Guideline on Consumer Promotions for Over-the-Counter Medicines

(including Registered Traditional Herbal Medicines)
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1. **Introduction**

It is a condition of PAGB membership that all over-the-counter medicines advertising aimed at consumers must be submitted to PAGB for review, and PAGB approval must have been given, prior to its release into the public domain. Member companies are responsible for ensuring that all applicable legal requirements and all requirements of the relevant self-regulatory codes of practice are complied with. Whilst PAGB’s approval system in intended to assist member companies in discharging this responsibility, the responsibility remains with member companies.

Rule 54 of the PAGB Consumer Code states: ‘No member shall be involved in promotional schemes which are hazardous to the public or bring the industry into disrepute.’ This guidance document is designed to complement rule 54 of the PAGB Consumer Code and to encourage best practice and an ethical approach to the promotion of over-the-counter medicines. Sales promotions (also generally referred to as ‘consumer promotions’) encompass any initiatives intended to promote increased sales or trial of a product. Sales promotions may form part of advertising or public relations (PR) activities. They generally involve providing additional benefits, usually on a temporary basis. Examples include discount pricing, coupons, prize promotions, charity promotions, gifts with purchase, ‘two for the price of one’ etc.

There are various laws, codes and guidelines that cover competitions, free prize draws, charity promotions and the like. The regulations do not include specific provisions for medicines, and so, many of the promotional techniques which are common for other consumer goods are also lawful for over-the-counter medicines. However, the fact that a promotion is not prohibited by legislation does not necessarily mean that it is ethical, or in the best interests of consumers. PAGB’s experience indicates that government, regulators and health professionals take the view that promotional methods which encourage people to buy medicines that are not currently needed, or to buy multiple packs of medicines are undesirable. The concern is that promotions which encourage stockpiling of medicines within the home increase the risk of accidents or misuse.

When planning any promotional activity, it is necessary to consider which types of promotion are appropriate for a particular medicine. Used to best advantage, sales promotions are an effective method of encouraging compliance with a treatment schedule. Promotions that encourage good compliance for some medicines may not be appropriate for others. For example, medicines such as NRT products, emollients, some weight loss aids and some hair loss treatments require long term use and careful adherence to a treatment schedule. Promotions that encourage repeat purchases in line with the treatment schedule are likely to be appropriate for these products. Other medicines are indicated for occasional use only, and in these cases promotions which encourage repeat purchase are unlikely to be in the consumer’s best interest.

This document should be read in conjunction with section 8 of the UK Codes of Non-Broadcast Advertising, Sales Promotion and Direct Marketing (the CAP Code). The CAP Code is available from [http://www.cap.org.uk/The-Codes/CAP-Code.aspx](http://www.cap.org.uk/The-Codes/CAP-Code.aspx). Marketing authorisation holders who promote products containing codeine or dihydrocodeine should also refer to ‘PAGB’s Best Practice Guideline on the Advertising and Promotion of Over-the-Counter Medicines containing Codeine and Dihydrocodeine’. Advertisers are also reminded that although the PAGB Medicines Advertising Codes do not cover public relations, these activities do fall under Part 14 of the Human Medicines Regulations 2012 and, therefore must comply with the legal requirements. All sales promotions,
whether in advertising or PR, must comply with the CAP Code and all applicable regulatory requirements.

1.1 Preapproval

Promotions will be considered on a case by case basis. Companies must provide a rationale for their proposed promotion – price reduction, volumes in a volume promotion etc. – see later.

2. Legal and Self-Regulatory Requirements

PAGB members are responsible for ensuring that all of their advertising and promotional activities comply with the relevant legal and self-regulatory requirements. The legislation covering promotions includes:

- Gambling Act 2005 for Great Britain
- Betting, Gaming, Lotteries and Amusements (Northern Ireland) Order, 1985 as amended (currently under review)

It is a condition of PAGB membership that all over-the-counter medicines advertising aimed at consumers must be submitted to PAGB for review, and PAGB approval must have been given prior to its release into the public domain. Promotions are judged under rule 54 of the Consumer Code which prohibits members from being involved in promotional schemes that are hazardous to the public or that bring the industry into disrepute.

Members must also ensure that they do not breach other applicable codes of practice. The Committee of Advertising Practice is the industry body responsible for writing and enforcing ‘The UK Code of Non-Broadcast Advertising, Sales Promotion and Direct Marketing’, otherwise known as the ‘CAP Code’. The CAP Code is available from www.cap.org.uk and includes a dedicated section on sales promotions. Members should familiarise themselves with this Code. Further guidance can be found at www.copyadvice.co.uk CAP also has a free advice service which may be accessed by phone: 020 7492 2100 or at http://www.copyadvice.org.uk/Ad-Advice/Bespoke-Copy-Advice.aspx.

CAP’s Broadcast Committee is contracted by the broadcast regulator, Ofcom, to write and enforce the code of practice that governs television and radio advertising, the ‘The UK Code of Broadcast Advertising’ (BCAP Code). This code is also available from www.cap.org.uk. Pre-broadcast clearance is usually required for TV advertising (from Clearcast) and radio advertising (from RACC).

Members must take particular care when advertising or promoting medicines which are subject to possible abuse or misuse. For example particular thought should be given to promotions involving analgesic products and a full justification for the promotion must be provided.

2.1.1 Pharmacists and Pharmacies
Pharmacists, pharmacy owners and superintendent pharmacists must comply with the General Pharmaceutical Council’s Standards of Conduct, Ethics and Performance which include:

- Being honest and trustworthy
- Making patients your first concern
- Using your professional judgement in the interests of patients and the public
- Complying with all legal obligations and relevant self-regulatory codes of practice.

Please refer to the GPhC website for details: www.pharmacyregulation.org

In addition, the Royal Pharmaceutical Society (RPS) publishes guidance on advertising pharmacy services and medication. The guidance advises that advertising materials should:

- Comply with relevant legislation
- Be decent and not bring the profession into disrepute
- Be trustworthy and not abuse the trust or exploit the lack of knowledge of the public
- Be presented in a manner that does not undermine the service of other pharmacies or pharmacy professionals
- Not promote inappropriate or excessive consumption or use of medicines, or promote their misuse, injudicious or unsafe use which may be injurious to health
- Not seek to persuade patients to obtain medicines that are not needed, or quantities substantially in excess of those needed.

Pharmacists are required to use their professional judgement for multiple purchase pack promotions, considering associated factors including the clinical condition, pack size, likely period of treatment, abuse potential and risks of supply.

When in doubt, companies are advised to consult the RPS Support Service via the online form available at www.rpharms.com/support/, by e-mail support@rpharms.com or telephone on 0845 257 2570.

Companies are required to submit all consumer promotions to PAGB for preapproval and are required to provide a rationale for their proposed promotion – including for example the size of a price reduction, the volumes in a volume promotion, the value of a prize, etc.

2.1.2 Further Information

Further information on promotions can be obtained from: the Institute of Sales Promotion web site: www.isp.org.uk and from the Committee of Advertising Practice: www.cap.org.uk.

3. Price Promotions

Price promotions include money-off coupons, vouchers, loyalty cards and discount pricing.

In general, it is acceptable to run price discounts, as a general rule of no more than 50%,
to issue money-off vouchers and to provide loyalty card points which can be given on, and redeemed against, medicines. Promotions will be considered on a case by case basis and a full justification for each promotion must be submitted.

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<th>Good Practice on Price Promotions</th>
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<td>• Money off should not be excessive</td>
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<td>• The proposed amount must be justified</td>
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<td>• Promotions must be long enough to avoid encouraging over-purchasing unrequired medicines.</td>
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The amount of money off should not be excessive, particularly for medicines with known safety issues.

Where a discount is offered, the duration of the promotion (or the expiry date for the money-off voucher) should be long enough to avoid encouraging consumers to purchase medicines likely to be surplus to their current or foreseeable requirements.

The acceptability of a particular price promotion will depend on the nature of the product, the size of the discount and the duration of the promotion and must be fully justified in the submission. Price promotions should not encourage consumers to purchase medicines that are not currently needed, or to purchase greater quantities than are likely to be needed. Special care should be taken when running price promotions on medicines which may give rise to safety concerns, if purchased for the intention of storage within the home for future use. For example, a 20 pence reduction on a cold and flu product is unlikely to result in consumers purchasing a medicine they do not currently need. However, a significantly larger price reduction could result in consumers stocking up on a product for future use, thus potentially increasing the risk of accidents or misuse.

The likelihood of consumers buying medicines they do not currently need is compounded if the price promotion is only valid for a short period.

It is acceptable to offer loyalty card points on medicines, but members are advised to remind retailers that offering a large number of points for products with particular safety issues is likely to lead to criticism. The number of points, and particularly, the duration of the promotion should also be considered.

The use of coupons, vouchers etc. must not result in a medicine being supplied to the general public free of charge. The Regulations prohibit marketing authorisation holders and commercial undertakings including retailers and third parties acting on behalf of these persons, or with their consent, from providing free samples of medicines to consumers.

**4. Promotions Involving Gifts**

Advertisers may offer non-medicinal items to consumers as gifts. The gift may, or may not, be dependent on the purchase of a medicine.

**4.1 Gifts-with-Purchase**

If members wish to offer a gift-with-purchase, the gift should be relevant to the product
and of lower value to the consumer than the cost of the medicine. This is to avoid consumers purchasing medicines they do not need, in order to obtain a desirable gift. Members should take into account both the actual cost (the amount paid for the gift) and the perceived value (the price at which consumers could purchase a similar item). Promotional materials should promote the product’s medicinal benefits, and not the gift, as the main reason for purchasing the medicine.

**Good Practice on Gifts-with-Purchase: key points**

- The gift should be of sufficiently lower value than the price of the medicine (both the actual and perceived value) so not to encourage purchase of the medicine to get the gift
- The gift should be related to the use of the medicine
- Consumers should not be required to purchase multiple medicines in order to obtain the gift; the gift should not be attractive to children, nor be likely to result in the consumer needing to use more of the medicine.

PAGB recommends that gifts-with-purchase are related to the therapeutic category of the medicine. Examples include a thermometer with a children’s analgesic product; an insect repellent with a bite cream or plasters with an antiseptic cream. PAGB discourages the use of particularly desirable items such as a CD or cinema ticket, as these items may lead to consumers purchasing medicines they do not need, in order to obtain the gift. Gifts should not be particularly attractive to children, dangerous to the recipient, nor be likely to result in the recipient needing to use the medicine.

Members should be aware of likely criticism if consumers are required to purchase more than one medicine in order to obtain a gift. In particular, it would not be desirable for consumers to be required to purchase multiple packs of the same medicine in order to obtain a gift. The acceptability of such promotions will depend on the particular medicines involved and whether those medicines are indicated for prolonged use.

Promotions involving gifts will be reviewed on a case by case basis and a full justification for each promotion must be submitted.

### 4.2 Promotional Aids

Promotional aids are gifts that have a purpose other than to promote a medicine and which display a product/brand name as a reminder. They are usually free give-aways that do not depend on the purchase of a medicine. Examples include T-shirts, pens, mugs, coasters, note pads and mouse mats. Promotional aids that merely state the product name or a reasonable abbreviation thereof and a trade mark protection are not required to include the consumer essential information (please refer to rule 57 of the PAGB Consumer Code). The umbrella brand name may be used as an alternative to the product name. For example, a pen simply stating ‘Brand X’ or the full product name does not need to include any additional information. However, if the pen displays a claim (including a visual representation of a claim), then the product name, indication, ‘Always read the label’, and the single active ingredient (if applicable), must be added. If the product name includes a medicinal claim e.g. ‘Brand X Pain Reliever’, then simply stating the name does not necessitate the inclusion of the essential information.
4.3 Reader offers

A reader offer is usually conducted through consumer magazines with a gift being made available to the first x number of readers to write in. Reader offers are generally not regarded as advertising because the pharmaceutical company does not have editorial control over the content. Where the publication controls the promotion and the text there is no requirement to submit copy to PAGB for approval. If the PAGB member controls the text and/or the gift, then those materials over which the member company has control must be submitted to PAGB for pre-publication approval.

Gifts should not be dangerous to the recipient, attractive to children, nor be likely to result in a need to use the medicine. Members are reminded that it is not acceptable to offer free medicines as part of the reader offer as the law prohibits the offer of samples of medicines to consumers.

Some reader offers require proof of purchase in order for the customer to obtain the item on offer. Companies should be aware that requiring purchase of more than one medicine for eligibility to receive a reader offer would be undesirable and may attract criticism. Please refer to section 4.1 on gifts-with-purchase.

Care should be taken to ensure that reader offers do not look like competitions. Gifts which consumers may qualify for should not be described as prizes.

4.4 Self-Liquidating Offers

A self-liquidating offer is a scheme where an item, such as a hot water bottle, is offered at a special price, below that at which it is generally available. It is a goodwill gesture on behalf of the company or brand. Such a scheme can be linked to the purchase of a medicine, although the actual and perceived value of the discount should not be greater than the cost of the medicine. This is to avoid consumers purchasing medicines they do not need, in order to obtain a reduced price on another item. The item on which the offer is made should not be attractive to children, dangerous to the recipient, nor likely to result in a need to use the medicine. Ideally, the item should be related to the use of the medicine.

5. Promotions with Prizes

Promotions with prizes include competitions, prize draws, instant win offers and premium-payment promotions.

Members are advised to take legal advice before embarking on promotions with prizes in order to ensure that they do not amount to unlawful lotteries. Please refer to the Gambling Act 2005 in Great Britain or the Betting, Gaming Lotteries and Amusements (Northern Ireland) Order, 1985 (as amended) in Northern Ireland. (The Northern Ireland legislation is currently under review.)

5.1 Free Prize Draws (including Instant Win Promotions)

A ‘prize draw’ is a promotion in which prizes are allocated by chance (or, for a draw with more than one stage, initially by chance) and no payment is required to participate. In traditional prize draws, the winner is chosen at random from all valid entries. Other free
prize draws include bingo-type random number cards, matching or collecting cards, predetermined winning number or coupon-linked free draws.

‘Instant win promotions’ are a type of prize draw in which winners must receive their winnings immediately, or know immediately what they have won and how to claim without delay, cost or administrative barriers. Please refer to rule 8.25 of the CAP Code for further details.

5.1.1 Key Characteristics of Free Prize Draws

The main characteristics are as follows:

- Winners are randomly selected. Prizes must either be allocated by a verifiably random computer process or under the supervision of an independent observer
- A free prize draw must not require payment to participate (see guidance below)
- A free prize draw does not require an element of skill. (If they wish, companies may require participants to answer questions, before being entered into a prize draw.)
- Appropriate terms and conditions must be included. Please see section 5.3
- The prize must conform to PAGB’s guidelines on prizes. Please see section 5.4.

Payment to Participate

It is not permissible to require payment to participate in a free prize draw. Prize promotions which require payment to participate, and in which prizes are allocated wholly on chance (or, for a draw with more than one stage, initially on chance) are lotteries (Gambling Act, 2005). Lotteries are generally illegal unless they have been licensed by the Gambling Commission.

‘Payment to participate’ includes:

- A requirement to call or text a premium rate phone number (where an entry route requires payment, a free entry route must also be available. The free entry route must be made clear to participants)
- A requirement to purchase a product/service at an increased price (requiring purchase of a medicine is not considered to be ethical for prize promotions involving medicines)
- A requirement to purchase a product/service where the composition of that product or service is reduced during the promotion
- A requirement to pay more than the ‘normal rate’ for delivery of the prize.

‘Payment to participate’ excludes:

- Expenses incurred at the normal rate such as sending an email, sending a letter by ordinary first or second-class post, making a telephone call or sending a text at the standard rate
- A requirement to purchase a product/service at the regular price as long as the composition of that product or service has not been reduced during the promotion (requiring purchase of a medicine is not considered to be ethical for prize promotions involving medicines)
- A requirement to pay the ‘normal rate’ for delivery of the prize.
Requirements for Northern Ireland

The Gambling Act does not apply to Northern Ireland. Prize promotions are subject to the Betting, Gaming, Lotteries and Amusements (Northern Ireland) Order, 1985 (as amended). Chance-based prize promotions, such as free prize draws, are unlawful in Northern Ireland if participants are required to pay for a product or service in order to enter, even if the payment for the product or service is at its normal price. Advertisers are required to offer a no-purchase necessary entry route for chance-based promotions in Northern Ireland.

5.2 Competitions

A ‘competition’ is a prize promotion in which prizes are allocated on the basis of skill, and for which a requirement for payment to participate is acceptable (see guidance below).

5.2.1 Key Characteristics of Competitions

The main characteristics of prize draws are as follows:

- Entrants are required to exercise skill or judgment, or to display knowledge such that it can reasonably be expected to prevent a ‘significant proportion’ of people from participating or from receiving a prize (there is no requirement for the questions used to be health or product related).
- Prize promotions which require payment to participate, and only require a minimal amount of skill, are likely to be considered to be illegal lotteries (there is no case law, as yet, to demonstrate the level of skill that would be acceptable. However, a non-obvious multiple choice question together with a tie breaker is likely to be sufficient).
- Prize-promotions which do not require proof of purchase but do require a minimal amount of skill should be referred to as prize draws.
- Appropriate terms and conditions must be included. Please see section 5.3.
- The prize must conform to PAGB’s guidelines on prizes. Please see section 5.4.

Payment to Participate

It is permissible to require payment to participate in a skill-based competition. Payment to participate may include a requirement to text or call a premium rate number, or to pay more than the standard postage/delivery costs. Please refer to section 5.1.1 for details. (Requiring purchase of a medicine is not considered to be ethical for prize promotions involving medicines).

Judges

Rule 8.26 of the CAP Code gives the following guidance on judges:

‘If the selection of winning entries is open to subjective interpretation, an independent judge, or a panel that includes at least one member who is demonstrably independent, especially from the competition’s promoters and intermediaries and from the pool of entrants, from which the eventual winner is picked, must be appointed. Those appointed to act as judges should be competent to judge the competition and their full names must be made available on request.’
5.3 Terms and Conditions for Promotions with Prizes

Rule 8.23 of the CAP Code states:

‘Promoters must avoid complex rules and only exceptionally supplement conditions of entry with extra rules. If extra rules cannot be avoided, promoters must tell participants how to obtain them; the rules must contain nothing that could reasonably have influenced consumers against buying or participating.’

The following list summarises the significant terms and conditions which must be communicated to participants at or before the time of entry (if a purchase is required, the terms and conditions must be provided prior to purchase):

- Details of how to participate including any payment / proof of purchase requirements
- Any free-entry route must be explained clearly and prominently
- Start date, if applicable
- Closing date
- Number and nature of prizes (if the exact number cannot be predetermined, a reasonable estimate)
- Whether a cash alternative can be substituted for any prize
- How and when winners will be notified of the results
- How and when the names and counties of winners will be announced or made available (where applicable the winning entries must also be made available)
- For competitions, the criteria for judging entries
- Whether appropriate, who owns the copyright of the entries
- Whether and how entries will be returned by promoters
- Any intention to use winners in post-event publicity
- Any restrictions on the number of entries
- Promoter’s name and address
- Any entry restrictions including geographical and personal restrictions (all prize promotions associated with medicinal products must state that only persons aged 16 years or over can enter).

In addition, the following also applies:

- Prize winners should receive their prize no more than 30 days after the promotion has ended, unless otherwise stated
- Participants must be able to retain the terms and conditions or easily access them throughout the promotion.

Marketing communications that include, advertise or make reference to a promotion should include the following information:

- How to participate
- Number and nature of prizes
- Start date and closing date
- Any proof of purchase/payment requirements
- Any entry restrictions including the minimum age for medicines promotions
- Promoter’s name and address.
Rule 8.18 of the CAP Code states:

‘Marketing communications that include a promotion and are significantly limited by time or space must include as much information about significant conditions as practicable and must direct consumers clearly to an easily-accessible alternative source where all the significant conditions of the promotion are prominently stated. Participants should be able to retain those conditions or easily access them throughout the promotion.’

Where an advertisement is very small, such as a banner ad that merely refers to a prize promotion and states ‘click here for details,’ or similar, PAGB advises that one click should take the consumer through to a webpage on which the terms and conditions are clearly stated, or from which they are clearly and easily accessible.

Members should also refer to Section 8 of the CAP Code and to the CAP Help Note on ‘Promotions with Prizes’.

5.4 Prizes

Good Practice on Prize Promotions involving Medicines:

- It is not ethical to require consumers to purchase a medicine in order to enter a prize promotion
- The terms and conditions must exclude persons under 16 years of age
- The maximum permitted value for the prize is £1500 per person. The full terms and conditions must be communicated to participants at or before the time of entry (please refer to section 5.3)
- Advertising materials that are significantly limited by time or space must include as much information about significant conditions as practicable and must direct consumers clearly to an easily-accessible alternative source where all the significant conditions of the promotion are prominently stated
- Members should refer to Section 8 of the CAP Code and to the CAP Help Note on ‘Promotions with Prizes’. PAGB members are required to comply with the following rules on prizes:
  - The maximum permitted prize value is £1500 per person. Members should take into account both the actual cost (they amount paid for the prize) and the perceived value (the price at which consumers could purchase the prize item themselves)
  - Where the prize consists of a holiday or a week-end away, companies may offer a prize value of £1500 per person. For example a week-end away for two could have a value of up to £3000, and a holiday for four could have a value up to £6000. (£6000 is the maximum permitted value for such promotions.
  - Prize promotions will be assessed on a case by case basis and a full justification for each promotion must be submitted
  - Prizes should not be dangerous to the recipient, nor be likely to result in the recipient needing to use the medicine. For example, it would not be acceptable for an indigestion remedy to offer vouchers for a high fat, spicy meal. Similarly, a headache remedy would not be permitted to offer a bottle of champagne as a prize. Offering tickets to a beer festival as a prize would not be acceptable for any medicine
  - Prizes should not be particularly attractive to children. For example, it would not be acceptable for a children’s medicine to offer a teddy as a prize.
However, PAGB has approved store vouchers as prizes as these tend to be used by the parent.

- Prizes which feature a product name, such as a dressing gown are not required to include the essential information for consumer advertising (see rule 57 of the PAGB Consumer Code), as long as no direct or implied claims are made.
- Medicines cannot be offered as part of the prize as the law prohibits the offer of free samples of medicines to consumers.

### 5.5 Sponsoring Competitions and Awards Run by Third Parties

Members may sponsor competitions run by a third party, such as a magazine or charity. PAGB will approve the involvement of the brand provided that the prizes are neither dangerous to the recipient nor likely to result in a need to use the medicine. Please also refer to rule 56 of the PAGB Consumer Code.

Such co-promotions must abide by the following:

- The competition details must make clear the nature of the sponsorship, such as ‘Magazine Y’s competition sponsored by Brand X’ or ‘Charity Y’s competition sponsored by Brand X.’
- Where the competition or award being sponsored is connected with material of an educational, self-help, or disease awareness nature, the material must give a clear and concise indication of the involvement of the company/brand sponsoring that competition or award. Please refer to rule 56 of the PAGB Consumer Code for further details.
- Advertising copy relating to the medicinal product should be in a separate box on the page and must be clearly identified as an ‘advertisement’ or words to that effect.
- All copy must be sent to PAGB for approval. However, it is recognised that the company is not paying directly for the space and may not have final editorial control over the competition. Members are reminded that although the PAGB Medicines Advertising Codes do not cover materials over which members do not have editorial control, these materials do fall under the Part 14 of the Medicines for Human Use Regulations, 2012.

### 6. Volume Sales Promotions

Volume sales promotions include offers such as ‘two for the price of one’. Consumers must still have the choice of buying a single product. However, members should bear in mind that there are important ethical and safety concerns associated with this type of promotion. The following points should be borne in mind when considering such promotions:

- Does the product contain ingredients which have the potential for accidental poisoning or misuse?
- Is the product intended for occasional or short term use only?
- Does the pack or patient information leaflet state that the consumer should consult a health professional if the condition is not resolved within a certain period?
- Are there any statutory or voluntary limitations on the amount permitted for sale to an individual consumer?
PAGB’s experience indicates that government and health professionals take the view that promotional methods which encourage people to buy multiple packs of medicines which have known safety issues are undesirable. Their concern is that people will use more and that stockpiling medicines in homes can lead to accidents.

Companies are required to justify why a consumer could reasonably expect to require the amount of the medicine(s) offered within the promotion. Most over-the-counter medicines are subject to pack size restrictions. These restrictions assist consumers in purchasing an appropriate amount for the duration of a condition or illness. Purchase of greater quantities could encourage people to self-medicate for longer, thus putting off a necessary visit to the doctor or pharmacist.

Volume promotions are more suitable for products which need to be used on a medium to long term basis, have few safety issues and are unlikely to be misused. Examples include emollients, some allergy products, licensed folic acid products, topical hair loss products and nicotine replacement therapy.

MHRA has stated that volume sales promotions are not acceptable for any oral medicines containing analgesic ingredients. Please refer to MHRA’s ‘Best Practice on the Sale of Medicines for Pain Relief’ which can be found at http://www.mhra.gov.uk/home/groups/pl-p/documents/websiteresources/con065560.pdf

Members are reminded that the guidance above is the same regardless of whether a product is classified as a P or GSL medicine.

Good Practice on Volume Sales Promotions
- The product should be intended for medium to long term use
- The product(s) should not contain ingredients which have the potential for misuse or accidental poisoning.

7 Linked Promotions on Medicines

Linked promotions include offers such as ‘Buy Brand X and get Brand Y for free’ or ‘Buy Brand X and get 50 pence off of Brand Y’. The linked items may include only medicines, or both medicines and non-medicines.

7.1 Linked Promotions Involving Medicines Only

Linked promotions of medicines include offers such as ‘buy one and get another medicine cheaper/free’. Members should also refer to the guidance given for volume sales promotions in section 6.

Good Practice on Linked Promotions Involving Medicines Only
- The medicines included in linked promotion should be complementary i.e. there is a benefit in using them together
- The promotion should not require consumers to purchase more than two medicinal products
The following points should be borne in mind:

- Medicines included in linked promotions should be complementary i.e. there is a benefit in using them together. Examples include: a day time cough medicine together with a night time cough medicine from the same brand, an internal and external thrush treatment, an athlete’s foot cream and an athlete’s foot spray to go into the shoe, a decongestant rub for colds together with a sore throat lozenge.
- Linked promotions should not encourage consumers to purchase multiple medicines for the same indication (unless the products are intended to be used together). Such promotions may encourage the excessive use or storage of medicines within the home.
- PAGB requires that linked promotions are limited to the purchase of two medicinal products.
- Linked promotions must not be used where there is a safety reason as to why the products should not be taken together.
- Depending on the therapeutic category, PAGB advises caution where a linked promotion is likely to encourage consumers to swap between products, rather than following a particular treatment course.

7.2 Linked Promotions Involving Medicines and Non-Medicines

Linked promotions of medicines with non-medicines include offers such as ‘buy one and get a non-medicinal item cheaper/free’. When running linked promotions, the following points should be considered:

- The free item (or the price reduction on the discounted item) should be of lower value to the consumer than the price of the medicine. This is to avoid consumers purchasing medicines they do not need, in order to obtain a desirable gift, or price reduction on another item. Members should take into account both the actual cost (the amount the company paid for the linked item) and the perceived value (the price at which consumers could purchase a similar item).
- The linked items should be related to the intended use of the medicine. Examples include: a bottle of water with an oral analgesic, tissues with a cold product or a heat patch with an oral pain reliever.
- The promotion should be organised such that consumers who purchase the medicine, are then offered the free or discounted non-medicinal item. It would not be acceptable to run a promotion in which the consumer is required to purchase a non-medicine and then receives a medicine as a gift consumers should not normally be required to purchase more than one medicine in order to benefit from the promotion. Please refer to section 4.1 on gifts-with-purchase.

Good Practice on Linked Promotions Involving Medicines and Non-Medicines

- The free item (or the price reduction on the discounted item) should be of lower value that the price of the medicine.
- The linked item should be related to the intended use of the medicine.
- Consumers should not be required to purchase more than one medicine in order to benefit from the promotion.
- Consumers should be required to purchase the medicine and the non-medicine is added as the free or discounted item. The following would not be acceptable ‘Buy X non-medicine and receive Y medicine for free’.
8. Charity Promotions

This guidance below should be read in conjunction with rules 8.33-8.34 of the CAP Code.

The following rules apply to charity promotions on both medicines and non-medicines:

- The advertiser must have a written agreement with the charity before it can solicit money on the charity’s behalf
- Advertising materials must state the name of the charity that will benefit
- If it is not a registered charity, the nature and objectives of the charity must be clearly defined
- Advertising materials must specify what amount will be gained by the charity and on what basis the contribution will be calculated e.g. ‘For each pack sold we will give 20 pence to Oxfam’. If there is more than one charity benefitting from the appeal, the materials should make clear the proportions in which each charity is to benefit
- If asked, the company should make available to the consumer a current or final total of contributions made.

Please refer to the CAP Code for rules on contributions to charities and how this information is communicated in advertising.

The following guidance relates specifically to charity promotions relating to over-the-counter medicines:

- The donation should be a low amount in relation to the price of the medicine. More generous contributions may encourage consumers to purchase medicines they do not currently need, in order to benefit a charity
- Charity promotions should be run for a medium to long duration. Running a charity promotion for a short period may encourage consumers to stock-up on a medicine whilst the promotion is running, rather than to wait until they need the product
- The charity chosen must not imply health professional endorsement, and must not be likely to confuse consumers as to the product indication. For example, it would not be advisable for an analgesic to run a promotion with an arthritis charity unless the analgesic is indicated for the relief of arthritic pain
- The choice of charity must not be likely to result in the consumer purchasing unnecessary amounts of a medicine, perhaps for emotive reasons. For example, it would not be appropriate to state ‘For each pack of Brand X sold, a lifesaving vitamin supplement will be donated to a child in country X.’ However, ‘For each pack of Brand X sold, a vitamin supplement will be donated to a child in country X’ is more likely to be acceptable, provided the promise made in the statement can and will be fulfilled.

Good Practice on Charity Promotions

- The donation should be of a low value relative to the cost of the medicine
- The promotion should be of a medium to long duration
- The choice of charity must not confuse consumers as to the product indication, and should not use emotive means to increase sales
- Members must ensure they comply with section 8 of the CAP Code.
9. **Offering Free Samples of Medicines to Consumers**

It is not acceptable to provide free samples of medicines to consumers. This applies even where the consumer solicits the sample.

Part 14 of the Human Medicines Regulations 2012 prohibits marketing authorisation holders, agents acting on behalf of marketing authorisation holders or any person in the course of a business consisting (wholly or partly) of manufacturing, selling or supplying medicines to the public from supplying medicines for promotional purposes. Please refer to rule 55 of the PAGB Medicines Advertising Codes (Consumer Code).

10. **Sponsorship**

Please refer to rule 56 of the PAGB Consumer Code for information on brand and corporate sponsorship.

Guidance on sponsoring competitions and awards run by third parties can be found in section 5.5 of this guideline.

11. **Packaging Promotions**

11.1 **Unacceptable Packaging Promotions**

The Medicines for Human Use Regulations, 2012 prohibit the inclusion in medicines’ packaging and labelling of ‘any element of a promotional nature’. It follows that the following schemes are not acceptable:

- Banding medicines together (unless the banded packs are specifically authorised by MHRA)
- The addition of in-pack or on-pack discount vouchers or advertising for other products
- Charity sponsorship logos on-pack (see section 8)
- Instant win packs (see section 5.1).

11.2 **Acceptable Pack Promotions**

The following packaging promotions are acceptable:

- Licensed combination packs/banded offers of medicines

  This is where a medicine is bound to another medicine, or where more than one medicine is included within the same carton. In such cases, the whole combination pack must be licensed by MHRA.

  MHRA has approved combination packs of over-the-counter medicines, where there is a particular benefit in using more than one product. Combination packs are/have been available for conditions such as athlete’s foot, thrush and nicotine replacement therapy.
• Licensed combination packs including medicines and non-medicines

This is where a non-medicinal item is included within the same carton as a medicine. In such cases, the whole combination pack must be licensed by MHRA t.

MHRA has approved non-medicinal items being included within medicine packs where the non-medicine is used in conjunction with the medicine. Examples include a measuring syringe for a children’s liquid medicine and a teething ring for use with a teething gel.

• Banded packs of medicines with non-medicines

This is where a medicine is bound to a non-medicine. The addition of the banded item to the already-authorised pack does not need to be submitted to MHRA for assessment. Members considering the addition of a banded, non-medicinal gift should bear the following in mind:

- The banded gift must not obscure the mandatory information on the medicine carton
- The procedure to band the gift to the medicine must take place within the authorised, regulated supply chain.

Members are advised to follow the guidance on gifts-with-purchase which can be found in section 4.1 of this document and to contact PAGB for advice and approval.

The following are not valid on pack promotions:

• Extra value packs

Companies may offer extra value packs, where this is appropriate for the particular product. The new pack size must be licensed by MHRA. For example, if a product is licenced as a 50g tube and the company wishes to provide 20% extra free, the Marketing Authorisation would need to be varied to add a new 60g pack. However, on-pack claims such as ‘20% extra free’ are considered to be promotional and are, therefore, prohibited. However, these claims could be made in advertising and point-of-sale materials – e.g. 60g pack for the price of a 50g pack.

• Low cost trial packs

It is acceptable to offer low cost trial packs, where this is appropriate for the particular product. Any new pack sizes must be licensed by MHRA.

On-pack claims such as ‘low cost trial pack’ would be considered to be promotional and are, therefore, prohibited. However, these claims could be made in advertising and point-of-sale materials.

11.3 Further Information

PAGB’s ‘Code of Practice for Pack Design for OTC Medicines’ has been developed to encourage best practice in medicines labelling and to provide practical advice to manufactures. The Code can be accessed at www.pagb.co.uk.