



PAGB's Best Practice Guideline on the Advertising and Promotion of Over-the-Counter Medicines containing Codeine and Dihydrocodeine

Introduction

In July 2009, the Committee on Human Medicines (CHM) undertook a review of abuse and misuse of OTC analgesics containing codeine or dihydrocodeine. The CHM has recommended a package of measures to minimize the risk of overuse and addiction. These measures involve changes to pack sizes, indications, patient information leaflets, labelling, advertising and promotional activities.

Summaries of Product Characteristics for codeine and dihydrocodeine-containing analgesics will state that the products are indicated for the short term treatment of acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone. This statement will be followed by a list of permitted conditions e.g. toothache, period pain and migraine. The Summaries of Product Characteristics will be amended to remove colds, flu, cough, sore throat and fever indications as well as references to the treatment or relief of mild, mild to moderate or strong pain.

Products containing codeine/dihydrocodeine are unlike most other OTC products in that they are indicated for second line use and have specific warnings to minimise the risks associated with the use of these products. Advertising should take special care to promote the rational use of the products by presenting the information objectively without exaggerating the benefits.

This guideline deals with MHRA's requirements for the advertising of codeine and dihydrocodeine-containing analgesics. All advertisements must make it clear that the product is intended for the short term treatment of acute moderate pain and must comply with the requirements set out below.

Advertising to Consumers

- Advertisements must include a clear statement that the product can be addictive and that it must not be used for more than three days e.g. 'Can cause addiction. For three days use only'.
- Advertising should focus on the specific conditions for which the product is indicated such as period pain, migraine pain, toothache etc.

- Advertising should not place particular emphasis on power or strength, either through words or visuals. Claims such as ‘strong/powerful pain relief’, or top parity claims such as ‘there’s nothing more powerful without prescription’ are not acceptable.
- Advertisers are not required to state that the products are indicated for the treatment of pain which is not relieved by paracetamol, ibuprofen or aspirin alone. Should advertisers wish to include such a statement, it must be presented in a factual and informative manner. Such statements are only acceptable in materials which do not imply any denigration of single-ingredient painkillers and which do not place particular emphasis on the power, strength or effectiveness of the advertised product through use of visuals, text and/or audio. Such advertisements will be looked at on a case-by-case basis.

Consumer Promotions

In line with current practice, PAGB advises its member companies that the following promotional techniques are not considered to be acceptable for products containing codeine or dihydrocodeine:

- volume sales promotions such as ‘two for the price of one’ or ‘buy one and get a second at a reduced price’ (MHRA has advised that volume sales promotions are not acceptable for any products containing analgesics)
- schemes which promote repeated purchases of a particular product such as brand loyalty schemes
- linked sales promotions such as ‘buy one and get x at a reduced price’
- gifts with purchase
- charity promotions such as ‘for each pack sold we will donate x pence to charity x’

Promotions on loyalty card points (over and above the normal points available on any purchase) and price promotions are also discouraged on the grounds of public safety. PAGB recognises that such promotions are generally retailer-led, and encourages retailers to check with their professional bodies before running such promotions on products containing codeine or dihydrocodeine.

Advertising to Persons Qualified to Prescribe or Supply

- Advertisements must include a clear statement that the product can be addictive and that it must not be used for more than three days e.g. ‘Can cause addiction. For three days use only.’
- Advertising should reflect the indications for the product as a second line treatment for the short term relief of acute moderate pain.