



PRACTISE UPDATE 03 SEPTEMBER 2009 CODEINE CONTAINING PRODUCTS

Background

Codeine containing analgesics have a potential for inducing dependency behaviour in those who take the drug inappropriately. Codeine containing OTC analgesics have been available for many years and are combined with paracetamol, aspirin or ibuprofen.

In 2005 the pharmaceutical industry entered a voluntary agreement with the MHRA to reduce the pack sizes of over the counter [OTC] medications containing codeine or dihydrocodeine [dhc] and add further warnings information provided with the product.

The indications from patient groups show that this has not been effective in reducing addiction to these products and those sales of larger pharmacy only packs are increasing.

The Commission on Human Medicines [CHM] has now strengthened its advice to minimise the risk of misuse of these products.

An advice bulletin has been produced by MHRA and is available at:

<http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON057115>

What the new measures mean

The new MHRA advice means sales of all medicines containing codeine/dihydrocodeine should:

- No longer be indicated for colds, flu, coughs and sore throats or other minor painful conditions;
- Only be indicated for use in acute moderate pain which is not relieved by paracetamol, ibuprofen or aspirin alone;
- Not be sold in effervescent formulation dispensary packs

Additionally, the Pharmaceutical Society of Northern Ireland also draws the attention of pharmacists to the following

- When marketing authorisation changes have been made to OTC packs of codeine containing products by the end of 2009, all packs containing more than 32 capsules or tablets will be reclassified from P to POM status
- Patient information leaflets [PIL] in codeine containing analgesics will be updated to:
 - reinforce the message that they are for short term use [three days] and for moderate acute pain
 - If treatment is required for more than 3 days then advice should be sought from a pharmacist or doctor
- A prominent warning will also be included on the pack and PIL of codeine containing analgesics highlighting that the product may cause addiction
- Promotion and advertising will be subject to a new code of practice for manufacturers and **retailers** reflecting the warnings and short term nature of use for these products

Professional requirements

Sales of medicines containing codeine and dihydrocodeine should:

- Only be undertaken by trained staff operating to written pharmacy procedures [SOPs] under the supervision of a pharmacist
- Be restricted to a single pack sold in any purchase
- Be assessed for potential misuse

Pharmacists should be mindful that they are uniquely positioned to intervene where addiction is suspected and they should seek to refer any such patient to appropriate help or support services.

Brendan Kerr

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