



NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE:

Guidance for Pharmacists on Safe Supply to Patients

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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 of 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 medicinal products. This risk applies to both short and long-term use.

Recent publications have highlighted the ongoing concerns regarding these medicinal products in other jurisdictions. This includes publications by the UK's Medicines and Healthcare products Regulatory Authority (MHRA), the Pharmaceutical Society of Northern Ireland (PSNI), the Royal Pharmaceutical Society of Great Britain (RPSGB), the Therapeutic Goods Administration (TGA) in Australia and pharmacy regulatory authorities in Canada.

This guidance aims to ensure the safe supply of these medicinal products and to assist pharmacists in discharging their legal and professional obligations to patients seeking advice, guidance and assistance in respect of the use of these medicinal products. The guidance includes the following key points:

- Non-prescription 'combination' products, containing codeine and paracetamol, aspirin or ibuprofen, should be supplied only when the pharmacist is satisfied that, in the exercise of his or her professional judgement, 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. For pain relief, single ingredient medicinal products such as paracetamol, aspirin or ibuprofen, should be used first in line with pain protocols and current evidence-based practice. Codeine-containing medicinal products should be supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective.
- Every time a non-prescription medicinal product containing codeine is supplied, the patient needs to be fully advised of the correct use of the product and the risks associated with its misuse. It is also essential that patients be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.
- Non-prescription medicinal products containing codeine should only be supplied and used in accordance with the terms of their marketing authorisations, which all state that the product be used for short-term use, i.e. no longer than three days.
- According to current legislative requirements, these products should not be accessible to the public for self-selection and therefore, in a retail pharmacy business (pharmacy), non-prescription medicinal products containing codeine should be stored in an area under the direct control of the pharmacist and out of the view of the public.

NON-PRESCRIPTION MEDICINAL PRODUCTS CONTAINING CODEINE: GUIDANCE FOR PHARMACISTS ON SAFE SUPPLY TO PATIENTS

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 opioid (narcotic) analgesic and has weak cough suppressant activity.¹ Codeine, due to its potential for misuse, is a controlled drug under the Misuse of Drugs Acts 1977 and 1984. Low dose preparations are regulated as a Schedule 5 controlled drug. 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 in single ingredient, non-prescription products, as a cough suppressant. These authorised products are available without a prescription through retail pharmacy businesses only.

The Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) require that all medicines supplied through a retail pharmacy business must be supplied by or under the personal supervision of a pharmacist (regulation 5(1)(d)) and that all non-prescription medicines supplied must be the subject of appropriate counselling (regulation 10). In addition, because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine), further restrictions are imposed which require that those medicinal products would not be accessible to the public for self-selection (regulation 5(1)(e)). Therefore, self-selection of medicinal products containing controlled drugs (i.e. CD5 medicines) without the provision of appropriate supervision, professional support, advice and information by the pharmacist is not appropriate.

Codeine medicines should only be supplied when the pharmacist deems such a supply is necessary and only when a non-opioid analgesic, e.g. paracetamol aspirin or ibuprofen, has not proven sufficient to relieve the patient's symptoms. If recommended, codeine medicines should be used for the shortest time possible and for no longer than three 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 consumption 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.¹ If a patient needs to use codeine medicines for periods longer than the three days, it is considered important that they consult their doctor to investigate unresolved symptoms and the most appropriate treatment.

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)²

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

Management and supervision of a retail pharmacy business

According to the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008) the sale and supply of all medicinal products must be by or under the personal supervision of pharmacist.

Regulation 5(1)(d): the sale or supply of medicinal products, including veterinary medicinal products, and the preparation, dispensing and compounding of prescriptions, including veterinary prescriptions, at the premises, are carried out by or under the personal supervision of a registered pharmacist,

Furthermore, Regulation 5(1)(e) of those Regulations requires that any medicinal product which is a Schedule 5 controlled drug (non-prescription medicinal products containing codeine) must not be accessible to the public for self-selection.

Regulation 5(1)(e): medicinal products that are subject to prescription control under the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (S.I. No. 540 of 2003) (as amended) and medicinal products that are controlled drugs listed in Schedule 5 to the Misuse of Drugs Regulations 1988 (S.I. No. 328 of 1988) (as amended) are not accessible to the public for self-selection,

Counselling in the supply of medicinal products other than on foot of a prescription

Regulation 10 of those Regulations, in particular, sets out the role and responsibility of pharmacists in the sale and supply of non-prescription medicines.

Regulation 10: A person carrying on a retail pharmacy business, the superintendent pharmacist and the supervising pharmacist shall ensure that, in the course of the sale or supply of a medicinal product other than on foot of a prescription and prior to such sale or supply, a registered pharmacist is satisfied that the purchaser or other such person is aware of what the appropriate use of the medicinal product is and that it is being sought for that purpose and, in so far as the registered pharmacist is aware, the product is not intended for abuse and/or misuse.

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 advertisementⁱ 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 tranquilliser".

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

ⁱ 'advertising', in relation to a medicinal product, includes any form of door to door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products and including in particular—

- (a) the advertising of medicinal products to the general public;
- (b) the advertising of medicinal products to persons qualified to prescribe or supply them;
- (c) visits by medical sales representatives to persons qualified to prescribe medicinal products;
- (d) the supply of samples of medicinal products;
- (e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in kind;
- (f) the sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products; and
- (g) the sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith; and cognate words shall be construed accordingly;

GUIDANCE

1. Supply of medicines containing codeine by a pharmacist from a retail pharmacy business

(a) Codeine medicines are currently authorised for the relief of pain in conditions such 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.³

(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. In addition, because of the particular characteristics of those medicines containing controlled drugs (i.e. codeine), further restrictions are imposed which require that those products would not be accessible to the public for self-selection.

(c) Every time a codeine medicine is supplied the pharmacist must be satisfied that, in the exercise of his or her professional judgement, the supply of such a medicine is the most appropriate treatment 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 medicinal products for the same indications should be considered as first-line treatments, e.g. ibuprofen, paracetamol or aspirin.⁴

(d) The pharmacist is often the first point of contact for a patient and therefore has an important role to discharge in the correct management of pain. This includes providing appropriate advice or medication, recognising the need for referral for further medical investigation and the need for vigilance in relation to the presentation of patients with medication overuse headache and chronic daily headache.

(e) Codeine medicines should only be taken when the pharmacist considers it necessary and for the shortest period considered necessary. Combination products with ibuprofen and paracetamol recommend that the duration of treatment should be for no longer than three days. Any requirement for more prolonged use should only be considered under medical supervision.

(f) 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.¹

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

(h) For products which also contain paracetamol or ibuprofen, the patient should be informed that these medicines have the potential to be harmful in overdose quantities or if used for a prolonged period of time.

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

(j) 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 addressed with patients.

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

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(es) to ensure compliance with all of these policies.

(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 is 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 current legislative requirements and the guidance criteria included in this document.

3. Management and supervision of the accessibility of codeine medicines (CD5 medicines) in retail pharmacy businesses

(a) According to the Regulation of Retail Pharmacy Businesses Regulations 2008 (S.I. No. 488 of 2008), any medicinal product containing a prescription-only medicine or a CD5 medicine must not be accessible to the public for self-selection.² Therefore codeine medicines must be in an area of the retail pharmacy business under the pharmacist's direct management and supervision, out of the sight of the public. The recommended location is in the dispensary unless, for justifiable reasons, e.g. a shortage of storage space, an alternative out-of-sight location within the pharmacy is used. This area must be close to the dispensary and therefore under the pharmacist's direct supervision.

4. Suspected abuse and/or misuse

(a) If a pharmacist becomes aware of a suspected abuse/misuse/addiction issue regarding a specific patient and directly associated with the use of codeine medicines, they should make all reasonable attempts to ensure that the patient is facilitated and encouraged in accessing services which will assist in the management of that addiction. The patient should be referred in the first instance to their general practitioner or an addiction outreach worker, if available in the area. Further information on the available services can be obtained from the HSE website, www.hse.ie.

(b) 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.

(c) 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. The management of any data or information recorded, collected or retained as part of this monitoring or audit should be in accordance with relevant legislative provisions, including those of the Data Protection Acts 1988 and 2003.

5. Pharmacovigilance

(a) As with all medicines, any suspected adverse reaction should be reported to the Irish Medicines Board (IMB), preferably online, via the IMB website www.imb.ie

6. Advertising of codeine medicines

(a) The advertising of codeine medicines is prohibited. This would include any form of window displays, in-pharmacy promotions and promotional displays, promotional leaflets and shelf stickers.

References:

1. Codeine-containing analgesics. *Irish Medicines Board Drug Safety Newsletter*. Issue No. 19, June 2004.
2. *The Regulation of Retail Pharmacy Businesses Regulations 2008* (S.I. No. 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.