



**Submission by the Irish Pharmacy Union to the  
Pharmaceutical Society of Ireland on  
Draft Guidance for Pharmacists on Safe Supply of  
Non-Prescription Medicinal Products Containing Codeine**

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# **IPU Submission to the PSI on Draft Guidance for Pharmacists on Safe Supply of Non-Prescription Medicinal Products Containing Codeine**

## **1. Introduction**

The Irish Pharmacy Union (IPU) is the representative and professional body for community pharmacists. Its mission is to promote the professional and economic interests of its members. Members of the Union aim to provide the best possible professional pharmacy service to all members of the public. They are committed to delivering a quality, accessible, personal and professional service that puts the patient first and has as its primary goal the optimisation of the health and well-being of society. Pharmacists are accountable for their professional conduct and strive to maintain the confidence and respect of their patients, customers, the State and other professionals in the healthcare field.

The Union welcomes the opportunity to make a submission to the Pharmaceutical Society of Ireland (PSI) on its draft guidance for pharmacists on the safe supply of non-prescription medicinal products containing codeine.

## **2. Pharmacy Policy on Codeine Supply**

The Union agrees that a pharmacy policy addressing the supply of medicines containing codeine should be in place. Over the past few years, the IPU has produced a number of Medicines Sales Protocols, designed to assist pharmacists and their staff in the appropriate sales of non-prescription medicines to the public. Indeed, in early December 2009, the IPU and the Irish Pharmaceutical Healthcare Association (IPHA) jointly produced a protocol to assist pharmacists in the sale of medicines containing codeine. This protocol was sent to all members of the Union and can be downloaded from the IPU website. A copy of the protocol is attached to this submission and the PSI is welcome to send it to all pharmacists on the PSI register.

## **3. Storage of Codeine Medicines**

The Union agrees with the draft guidance that any medicinal product containing codeine must not be accessible to the public for self selection and that codeine medicines must be stored in an area of the retail pharmacy business where patients cannot self-select the product. The Union believes that this area would be behind the counter. This would ensure that all sales of codeine medicines would

be under the supervision of the pharmacist, as recommended by the IPU/IPHA Codeine Sales Protocol. This is also in line with the guidelines from the Royal Pharmaceutical Society of Great Britain (RPSGB), following their consultation in March 2007, in which they highlighted that *'restrictions should not preclude methods of display which allow patients to better view pharmacy medicines'*. It is not practical to store codeine medicines in the dispensary. It is equally important that they should be placed in the patient environment, i.e. behind the counter, to facilitate patient choice, supported by the advice and supervision of the pharmacist, according to the Codeine Sales Protocol.

#### **4. Supply of Codeine Medicines**

The Union agrees with the draft guidance that the appropriateness for the supply of codeine medicines should be determined before each sale and that the duration of treatment should be no longer than 3 days. The IPU spearheaded a public awareness initiative, in conjunction with other organisations, in August 2007 highlighting the safe use of pain relievers and the problems associated with their overuse or abuse. In particular, people were advised to speak to their pharmacist on the appropriate use of codeine. The campaign recommended that people always follow the instructions which accompany the medicines and not use them for longer than stated on the pack, unless advised to do so by their doctor. The campaign highlighted that taking medicines which contain codeine for longer than instructed or misusing them can lead to physical and psychological dependence. The leaflets distributed during the campaign gave information on how and when to use products containing paracetamol, aspirin, ibuprofen and codeine. Posters in the pharmacy encouraged people to ask their pharmacist about pain relief. Pharmacists were provided with a Medicines Sales Protocol to use for all OTC sales. Local pharmacists around the country gave local media interviews. The Union would welcome the opportunity to run such a campaign again in association with the PSI.

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

The Union supports the proposal that patients should be facilitated in accessing services which will assist in the management of codeine addiction. Indeed, in September 2005, the IPU, in partnership with the Health Promotion Unit of the Department of Health and Children, ran a Drugs Awareness Campaign. Posters in pharmacies encouraged patients to ask their pharmacist about drugs misuse and abuse and leaflets gave details of how to access services. The Union would welcome the opportunity to run such a campaign again in association with the PSI.

The Union does not believe that an audit or monitor of the sale and supply of codeine medicines is necessary as, if pharmacists comply with the Codeine Sales Protocol, any issues of abuse/misuse will be addressed.

## **6. Pharmacovigilance**

The Union regularly reminds members to ensure that any suspected adverse reactions should be reported to the Irish Medicines Board via their online reporting system and will continue to do so.

## **7. Advertising of Codeine Medicines**

The Union agrees that advertising of codeine medicines should be prohibited.

## **8. Conclusion**

In conclusion, the Union welcomes the intent of the draft guidance from the PSI on the safe supply of non-prescription medicinal products containing codeine. The Union accepts that it is desirable that medicines containing codeine should not be available for self selection by the public. However, it is not necessary to locate the medicines in the dispensary in order to achieve the objectives of the guidance nor is it practical from a pharmacist's perspective in relation to the efficient workflow in a pharmacy or from the patient's perspective in relation to choice of medicines. The Union looks forward to working with the PSI on the production of final guidance to incorporate the issues addressed in this submission.

The Union is available to meet with the PSI to discuss the issues raised above or indeed any other relevant issues.

## **PROTOCOL FOR THE SALE OF CODEINE-CONTAINING MEDICINES**

This protocol is in line with the requirements of the Pharmacy Act 2007 (20 of 2007), Section 2 of the Misuse of Drugs Act 1977 (12 of 1977), Medicinal Products (Control of Advertising) Regulations 2007 (541 of 2007).

### **Sale and Supply**

- THE SALE OF CODEINE-CONTAINING PRODUCTS MUST BE UNDER THE SUPERVISION OF THE PHARMACIST
- The customer should be interviewed to ascertain if a codeine-containing product is suitable for the condition they are seeking treatment

### **Precautions & Warnings**

- OTC codeine-containing analgesics are for short term use only and should not be taken for longer than 3 days, unless advised by a doctor
- Prolonged regular use, except under medical supervision, may lead to physical and psychological dependence (addiction)
- Pharmacists should advise the customer that it is important to follow the dosage instructions on pack and not to exceed the stated dose
- Codeine-containing products should not be taken while breast-feeding unless under the supervision of a doctor

### **Undesirable effects**

- Frequent use of pain-relievers for persistent headaches may make them worse. If you believe that a customer may be suffering from Medicine Overuse Headache, offer advice and information leaflets. If it persists, recommend they see a doctor.
- Codeine can cause constipation, nausea, dizziness and drowsiness according to dosage and individual susceptibility

### **Identifying potential for misuse or abuse**

- Frequent request for the same product by the same person
- Unusual requests from new customers in times of short supply
- Customer's behaviour and/or state
- Customer refusal to purchase an alternative product
- Irritation by customer about pharmacy staff intervention
- Customer wants to purchase large quantities of a product
- Customer gives the excuse that they are buying the product for someone else
- Product asked for by name or customer has a detailed knowledge of the product
- Headache present for more than 15 days per month

### **What to do if Abuse / Misuse is Suspected**

- Politely but firmly inform the patient that you cannot recommend any codeine-containing medicine for them and suggest they talk to their doctor.
- If you suspect that the customer is abusing codeine containing products, alert other pharmacies in the area, explaining your observations including a description of the person.
- Be prepared to offer advice to customers and have useful numbers and information leaflets to hand
- Offer alternative products, treatments or advice to people seeking codeine-containing products, where you believe a codeine-containing product to be inappropriate
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