



**Royal
Pharmaceutical
Society**
of Great Britain

Law and Ethics Bulletin

Restriction on over-the-counter pack sizes of analgesics containing codeine and dihydrocodeine

Following a voluntary agreement between manufacturers and the Medicines and Healthcare products Regulatory Agency, over-the-counter (OTC) pack sizes of analgesics containing codeine and dihydrocodeine have been restricted to a maximum of 32 tablets or capsules. This applies to both effervescent and non-effervescent preparations.

The MHRA has also asked manufacturers to update the patient information on all such products to include warnings in relation to addiction and overuse headache. The new warnings state:

- If you need to use this product for more than three days at a time see your doctor, pharmacist or health care professional.
- Taking codeine/dihydrocodeine 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 pain killer for headaches too often or for too long can make them worse.

As there have been no changes in the legislation, a pharmacist may still legally supply larger OTC pack sizes of products containing codeine or dihydrocodeine until current stocks are exhausted. Pharmacists are expected to exercise their professional judgement in deciding whether or not to make such a supply and would need to be satisfied that the supply of a larger pack size was in the patient's best interest.

Where a pharmacist intends to supply a larger pack size over the counter, he or she must ensure that the pack is intended for OTC sale. Therefore, the pack should not contain words to the effect of "dispensary pack only". Pharmacists wishing to sell packs intended for OTC sale, which do not contain the new warnings (see above), are advised to verbally counsel the patient on these warnings.

Good practice currently recommends that the supply of products containing codeine or dihydrocodeine should be restricted to only one pack, of any size, per purchase.

28th March 2007