



Self Care Medical Devices Advertising Guideline

11 July 2016

**FOR MORE INFORMATION OR CLARIFICATION ABOUT ADVERTISING SELF
CARE MEDICAL DEVICES, PLEASE CONTACT regulatory@pagb.co.uk**

Introduction

PAGB has a long and distinguished track record as the self regulatory body for advertising of OTC medicines. In 1919, medicines manufacturers set up PAGB expressly for the purpose of controlling the claims made on medicines. By the 1930's this had evolved into an industry Code of Practice and a system of pre-publication copy clearance. Ever since PAGB has operated the self-regulatory system to ensure that medicines advertising is balanced and responsible.

The last few years have seen significant innovation and growth in the number of medical devices available on European markets in numerous therapy areas in self care.

For most self treatable conditions OTC medicines and substance based medical devices compete head to head and sit side by side on the shelf.

Substance based medical devices are devices that due to their presentation in a pharmaceutical form look very similar to medicinal products. They are categorised differently because they do not achieve their principle intended action in or on the human body by pharmacological, immunological or metabolic means. Instead they work by physical mechanisms, such as forming physical barriers, eg. alginate rafts or a liquid barrier that protects minor wounds from infection.

To the general public the difference between OTC medicines and self care medical devices is difficult to see; often they look the same, treat the same conditions and are used the same ways. However, the environment for marketing the two categories is markedly different. Unlike medicines there are no specific advertising rules for medical devices.

PAGB and its members have now undertaken to implement self regulation for substance based medical devices to maintain the high standards of promotion across the UK substance based self care industry. This specific advertising guidance for substance based medical devices has been written with this in mind.

Scope

This Guideline applies to advertising materials relating to substance based self care medical devices intended for the public marketed by PAGB member companies. All eligible medical devices owned by PAGB members are automatically in PAGB membership and therefore should comply with this Guideline. This Guideline covers all branded promotional materials over which the company has editorial control including public relations (PR) material up to the point where the company relinquishes control. PR material is not required to be submitted to PAGB for copy clearance.

Materials covered by this Guideline 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
- consumer leaflets
- direct mail materials
- display packs, including dummy P packs
- labels and packaging
- online advertisements (please refer to [rule 41](#))
- outdoor advertising
- pay-per-click advertising, such as that used on internet search engines
- point-of-sale materials
- posters
- print advertisements (for use in newspapers, magazines etc.)
- promotional aids
- promotional scripts for use by telephone help lines
- sales promotions
- shelf-ready packaging
- social media - refer to guidance documents
- television and radio commercials
- text messages
- 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 41](#))
- 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).

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.

What this Guideline does not cover

Claims relating to price

This Guideline does not cover simple price claims. Member companies are responsible for ensuring that such claims are not misleading.

Public relations

PAGB recognises that this Guideline 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 ensure that all PR materials comply with this Guideline and the law at the point when the company relinquishes editorial control.

Materials intended for third parties

The Guideline 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 this Guideline. All materials intended to be passed directly to potential consumers, and over which PAGB members have editorial control, do come under this Guideline.)

Corporate sponsorship

This Guideline does not cover corporate sponsorship however, materials that carry brand sponsorship are covered by this Guideline (please refer to [rule 43](#)).

Legal notices and disclaimers included on websites

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

The Guideline does not apply to advertising aimed at healthcare professionals or persons involved in the trade of medical devices.

Food supplements

This Guideline does not cover the advertising of food supplements. Please contact PAGB for advice on food supplement advertising.

OTC Medicines

This Guideline does not cover the advertising of OTC medicines. Please contact PAGB for advice on OTC medicine advertising.

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General Principles

1. No PAGB member company shall advertise a substance-based self care medical device to the public unless it complies with the requirements laid down by the relevant statutory instruments^{1,2}. The medical device must be the subject of the manufacturer's Declaration of Conformity, and for Class IIa, IIb and III medical devices, must have EC Certification from a Notified Body.

2. All advertising claims must be in line with the device's technical documentation. Claims for intended uses which are not listed in the instructions for use, labelling or clinical evaluation of the technical documentation are prohibited.

Information in the product's Instructions for Use, Labelling and in the Clinical Evaluation report sections of the technical documentation will form the basis of the claims that can be made in advertising (subject to appropriate justification, see [rule 4](#)).

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

All advertisements for medical products must encourage their rational use 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 intended purpose of the product. (Please also refer to [rule 17](#) 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 medical device.

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

¹ Medical Device Directive - Council Directive 93/42/EEC.

² Medical Device Regulation -

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.

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

The High Court has confirmed that the Medical Devices Directive and UK advertising law are distinct regimes with different requirements, and that the Medical Devices Directive does not harmonise the law in relation to the advertising of medical devices. The ruling confirms that obtaining certification for a claim under the Directive does not mean that the requirements of UK advertising law, the CAP code and the PAGB Guideline.

Appropriate evidence for all claims must be submitted to PAGB before approval can be given. PAGB needs to perform its own assessment of claims to ensure compliance with UK advertising rules and regulations. PAGB recognises that in order for medical devices to be placed on the market, prior to certification the technical documentation (design dossier) of Class III, IIb and IIa are required to undergo assessment by a Notified Body and will take this into consideration when assessing claims.

For each individual Class III medical device, the technical documentation (design dossier) undergoes substantive evaluation by a Notified Body prior to certification and the device being placed on the market. In these cases the intended uses, labelling and clinical evaluation have already been assessed by the designated regulatory body. Class IIb medical devices, also undergo substantive evaluation by a Notified Body prior to certification. In some cases they are certificated on a group basis if they meet the statutory requirements of a 'generic device group'³. Although for Class IIb medical devices meeting the requirements of a generic device group the Notified Body's substantive evaluation is performed on a sampling basis, the generic similarity of their intended uses and technology are such that all devices within a particular generic device group are deemed to have undergone a substantive evaluation by a Notified Body. In these cases the intended uses, labelling and clinical evaluation have already been assessed, on an individual or generic device group basis, by the designated regulatory body.

Class IIa medical devices are also certified on a collective basis according to the less specific statutory requirements of 'device subcategory'⁴. For subcategories of Class IIa medical devices, the Notified Body's substantive evaluation is performed on a sampling basis. However, in this situation the possible dissimilarity of their intended uses and technology are such that the substantive evaluation performed by a Notified Body **may** not apply equally to all devices within a particular device subcategory. In such cases where the device in point has not already been the subject of substantive evaluation by a Notified Body, PAGB's position is therefore to require advertisers to submit supporting clinical evidence for the intended use in accordance with the requirements of the medical device guidance note MedDev 2.7.1, in addition to the certification, labelling and instructions for use.

³ MDD Article 1(m) 'generic device group' means a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics

⁴ MDD Article 1(l) 'device subcategory' means a set of devices having common areas of intended use or common technology

For Class I medical devices, the supporting technical documentation including the products' intended uses, labelling and clinical evaluation reports are effectively self-assessed by the manufacturer without any independent verification by a regulatory body. For clinical claims, advertisers must be able to demonstrate that they have taken a systematic approach to reviewing the available evidence in accordance with the requirements of the medical device guidance note MedDev 2.7.1. All advertising claims must be in line with the device's technical documentation. Claims for intended uses which are not listed in the instructions for use, labelling or clinical evaluation of the technical documentation are prohibited. For purposes of substantiating performance or characteristic claims not addressed in the aforementioned intended use claims (including, for example, the sales claims in [rule 23](#) and the comparative claims in [rule 31](#)), 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 performance or characteristic 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 key ingredients of all other laxative products. (Please refer to [rule 22](#) 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 pain relief products regardless of their legal status. (Please refer to [rule 36](#) for guidance on evidence required for superiority claims.)

In evaluating claims in accordance with MEDDEV 2.7.1 all claims will be considered individually, but the following types of evidence are likely to be acceptable:

- published data in a peer-reviewed journal
- 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.

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

Guarantees

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.

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 itching', featured next to medical device pack shot is likely to be seen as a product guarantee. (PAGB takes the view that 'stops coughing', 'stops scratching', etc. are guarantees.)

Clearcast and ASA

Members are reminded that Clearcast will always require advertisers to submit data to support **all claims** (including the intended use and claims made in the labelling and instructions for use) made about a medical device in TV advertising submitted to them. Products that have undergone substantive evaluation by a Notified Body are not exempt from this requirement.

ASA have stated that Notified Bodies assess the compliance with the EC directive, which makes no reference to the advertising or marketing communications on the behalf of the medical device. ASA have published a number of rulings against medical devices advertising

that have make it clear that they consider themselves responsible for the regulation of advertising in the UK against the Advertising Codes.

5. Advertising shall not bring the self care medical industry into disrepute, neither shall it undermine nor prejudice consumer confidence in medicines or medical devices.

Shocking or offensive advertisements

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
- 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 for medicine's advertising 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 for medicine's advertising:

- 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. In order for medical devices to be placed on the market they must conform with the relevant statutory requirements, this includes safety and performance. Therefore it is not acceptable to suggest in advertising that a medicine or medical device is unsafe, of poor quality or ineffective. (For further information on denigration, please refer to [rule 32](#).) If an advertiser has reason to believe that another product is unsafe, of poor quality or ineffective, they should use the appropriate regulatory complaints procedure.

6 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).

7. Advertising shall use language which can be understood by the public. 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.

8. 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.

9. Advertising shall not cause the public 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 5](#)), 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 intended.

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.

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

Most self care medical devices 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.

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

Advertisers should be cautious when describing a range of symptoms which could be consistent with conditions other than the purpose for which the product is intended 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.

Where a product is intended for use in a condition where medical professional diagnosis is required before the person can self treat, this must be reflected in the advertising.

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

Advertising should not suggest that it is acceptable to self treat/care 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 intended for self-limiting conditions. In many cases, if such conditions persist, consumers should seek advice from their pharmacist or GP.

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

'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 medical device
- 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.)

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

All advertising claims must be in line with the device's technical documentation (see [rule 2](#)). Advertising should encourage consumers to take a responsible and cautious approach to self treatment/care. On this basis, long term use can be promoted when supported by the product's technical documentation, eg. for the treatment of eczema, however advertising cannot suggest that it is good practice to use medical devices 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 medical devices. 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.

Potentially misleading advertising

15. Advertising shall not mislead as to the nature of the product, its ingredients or intended use

All advertising must make the product's intended use, as stated in the technical documentation, clear. 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 technical documentation. 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 technical documentation. Such implied benefits could confuse the consumer and result in their using the product incorrectly.

16. Advertising claims relating to speed of action or duration of action, are only acceptable if supported by evidence

Evidence will be required to support claims relating to speed and duration of action, unless they are presented in the technical documentation and the device itself has been the subject of an objective evaluation by a Notified Body as described in [rule 4](#).

Advertising claims relating to pharmacological or pharmacokinetic particulars shall only be made for products certified as Class III medical devices with an ancillary medicinal substance. Such claims are only acceptable if they are in line with the claims certified (by the Notified Body) in the Technical Documentation for the medical device.

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.

PAGB requires advertisers to include an appropriate indication of time lapse between using the medical device and experiencing the effects. This is particularly important for television advertising and where before-and-after images are used (please also refer to [rule 17](#) 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 therapy areas '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

Duration of action claims

Member companies are asked to submit evidence to PAGB in support of duration of action claims. 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.

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

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 in line with the intended purpose of the product. 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.
- 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 16](#) for guidance on showing that time has passed.)

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

Care must be taken that all diagrams relate accurately to the intended use. For example, diagrams must be representative of the degree of severity for which the self care medical device is intended for, rather than depicting a more serious or chronic complaint.

19. Advertising shall not suggest that using a medical device can further enhance normal good health

All advertisements must be clearly targeted at people who are suffering from the complaint(s) for which the product is intended. Where the product is intended 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 intended 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'.

20. Information and claims about side effects must reflect available evidence. It must not be stated that a product is side-effect-free

For medical devices the term "safe" refers to a "freedom from unacceptable risk" and all devices placed on the market must be "safe". However, the perception of the public to the term "safe" on a substance based medical device may be different from the defined regulatory term. PAGB will therefore treat the use of the term "safe" in advertising as follows.

'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. In instances where a medical device has 'no known side effects' and such claim has been assessed as part of a substantive evaluation performed by a Notified Body (see [rule 4](#)), 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. PAGB members are expected to be able to show that they have undertaken reasonable vigilance in order to make claims relating to the safety profile of a product.

It is acceptable to highlight the absence of a specific side effect if that side effect is common among other, similar, products.

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.

21. 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 key ingredient (or the combination of key ingredients) was first available for purchase.

If the key ingredient (or the combination of key 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 is now available for an additional therapeutic use
- '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 key 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.

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.

22. 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. 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 key 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 available for a specific use

23. 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 head lice treatment'
- 'best-selling heartburn tablet'
- 'nation's favourite spray for nasal congestion'
- 'Brand X - leading sales for veruccas and warts'

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 head lice treatment'
- 'first choice spray for nasal congestion'

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

'no.1selling pharmacy head lice treatment- the head lice treatment that sells the most packs from pharmacies. The product could be a medical device, GSL or a P medicine. Sales data should take account of all Pharmacy sales of medical devices, GSL and P medicines

Advertising for use in pregnancy

24. Advertisements that promote the use of a medical device during pregnancy are only acceptable where there is a positive risk benefit. All such advertisements must encourage a cautious approach to the use of substance based self care medical devices in pregnancy.

Advertising for use in pregnancy is only acceptable if:

- Such use is justified in the technical documentation and the device itself has been the subject of a substantive evaluation by a Notified Body as described in [rule 4](#). For all other medical devices, it is in line with the claims in the intended uses, labels and clinical evaluation report which form part of the Technical Documentation to which the Declaration of Conformity relates, and such use has been justified to PAGB's satisfaction.

Natural and herbal claims

25. Advertisers shall not suggest that a product is herbal unless it complies with the definition in this guidance document

Products that are principally herbal are unlikely to be medicines however there are examples of herbal medical devices on the European market. eg Icelandic moss is marketed as a medical device in many EU member states.

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

- 'Herbal medical device, exclusively containing as key 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 key ingredients are of plant origin but do not comply with the criteria set out above, advertisers may state that the key ingredients are 'of plant origin' or words to that effect.

26. 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 key ingredients are natural, the claim must be limited to those ingredients (e.g. 'Brand X contains [name of ingredient], a natural key ingredient' or 'Brand X contains the natural key 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', , 'made from natural ingredients', 'a natural choice'
- products in which the ingredient referred to is of natural origin, e.g. 'contains natural ingredient Y'
- products which have a natural mode of action i.e. an action which mimics a physiological mechanism of the body e.g. 'works naturally' and 'acts naturally'. A bulk forming laxative could claim to 'act naturally' even if the product is not made from natural key 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'.

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

This does not prohibit advertising 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'.

Sensory claims

28. Whilst it is acceptable to make flavour claims, advertising should present the medical benefits as the primary reason for purchasing a device.

29. Advertising shall not emphasise the sensory aspects of a medical device, such as flavour or cosmetic attributes, to the extent that consumers may believe that the product is a food, cosmetic or other non-medical item.

Although it is acceptable to indicate that a product is palatable, advertising shall make it clear that it is a medical device. 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 medical device and so misleads the public into assuming that it is a food, cosmetic or other non-medical item.

Advertisements that feature more than one product

30. Advertisements that feature multiple products must make it very clear which claims apply to which products

Several brands include products that span different legal categories, eg medicines, medical devices and cosmetics. For example, some include emollients that are medical devices for the relief of eczema, alongside cosmetic bath and shower products. Other ranges include both medicines and medical devices. Where advertising features multiple products, whether medical devices and medicines and/or 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 medical claims.

Comparative advertising

31. All comparisons shall be balanced, fair and supportable

It is acceptable to make comparative statements, provided they are balanced and fair, and do not refer to an identifiable product or treatment (please refer to [rule 32](#) for details). PAGB does not accept comparisons which denigrate another ingredient, product or product category (please refer to [rule 32](#)).

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’
- ‘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.

32. 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 healthcare products.

In order for medical devices to be placed on the market they must conform with the relevant statutory requirements, this includes safety and performance. Therefore it is not acceptable to suggest, in advertising, that another medical device is unsafe, of poor quality or ineffective. This rule also applies for medical devices where a comparison to a medicine is being made.

PAGB can accept copy that compares the different attributes of products, provided this does not stray into denigration. For example, “saline nasal sprays work faster on congestion than oral decongestant tablets” would be acceptable provided there is sufficient evidence to support the claim (please also refer to [rule 4](#)). However, PAGB would not accept “topical nasal sprays are better than oral decongestants” 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 'medicines can be fatal in overdose' for a medical device. Even though the statement is factually true, it denigrates medicines. Nor would PAGB allow "medical devices are less likely to be fatal".

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.

Ingredient free

Advertising shall not state that a product does not contain one or more ingredients present in competitor products where such a statement would imply that these ingredients are always unsafe or should necessarily 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.

It is acceptable to highlight the absence of an ingredient where this may be of benefit to a particular group of consumers. For example 'steroid free' may be acceptable for an emollient as this is useful information for users who do not wish to use steroid-containing products for long term management of their eczema.

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.

Drug free

'Drug free' can be used however the context is important. Simply stating that the product does not contain a medicine is likely to be acceptable eg. "drug free" could be used in advertising to help distinguish this product from medicines in the same therapy area.

'Drug free so you can avoid side effects' would be considered to be denigratory.

33. 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 32](#) 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 32](#)).

34. Hanging comparisons shall not be used

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

- '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).

35. 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 more effective/powerful'

In order to make a top parity claim, advertisers must ensure that they consider all similar over-the-counter healthcare products, medicines and medical devices, 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.

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'.

36. 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 often offer the same degree of relief .

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 pain relief patch' implies that it is the best pain relief patch 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 23](#) for guidance on sales claims.)

Children

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

This rule aims to protect children from marketing tactics that would encourage them to use medical devices 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 and medical devices. The various organisations involved in the regulatory and self-regulatory control of medicines and medical devices 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 medical devices.

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

- an advertisement featuring a child recommending a medical device
- 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 medical devices 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 give-aways

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 41](#) 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 43](#) on sponsorship.)

Young adults

The main categories of OTC healthcare products 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 medical devices. Medical devices advertising aimed at young adults must feature models who are at least 16. Models that look younger than 16 years should not be used.

38. Advertising shall not show children using, or within reach of medical devices without adult supervision.

The aim of the PAGB is to encourage a responsible attitude towards self-treatment/care. Depicting an unsupervised child handling medical devices could encourage parents to allow their child to do the same, with potentially dangerous consequences.

Testimonials

39. Testimonials must comply with the other principles of this Guideline

Testimonials must comply with all other rules of the Guideline. 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 31](#) and [32](#))
- "Brand X made me feel better instantly" (where this is not in line with the evidence and registered intended use)
- "Brand X works better" (this contravenes [rule 34](#))

- “It also works on my arthritis” (where the technical documentation for the product does not support its use for arthritis).

40. 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.

Internet Advertising

41. All web-based promotional materials over which companies have full editorial control must comply with this Guideline

What the Guideline covers

Internet materials that fall under this Guideline 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.

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, members must provide a copy on which all of the amendments have been highlighted.

Promotional materials that are attractive to children

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

. 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-medical product (not medicines or medical devices) and where the non-medical products 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 or medical devices within the range.

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

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 medical devices or medicines, 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 medical devices or 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 37](#) for further details regarding promotional materials that may be attractive to children.

Message boards

Messages submitted by members of the public do not come under the PAGB Self Care Medical Devices Advertising Guideline as member companies do not have full editorial control over the resulting content. 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 PAGB expect member companies to check the message boards for which they are responsible 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 beyond its intended use (see [rule 4](#))
- 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 4](#))

- entries suggesting that the directions for use do not need to be adhered to (see [rule 4](#))
- entries likely to cause offence (see [rule 5](#))
- entries likely to lead consumers to make an erroneous self-diagnosis (see [rule 11](#))
- entries that discourage consumers from seeking professional advice when it would be pertinent to do so (see [rule 12](#))
- entries that mislead as to the nature of the product or its ingredients (see [rule 15](#))
- entries that suggest the product is side-effect free, or that use the word 'safe', unless this claim has been approved by PAGB (see [rule 20](#))
- entries that suggest use of the product during pregnancy unless [rule 24](#) is complied with
- entries that unfairly denigrate other products, ingredients or types of treatment (see [rules 31-32](#))
- entries that suggest that a [medicine](#) or medical device 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 apply.

Promotions

42. 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', which includes guidance on prize promotions, charity promotions, reader offers, value and volume sales promotions.

Sponsorship

43. 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.

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 37](#).) 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 Substance Based Self Care Medical Devices Advertising Guideline, but any advertising or sponsorship statements containing references to the brand, or any promotional give-aways, would be covered by the PAGB Guideline. 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 and comply with this Guideline.

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.

Annex 1 MEDDEV 2.7.1 (Rev 3)



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