PAGB Medical Devices Consumer Code

Code of practice for advertising self care medical device products in PAGB membership

PAGB Medical Devices Consumer Code

This First Edition of the PAGB Medical Devices Consumer Code was adopted by the membership at PAGB's Annual General Meeting of 27 September 2018 and came into force on 2 January 2019.

What is PAGB?

PAGB (Proprietary Association of Great Britain) is the UK trade association which represents manufacturers of branded over-the-counter (OTC) medicines, self care medical devices 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.

PAGB and its members have undertaken to implement self regulation for medical devices (as categorised in this document) to maintain the high standards of promotion across the UK consumer healthcare industry PAGB represents.

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. Please see pagb.co.uk for more information.

Introduction to the PAGB Medical Devices Consumer Code ("the/this Code")

Broadly, a medical device is described as any instrument, apparatus, appliance, software, material or other article used alone or in combination for human beings to:

- diagnose, prevent, monitor, treat or alleviate disease
- diagnose, monitor, treat, alleviate or compensate for an injury or handicap
- investigate, replace or modify the anatomy or a physiological process
- control conception.

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.*

Products this Code applies to:

This Code applies to all self care medical devices which are covered by PAGB membership.

For medical device products to be within scope of PAGB membership they must:

- be CE marked under the relevant medical device legislation with the manufacturer holding registration or CE certification as relevant and having issued a valid declaration of conformity;

and

- be for self care use and compete in an existing OTC therapeutic category within the PAGB OTC directory.

Products this Code does not apply to:

- medical devices used for non OTC conditions
- medical devices for diagnostic use (including diagnostic software applications)
- products for a cosmetic condition.

A detailed list of products which will be considered in (or out) of membership is available for members in the members' area of PAGB's website.

For further information email regulatory@pagb.co.uk

* for the legal definition of a medical device please see the Medical Devices Regulations 2002 or Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 as appropriate.

Advertising material covered by this Code

This Code applies to advertising materials aimed at consumers and those persons who may legitimately purchase medical devices on behalf of another consumer (e.g. parents who purchase medical devices 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. Materials covered 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
- digital marketing
- direct mail materials
- non-statutory information and claims made on packaging
- online advertisements
- outdoor advertising
- pay-per-click and sponsored search ads
- point-of-sale materials
- posters
- print advertisements
- promotional aids
- promotional scripts for use by telephone help lines
- public relations (PR) materials which are hosted in the consumer facing section of a member's website.
- materials which refer to sponsorship (but not the sponsorship itself)
- sales promotions
- social media
- television and radio commercials
- text messages
- viral advertising
- 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
- 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).

Material this Code does not apply to

- genuine user generated content
- Facebook posts and Twitter messages which do not mention the product, do not contain any direct or implied claims or any references to its intended purpose
- materials such as legal notices and disclaimers or website registration forms
- public relations (PR) activities (e.g. press releases and product launches) once the material has been passed to a journalist
- statutory information required by law on the labelling or packaging
- the product name as it appears on packaging
- the instructions for use (information leaflet)
- material targeted at healthcare professionals
- material targeted at retailers, buyers or wholesalers.

The rules

1 It is a condition of PAGB membership that companies ensure that advertising for self care medical devices which are covered by PAGB membership complies with this Code in both the letter and the spirit. Advice on the interpretation of this Code can be sought from PAGB.

Members are required to provide details of a named contact who is responsible for making sure that the member company has an appropriate procedure in place for ensuring compliance with this Code and that such process is followed.

PAGB will consider inter-member complaints.

The named contact is also responsible for ensuring that any undertakings given as a result of a breach of the Code are carried out and will be the default contact in the event of an inter-member complaint.

2 No PAGB member company shall advertise a medical device to the public unless it complies with the relevant legal requirements.

Advertising claims must not exceed the scope of the CE certification, where applicable, or the technical documentation of the medical device.

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

In order for medical devices to be placed on the market they must conform with the relevant statutory requirements, this includes safety and performance. Medicines are licensed on the basis of safety, quality and efficacy. Therefore it is not acceptable to suggest in advertising that a medical device or medicine is unsafe, of poor quality or ineffective.

4 Advertising shall not cause offence. Particular care must be taken to avoid causing offence for example on the grounds of age, disability, gender, race, religion or sexual orientation.

5 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.

6 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 average consumer.

Although it is acceptable to use less commonplace terminology and medical terms (and in some circumstance the intended use statement may include them), where advertisers have a choice, 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.

7 Advertising must be clearly distinguished from editorial matter.

This rule applies regardless of the media used. It applies as much to online media, including 'native' advertising and paid-for social media posts as to advertorials in magazines.

8 Advertising shall not cause the public unwarranted anxiety with regard to any ailment.

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

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.

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

Aiming advertising at people who already know the nature of their condition is acceptable, as is providing information in relation to specific symptoms associated with a certain condition.

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

11 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. If confusion is likely to arise, including a statement such as 'If you are unsure about your diagnosis, please speak to your doctor or pharmacist' is recommended.

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 doctor and including a statement to that effect may be necessary.

12 Care should be taken not to encourage, either directly or indirectly, the indiscriminate, unnecessary or excessive use of any medical device where such use could cause harm or mask an underlying condition.

Advertising should encourage consumers to take a responsible and cautious approach to self-treatment/care. On this basis, long term use or use once the condition has been resolved can be promoted provided it is supported by the product's technical documentation, e.g. for the treatment of atopic dermatitis. However, advertising cannot normally 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 where this would be inappropriate. The acceptability of the phrase 'stock up' will depend on the type of medical device advertised and the context of the advertisement as a whole.

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 should not suggest that the consumer can indulge in reckless behaviour or adopt an unhealthy lifestyle, provided they take a preventative treatment.

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

For the purposes of this Code, a child is someone under 16.

14 Advertising shall not show children using, or within reach of medical devices without adult supervision unless it is appropriately safe for them to do so.

The acceptability of showing a child using a medical device without supervision will depend on the type of product and the age of the child. For example, showing a teenager using an acne product or coming in from a sporting activity and applying a cooling patch without supervision might be acceptable, whereas a young child using a nasal spray would not be.

The aim of the PAGB is to encourage a responsible attitude towards self-treatment/care. Depicting an unsupervised child handling medical devices when it is not appropriate for them to do so could encourage parents to allow their child to do the same, with potentially dangerous consequences.

15 Advertising shall be true and must not mislead. It shall not contain any exaggerated claims, either direct or implied. It shall not use text, names, trademarks, pictures and figurative or other signs to mislead.

Both the claims made and the overall impression given by the advertisement must be in line with the product's intended purpose and clinical evidence. Advertisers should consider the overall consumer take-out from the advertisement.

Asterisks may be used to provide further information to qualify or clarify claims. 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, advertisers should take into account: the significance of the qualification, the positioning of the qualifying statement, the prominence of the original claim, legibility, and the content and layout of the advertisement as a whole.

16 Advertising must not mislead with regard to the device's intended purpose, safety and performance by:

16.1 ascribing functions and properties to the device which the device does not have.

16.2 creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have.

16.3 failing to inform the user of a likely risk associated with the use of the device in line with its intended purpose.

16.4 suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

17 Advertising must not mislead consumers as to the status of the device by implying it is a medicine or other consumer good.

18 Evidence must be held for all claims made. The type of evidence necessary will depend on the nature of the claim.

In addition to evidence held or submitted as part of the technical documentation and conformity assessment, advertisers must hold appropriate evidence for claims which do not relate to the device's intended purpose, safety and performance such as (but not limited to) consumer preference or sensory claims.

The CE mark demonstrates that the device is safe and fit for its intended purpose however CE certification alone will not be considered appropriate evidence for safety or performance claims.

A guarantee of safety or performance would require evidence that, when used according to its instructions, the device will work for 100% of the population.

When showing before-and-after pictures of a sufferer using a product, the visuals should reflect the evidence held as to the level of benefit that the average user could expect.

19 Testimonials must be the genuine views of the user.

Advertisers and their agents must not supply testimonials regarding their own products.

Testimonials are not appropriate substantiation for claims relating to safety, performance or intended purpose (how the device works).

Evidence must be held that a testimonial used is genuine and advertisers must hold contact details for the person (or organisation) that gave it. Care should be taken if editing a testimonial to ensure that the original meaning is not altered. Advertisers need to ensure that testimonials relate to the product as currently sold.

20 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. If only an aspect of the product, rather than the whole product is new, advertising must make clear which aspect of the product is new.

21 Advertisers may only refer to the product as having a 'herbal' element if this is in line with its classification and such references must not mislead or confuse as to the product's status.

22 When making 'natural' claims, advertising must make clear to which elements of the product the claim 'natural' refers.

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

24 Advertising shall not claim a product, or any of its attributes, is unique unless it differs significantly from others on the market.

'Unique' claims can only be used until another product becomes available that offers the same attribute.

25 When making speed or duration of action claims, advertisers must take into consideration the average consumer's perception of the therapeutic category.

For example the perception of a claim to be 'fast acting' will be different for pain relief compared to verruca relief.

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

27 Where a comparative claim is made in a context that allows a competitor to be identified, advertisers must provide information enabling the consumer to verify the claim.

Proprietary Association of Great Britain
New Penderel House
283-288 High Holborn
London WC1V 7HP

Telephone: 020 7242 8331
Email: info@pagb.co.uk

PAGB
Representing the Consumer Healthcare Industry since 1919
Then. Now. Tomorrow.