



# **NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE:**

## **Draft Guidance for Pharmacists on Safe Supply**

## BACKGROUND

The safety concerns around the misuse of non-prescription medicinal products containing codeine are well established. Consumption of quantities of these medicines in excess of the recommended dose, or over a prolonged period of time, may cause tolerance and dependence, as well as the risk of other adverse effects. Furthermore, the consumption in excessive quantities of 'combination products', i.e. those containing codeine and another analgesic such as paracetamol, aspirin or ibuprofen, also increases the risk of harm from these other substances.

Recent publications by the UK's Medicines and Healthcare products Regulatory Authority (MHRA), the Pharmaceutical Society of Northern Ireland (PSNI) and the Royal Pharmaceutical Society of Great Britain (RPSGB) have highlighted the ongoing concerns in regard to these products.

The Standards and Practice Committee of the PSI Council has developed draft guidance on the safe supply of non-prescription medicines containing codeine. This guidance aims to ensure the safe supply of these products and to assist pharmacists in discharging their professional obligations to patients seeking advice, guidance and assistance in respect of the use of these products.

The guidance includes the following key points:

- Non-prescription medicinal products containing codeine should be stored in a retail pharmacy business (pharmacy), out of the view of the public, to facilitate the legislative requirement that these products must not be accessible to the public for self-selection.
- Non-prescription 'combination' products, containing codeine and paracetamol, aspirin or ibuprofen, should be supplied only as 'second line' products for the treatment of pain relief, when single ingredient products, such as paracetamol, aspirin or ibuprofen, have not shown to be effective.
- Non-prescription medicinal products containing codeine should only be used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, no longer than three days.
- Patients need to be fully advised of the correct use of these products and the risks associated with their misuse. It is also essential that patients be facilitated in obtaining medical assistance for any health problems related to their misuse that may arise.

## CONSULTATION

This guidance document, which is printed in full below, is now released for public consultation.

Comments are welcome, in writing, to [consultation@pharmaceuticalsociety.ie](mailto:consultation@pharmaceuticalsociety.ie) or to Public Consultation, Pharmaceutical Society of Ireland, 18 Shrewsbury Road, Ballsbridge, Dublin 4.

This period of public consultation will end at 5.00pm on Friday 15 January 2010.

# **NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE:**

## **DRAFT GUIDANCE FOR PHARMACISTS ON SAFE SUPPLY**

### **INTRODUCTION**

This guidance sets out the criteria to be adhered to by pharmacists, with a view to ensuring the safe supply of non-prescription medicinal products containing codeine (hereafter called 'codeine medicines') to patients. It is intended to assist pharmacists in meeting their professional and legal responsibilities in the supply of these medicines, and to assist superintendent and supervising pharmacists in securing compliance with relevant legislative and professional obligations under the Pharmacy Act 2007, including the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008). The overall purpose of this guidance is to improve patient safety in the use of these medicines.

### **CODEINE**

Codeine phosphate is a mild to moderate analgesic and has weak cough suppressant activity. As an analgesic, it is most often used in combination with other analgesics such as paracetamol or ibuprofen and is currently authorised in Ireland in such non-prescription products for pain relief. It is also available as single ingredient non-prescription products as a cough suppressant. Codeine is regulated as a Schedule 5 controlled drug and is currently available without a prescription through retail pharmacy businesses only, for sale and supply by or under the personal supervision of a pharmacist.

Codeine products should only be used when necessary and only when a non-opioid analgesic, e.g. paracetamol aspirin or ibuprofen, have not proven sufficient to relieve symptoms. If recommended, codeine medicines should be used for the shortest time possible and no longer than 3 days without medical supervision.

Codeine is a narcotic analgesic and it is important that the recommended dose should not be exceeded in any 24-hour period. Consumption of quantities in excess of the recommended dose, or over a prolonged period of time, may cause tolerance and dependence and may result in withdrawal symptoms such as restlessness and irritability upon cessation of the medicine.<sup>1</sup> It is considered important that patients consult their doctor if a need to use codeine medicines all the time is experienced.

## LEGAL CONSIDERATIONS

### Code of Conduct for Pharmacists

The first principle of the Code of Conduct for pharmacists requires that the practice by a pharmacist of his/her profession must be directed toward maintaining and improving the health, wellbeing, care and safety of patients. Pharmacists should use their professional skills and competence, and specialised knowledge, to encourage the rational and proper use of medicines. They may be required to use their professional skills in decision-making, which may at times come into conflict with the demands of the patient.

Pharmacists, in particular superintendent and supervising pharmacists, should ensure that, in whichever areas of practice they operate, suitable controls and accountability mechanisms are in place, in order to appropriately control the supply of all medicinal products which are known to have the potential for abuse and/or dependency.

### Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008)

These Regulations set down the requirements that must be complied with by persons carrying on retail pharmacy businesses in their dealings with medicinal products.

Regulation 10 of those Regulations, in particular, sets out the role and responsibility of pharmacists in their sale and supply of non-prescription medicines. This role requires that, prior to and in the course of the sale or supply of any non-prescription medicinal product, the pharmacist must be satisfied that: -

- (a) the purchaser is aware of appropriate use of the medicinal product concerned,
- (b) the medicine is being sought for that purpose, and
- (c) in so far as the pharmacist is aware, the product is not intended for misuse and/or abuse.

Furthermore, Regulation 5(e) of those Regulations requires that any medicinal product which is a Schedule 5 controlled drug (which includes medicinal products containing codeine) must not be accessible to the public for self-selection.

### **Medicinal Products (Control of Advertising) Regulations 2007 (S.I. No. 541 of 2007)**

Regulation 10 of these Regulations, in relation to advertising directed wholly or mainly at members of the general public, provides that "A person shall not issue an advertisement in respect of any medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 (No. 12 of 1977)".

In addition, Regulation 22(2) of those Regulations provides that: "a person shall not supply a sample of a medicinal product which is a controlled drug under section 2 of the Misuse of Drugs Act 1977 or which is an antidepressant, hypnotic, sedative or tranquillizer".

As a consequence of these provisions, any form of advertising of a medicinal product that is a controlled drug, that is directed at the public is prohibited. This would include any form of window displays, in-pharmacy promotional displays, promotional leaflets and shelf stickers.

## GUIDANCE

Superintendent pharmacists must ensure that the policies in the retail pharmacy business(es) under their control adhere to this guidance and the associated legislative requirements. They and their supervising pharmacists must ensure that there are adequate procedures in place in the retail pharmacy business to ensure compliance with all of these policies.

### 1. Appropriate policies and procedures within a retail pharmacy business (pharmacy)

(a) The pharmacist should ensure that suitable controls and accountability mechanisms are in place, to govern the management of the supply and distribution of medicinal products which have the potential for abuse or dependency.

(b) A pharmacy-specific policy addressing the supply of medicines containing codeine should be developed, with specific patient consultation protocols included. All pharmacy staff should be familiar with these policies and should be trained in associated procedures.

(c) In any retail pharmacy business supplying codeine medicines, it is the responsibility of the superintendent pharmacist to ensure there is a policy in place to manage such supply. It is the responsibility of the supervising pharmacist to develop, maintain and ensure adherence to this policy and it the responsibility of each pharmacist to ensure they and their staff fully comply with its provisions.

(d) These policies and procedures should take account of the following guidance criteria:

### 2. Storage of codeine medicines in retail pharmacy businesses

(a) According to the Regulation of Retail Pharmacy Businesses Regulations 2008, any medicinal product containing codeine must not be accessible to the public for self-selection.<sup>2</sup> Therefore codeine medicines must be stored in an area of the retail pharmacy business where patients cannot self-select the product - either visually or physically. The recommended location is in the dispensary, out of sight of the public.

### **3. Supply of medicines containing codeine by a pharmacist in a retail pharmacy business**

(a) Codeine medicines are currently authorised<sup>3</sup> for the relief of pain in such conditions as rheumatic and muscular pain, migraine, headache, menstrual pain, toothache, backache and for symptoms of the common cold and influenza and the majority are available as non-prescription medicines, from retail pharmacy businesses only.

(b) The supply of codeine medicines may only be made by or under the personal supervision of a pharmacist who would be in a position to determine the appropriateness of the request for and the supply of these medicines.

(c) In each supply of a codeine medicine, the pharmacist must be satisfied that, in the exercise of his or her professional judgment, the supply of such a medicine is the most appropriate therapy available at the time and that such supply is in the best interest of the patient. It should also be taken into account that non-codeine-containing products for the same indications should be considered as first line treatments, e.g. ibuprofen, paracetamol or aspirin.<sup>4</sup>

(d) Codeine medicines should only be taken when considered necessary, for the shortest period considered necessary. Product information for combination products with ibuprofen and paracetamol recommend that duration of treatment should be for no longer than 3 days. Any requirement for more prolonged use should only be considered as requiring medical supervision.

(e) Patients should be advised of the importance of adhering to the recommended dosage and duration of use. Patients should be informed that chronic use and consumption of quantities in excess of the recommended dose, or for a prolonged period of time, may lead to tolerance, psychological and physical dependence and may result in the development of symptoms such as restlessness and irritability upon cessation of this medicine.<sup>1</sup>

(f) The risks associated with overdose and/or prolonged use should be addressed with the patient.

(g) For products which also contain paracetamol or ibuprofen the patient should be informed that these substance have the potential to be harmful in overdose quantities.

(h) If patients experience the need to use codeine medicines over a prolonged period of time (i.e. more than 3 days) for pain relief or other effect, the patient should be referred to a medical practitioner that would be able to review their symptoms and provide appropriate treatment under medical supervision.

(i) Patients should also be counselled in the course of each supply in respect of other potential adverse reactions or side effects, including nausea, constipation, dizziness and drowsiness (which may impair their ability to drive safely). They should also be counselled, as appropriate, regarding the contraindications for use, drug interactions, or existing medical conditions which may preclude the use of these medicines. The need for safe storage of these medicines should also be referred to.

#### **4. Suspected abuse and/or misuse**

(a) If a pharmacist becomes aware of a suspected abuse/misuse/addiction issue particular to a patient and directly associated with the use of codeine medicines, they should make all reasonable attempts to ensure that the patient is facilitated in accessing services which will assist in the management of that addiction. The policy and procedures documentation in the retail pharmacy business should include contact details for the national and/or local support and treatment services which are available to patients.

(b) In order to ascertain whether abuse and/or misuse is occurring, pharmacists will need to monitor or audit the sale and supply of these medicines on an ongoing basis.

#### **5. Pharmacovigilance**

(a) Any suspected adverse reaction should be reported to the Irish Medicines Board, preferably online, via the IMB website [www.imb.ie](http://www.imb.ie)

#### **6. Advertising of codeine medicines**

(a) The advertising of codeine medicines is prohibited and therefore displays of such products, or of merchandising material or promotional material relating to such products, must not occur. This includes window displays, in-pharmacy promotional displays, promotional leaflets, or shelf stickers.

#### **References:**

1. Codeine-containing analgesics. *Irish Medicines Board Drug Safety Newsletter*. Issue No. 19, June 2004.
2. Regulation 5(1)(e) of the *Regulation of Retail Pharmacy Businesses Regulations 2008* (S.I. 488 of 2008).
3. Marketing authorisations granted by the Irish Medicines Board.
4. Pharmacological management of pain in primary care (2): opioids. National Medicines Information Centre. Volume 11, Number 6, 2005.