifestyle advice.**

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

### **8 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 that 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 that 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 exaggerating the benefits likely to be gained from a particular product.

## **9 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 to inform the consumer that the material is advertising and not editorial. PAGB advises that words to this effect should appear at the top of each page. Most magazines have a similar stipulation.

This rule also affects materials such as leaflets that have been written by a third party, such as a pharmacy chain or charity, or that give the impression that they have been written by a third party. Where member companies are involved in writing such materials, it must be made clear what is advertising and what is editorial. Practical means by which advertising can be separated from editorial information include the use of different background colours and/or separate text boxes, and stating ‘Advertisement’ or ‘Promotion’ clearly at the start of the promotional section.

## **10 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 6), or by suggesting that there is greater urgency to treat the condition than is actually the case. Advertising shall not falsely suggest that the condition will deteriorate or become more severe unless it is treated. Advertising should not imply that the condition being treated is of greater severity than that for which the product is indicated.

Special care is required when advertising is sent in the form of personalised letters or emails. Advertising should not cause unnecessary anxiety by suggesting that a particular individual may be suffering from a medical condition.

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

Most OTC medicines are for self-limiting conditions where it would be misleading to imply that not treating may lead to the condition worsening. Advertisements must not falsely suggest that a product is necessary for the maintenance of health or that health could be enhanced by taking the product or affected by not taking it. However, there may be instances for some conditions where additional healthcare advice may be acceptable.

## **12 Advertising may only refer to prevention, or to the use of the 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.

## **13 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 Regulation 286 (3) of the Human Medicines Regulations 2012.

Advertisers should be cautious when describing a range of symptoms which could be consistent with conditions other than those for which the product is indicated and could lead consumers to make the wrong self-diagnosis.

This rule particularly affects products used to treat conditions that are not easy to self-diagnose. Examples include irritable bowel syndrome, vaginal thrush and migraine. 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 with that condition.

Some product SmPCs state that the condition must have been diagnosed by a doctor or pharmacist before the person can self-treat using an over-the-counter medicine. Where such warnings are stated on the SmPC, they must be reflected in advertising. For example:

- where the SmPC says that a doctor's diagnosis is required, this must be stated in advertising
- where the SmPC states that a diagnosis by a pharmacist or other health professional is required, this needs to be stated in advertising if the product is a general sales list (GSL) medicine
- where the product is a pharmacy only (P) medicine and where the SmPC states that a diagnosis by a pharmacist or a pharmacy consultation is required as part of the purchasing procedure, it is not essential to state this in advertising. However, where space allows, it is good practice to alert consumers to the fact that a pharmacy consultation/diagnosis will be required.

**14 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 Regulation 286 (1) of the Human Medicines Regulations 2012.

Advertising should not suggest that it is acceptable to self-medicate when consumers may need help from a doctor or specialist. 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 does not prohibit statements suggesting that, for most self-limiting conditions such as colds, people may not always need to consult a doctor. For example, statements such as 'It is not usually necessary to consult your doctor when you have a cold' may be acceptable.

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

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

This rule reflects Regulation 286 (1) of the Human Medicines Regulations 2012.

'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
- advice on whether a consumer should continue using prescribed medication
- advice on whether a consumer should follow their GP's guidance.

This rule does not prohibit the following:

- advice in response to a consumer's request for information in relation to a medicine
- telephone help lines, although care must be taken not to personally advise or diagnose.

The information provided in 'Frequently Asked Questions' sections on websites should be fairly straightforward and should not give the impression that it is personalised advice to individual consumers. (For example, when the question is written in the first person, and where the condition and the steps taken to resolve it are detailed, the reader is likely to conclude that this is personalised advice.)

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

Advertising should encourage consumers to take a responsible and cautious approach to self-medication. 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.

Consumers should not be encouraged to purchase excessive amounts of medicines. Use of the phrase 'stock up' is not acceptable. Phrases such as 'be prepared' (e.g. for the allergy season) could be acceptable.

Adverts must not portray people behaving irresponsibly because they know that there is a product available to treat the symptoms that may follow. Similarly, advertising shall not suggest that the consumer can indulge in reckless behaviour or adopt an unhealthy lifestyle, provided they take a preventative treatment.

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

This rule reflects Regulation 287 (1) (a,b,c) of the Human Medicines Regulations 2012.

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 the product being taken and hence it is a guarantee.

### **Acceptable claims**

Depending on the particular context, PAGB generally takes the view that the examples listed below are not guarantees, and are therefore likely to be acceptable under this rule:

- claims which are preceded by 'can', 'to', 'may' or 'helps', for example:
  - 'to' (e.g. 'to get rid of pain')
  - 'can' (e.g. 'can get rid of pain')
  - 'may' (e.g. 'may relieve your symptoms for 24 hours')
  - 'helps' (e.g. 'helps get rid of pain')
  - 'could' (e.g. 'could relieve your symptoms for 24 hours')
- claims such as 'relieves' or 'soothes', (e.g. 'relieves pain'). Although these claims indicate an improvement in symptoms, they do not imply that the symptoms will be completely resolved
- claims such as 'treats,' (e.g. 'treats heartburn'). Such claims describe what the product is intended for, rather than guaranteeing that the condition will be completely resolved
- claims that make it clear that the cessation of symptoms applies to one specific episode, usually in the past tense (e.g. "Six weeks ago I had a verruca, now it has gone.")
- claims that make it clear that they refer to the process of treating a condition/symptoms, rather than guaranteeing that the condition/symptoms will be completely resolved should be acceptable (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 is likely to be seen as a product guarantee. (PAGB takes the view that 'stops coughing', 'stops scratching', etc. are guarantees.)

The only product category for which PAGB will allow guarantees are the anti-fungals. Even in this instance, the word 'cure' is not acceptable as it implies that once treated the condition will never return.

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 57.)*

## **18 Offers to refund money must not imply that the effects of the product are guaranteed. Offers to refund money must not be combined with comparative claims or safety claims.**

Part 14 of the Human Medicines Regulations 2012 prohibits advertisers from making guarantees of efficacy. Whilst it may be legally acceptable for an advertisement to offer to refund money on the basis of convenience or other non-efficacy factors, it is not acceptable to make money-back offers



that guarantee efficacy. Members should seek PAGB advice if they are considering including any offers to refund money within advertising materials.

#### Unacceptable claims

The following claims would not be acceptable as they imply guaranteed efficacy:

- 'money-back guarantee'
- 'if you are not completely satisfied we will refund you'
- 'if you are not better in five days we will give you a refund'.

It is not acceptable to combine money-back offers with comparative claims. For example, the following is not acceptable:

- 'if you find a better-tasting sore throat lozenge we will refund you' (please also refer to rule 34).

It is not acceptable to combine money-back offers with safety claims. For example, the following is not acceptable:

- 'if you experience any side effects we will refund you'.

**19 Advertising that states that a product is licensed must not imply that the particular medicine has been endorsed by the Department of Health, the Medicines and Healthcare products Regulatory Agency, the European Medicines Agency, the Commission on Human Medicines or any other MHRA advisory committees.**

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

#### Acceptable claims

The following claims are likely to be acceptable:

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

For THMs the following claims are likely to be acceptable:

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

#### Unacceptable claims

The following claims would not be acceptable:

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

## 1.5.2 Potentially misleading advertising

**20 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. Special care is needed to avoid confusion with advertorials where other topics, such as lifestyle factors, are discussed, or if a product is featured in a leaflet that references other conditions.

#### Advertisements placed near related editorial

Where advertising is placed in close proximity to a related editorial, the editorial content may imply benefits that 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 that is contrary to the product SmPC. Such implied benefits could confuse the consumer and result in their using the product incorrectly.

#### Claims relating to pharmacy medicines

Claims that a product is more effective because it is a pharmacy-only medicine, rather than GSL, are not permissible. GSL products are just as efficacious, often differing only in pack size. It is permissible to state that a product has a 'pharmacy-only formula' if the ingredients, or the quantities of the ingredients, are such that they are only available from a pharmacy.

#### Prescription strength

Claims that a product/ingredient is 'prescription strength' are only permitted where the product/ingredient is the same strength as a prescription-only variant and is the highest strength available over-the-counter.

#### Strength of evidence for THM products

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.

**21 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.**

Evidence will be required to support claims relating to speed of action, duration of action, speed of absorption and dissolution, etc., unless they are present in the SmPC.

#### Speed of absorption claims

All speed of absorption and speed of action claims must be in line with the SmPC. For example, if the SmPC states that relief is obtained within 30 minutes, PAGB would be unable to agree a claim that the product relieves within 15 minutes, despite supporting evidence. In these circumstances, a variation to the SmPC would need to be agreed by MHRA before such a claim could be made.

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

The phrases 'gets into the system' or 'gets to work' are sometimes used to describe the rate of absorption of the active ingredient(s). Where 'gets to work' is used, the advertiser must specify that the claim relates to the speed of absorption. (PAGB is of the opinion that 'gets into the system' is

less likely to be misinterpreted and further qualification is not needed.) The criteria for 'gets into the system', 'starts to get into the system', and any qualified uses of 'gets to work' and 'starts to get to work' are as described in the paragraph on absorption claims above.

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

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

Advertisers should be careful to avoid claims relating to speed of absorption, action and dissolution etc. inferring a guaranteed speed or effect. Please refer to rule 17 for details. Where a claim is closely defined, it is usual for a qualifier of 'can' or similar to be used to take account of any variability of response (e.g. 'can provide relief in half an hour'). The requirement for such a qualifier will depend on the actual claim used and the data provided.

PAGB requires advertisers to include an appropriate indication of time lapse between taking the medicine and experiencing the effects. This is particularly important for television advertising and where before-and-after images are used (please also refer to rule 23 below on claims relating to recovery). Commonly used techniques include:

- different background visuals to suggest a change of location
- characters changing clothing
- change in lighting conditions (e.g. day and night)
- different background sounds to suggest a different time
- the addition of a 'super' (e.g. 'later on' or 'an hour later')
- clocks changing in the background (where clocks are used, advertisers should ensure they are sufficiently prominent that viewers are unlikely to miss them).

#### **'Fast' claims**

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

#### **'Immediate' and 'instant' claims**

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

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

#### **Duration of action claims**

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

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

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

### **23 Advertising shall not contain improper, alarming or misleading claims of a recovery.**

This rule reflects Regulation 287 (3) of the Human Medicines Regulations 2012.

This prohibits claims such as 'miracle' and 'wonder product'. It also prohibits visuals that imply a cure, such as before-and-after pictures showing a dramatic improvement that most users could not

expect to achieve.

### **'Before' and 'after' pictures**

The following precepts should be applied when the use of before-and-after pictures is being considered:

- the 'before' picture must relate to the degree of severity allowed by the Marketing Authorisation. For example, advertisements for products for the treatment of pain of non-serious arthritic conditions should not show a sufferer with severe arthritis
- any 'after' pictures must show an improvement that could realistically 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
- the use of time periods must accurately reflect the length of time it would take to achieve benefit. For example, suggesting that relief of pain takes place instantly, when benefit actually takes longer, would not be acceptable. (Please refer to rule 21 for guidance on showing that time has passed.)

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

This rule reflects Regulation 287 (2) (a,b) of the Human Medicines Regulations 2012.

Care must be taken that all diagrams relate accurately to the licensed indication. For example, diagrams must be representative of the degree of severity for which the over-the-counter product is indicated, rather than depicting a more serious or chronic complaint.

### **25 Advertising shall not suggest that using a medicine can further enhance normal good health.**

This rule reflects Regulation 287 (4) (a,b) of the Human Medicines Regulations 2012.

All advertisements must be clearly targeted at 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, at increased risk of developing the complaint) for which the product is intended will also benefit from using it. For example, the following would not be permitted: 'even though you feel good now, use Brand X and notice the difference'.

### **26 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 Regulation 287 (1) (c) of the Human Medicines Regulations 2012.

'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 instances where a product's Marketing Authorisation 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. Product liability should also be considered. PAGB would allow qualified uses of the word 'safe' (e.g. 'good safety profile') 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 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, that is not to say that consumers will not experience a psychological dependency. For this reason, PAGB advises advertisers to say ‘not known to be habit-forming’ or ‘not known to be addictive’, provided there is evidence to support this.

**27 Advertisers shall not mislead consumers about the novelty of a product. 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**

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

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

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

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

Advertisers of THMs need to avoid confusion when combining ‘new’ claims with the required traditional use statement. Please refer to Rule 57.

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

#### **‘Now’ claims**

‘Now’ often implies that a product is ‘new’ (e.g. ‘now available’) and so the same time restrictions apply. However, ‘now’ may 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 Brand X is the only product that treats pain quickly.

Advertisers should bear in mind that the above guidance is not exhaustive. ‘New’ and ‘now’ claims will be looked at on a case by case basis.

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

Where advertising claims that a product is unique, it must make it clear which aspect is unique e.g. ‘unique once-daily dose’ or ‘unique formulation’. ‘Unique’ claims can only be used until another product becomes available that offers the same attribute. A product can claim to be unique within the over-the-counter sector, even if there are prescription-only medicines available with the same attributes.

For example, products with the following attributes could claim to be unique for the reasons stated:

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

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

PAGB requires three months of most recent sales data in order to support sales claims. This data must be volume-sales data. Where clear superiority is not demonstrated on the basis of three months' data, PAGB may request data over a longer period. If the sales data shows frequent fluctuations in the leading brands, advertisers are 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 children's painkiller'
- 'best-selling antacid'
- 'nation's favourite decongestant spray'
- 'market leader for hayfever'
- 'most popular choice for athlete's foot'
- 'Brand X - leading sales for allergies'.

Claims of 'no.1' or 'first choice' may also imply that the product is the most effective product in its category. PAGB requests that these claims be further qualified (e.g. 'no.1 selling'). The examples listed below could be viewed as either best-selling claims or as claims that imply some other form of superiority. Advertisers would need to qualify these claims and send the appropriate evidence:

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

Where advertisers wish to differentiate between pharmacy and general retail sales, PAGB will interpret claims in the following way:

- 'no.1 selling pharmacy painkiller'- the painkiller that sells the most packs from pharmacies. The product could be either a GSL or a P medicine. Sales data should take account of all Pharmacy sales of both GSL and P medicines
- 'no.1 selling pharmacy-only painkiller' – the top-selling painkiller that is only sold through pharmacies. This is most likely to be a P medicine.

### 1.5.3 Advertising medicines for use in pregnancy

**30 Advertisements that promote the use of a medicine during pregnancy are only acceptable where a positive statement in section 4.1 or 4.6 of the Summary of Product Characteristics supports the use of the product in pregnancy. All such advertisements must encourage a cautious approach to the use of medicines in pregnancy.**

Section 4.6 of the SmPC provides information on whether a product can be used in pregnancy. Members who are unsure as to whether an SmPC supports the use of the product during pregnancy should contact PAGB for advice.

Advertising should not convey that it is routine practice for pregnant women to take medicines. It must not suggest that the advertised product, or any other medicine, cannot harm the developing

fetus. Claims that a product is 'safe for use in pregnancy' are prohibited. It is not acceptable to use ultrasound scans or images of a fetus in advertising.

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

All advertisements referring to the use of a medicine(s) during pregnancy must include a statement that women should consult their doctor or pharmacist before using any medicine during pregnancy. PAGB recommends that such a statement is also included on all advertisements for medicines where the target audience is mainly pregnant women, e.g. advertisements placed in pregnancy magazines. MHRA's suggested wording for the warning statement is:

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

## 1.5.4 Natural and herbal claims

**31 Advertisers shall not suggest that a product is herbal unless it complies with the definition of 'herbal medicinal products' as set out in EU Directive 2004/24 EC (as amended).**

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

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

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

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

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

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

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

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

In deciding whether an ingredient is ‘natural’, PAGB may refer to the Food Standards Agency’s document ‘Criteria for the use of the Terms Fresh, Pure, Natural etc. in Food Labelling’.

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

This rule reflects Regulation 288 (b) of the Human Medicines Regulations 2012.

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

### 1.5.5 Flavour claims

**34 Whilst it is acceptable to make flavour claims, advertising should present the medicinal benefits as the primary reason for purchasing a medicine.**

**35 Advertising shall not emphasise the sensory aspects of a medicine, such as flavour or cosmetic attributes, to the extent that consumers may believe that the product 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.

This also prohibits advertising that 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.

### 1.5.6 Advertisements featuring both medicines and non-medicines

**36 Advertisements that feature both medicines and non-medicines must make it very clear which claims apply to which products.**

Several brands include both medicines and non-medicines. For example, some include licensed emollients for the relief of eczema, alongside cosmetic bath and shower products. Other ranges include both medicines and medical devices. Where advertising features medicines and non-medicines together, it must be very clear which claims apply to which products. Companies may be required to include a statement such as... ‘Product X is a medical device’ or ‘Product Y is a medicine’. Advertisers should bear in mind that cosmetics and food products are not permitted to make medicinal claims.

### 1.5.7 Comparative advertising

**37 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 rules 38 and 39 for details). PAGB does not accept comparisons which denigrate another ingredient, product or product category (please refer to rule 38).



The most commonly accepted comparisons are those relating to product palatability, speed of action or duration of action. For example, the following would be acceptable, provided there is sufficient evidence to support them:

- ‘antacids can offer faster relief of the pain of excess acid, compared with H2 antagonists’
- ‘some people find traditional treatments for vaginal thrush less convenient than oral remedies’
- ‘a topical nasal spray gets straight to work, while tablets need to get into the system before they start to work’.

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

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

The claim below would be acceptable:

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

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

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.

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

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

Medicines are licensed on the basis of safety, quality and efficacy. Therefore it is not acceptable to suggest that another medicine is unsafe, of poor quality or ineffective.

PAGB can accept copy that compares the different attributes of products, provided this does not stray into denigration. For example, ‘H2 antagonists have a longer duration of action than antacids’, would be acceptable provided there is sufficient evidence to support the claim (please also refer to rule 5). However, PAGB would not accept ‘H2 antagonists are better than antacids’ as PAGB takes the view that such all-encompassing statements are denigrating.

There are circumstances when statements that are technically correct would still be denigrating. For example, PAGB would not approve the claim ‘paracetamol products can be fatal in overdose’ for an ibuprofen-based product. Even though the statement is factually true, it denigrates another active ingredient. Nor would PAGB allow ‘ibuprofen is less likely to be fatal in overdose’.

This rule also prohibits statements that question the value of other product categories. For example, PAGB would not allow the sentence: ‘oral rehydration products are not necessary for adults’. These products are indicated for use in adults and hence the statement would be a denigration.

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

This rule reflects Regulation 287 (1) (b) of the Human Medicines Regulations 2012.

Advertising shall not suggest that a product's effects are better than or equal to another identifiable product or treatment through references made to the:

- brand name
- packaging
- well-known brand strap lines or other recognisable brand imagery
- 'best-selling product'.

#### Acceptable claims

The following claims would be acceptable under this rule (if there is sufficient evidence to support them):

- 'tablets work as well as nasal sprays' (even where there is only one product for the condition which is available as a spray)
- 'research shows that ingredient Y provides faster relief than ingredient X' (even where there is only one product that contains ingredient X).

#### Unacceptable claims

The following claims would not be acceptable under this rule:

- 'I used to use this [holding a pack that looks similar to a competitor pack], but I've found that Brand X works better'
- 'it works as quickly as the brand leader'. There may be many brands that can claim to be 'brand leader'; their makers 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 to the use of basic brown bottles or white boxes to represent another brand, except where the bottle is a distinctive shape and so could be recognised as that of a competitor.

**40 Advertising shall not state that a product does not contain one or more active ingredients present in competitor products where such a statement would imply that these ingredients are unsafe or should be avoided.**

Negative content claims such as 'does not contain aspirin' and 'aspirin-free' are not acceptable as they are regarded as a form of denigration. The implication is that products containing aspirin are inferior.

#### Acceptable claims

It is acceptable to highlight the absence of an ingredient where this may be of benefit to a particular group of consumers. For example the following is likely to be acceptable: 'This product does not contain caffeine, so it can be used at night'.

Advertisers may state that a product does not contain certain excipients. Statements such as 'perfume-free', 'preservative-free', 'sugar-free', 'colour-free' would be acceptable.

**41 Competitors' brand names shall not be used without permission of the owner.**

Advertisements may not make comparisons with or feature other products/brand names except with 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 approving such a claim. Even where an advertiser succeeds in gaining permission to use a competitor's brand name, companies should note that rule 38 still applies.

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.

It may be possible to show competitors' packs in educational videos, or in advertising that features

a retail outlet, as long as the advertisement does not imply that the advertised product is in any way superior to the competitors' products. For example, competitor products may be glimpsed in a scene that takes place in supermarket without giving any impression that the advertised product is superior. Advertisers should bear in mind that PAGB will be cautious when approving advertisements that show competitors' brands. A range of factors influence the overall acceptability of the advertisement. For example, simply having more of the advertised product on show compared to competitor products can imply that the advertised product is more popular or that it is favoured/endorsed by the particular retail outlet.

This rule does not apply to questionnaires where the intention is simply to ask consumers which products they have used or may use in the future. Please note that the wording of such questionnaires must not imply any denigration of competitors' brands (please refer to rule 38).

#### **42 Hanging comparisons shall not be used.**

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

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

PAGB will often ask that 'faster', 'better', 'stronger', 'longer', 'quicker', etc. are amended to 'fast', 'strong', 'long' or 'quick' and that 'more' or 'extra' are removed, unless they are qualified.

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

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

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

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

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

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

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

be able to demonstrate that they have taken a systematic approach to reviewing the available evidence relating to competitor products.

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

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

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

#### **44 Superiority claims must be supported by direct comparative tests or other demonstrations as appropriate.**

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

##### **Clinical superiority**

It is unusual for PAGB to agree a superiority claim, such as 'the best', 'the fastest', 'the strongest', 'the most effective'. Any such claim would require full substantiation, usually direct comparisons with all other formulations on the market. All available data should be submitted, whether or not it supports the claim. Advertisers are required to build in additional copy-approval time to allow for data assessment.

##### **Use of the definite article**

PAGB regards 'the' as a superiority claim. For example, 'the painkiller' implies that it is the best painkiller 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.

##### **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 specialist for assessment. 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 based on sales data must be carefully worded to avoid implying clinical superiority. (Please refer to rule 29 for guidance on sales claims.)

## **1.5.8 Health-professional endorsement**

#### **45 Advertising shall not state or imply that a product is recommended by or used by a health professional or scientist.**

This rule reflects Regulation 289 (a,b,c) of the Human Medicines Regulations 2012.

While the exact definition of a health professional is not enshrined in law, for the purposes of this rule PAGB and MHRA regard the following as health professionals (the list is not exhaustive and will depend on how a particular profession is likely to be viewed by consumers):

- doctors
- dentists
- dental hygienists
- health visitors
- midwives
- nurses
- physiotherapists
- dieticians
- chiropodists

- pharmacists
- pharmacy assistants
- herbal practitioners
- ophthalmologists
- opticians
- chiropractors
- osteopaths
- smoking cessation advisers.

#### 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'
  - '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 stamp in a leaflet where an impression is given that the pharmacists at that store recommend the brands featured. For example, 'recommended by' followed by a space for pharmacies to place their address stamp
- advertisers asking health professionals to wear badges that feature the name of, or imagery associated with a medicinal product
- companies asking health professionals to selectively hand out advertising materials such as leaflets or flyers to individual customers/patients
- having a GP surgery or pharmacy scene in an advertisement may be taken to be endorsement, (for example, a customer asking the pharmacist for advice beside prominent displays of the product). Such advertisements will be considered on a case-by-case basis. Similarly, a pharmacist 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 that are of a public health/ advisory nature and merely state that they are sponsored by a particular brand
- companies can provide pharmacists and other retailers with information leaflets that can be handed to the consumer at the time of purchase to assist in the correct use of the product. Such leaflets must not be promotional
- it is acceptable for companies to place adverts on till receipts, etc., that 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 9)
- it is acceptable to include a pharmacy 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 to state that a particular health professional recommends an ingredient or treatment type only where this is part of a balanced overview of the ingredients or treatment types available for that particular indication.

Advertisers should note that the BCAP Broadcast Advertising Standards Code prohibits any references to the approval of, recommendation of, or preference for, any relevant ingredient, or its use by health professionals.

The following may be acceptable in non-broadcast advertising:

- 'ingredient X is often recommended by doctors for the treatment of...'
- 'this kind of treatment has been recommended by opticians for 20 years'
- 'dentists often use products containing these ingredients'.

The following would not be acceptable as it is too close to being a product endorsement:

- 'clotrimazole, present in Brand X, is recommended by doctors'.

**Voice-overs**

It is possible to have health professionals doing radio and television 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.

**Television advertising**

It is acceptable to show healthcare settings as long as there is no suggestion of endorsement. Such advertisements require careful planning. For example, an advertisement could show a consumer entering a pharmacy and purchasing a medicine. The consumer must ask for a named medicine. It would not be acceptable for the pharmacist to suggest or recommend a particular product. The pharmacy scene also requires careful consideration in order to avoid giving the impression that the pharmacy recommends a particular product or range.

**Printed materials and websites**

It is possible to include a section giving general health advice 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 Flu’. There must not be any references to brands within the section that is identified as having been written by a health professional. 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 written by a health professional about a therapeutic category must be unbranded and care must be taken to distance them from any accompanying advertising materials.

**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.

It is also possible for branded videos to include a section in which a health professional gives unbranded general health advice. Any information presented by a health professional must be balanced and must be in line with current medical opinion. It must be clearly separated from the brand advertising. Such information will be judged on a case-by-case basis.

**Public relations**

PAGB recognises that the PAGB Consumer Code for Medicines cannot cover public relations activities (e.g. press releases and product launches) once the material is passed to a journalist. It is unlikely that such activities will be completely under the company’s control or that materials such as press releases will not be changed by journalists who use the material. However, member companies should note that PR is covered by the Human Medicines Regulations 2012, and ensure that all PR materials comply with the Consumer Code and the law at the point when the company relinquishes editorial control. Members are advised to exercise caution if inviting a health professional to an event aimed at consumers. Great care must be taken to ensure that they do 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.

**46 Advertising shall not claim that a product is, or has been, available on prescription. However, it is acceptable to state that a product’s active ingredient, formulation or preparation has been prescribed by a health professional, provided there is evidence that this is the case.**

Regulation 284 of the Human Medicines Regulations 2012 prohibits the advertising of prescription-only medicines to consumers. Therefore, phrases such as ‘Brand X, available on prescription’ or ‘Brand X, prescribed by doctors’ would constitute both health-professional endorsement and an advertisement for a prescription medicine. However, in line with other regulators and self-regulators,

PAGB will accept the phrase 'now available without prescription'.

It is acceptable to state that the ingredients, preparation, treatment type or formulation have been available on prescription. (Advertisers should bear in mind that this may not be permitted in broadcast advertising.)

The following examples would be acceptable in non-broadcast advertising provided they are supported by evidence:

- 'Brand X contains paracetamol, the most widely prescribed ingredient for pain relief'
- 'paracetamol, the active ingredient in Brand X, is prescribed by doctors'.

## 1.5.9 Celebrity endorsement

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

This rule reflects Regulation 289 (c) of the Human Medicines Regulations 2012.

Any inclusion of a celebrity within advertising materials, even if not overtly endorsing or recommending the product, is likely to be taken to be 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 benefit in using a celebrity.

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 of their favourite Hugh Grant movie in the context of an advertorial promoting a sleep aid.

### Fictional characters

It may be possible to use fictional characters where:

- the character featured is unlikely to encourage excessive use of a medicine
- the overall impression of the advertisement does not encourage excessive use
- the character would not be overly appealing to children and so breach rule 48.

Many fictional characters would not be acceptable as they would be too closely identified with the actor playing the role (e.g. a doctor from a television soap opera). Biggles has appeared in advertising as he is considered to be a character, rather than a person.

The use of a fictional character will be considered on a case-by-case basis.

### 'Look-alike' celebrities

It may be acceptable to use 'look-alike' celebrities. However, the model would need to look sufficiently different to the actual celebrity that the public would not assume that a celebrity was endorsing the brand. For example, Ken Livingstone look-alikes were used to advertise decongestant products when the London congestion charge was introduced. The advertisements were humorous and did not imply that Mr Livingstone used or endorsed the products featured. Such advertising will be considered on a case-by-case basis. Advertisers should also refer to the CAP Code before undertaking such activities in non-broadcast advertising.

### Deceased persons

It may be possible to use deceased persons where:

- the person has been dead for a long time so that there is no confusion in the public's mind that the person is deceased
- consideration has been given to the 'taste' issues of featuring someone who is deceased
- consideration has been given to the audience, the status of the persons featured and whether it



would encourage excessive use

- advertisers have obtained all necessary clearance from the person's estate.

The only instance where this has been agreed is the use of Laurel and Hardy to promote a hayfever product.

#### Public relations

PAGB recognises that the PAGB Consumer Code for Medicines cannot cover public relations activities (e.g. press releases and product launches) once the material is passed to a journalist. It is unlikely that such activities will be completely under the company's control or that materials such as press releases will not be changed by journalists who use the material. However, member companies should note that PR is covered by the Human Medicines Regulations 2012, and ensure that all PR materials comply with the Consumer Code and the law at the point when the company relinquishes editorial control. It is not acceptable to use celebrity endorsement in a press release aimed at consumer journalists. While it may be 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. 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 has been or will be present at an event.

#### Radio and television voice-overs and telephone help lines

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 event, 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 of a team that 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.

### 1.5.10 Children

#### 48 Advertising shall not be aimed principally or exclusively at children.

This rule reflects Regulation 290 of the Human Medicines Regulations 2012.

This rule aims to protect children from marketing tactics that 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 over-the-counter medicines. The various organisations involved in the regulatory and self regulatory control of medicines advertising set this age at 16 years.

When deciding whether an advertisement is likely to be particularly appealing to children advertisers should consider the following:

- the readership/audience profile of the magazine, programme or website. PAGB will request evidence that the average readership/audience is over 16 years of age. PAGB is unable to allow advertising in magazines and websites and around programmes that have a predominantly younger audience. 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 any cartoons, characters and designs would be particularly appealing to children
- whether the advertisement encourages the cautious use of medicines.

Children should not be used to actively promote a medicine. For example, the following would not be acceptable:

- an advertisement featuring a child recommending a medicine
- an advertisement featuring a testimonial given by a child
- advertisements in which children are wearing branded clothing.

#### Characters, cartoons and branding

Advertisements which are likely to be widely viewed by children should not feature cartoons, characters and designs that are particularly appealing to children. Advertisements that are likely to be widely viewed by children include posters, point-of-sale materials and some magazines, such as celebrity magazines and television guides. If cartoons, characters and designs are featured in television advertising, Clearcast may impose a post-9pm restriction on the advertisement.

Advertisers are reminded that whilst teddies and similar characters may be allowed on pack to highlight medicines that are intended for children, the use of these characters in advertising is unlikely to be acceptable. Whilst it is unlikely that a very small image of a toy would result in an advertisement being viewed as attractive to children, the inclusion of a larger, brighter image may do so.

#### Branded items and giveaways

Brand names or brand imagery cannot be used on promotional aids or goods that 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. Please refer to rule 53 for further information.

#### 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. (Please refer to rule 56 on sponsorship.)

#### Young adults

The main categories of medicines promoted to young adults are those indicated for acne and period pain. When advertising to young adults, special care is needed to only target those of 16 years and over, and to promote a responsible and cautious approach to using medicines. Medicines advertising aimed at young adults must feature models who are at least 16. Models that look younger than 16 years should not be used.

### **49 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 parents to allow their child to do the same, with potentially dangerous consequences.

## **1.5.11 Testimonials**

### **50 Testimonials must comply with the other principles of this Code.**

Testimonials must comply with all other rules of the Code. Testimonials in themselves are not substantiation of the claim being made. Evidence will be required to support the claim. Testimonials must reflect the level of change that the average user could expect. This prohibits such testimonials as:

- "I have tried many other products but this is the only one I've found that works" (this contravenes rules 37 and 38)
- "Brand X made me feel better instantly" (where this is not in line with the SmPC)
- "Brand X works better" (this contravenes rule 42)
- "It also works on my arthritis" (where the product is not indicated for arthritis).

**51 Testimonials shall be less than three years old and must 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 to ensure that the original meaning is not altered. PAGB will ask to see a copy of the testimonial that has been signed and dated by the testimonee.

All testimonials used must be the genuine views of consumers. Advertisers and their agents must not supply testimonials regarding their own products.

Advertisers should note that quotation marks around a claim may be taken to imply that the claim is a testimonial, likewise, any copy that carries the name of a testimonee. However, testimonial-style advertisements are acceptable, provided it is very clear that it is not a genuine person.

Care should be taken when using actors' photographs to avoid any implication that the actor is the testimonee, unless this is the case.

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

This rule reflects Regulation 289 (a,b,c) of the Human Medicines Regulations 2012.

This prohibits testimonials from celebrities, doctors, 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 from 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'). Please also refer to rules 45 and 47.

**1.5.12 Internet advertising****53 All web-based promotional materials over which companies have full editorial control must comply with the Code and must be submitted to PAGB for approval.****What the Code covers**

Internet materials that fall under the PAGB Medicines Advertising Codes include brand websites, social media sites (e.g. Facebook and Twitter), pay-per-click advertising, banner ads and press releases intended for Internet publication that are under the editorial control of the member company. (Please refer to section 1.2.1 for further details.)

**What the Code does not cover**

The following items do not need to be submitted to PAGB for approval:

- Facebook posts and Twitter messages which do not mention the product, do not contain any direct or implied claims or any references to the therapeutic category
- legal notices and disclaimers – these materials are not intended to promote brands and hence do not require PAGB approval. Similarly, website registration forms that do not promote brands do not require PAGB approval.

**Submitting websites for PAGB approval**

All web materials must be submitted to PAGB in an offline format, such as a PDF or Microsoft Word document. When resubmitting websites that PAGB has previously reviewed, please provide a copy on which all of the amendments have been highlighted. (Please refer to sections 1.4.3 and 1.4.8 for further information.)

**Promotional materials that are attractive to children**

Websites promoting medicinal products should avoid featuring cartoons, characters and designs that are likely to be particularly appealing to children.

The main categories of medicines that are promoted to young adults are those indicated for acne and period pain. Advertisers must be careful to avoid creating websites for these products that are particularly appealing to persons aged less than 16 years. Where companies have a range of products, most of which are non-medicines and where the non-medicines are promoted in a way that would be appealing to children, it may be necessary to ask users to confirm their date of birth before allowing them to access information on the medicines within the range.

When advertising to young adults, special care is needed to promote a responsible and cautious approach to self-medication.

### Games

Special 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 that is clearly aimed at adults. Parents could then use the link to access a game that they may wish to show their children (e.g. 'click here for a game to help children understand the importance of emollients').

Please refer to rule 48 for further details regarding promotional materials that may be attractive to children.

### References to health professionals

It is possible to include on a website a section giving health advice that has been written by a health professional. The health professional may also provide general information about active ingredients. However s/he must not refer to any brands. 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. For further information, please refer to rule 45, printed materials and websites.

### Message boards

Messages submitted by members of the public do not come under the PAGB Consumer Code for Medicines as member companies do not have full editorial control over the resulting content. However, member companies should note that such material does fall under Part 14 of the Human Medicines Regulations 2012, and must ensure that all such entries comply with the law. Member companies should have very clear terms of reference as to the type of material that is permitted. Message boards should make it clear that all persons submitting messages must be aged 16 or over.

PAGB advises that where each entry is not reviewed before it is uploaded onto the website, the MHRA expect Marketing Authorisation holders to check the message board once every working day in order to remove any entries that do not comply with the relevant regulations. Advertisers should ensure that the staff who carry out this function have adequate training.

Member companies should consider adding a disclaimer that the views expressed on the message board are those of individual submitters and not the views of the advertiser.

### Example checklist for moderating message boards

The following are examples of entries that should be removed when message boards are moderated (companies should note that this is not an exhaustive list):

- entries that suggest use of the product for an indication not on the SmPC (see rule 3)
- entries that suggest use of the product amongst groups for whom the product is contraindicated e.g. due to age, other medical conditions. (see rule 3)
- entries suggesting that the directions for use do not need to be adhered to (see rule 3)
- entries likely to cause offence (see rule 6)
- entries likely to lead consumers to make an erroneous self-diagnosis (see rule 13)
- entries that discourage consumers from seeking professional advice when it would be pertinent to do so (see rule 14)
- entries that mislead as to the nature of the product or its ingredients (see rule 20)
- entries that suggest the product is side-effect free, or that use the word 'safe' (see rule 26)

- entries that suggest use of the product during pregnancy unless rule 30 is complied with
- entries that unfairly denigrate other products, ingredients or types of treatment (see rules 37-39)
- entries that suggest that a medicine can be used alongside other products (such as other medicines or alcoholic drinks) where this is not appropriate.

#### Social networking sites

PAGB advises members to be very cautious about opening discussion groups on websites that do not allow PAGB members to moderate the comments added by members of the public. Where comments can be deleted, member companies should follow the guidance given above.

#### Viral advertising

The rules for viral advertising are the same as for all other advertising media. The usual requirements for essential information apply.

#### Essential information and pay-per-click advertising

Please refer to rule 57, for details regarding the requirements for essential information on websites and other Internet materials such as pay-per-click advertising.

Please note that all other requirements of the PAGB Consumer Code for Medicines also apply to web-based promotional materials over which members have editorial control.

### 1.5.13 Promotions

**54 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 Public Relations', which includes guidance on prize promotions, charity promotions, reader offers, value and volume sales promotions.

**55 No member shall distribute free samples of medicines to consumers or advertise the availability of free samples.**

Members must not provide free samples, or vouchers relating to the supply of free samples of over-the-counter medicines to the consumer, even if the consumer solicits the sample.

Regulation 293 of the Human Medicines Regulations 2012 prohibits Marketing Authorisation holders, agents acting on behalf of Marketing Authorisation holders or any person in the course of a business consisting (wholly or partly) of manufacturing, selling or supplying medicines to the public from supplying medicines for promotional purposes.

### 1.5.14 Sponsorship

**56 Advertisers may sponsor a range of materials and activities. All materials must include an appropriate indication of the nature of the sponsorship provided.**

#### Corporate sponsorship

The PAGB Code does not cover corporate sponsorship and such sponsorship schemes do not have to be submitted for PAGB approval. However, if the corporate name is the same name as the brand name, then this is considered to be brand sponsorship.

#### Umbrella brand sponsorship and product sponsorship

If no claims are made it is permissible to use 'Sponsored by Brand X' without adding the consumer essential information. This applies even where there is a claim inherent in the licensed name e.g. Brand X Hayfever Relief. However, if any claims are added then the consumer essential information must be included (please see rule 57).

The use of an umbrella brand name is only acceptable where no general or specific claims are made. If a direct or implied claim is made, then specific products must be named, together with the consumer essential information.

**Sponsoring television or radio programmes**

It is acceptable to sponsor television or radio programmes, or to sponsor elements of programmes, such as the weather or pollen count. (This does not include programmes aimed at persons under 16 years. Please refer to rule 48.) Advertisers should refer to 'The Ofcom Broadcasting Code' which prohibits the inclusion of advertising claims in TV sponsorship. This applies only to TV sponsorship; radio sponsorship can include product claims. Member companies should contact PAGB for advice when considering TV sponsorship.

**Sponsoring of an event**

When sponsoring an event, the event itself would not fall under the PAGB Code, but any advertising or sponsorship statements containing references to the brand, or any promotional give-aways, would be covered by the PAGB Code. Events must be appropriate and should be in keeping with a healthy lifestyle.

**Sponsorship involving children**

As a rule, it is not permissible to have product branding of programmes, events and competitions aimed at children. It is sometimes possible, however, to sponsor activities directed at parents but where children are also involved. However, any promotional activity must be directed at the parents.

**Sponsoring educational or other materials**

It is acceptable for a brand to sponsor printed, electronic or audio-visual self-help, disease-awareness or health-education material produced by a third party. In such cases it must be clear that the opinions and material produced by the third party are genuinely independent of influence from the brand. Such materials must give a clear and concise indication of the exact involvement of the company/brand producing or sponsoring the materials, for example:

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

Note: Company X could be used instead of Brand X in the examples above.

If a claim is included for the brand, then this must be clearly separated from the third party material and the consumer essential information must be included.

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

It is not acceptable for materials that have been produced by a pharmaceutical company to include brand-sponsorship statements. Such statements would imply that the materials are independent in nature, which is not the case. This does not prohibit companies from producing unbranded materials offering information on disease awareness or health education, etc.

**Sponsorship of sports teams involving celebrities**

Please refer to rule 47.

**1.5.15 Essential information in consumer advertising****57 All medicines advertising aimed at consumers must carry certain items of essential information.**

Under Regulation 291 (2) (a,b,c,d) of the Human Medicines Regulations 2012, all medicines advertising aimed at consumers is required to carry certain 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:

- the name of the product
- the therapeutic indication (and any additional information that is required for that particular product)
- the single active ingredient (where appropriate)

- an invitation to read the leaflet or label.
- the traditional use statement 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 remedy.' The name of the product should be as listed on the SmPC.

### The name of the product

Advertising must include the name of a product and not just an umbrella brand name. Advertisers should note that where the format is part of the product name on the SmPC, this must be stated in the advertisement.

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 product name even where the full name may be 'Brand X Throat Lozenges Lemon Flavour'.

Some product names include the number of grams of the active ingredient. PAGB does not generally require advertisers to state this in advertising as long as it is clear which product is being referred to and as long as omitting this information would not lead to confusion in terms of advertising claims or potential safety issues.

### Therapeutic indication

Advertisements must include the therapeutic indication (i.e. what the product is to be used for). This is described in section 4.1 of the SmPC. 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, a product indicated for headache with upset stomach cannot be advertised for upset stomach alone. Companies must make sure that the indication used in advertising 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.

For THMs, 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 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.

### Additional information

Some products are required to include additional information. For example, advertisements for conditions that are difficult to self-diagnose are usually required to state that people should obtain a doctor's diagnosis before using the product for the first time. Where such warnings are stated on the SmPC, they must be reflected in advertising. (For further information, please refer to rule 13.)

Advertisements for products intended to assist consumers in giving up smoking should make reference to the requirement for willpower in order to quit smoking successfully. This requirement is usually met by the inclusion of 'Requires willpower' as part of the essential information, unless the body copy includes a clear reference to willpower.

When promoting medicines for use during pregnancy, member companies should refer to rule 30 and to the MHRA's guideline 'Medicines which are promoted for use during pregnancy'.

Other wording may be required as a condition of the Marketing Authorisation, or as a result of any additional guidance that may be developed for particular types of advertising. For example, some products intended to help people lose weight are required to state that they should be used as part of a calorie-controlled diet.

Please refer to the product SmPC for details and contact PAGB for further advice.

**The active ingredient, if there is only one**

The most common way of including this is simply to state 'Contains ...'. Including a pack shot may be used to fulfil this requirement where the text is large enough to enable the active ingredient to be clearly legible. There is no requirement to list the active ingredient separately if it is already present in the brand name (e.g. Brand X Aspirin).

Advertisers should also bear in mind that if the single active ingredient is only available in one chemical form it is acceptable to abbreviate it (e.g. diphenhydramine hydrochloride can become diphenhydramine). If the active ingredient is available in more than one chemical form, then it must be listed in full (e.g. calcium carbonate and calcium gluconate cannot be abbreviated to calcium).

**An instruction to 'always read the label/leaflet'**

This is based upon Part 14 requirement of the Human Medicines Regulations 2012 that there is 'an express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be'. For products that do not have an in-pack leaflet, all of the required information will be on the label and 'always read the label' will suffice. For products that 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'.

Note: There is no legal requirement for companies to include 'ask your pharmacist' on advertisements for pharmacy medicines. While many companies choose to include it, this is at the discretion of the advertiser.

## 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:

**Materials that do not contain any claims or references to a therapeutic category<sup>1</sup>**

Promotional materials that highlight an umbrella brand name or a product name only, that do not contain any direct or implied claim, and do not refer to any therapeutic category, are not required to display the essential information normally required for consumer advertising. Price claims and claims that the product is new may also be used. (Sales claims may only be used if they do not refer to a therapeutic category.)

**Pack shots used in isolation<sup>1</sup>**

Materials that consist solely of a genuine pack shot, and do not include any other claims either direct or implied, may not be required to include the consumer essential information. This will depend on the intended advertising medium. Please contact PAGB for advice. Price claims and claims that the product is new may also be used. (Sales claims may only be used if they do not refer to a therapeutic category.)

**Brand imagery**

Materials consisting solely of an image associated with a brand and a product name or umbrella brand name are not required to display the essential information normally required for consumer advertising.

**Point-of-sale materials**

Certain items of non-promotional information may be included in point-of-sale materials, such as shelf-edgers, shelf-ready packaging and display units, without necessitating the inclusion of essential information. The purpose of this information is to enable the consumer to easily locate the correct product:

- product name
- price

<sup>1</sup> Please note, both the CAP Code and the BCAP Broadcast Advertising Standards Code include requirements for essential information. Therefore the requirements for essential information will also depend on the advertising media. Please ask PAGB for advice.



- pack size
- flavour
- dosage
- pack shots.
- sugar-free (or similar)
- format
- 'new' claims

In order to avoid the requirement for essential information, the information must be provided in a way that is informative and non-promotional. For example, whilst 'lemon flavour' would be acceptable, 'zesty lemon flavour' would be regarded as a claim. Similarly, whilst '5mg dose' would be acceptable, claims such as 'high strength' and 'medium strength' would necessitate the inclusion of consumer essential information.

Sales claims are not permitted unless the essential information is included.

### Clam shells

Where the clam shell is removed by the retailer prior to the consumer leaving the store, then any information placed on the backing card (or similar) is considered to be point-of-sale advertising. Where the clam shell is part of the packaging that consumers take home with them, any information contained within the clam pack is viewed to be part of the product packaging, and hence does not come under this Code.

### Dummy packs

Display dummy packs that are simply an enlarged pack, or a simplified enlarged pack do not have to include 'always read the label/leaflet', as the MHRA agrees that this looks out of place on a large pack. The pack must include the name and indication, and the single active ingredient, if appropriate. (This exception does not apply to dummy P packs that are used to enable consumers to self-select pharmacy-only medicines. Most dummy P packs have a backing card telling the consumer to take the dummy pack to the pharmacist. It is usual practice to add 'always read the label/leaflet' to the backing card.)

### Coupons

Coupons that are intended merely to state a price reduction on purchase of a product do not need to include the indication, single active ingredient and 'always read the label/leaflet'. 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. Similarly, the inclusion of brand imagery does not necessitate the inclusion of the essential information as long as the brand imagery does not constitute a visual representation of a claim.

### Pay-per-click advertising on Internet search engines (sponsored links)<sup>1</sup>

Sponsored links that appear on Internet search engines are items over which advertisers have full editorial control and are, therefore, viewed as advertisements. These items must be submitted to PAGB for approval.

Companies are not required to include the essential information in sponsored links where all of the following circumstances apply:

- when the consumer clicks on the link, they are taken directly to a web page that contains the essential information in a format that is both prominent and clearly legible (please refer to rule 58 on legibility of essential information)
- where the only medicinal claims (please refer to section 2.1.1 for a definition of 'medicinal claims') made are simple, factual statements, for example claims relating to the product indication, or a simple reference to the therapeutic category
- if an umbrella brand is included but not a product name, any statement relating to the product indication or therapeutic category must apply to the whole brand.

Consumer-preference claims (please refer to section 2.1.2 for a definition of 'consumer preference claims'), new claims and sales claims may also be included without necessitating the inclusion of consumer essential information.

The following claims would not be acceptable for inclusion in pay-per-click advertising without the

<sup>1</sup> Please note, both the CAP Code and the BCAP Broadcast Advertising Standards Code include requirements for essential information. Therefore the requirements for essential information will also depend on the advertising media. Please ask PAGB for advice.



addition of the essential information:

- comparative claims, including top parity and superiority claims
- claims which require additional qualification
- direct invitations to use a product such as 'try Brand X'.

#### SMS text messages<sup>1</sup>

Text messages that are sent to existing users, as part of a support package merely to encourage people to continue using their medicine as instructed, are not considered to be advertising and essential information is not required. However, should the text encourage recipients to try another medicine they are not currently using, then the text would be regarded as advertising and the normal requirements for essential information would apply.

#### Promotional aids

Promotional aids are items that have a purpose other than to promote a medicine but which display a product/brand name as a reminder. Examples include T-shirts, pens, mugs, coasters, note pads and mouse mats. Promotional aids that only state the product name or a reasonable abbreviation thereof and a trade mark protection do not have to include the indication, the single active ingredient and 'always read the label/leaflet'. 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 product name, indication and 'always read the label', and the single active ingredient (if applicable), would have to be added. If 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.

#### Sponsorship

It is acceptable to simply state 'Sponsored by Brand X' without the addition of the essential information. However, if any direct or implied claims are included, then the essential information must also be present. (Please refer to rule 56 for further details on sponsorship.)

#### Public relations

Companies are reminded that although the PAGB Medicines Advertising Consumer Codes do not cover PR up to the point where the material is passed to a journalist, these activities do also fall under Part 14 of the Human Medicines Regulations 2012 and, therefore, press releases and other PR materials should comply with the legal requirements for essential information.

### 58 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 following points should be considered:

- the essential information must be large enough to be clearly legible and should be in proportion to the rest of the text. Companies should consider the distance from which a consumer might be viewing the advertisement. (Please refer to the media-specific guidance below.)
- the essential items must be placed horizontally and not vertically, or spiralling round the advertisement
- attention should be paid to issues such as contrast between text and background, type style and print quality. Using a dark-coloured font on a dark background should be avoided. Similarly, using a light font on a pale background should also be avoided
- the essential information must be placed prominently so that consumers are likely to notice it. It should not be placed on part of the advertisement or website that consumers are unlikely to look at. For example, where a print advertisement includes details of a promotion, the medicines essential information should usually be placed before the terms and conditions of the promotion. (Each advertisement will be looked at on a case-by-case basis.)

#### Printed media and shelf-edgers

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

#### Display units

The essential information should be placed in a position where consumers are likely to notice it, for

<sup>1</sup> Please note, both the CAP Code and the BCAP Broadcast Advertising Standards Code include requirements for essential information. Therefore the requirements for essential information will also depend on the advertising media. Please ask PAGB for advice.

example, on the header card. Where a display unit is floor-standing, the essential information should not be placed at floor level unless it is also repeated in a prominent position. The font size used for the essential information should be in proportion to the rest of the text and visuals and should be at least the same size as the smallest body copy. Where there is no body copy the essential information should be in proportion to the rest of the advertisement.

### Posters

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

### Websites

The best way to ensure that company-owned websites comply with the requirements for essential information is to place the essential information on each page of the website. If the essential information is not placed on every page, it must be included on the first page on which medicinal products are mentioned, and repeated at regular intervals throughout the site. The essential information must always be included on pages where information/claims are made about particular products.

The font colour used for the essential information should be significantly different from the background colour.

The lower case letter 'a' must be at least 2mm in height when the webpage is viewed on a standard 17" monitor. The essential information should be positioned above the links to sitemap, privacy policy, legal notices, etc.

### Television

Both duration of hold and size of font are important here. Clearcast requires that all supers are held on screen for at least two seconds, with additional time that is calculated pro rata at the rate of five words per second (0.2 seconds per word). For example, a six-word super such as 'Contains aspirin. Always read the label' should be held on screen for at least 3.2 seconds. Supers should appear in a minimum of 16 television lines high for advertisements made in widescreen. Clearcast also requires supers to be presented in lower case, with upper case used only where appropriate for punctuation. Where the name of the product is given in the pack shot only, advertisers must ensure that both the visibility and the hold time are long enough for the product name to be clearly legible. Please consult Clearcast for further information.

## 1.6 PAGB Consumer Code for Medicines advertising checklist

It is a condition of membership that all advertising aimed at consumers must be submitted to PAGB for review, and PAGB approval must have been given prior to its release into the public domain. Please refer to section 1.4.3 to 1.4.9 for details.

### 1 Before you submit advertising to PAGB for approval, please check that the following are included in the draft advertisement (rule 57):

- full product name
- indication
- single active ingredient (where applicable)
- 'always read the label/leaflet'
- any other additional information necessary for correct use of the product (e.g. 'suitable for people who have a doctor's diagnosis of ...' or 'Medicines can affect the unborn baby. Always talk to your doctor or pharmacist before using any medicines in pregnancy')
- 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 remedy.'

## **2 Is all of the essential information clearly legible and sufficiently prominent (rule 58)?**

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

- are the claims in line with the SmPC (rule 3)?
- can you substantiate all of the claims (rule 5)?
- does it undermine current healthy-lifestyle advice (rule 7)?
- is it clearly distinguished from any editorial matter (rule 9)?
- is it likely to cause unwarranted anxiety (rule 10)?
- could it lead to consumers making an incorrect self-diagnosis (rule 13)?
- does it promote the responsible use of medicines (rule 16)?
- does it contain any guarantees (rule 17)?
- if it is a TV ad, does it include an appropriate indication of time change before the person looks better (rule 23)?
- does it claim to be 'side-effect free' or 'safe' (rule 26)?
- if it claims to be 'new', has it been available for over a year (rule 27)?
- does it claim to be 'unique' (rule 28)?
- does it mention the use of the product in pregnancy (rule 30)?
- does it claim to be 'natural' (rule 32)?
- if both medicines and non-medicines are included is it clear which claims and which essential information apply to each product (rule 36)?
- does it make any comparisons other than those that are fair and capable of substantiation (rule 37)?
- does it unfairly denigrate or discredit competitor products (rule 38)?
- does it claim the product is better than or equal to another identifiable product (rule 39)?
- does it claim to be free of ingredients present in competitor products (rule 40)?
- does it include any competitor brand names (rule 41)?
- does it make any hanging comparisons (rule 42)?
- does it make a superiority claim (rule 44)?
- is it particularly attractive to children (rule 48)?
- does it feature a celebrity or health professional (rules 47 and 45)?
- if there is a testimonial, is it sufficiently up to date and does it comply with the rest of the PAGB Consumer Code for Medicines (rule 50 and 51)?

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

- if it is a new product, a copy of the Marketing Authorisation (including the SmPC), the product packaging and the patient information leaflet (if applicable)
- evidence to support the claims made
- if you have included a sales claim, volume-sales data
- if the advertisement features a prize promotion, the terms and conditions
- a signed and dated copy of any testimonials.

### **5 Has the advertisement undergone internal compliance checks and sign-off before being submitted to PAGB for approval?**

### **6 Have you included your contact details?**

## **1.7 Advertising case studies**

### **Consumer Poster**

#### **1. The poster needs to include:**

- 'Always read the label.' or 'Always read the leaflet.'

- single active ingredient.

**Comment:** The indication, i.e. 'tickly cough' is only on the pack shot and is small in relation to the rest of the copy. Depending where the poster is going to be placed, the advertiser will need to make sure that this will be clearly legible. The single active ingredient is stated on the pack but it is unlikely that this will be sufficiently legible for a poster. (Rules 57 and 58)

### 2. 'It helps my baby to sleep soundly through the night'

**Comment:** This claim is not in line with the product's SmPC. It also misleads the consumer about the product indication. (Rules 3, 4 and 20)

### 3. 'Medicine cabinet essential'

**Comment:** The MHRA has advised that medicines are indicated for specific medical conditions and should not be described as 'essential' for the general population. (Rule 16)

### 4. 'Cough mixture works better and quicker than Brand X'

**Comment:** The Medicines (Advertising) Regulations prohibit claims that suggest that a product is equal to, or better than another identifiable product. The claim 'works better' is too all-encompassing and would be viewed as 'unfairly denigrating'. The claim also uses a competitor's brand name without permission from the owner. (Rules 38, 39 and 41)

## Consumer A4 Press Advertisement

### 1. The advertisement needs to include:

- 'Always read the label.' or 'Always read the leaflet.'

**Comment:** The full product name and single active are clearly legible on the pack shot. The product indication i.e. 'tickly cough' is included in the product name. (Rules 57 and 58)

### 2. Unbeatable formulation

**Comment:** This is a superiority claim which implies that the effects of the product can never be surpassed. (Rules 37 and 44)

### 3. Works within 15 minutes

**Comment:** This claim is not acceptable as it is a guarantee. It may be possible to make a claim such as 'Starts to relieve symptoms in X minutes' on the basis of supporting data. (Rules 3, 4, 17 and 20)

### 4. Stops cough from developing into chronic cough

**Comment:** This claim is not in line with the product's SmPC and is misleading. It is also a guarantee. (Rules 4 and 11, 17 and 20)



## 5. Delicious cherry flavour

**Comment:** This is misleading as the flavour is blackcurrant. In addition, medicines should be promoted primarily on their medicinal benefits. 'Delicious' is more suitable for a food product. 'Tasty' would be better. (Rules 3 and 4)

## 6. Approved by the MHRA

**Comment:** This claim is not acceptable as it implies that MHRA endorses the product. 'Licensed/authorised by MHRA' would be acceptable. (Rule 19)

## 7. No 1 best selling children's cough syrup

**Comment:** This claim is acceptable if it is supported by three months' recent volume sales data. (Rule 29)

## 8. Recommended by health visitors

**Comment:** This is health professional endorsement which is not permitted. (Rule 45)

## 9. Safe

**Comment:** Advertisers are not permitted to claim that a medicine is 'safe' without further qualification. 'Good safety profile' would be acceptable based on supporting data. (Rule 26)

## 10. Use for 5 days

**Comment:** This claim is misleading as the SmPC states that a doctor should be consulted if symptoms persist for more than 3 days. (Rule 3)

# Consumer A5 Press Advertisement

## 1. Consumer essential information

**Comment:** 'Always read the label' should be in a darker font so that it is clearly legible and needs to be positioned horizontally, rather than vertically. The current font size 8 is too small and needs to be increased to font size 10. (Rule 58)

The full product name and single active are clearly legible on the pack shot. The product indication i.e. 'tickly cough' is included in the product name. (Rules 57 and 58)



## 2. Wave goodbye to coughs and colds

**Comment:** The product is indicated for symptom relief, not for getting rid of the infection. In addition, the product is not indicated for colds. (Rules 3 and 4). This is also a guarantee of efficacy (Rule 17)

## 3. Faster relief

**Comment:** This is a hanging comparison. The claim could be changed to 'fast relief' if the advertiser

has evidence that the product relieves symptoms within 30 minutes. (Rules 42 and 21)

#### 4. Suitable for use in pregnancy

**Comment:** Products may be advertised for use in pregnancy where the SmPC supports use in pregnancy. Please refer to sections 4.1 and 4.6 of the SmPC for details. However the appropriate pregnancy warning statement must be added. (Rule 30)

#### 5. Better than Brand X

**Comment:** The Medicines (Advertising) Regulations prohibit claims that suggest that a product is equal to, or better than another identifiable product. The claim 'better than Brand X' would also be viewed as 'unfairly denigrating' and uses a competitor's brand name without the owner's permission. (Rules 38, 39 and 41)

#### 6. As recommended by Dr Jones

**Comment:** This is health professional endorsement which is not permitted. (Rule 45)

#### 7. Does not contain codeine

**Comment:** It is not acceptable to state that a product does not contain an active which is present in a competitor product, where the statement implies that this ingredient is unsafe or should be avoided. Claims such as 'sugar free' or 'free from artificial colours' are acceptable if in line with the SmPC. (Rule 40)

#### 8. Suitable for children under 2 months

**Comment:** Unacceptable. (Rules 3 and 4)

#### 9. Stock up before the winter comes

**Comment:** It is not acceptable to encourage customers to purchase medicines they do not currently need, or to purchase excessive quantities of medicines. (Rule 16)

#### 10. Nothing is more effective

**Comment:** Top parity claims are only acceptable when supported by evidence. (Rule 43)

#### 11. No 1

**Comment:** This would need to be changed to 'No. 1 selling children's cough medicine' and needs to be supported by 3 months volume sales data (Rule 29)

### Customer Flyer

#### 1. As recommended by

**Comment:** The current text implies that the pharmacy recommends a particular medicine. This would be viewed as health professional endorsement which is prohibited by the Medicines (Advertising) Regulations. If 'As recommended by' were changed to 'Available from',





**NEW AND UNIQUE**  
**PAGB children's tickly cough syrup**

- 100% natural
- Soothes coughs and aids sleep
- Treats catarrh

**ASK YOUR PHARMACIST FOR FREE SAMPLE**

Gift with purchase - pick up your baby changing kit here

the advertisement would be acceptable. The leaflet would not require the consumer essential information as no claims are made. (Rule 57)

## Point of Sale Strip

### 1. The strip needs to include:

- 'Always read the label.' or 'Always read the leaflet.'
- single active ingredient.

**Comment:** The full product name is included in the body copy and the product indication i.e. 'tickly cough' is included in the product name. (Rules 57 and 58)

### 2. 100% natural

**Comment:** In order to make this claim, all of the actives and excipients would need to be natural. Looking at sections 2 and 6.1 of the SmPC, we can see that the claim is not supportable. (Rule 32)

### 3. Soothes coughs and aids sleep

**Comment:** 'Soothes coughs' is acceptable, particularly because 'tickly cough' is specified elsewhere in the advertisement. The product is not indicated for 'aids sleep', so this will need to be removed. (Rules 3, 4 and 20)

### 4. Treats catarrh

**Comment:** The product is not indicated for 'Treats catarrh', so this will need to be removed. (Rules 3, 4 and 20)

### 5. Gift with purchase - pick up your baby changing kit here

**Comment:** It is acceptable to offer a gift with purchase but there are some caveats. The gift with purchase must be of lower value than the price of the medicine. (Both the cost to the advertiser and the cost the consumer would pay to purchase a similar item must be considered.) Please refer to 'PAGB's Guideline on Consumer Promotions' for further information.

### 6. Ask the pharmacist for your free sample

**Comment:** The provision of free samples to consumers is prohibited. (Rule 55)



**Use the NEW and UNIQUE PAGB children's tickly cough syrup and notice the difference in 5 days**

**Money back if not satisfied**

Consumer guarantee. Always read the label



## Consumer Shelf Edge

### 1. Consumer essential information

**Comment:** The full product name is included in the body copy and the product indication i.e. 'tickly cough' is included in the product name. (Rules 57 and 58)

The single active and 'Always read the label' are also included but the font is too small to be clearly legible. It should be at least font size 10. (Rules 57 and 58)

### 2. New

**Comment:** The active ingredient has been available in the UK for more than one year. Therefore, the claim should be amended to 'New to the PAGB range', or similar. (Rule 27)

### 3. Unique

**Comment:** Where advertising claims that a product is 'unique', it must make clear what aspect of the product is unique. (Rule 28)

### 4. Notice the difference in 5 days

**Comment:** This claim is not in line with the SmPC. Section 4.4 of the SmPC states that a doctor should be consulted if symptoms persist for more than three days. (Rule 17) Claims such as 'You can notice the difference in XX' are usually acceptable if supported by evidence and in line with the SmPC.

### 5. Money back if not satisfied



**Comment:** It is not acceptable to make money back offers on the basis of product efficacy. (Rule 18)

## Consumer Tray Sticker

### 1. Consumer essential information

**Comment:** Certain items of non-promotional information may be included in point-of-sale items without necessitating the inclusion of consumer essential information. In order to avoid the requirement to add 'Always read the label.' and the single active, the information included on the tray sticker must be provided in an informative and non-promotional manner. The inclusion of the word 'tasty' would be viewed as promotional and hence the essential information is required. If the advertiser removes the word 'tasty', then the shelf edge would be acceptable without further amends. The inclusion of 'tickly cough' within the product name is not viewed as a claim, since this is part of the product name. (Rule 57)



## 2. Glossary

### 2.1 Product Claims

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

#### Medicinal claims

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

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

#### Consumer preference claims

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

Examples include:

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

### 2.2 Advanced

#### An efficacy advance

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

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

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

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

#### **A formulation advance**

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

#### **Product reformulation advance**

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

#### **A format advance**

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

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

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

## **2.3 Breakthrough**

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

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

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

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

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

## 2.4 Revolutionary

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

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

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

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

	PAGB CONSUMER CODE	PAGB PROFESSIONAL CODE
PAGB pre-publication approval of advertising?	Yes	No
PAGB complaints process?	Informal conciliation	PAGB considers formal complaints
General principles	Additional rules relating to: <ul style="list-style-type: none"> <li>• use of medicinal terminology</li> <li>• not causing unnecessary anxiety</li> <li>• not suggesting health could be adversely affected if the consumer chooses not to use the medicine featured</li> <li>• not providing information that could lead to the consumer making an erroneous self-diagnosis</li> <li>• not discouraging consumers from seeking advice from a health professional</li> <li>• not offering to diagnose or advise by correspondence</li> <li>• not encouraging unnecessary use of medicines</li> <li>• prohibition on implying that the product's effects are guaranteed</li> </ul>	Additional rules relating to: <ul style="list-style-type: none"> <li>• use of graphs and tables</li> </ul>
Misleading advertising	Additional guidance relating to: <ul style="list-style-type: none"> <li>• basing no.1 selling claims on volume-sales data</li> <li>• indicators of time change, particularly for TV advertising</li> </ul>	Additional guidance relating to: <ul style="list-style-type: none"> <li>• no.1 selling claims - may be based on value-sales data but must be referenced</li> </ul>
Pregnancy	A positive statement in section 4.1 or 4.6 of the SmPC is required	Images of pregnant women are only permitted where the product is indicated for use in pregnancy (4.1 of the SmPC)
Natural and herbal claims	No significant differences	No significant differences
Flavour claims	Additional rules relating to the use of flavour claims	
Advertising including medicines and non-medicines	Additional guidance relating to materials promoting medicines and non-medicines together	
Comparisons	Additional rules relating to: <ul style="list-style-type: none"> <li>• prohibition on implying that the product's effects are better than or equal to another identifiable product</li> <li>• prohibition on the use of a competitor's brand name, unless permission is given</li> <li>• prohibition on stating that a product does not contain an active present in a competitor product where this would be denigrating</li> </ul>	
Endorsement	Additional rules relating to: <ul style="list-style-type: none"> <li>• prohibition on health-professional endorsement</li> <li>• prohibition on celebrity endorsement</li> <li>• prohibition on advertising stating that a product is, or has been available on prescription</li> </ul>	
Testimonials	Rules are similar in both Codes	Rules are similar in both Codes
References		Additional rules relating to: <ul style="list-style-type: none"> <li>• sales claims, graphs, tables and product claims that are not present on the SmPC</li> </ul>
Gifts, prizes and inducements	Further guidance can be found in 'PAGB's Guideline on Consumer Promotions	Specific rules regarding gifts and prizes
Hospitality and meetings		Specific rules regarding hospitality and meetings
Training and educational materials	Sponsored materials must give a clear indication of the involvement of the sponsoring company/brand	Sponsored materials must give a clear indication of the involvement of the sponsoring company/brand
Sampling	Prohibited for Marketing Authorisation holders	Possible in very limited circumstances
Company representative activities		Specific rules
Essential information	Refer to Codes for information	Refer to Codes for information

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

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

#### Medicines and Healthcare Products Regulatory Agency (MHRA)

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

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

#### MHRA sanctions

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

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

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

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

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

#### ASA Sanctions

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

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

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

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

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

#### Ofcom (Office of Communications)

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

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

#### Clearcast

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

#### Radio Advertising Clearance Centre (RACC)

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

#### Cinema Advertising Association (CAA)

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

**4.1.13** PAGB is the self-regulatory body for over-the-counter medicines advertising. It offers a pre-publication approval service for consumer advertising in relation to over-the-counter medicines and food supplements, and advice on advertising aimed at professionals. Details of these services are given in sections 1.4, P7-10, and in the PAGB Professional Code for Medicines respectively.

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

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

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

TABLE 3: SUMMARY OF THE ORGANISATIONS FROM WHICH PAGB MEMBERS ARE REQUIRED TO OBTAIN PRE-PUBLICATION APPROVAL FOR CONSUMER ADVERTISING, TOGETHER WITH INFORMATION ON THE RELEVANT COMPLAINTS BODIES		
CONSUMER PROMOTIONAL ACTIVITY	APPROVAL NEEDED	COMPLAINT BODIES
Print advertisements and direct marketing	PAGB	MHRA and ASA
Point-of-sale materials (not including promotions)	PAGB	MHRA
Sales promotions	The advertising material requires approval by PAGB	MHRA and ASA
Radio advertising	PAGB and RACC	MHRA and ASA
TV commercials	PAGB and Clearcast	MHRA and ASA
Cinema commercials	PAGB and the Cinema Advertising Association	MHRA and ASA
TV sponsorship	PAGB	MHRA and Ofcom
Radio sponsorship	PAGB	MHRA and Ofcom
Sponsorship, non-broadcast	PAGB	MHRA
Internet advertising	PAGB	MHRA and ASA
Internet home page	PAGB	MHRA and ASA

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

### Legislation

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

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

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

### Codes of Advertising Practice

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

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

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

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



## 5. External contacts

### **The Advertising Standards Authority**

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

Tel: 020 7492 2222

Website: [www.asa.org.uk](http://www.asa.org.uk)

### **The Association of the British Pharmaceutical Industry**

7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

Tel: 0870 890 4333

Website: [www.abpi.org.uk](http://www.abpi.org.uk)

### **Cinema Advertising Association**

Corinthian House, 279 Tottenham Court Road, London W1T 7RJ

Tel: 0207 199 2433

Website: [www.cinemaadvertisingassociation.co.uk](http://www.cinemaadvertisingassociation.co.uk)

### **Clearcast**

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

Tel 020 7339 4700

Website: [www.clearcast.co.uk](http://www.clearcast.co.uk)

### **The Committee of Advertising Practice**

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

Tel: 020 7492 2222

Website: [www.cap.org.uk](http://www.cap.org.uk)

### **The Medicines and Healthcare Products Regulatory Agency**

151 Buckingham Palace Road, Victoria, London SW1W 9SZ

Tel: 0203 080 6000

Website: [www.mhra.gov.uk](http://www.mhra.gov.uk)

### **Office of Communications**

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

Tel: 020 7981 3000

Website: [www.ofcom.org.uk](http://www.ofcom.org.uk)

### **The Prescription Medicines Code of Practice Authority**

7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

Tel: 020 7747 8880

Website: [www.pmcpcpa.org.uk](http://www.pmcpcpa.org.uk)

### **The Radio Advertising Clearance Centre**

The Radiocentre, 6th Floor, 55 New Oxford Street, London WC1A 1BS

Tel: 0207 010 0608

Website: [www.racc.co.uk](http://www.racc.co.uk)

### **The Royal Pharmaceutical Society of Great Britain**

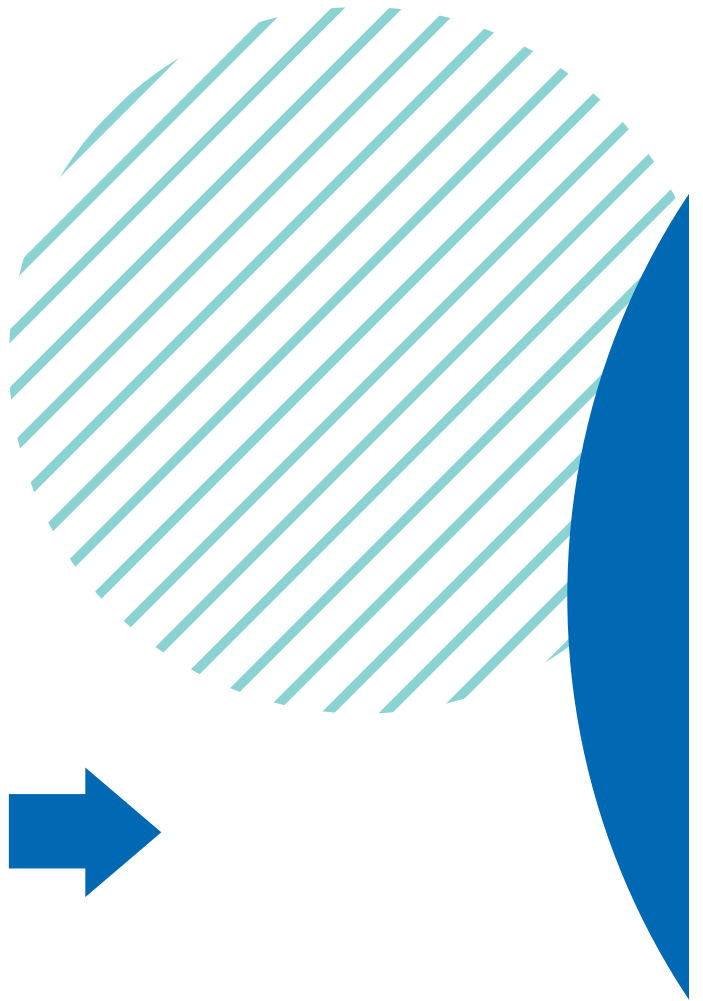
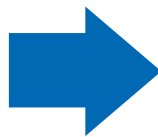
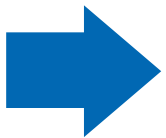
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Further information about the over-the-counter medicines industry and the work of the PAGB is available from: PAGB, Vernon House, Sicilian Avenue, London WC1A 2QS.

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