

QUICK FACTS

Prepared by PAGB in response to the APPG recommendations

Context

- PAGB submitted research and gave oral evidence to the inquiry and we welcome the report - the safe use of OTC medicines is of paramount concern to the industry.
- The scale of dependency linked to OTC products in the UK is not known. While virtually all researchers agree that misuse of OTC medicines is a small problem, much of the information available is anecdotal.
- Used correctly, codeine containing products are useful and effective medicines. The vast majority of people do use them correctly when they have a problem that needs strong pain relief.
- Combining codeine with paracetamol or ibuprofen produces stronger pain relief products - particularly effective for ailments such as back ache, dental pain and period pain.

Awareness campaign

- Industry supports a MHRA / DH awareness campaign which should involve pharmacists and pharmacy assistants as well as doctors.

Pack warnings

- In 2005, addiction warnings were voluntarily added to packs and patient information leaflets. All the leading brands display this information on the packs.
- PAGB is happy to discuss whether additional warnings should be added or if the existing ones can be improved.

Pack size reductions

- The majority of over-the-counter medicines containing codeine come in pack sizes containing less than 32 tablets, following a voluntary reduction in pack size in 2005. The dosage instructions say speak to a doctor if the problem goes on for over 3 days
- PAGB does not support a further reduction to 18 tablets as this is only 3 days treatment for the ibuprofen products and just over 2 days treatment for paracetamol. People will have to buy another pack just to tide them over until they get an appointment
- It will have no effect on addiction but it will inconvenience everyone

Advertising

- Industry does not support restrictions on advertising.
- Advertising is not what makes people addicted.
- Over the past year there has been very little advertising of these products – about one or two campaigns for migraine or toothache.

INFORMATION ON CODEINE

What is codeine?

Codeine is a pain reliever.

The body's natural pain relief mechanisms involve receptors within the central nervous system. When the body is recovering from an injury, substances are produced in the body that interact with these receptors to reduce pain naturally. These substances include: Endorphins and Enkephalins. These are known as physiological opioids.

Drugs like codeine, which is a medicinal opioid, also interact with these receptors, to mimic the natural pain relieving process.

Opioid medicines are split into strong and weak opioids.

Strong opioids are only available on prescription e.g. morphine, diamorphine and are used to relieve severe pain, including cancer pain and post-operative pain. Weak opioids e.g. codeine, dihydrocodeine are available over-the-counter in low dose to provide pain relief. They are also available at higher doses on prescription.

In over-the-counter medicines codeine is always combined with either paracetamol or ibuprofen.

Why are codeine and dihydrocodeine included in pain relief products along with other pain relievers?

Combining codeine with paracetamol or ibuprofen produces pain relief products which some people find more effective than simple analgesics in treating pain. Doctors prescribe codeine and paracetamol combinations to help manage the pain of arthritis

What is the difference between the codeine products you can buy OTC and those you get on prescription?

In some cases there is no difference, co-codamol tablets which doctors prescribe are available in two strengths, the lower dose products can be bought without a prescription.

What levels of codeine and dihydrocodeine are permitted in OTC products?

Codeine is available in the UK at a maximum dose of 20mg codeine monohydrate (equivalent to 25.6mg of codeine phosphate). Dihydrocodeine is available in UK at a maximum dose of 10 mg (equivalent to 7.45 mg of dihydrocodeine tartrate) A 'dose' is the total amount taken on one occasion so may consist, for example, of two tablets.

Why doesn't the industry take codeine out of the products?

Removal of the codeine component would result in products with decreased benefit for short term moderate pain of minor ailments.

Making the products prescription only or removing the codeine may drive people to their GPs for a prescription product which is wasteful of NHS resource and money.

Is the UK the only country where codeine and analgesics can be bought without prescription?

Codeine is available in the UK, Belgium, Denmark, France, Ireland, Netherlands, Japan, Singapore, Canada, New Zealand and Australia without prescription.

What is the risk of some people becoming addicted to codeine or containing medicines?

OTC products containing codeine do not lead to addiction if used according to the instructions on the pack. They should be taken only to relieve symptoms of pain and only for short periods unless a doctor has advised otherwise. The label says consult a doctor after 3 days continuous use.

In 2005 a review of OTC products containing codeine, was conducted by the regulatory body, the MHRA. The MHRA reviewed literature and adverse drug reaction (yellow card) submitted data, as well as company adverse drug reaction and sales data.

This data showed that the number of reports of misuse or abuse of OTC codeine and dihydrocodeine containing medicines is exceedingly small compared to volume of sales. The MHRA therefore concluded that there was unlikely to be a huge hidden problem relating to misuse of these medicines and that the benefits of OTC codeine medicines outweighed any potential risks.

However, any product containing codeine (including those prescribed by doctors) may induce addiction if used incorrectly over prolonged periods.

How much do you need to take to risk becoming addicted?

The exact amount or length of time will vary from person to person. It is only if the products are taken at high doses or more frequently than the recommended dose and over a long period of time that addiction may develop.

If an OTC product is taken in accordance with the instructions on the pack, there is no danger of addiction.

What are the dangers of addiction?

Any medicine taken for longer, or at higher doses, than recommended can lead to an increased risk of side effects. In the case of a combination product (one containing more than one active drug), side effects due to any of the active components may be experienced.

All products contain a leaflet explaining possible side effects and advise patients to tell their pharmacist or doctor if they experience any unusual side effects.

How many people are addicted to products containing codeine?

The scale of dependency linked to OTC codeine products in the UK is unknown. Whilst virtually all researchers agree that misuse of OTC medicines is a small problem and that the vast majority of people use products safely and responsibly, much of the information available is anecdotal.

Is the number of people addicted increasing?

There is no evidence to suggest that this is the case, although increased media coverage of addiction to OTC painkillers would indicate that awareness is increasing.

What should you do if you think you or a member of your family might be taking too much codeine based medicines?

Anyone who thinks they may be regularly taking too much of a certain medicine or are not taking it for the right reason as a painkiller should seek advice from their doctor or pharmacist.

What current controls are there in place to stop people taking too much?

Products containing codeine or dihydrocodeine are only available from pharmacies. This means that they are sold under strict protocols with the

pharmacist in a position to intervene and stop the sale of the medicine to anyone suspected of misusing the product.

In addition, all products carry instructions on the label advising on correct use.

The instructions cover:

- What the product is for
- How to use it
- When not to use it
- People are told:
 - Not to exceed the stated dose and not to take for more days than recommended on the dosage instructions
 - To consult a doctor or pharmacist if symptoms persist
 - To consult a doctor or other health professional for advice if above the recommended dose is taken accidentally.

What controls have been introduced to further minimise risk?

In 2005, to minimise further risk the MHRA made the following recommendations:

- A maximum pack size of 32 tablets for all pharmacy medicines containing codeine or dihydrocodeine
- Strengthened warnings to be put on packs of painkillers which state
 - if you need to use codeine or dihydrocodeine containing medicines for more than three days at a time, see your doctor, pharmacist or healthcare professional.
 - Taking codeine regularly for a long time can lead to addiction, which might cause you to feel restless and irritable when you stop the tablets.
 - Taking a painkiller for headaches too often or for too long can make them worse.

Why do pharmacists sell packs which are larger than 32 tablets

Because the pack size reduction is a voluntary one, larger packs can legally be sold by pharmacists. They tend to do that when they know a regular customer needs more than a few days supply.

Wouldn't it be better to make the products prescription only?

In its review, the MHRA decided that the likely prevalence of addiction was not great and the benefits of continued pharmacy supply of codeine containing medicines outweighs any potential risks.

Making the products prescription only may drive people to their GPs for a prescription product which is wasteful of NHS resource and money.

How many packs of products containing codeine are sold in the UK each year?

In 2008, there were 290 million packs of OTC analgesics sold. About 10% of these packs (27.5 million) were products containing codeine.