

1) Audit title

Van Hout, MC. (2014) A Pharmacy Process Audit of compliance to the Pharmaceutical Society of Ireland (PSI) guidelines for safe supply of non-prescription codeine containing products, and audit of training of pharmacy staff in how to comply with these guidelines. CODEMISUSED Project European Commission 7th Framework Programme, EU. Brussels.

2) Introduction

The audit topic centres on pharmacy compliance of the PSI guidelines for safe supply of codeine (I-IV). The PSI guidance states;

I • 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.

II • 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.

III • 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.

IV • 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.

3) Rationale

The rationale for the audit is as follows;

1) Professional concern

A variation in professional practice across different pharmacies has been noted (i.e. delivery of patient information around safe use of codeine, adherence to medical advice and labelling, awareness of dependence and harm, pharmacist decisions or refusal to supply the product, counter staff awareness of the PSI guidelines for safe supply of non prescription codeine. An increase in the number of reported

adverse events has been reported (for example customers reporting medication overuse headache associated with codeine withdrawal, and customer requests for over the counter codeine for symptoms, whilst unaware of actual withdrawal)

2) High risk procedures/situations

The issue of over the counter codeine misuse, both therapeutic and non-therapeutic is an area where pharmacy risk management requires focus. The cost of `getting it wrong` has major consequences for the patient (pharmacy risk management, impact of co-prescribing and use of over the counter codeine)

3) Financial considerations

Given the focus on retail conflicting with customer care, not all pharmacies employ the same level of stringency and customer care.

4) Practical considerations

The audit aims to measure practice compliance against national regulatory standards for safe supply. The audit is two-fold, auditing for compliance of standards and training audit of pharmacists and pharmaceutical assistants. Improvements included compliance, patient/customer care and evaluation of PSI guidelines in operation.

4) The audit aim and objectives

The aim of the audit is ensure correct pharmacist compliance in adhering to the PSI guidelines I-IV for safe supply of codeine, so that public awareness of correct use of codeine and safe supply of non-prescription medicinal products containing codeine occurs in Irish pharmacies. The objectives are as follows;

1. To improve pharmacy practice with regard to supply of non-prescription medicinal products containing codeine occurs according to the PSI guidelines for safe supply of codeine (standards I-IV).
2. To raise awareness among pharmacy staff (pharmacists, technicians, over the counter assistants) that according to the PSI standard I, non-prescription medicinal products containing codeine can only be supplied 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.
3. To raise awareness among pharmacy staff (pharmacists, counter assistants) that according to the PSI standard II, 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.

4. To raise awareness among pharmacy staff (pharmacists, counter assistants) that according to the PSI standard III, 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.

5. To raise awareness among pharmacy staff (pharmacists, counter assistants) that according to the PSI standard IV, codeine 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.

6. To improve public awareness of safe use of codeine products, in terms of medical guidelines for safe use, potential for dependence and risk of adverse health consequences if misused¹.

5) The type of audit

The audit is a process audit and has two components, the compliance to the PSI guidelines for safe supply of non-prescription codeine containing products (A), and the training of pharmacy staff in how to comply with these guidelines (B).

6) The audit team

The audit team consists of the Audit Facilitator responsible for running the audits and providing the training (Part B), expert consultation with the PSI, and administration support (data input and administration support).

7) The standard statement

Audit Standard A: All customers requesting non-prescription codeine containing products will be consulted, advised and supplied the product according to the PSI Guidelines (I-IV).

Audit Standard B: Staff will score 70% of above following training in how to supply non-prescription codeine containing products according to the PSI Guidelines (I-IV).

8) Evidence base

¹ Casati et al (2012) define 'misuse' of codeine as:

'The problematic consumption of codeine where risks and adverse consequences outweigh the benefits, and which includes use of codeine with or without prescription, outside of acceptable medical practice or guidelines, for recreational reasons, when self-medicating, with higher doses and for longer than advisable.'

The PSI guidelines for safe supply of codeine state that;

- I. 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 products should be supplied as '*second line*' products for the treatment of pain relief, when the above products have not shown to be effective.
- II. Every time a non-prescription codeine containing product 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.
- III. Non-prescription codeine containing products 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.
- IV. 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.

9) The sample

Part A: A process audit of pharmacy compliance in the safe supply of non-prescription codeine containing products according to the PSI guidelines (I-IV)

All pharmacies registered in Ireland (total 1836 (<http://public.thepsi.ie/>)) will be advised that during one calendar month, a test shopper may visit their site, and request to purchase codeine using various scenarios in their pharmacies. These test shoppers will complete the data collection sheet to audit compliance. A stratified random sampling of every 10th pharmacy in each county will be audited by a test shopper requesting to purchase over the counter codeine. Test shoppers will present with a variety of scenarios to request codeine and inclusive of legitimate requests, inappropriate use, requesting codeine products by name, suspected misuse for intoxication purposes, suspected misuse for therapeutic purposes, suspected misuse for opiate withdrawals, suspected pharmacy hopping, lack of patient awareness of other forms of pain management and lack of patient awareness of codeine related harm.

Part B: A process audit of increase in knowledge around the safe supply of non-prescription codeine containing products according to the PSI guidelines (I-IV)

after training.

A stratified randomised listing of pharmacists (5280) and pharmaceutical assistants (452) registered in Ireland (male/female/county) will partake in 1 day training provided by the Audit Facilitator and requested to complete the data collection sheet to assess knowledge of the PSI guidelines at Time 1 before training, and Time 2 after training. Stratification will occur via job type (pharmacist/pharmaceutical assistant), gender and county, with every 10th case per subgroup sampled.

9) Data collection

The audit instruments will be piloted with a group of pharmacists (n=10) not partaking in the audit.

10) Ethical considerations

All pharmacists and pharmaceutical assistants (prior to randomisation) will be provided with an information sheet outlining the purpose of the audit, will provide written consent to partake in the audit and be assured complete anonymity, that neither they nor their pharmacy be identified in the final report. Data will be stored on a password protected computer and only accessed by the author. Dissemination of the findings will be approved by the Lead Audit Facilitator and the PSI prior to release.

11) Dissemination of findings

The findings will be collated and presented in a report. Findings will be presented to a group of pharmacists to see if they are surprised or dispute findings. It is envisaged that two journal publications will present data relating to Part A and B respectively.

12) Timetable

| Month | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 |
|---------|--|--------------------|--------------------|------------------|----------------------|----------------------|--------------|------------------|----------------------|
| | Planning. Design and piloting of instruments Circular Email advising of the audit Sampling frame finalised. | | | | | | | | |
| Audit A | Recruitment and training of test shoppers | Audit Test Shopper | Audit Test Shopper | Analysis of data | | | | | Report Dissemination |
| Audit B | | | | Audit Time 1 | Delivery of Training | Delivery of Training | Audit Time 2 | Analysis Of data | Report Dissemination |

13) Resources required

Administration support, travel and subsistence for logistics.

Part A: A process audit of pharmacy compliance in the safe supply of codeine according to the Pharmaceutical Society of Ireland guidelines (I-IV)

| Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the PSI Guidelines (I-IV) for safe supply of codeine. | | | | | |
|---|---------------|-----------------------------|--------------------|---|--|
| Criteria | Target | Allowable exceptions | Definitions | Evidence base * | Location |
| <p>Criterion 1)</p> <p>Codeine is only supplied 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 product is only supplied as ‘second line’ products for the treatment of pain relief, when the above products have not shown to be effective.</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | In the test customer’s record sheet for each pharmacy. |
| <p>Criterion 2)</p> <p>Every time a non-prescription medicinal product containing codeine is supplied, all patients are fully advised of the correct use of the product and the risks associated with its misuse.</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | In the test customer’s record sheet for each pharmacy. |
| <p>Criterion 3)</p> <p>Every time a non-prescription medicinal product containing codeine is supplied, all patients are facilitated and encouraged to obtain medical</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of | In the test customer’s record sheet for each pharmacy. |

| | | | | | |
|--|------|-------|-----|---|--|
| assistance for any health problems related to their misuse that may arise. | | | | codeine. | |
| Criterion 4) Non-prescription medicinal products containing codeine shall 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. | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | In the test customer's record sheet for each pharmacy. |
| Criterion 5) 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. | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | In the test customer's record sheet for each pharmacy. |

Data Collection Sheet

Standard A: All customers requesting non-prescription medicinal products containing codeine will be consulted, advised and supplied the product according to the PSI Guidelines (I-IV) for safe supply of codeine.

Test Shopper Scenario

Legitimate use

Inappropriate use

Requesting codeine products by name

Suspected misuse for intoxication purposes

| Suspected misuse for therapeutic purposes | | | | | |
|---|---|---|----|----|--|
| Suspected misuse for opiate withdrawals | | | | | |
| Suspected pharmacy hopping | | | | | |
| Lack of patient awareness of other forms of pain management | | | | | |
| Lack of patient awareness of codeine related harm | | | | | |
| Criteria | | | | | Comments (these are for the data collector to add notes on each criterion if they think clarification is required) |
| Criterion 1) The patient is only supplied codeine 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 product is only supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective. | Y | N | DK | NA | |
| Criterion 2) Every time a non-prescription medicinal product containing codeine is supplied the patient is fully advised of the correct use of the product and the risks associated with its misuse. | Y | N | DK | NA | |
| Criterion 3) Every time a non-prescription medicinal product containing codeine is supplied, the patient is facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may | Y | N | DK | NA | |

| | | | | | |
|---|---|---|----|----|--|
| arise. | | | | | |
| Criterion 4) Non-prescription medicinal products containing codeine is only supplied and to be 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. | Y | N | DK | NA | |
| Criterion 5) According to current legislative requirements, the product is not accessible to the public for self-selection and therefore, in a retail pharmacy business (pharmacy), non-prescription medicinal products containing codeine are stored in an area under the direct control of the pharmacist and out of the view of the public. | Y | N | DK | NA | |
| Criterion 6) Patient is refused to supply. | | | | | |

Part B: A process audit of increase in knowledge around the safe supply of codeine according to the Pharmaceutical Society of Ireland guidelines for safe supply of codeine (I-IV) after training.

Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the PSI Guidelines (I-IV) for safe supply of codeine.

| Criteria | Target | Allowable exceptions | Definitions | Evidence base * | Location |
|--|--------|----------------------|-------------|---|--|
| <p>Criterion 1)</p> <p>Accurately describe when non-prescription medicinal products is the most appropriate therapy available at the time, supply is in the best interest of the patient and can be supplied to the patient. Refer to a) 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. Refer to b) Codeine-containing medicinal product is only supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective.</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | End of test sheets at time One and Two |
| <p>Criterion 2)</p> <p>Accurately describe when a non-prescription medicinal product containing codeine is supplied, the advice provided to patients of the correct use of the product and the risks associated with its misuse.</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | End of test sheets at time One and Two |
| <p>Criterion 3)</p> <p>Accurately describe when a non-prescription medicinal product containing codeine is supplied, how patients will be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | End of test sheets at time One and Two |
| <p>Criterion 4)</p> | 100% | None. | N/A | Pharmaceutical Society of Ireland | End of test sheets at time |

| | | | | | |
|---|------|-------|-----|---|--|
| Accurately describe that non-prescription medicinal products containing codeine shall 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. | | | | Guidelines (I-IV) for safe supply of codeine. | One and Two |
| Criterion 5) Accurately describe that 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. | 100% | None. | N/A | Pharmaceutical Society of Ireland Guidelines (I-IV) for safe supply of codeine. | End of test sheets at time One and Two |

Data Collection Sheet

| Standard B: Staff will score 70% of above following training in how to supply non-prescription medicinal products containing codeine according to the PSI Guidelines (I-IV) for safe supply of codeine. | | | | | |
|--|---|---|-----------|---|--|
| Criteria | | | | Comments (these are for the data collector to add notes on each criterion if they think clarification is required) | |
| Criterion 1) Accurately describe when non-prescription medicinal products is the most appropriate therapy available at the time, supply is in the best interest of the patient and can be supplied to the patient. Refer to a) 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. Refer to b) Codeine-containing medicinal | Y | N | No answer | | |

| | | | | |
|--|---|---|----|--|
| product is only supplied as 'second line' products for the treatment of pain relief, when the above products have not shown to be effective. | | | | |
| Criterion 2) Accurately describe when a non-prescription medicinal product containing codeine is supplied, the advice provided to patients of the correct use of the product and the risks associated with its misuse. | Y | N | DK | |
| Criterion 3) Accurately describe when a non-prescription medicinal product containing codeine is supplied, how patients will be facilitated and encouraged to obtain medical assistance for any health problems related to their misuse that may arise.. | Y | N | DK | |
| Criterion 4) Accurately describe that non-prescription medicinal products containing codeine shall 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. | Y | N | DK | |
| Criterion 5) Accurately describe that 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 | Y | N | DK | |

| | | | | |
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| in an area under the direct control of the pharmacist and out of the view of the public. | | | | |
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