



Medicines & Healthcare products  
Regulatory Agency

## **Public Consultation on proposal to make Codeine linctus and Codeine Oral Solutions available as a prescription only medicine (POM)**

The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency responsible for regulating medicines and medical devices. We continually review the safety of medicines and vaccines in the UK and inform healthcare professionals and the public of the latest updates through several means, including public reclassification reports. Suspected side-effects to any drug or vaccine can be reported to MHRA by both healthcare professionals and members of the public via the Yellow Card Scheme at <http://www.mhra.gov.uk/yellowcard> or search for MHRA Yellow Card in the Google Play or Apple app store.

**Ref: ARM 103**

## Consultation description

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Codeine linctus and codeine oral solutions are used in the treatment of dry cough, in adults and children over 12 years of age without difficulties in breathing.

The full names of these medicines are provided in the proposal document, and all codeine oral solutions will be referred to as “Codeine linctus” throughout the remainder of this consultation.

Codeine linctus is currently available under the supervision of a pharmacist without prescription. Codeine is an opioid medicine, therefore there is the potential risk of addiction. The [Commission on Human Medicines](#) (CHM), the governments independent expert scientific advisory body, have previously considered this possibility and concluded that the potential risk of addiction was manageable through warnings in the product information and restriction on sales and advertising.

Recent safety information has revealed use of Codeine linctus in the UK is an ingredient of a recreational drink. This carries a risk of overdose which can be fatal. The MHRA have also received reports of criminal activity in association with the diversion of Codeine linctus which is then used for the production of the recreational drinks. In addition, over the past 10 years, the number of fatalities from Codeine only medicines have also risen.

This consultation concerns whether Codeine in an oral solution should be available as a Pharmacy (P) medicine (at present) or as a prescription Only medicine (POM). This consultation is being made available in England, Wales, Scotland, and Northern Ireland. The proposed changes would apply throughout the United Kingdom.

The CHM has advised that this product could be made available as a POM medicine and are keen to hear your views to inform their final decision. Once you have read through the information below, we want to know what you think about this proposed change.

**Please use [this form](#) to tell us your views.**

The consultation is open for **4 weeks from 18 July, 2023 to 15 August, 2023.**

**Reference:** ARM 103

**Contact:** [mhracustomerservice@mhra.gov.uk](mailto:mhracustomerservice@mhra.gov.uk)

### **You will find the following documents below:**

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- A summary of the proposed change and the background
- A link to form for your response

If you have any questions about this consultation, please send an email to [mhracustomerservices@mhra.gov.uk](mailto:mhracustomerservices@mhra.gov.uk)

# Proposal to make Codeine linctus available by prescription only

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1. Background about deciding where medicines are available
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## Product details

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**Active substance:** Codeine in an oral solution

Product names	Licence holders	Marketing Authorisation numbers
Codeine Linctus BP	LCM Limited	PL 12965/0009
	Pinewood Laboratories Limited	PL 04917/0001
Bells Healthcare Codeine Linctus 15mg/5ml Oral Solution	Bell Sons & Company (Druggists) Limited	PL 03105/0063
Care Codeine 15mg/5ml Oral Solution Sugar Free, Galcodine Linctus	Thornton & Ross Limited	PL 00240/0099
Pulmo Bailly	Dendron Brands Limited	PL 52731/0008

**Route of sale/supply:** Current: from pharmacies; (P). Proposed: prescription (POM)

**Indication:** For the relief of an unproductive dry or painful cough in adults and children aged 12 – 18 years without compromised respiratory function.

# 1. Background on deciding where medicines are available

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## The role of MHRA

MHRA regulates medicines and medical devices in the UK, on behalf of the UK Licensing Authority. As part of the licensing procedure, MHRA decides whether medicines are available:

- on prescription only - 'prescription only medicine' (POM)
- bought from behind the counter at pharmacies under the supervision of a pharmacist - 'pharmacy medicine' (P)
- bought from other shops - 'general sales list medicine' (GSL)

## What is reclassification of a medicine?

Making a change on how a medicine is available is called 'reclassification'. This is sometimes referred to as 'switching'. To decide on this change, MHRA may:

- take advice from its committees of external experts
- take advice from a group ('stakeholder group') of health professionals and representatives of people affected by the classification change
- run a public consultation.

When a medicine is reclassified, it is usual for reclassification from POM to P to occur in the first instance, and once some experience is gained with the product in the pharmacy (P) setting, further reclassification from P to GSL may occur. In some cases, a medicine may be reclassified directly from POM to GSL, where it meets the necessary requirements, and it is safe to do so. To be reclassified directly from POM to GSL, a medicine must meet both the requirements of POM to P and P to GSL reclassification.

If a significant safety issue arises from use of a P medicine, then a medicine may be reclassified from P to POM to protect public health.

To be reclassified from P to POM a medicine must meet at least one of the criteria set out in the Human Medicines Regulations 2012, regulation 62(3):

- *It is likely to present a direct or indirect danger to human health, even when used correctly, if used without medical supervision; or*
- *It is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; or*
- *It contains substances or preparations of substances of which the activity requires, or the side effects require, further investigation; or*
- *is normally prescribed by a doctor for parenteral administration (that is, by injection).*

In addition, we must take into account whether, if correctly used, the product is likely:

- to present a substantial risk of medicine abuse
- to lead to addiction, or
- to be used for illegal purposes.

## What evidence is needed?

This evidence needs to focus on the risk to the public and this includes evidence on the possible abuse or misuse of the medicine.

The evidence may also include:

- clinical studies
- evidence showing acceptable level of side effects

- advice of experts
- views of relevant health professionals and their professional bodies
- views of relevant public associations and individuals with an interest in the medicine under consideration.

### **Who makes the final decision?**

The final decision on whether to approve a change is made by the MHRA, on behalf of the UK Licensing Authority.

## **2. About Codeine linctus**

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This consultation relates specifically to the proposal to reclassify Codeine linctus and codeine oral solutions from pharmacy to a prescription only medicine. All codeine oral solutions will be referred to as “Codeine linctus” throughout the remainder of this consultation.

Codeine linctus is used for the treatment of dry or unproductive cough. Coughs can occur as a symptom of colds and flu and are usually self-limiting. This means that they will get better by themselves without further treatment. Many other cough medicines which do not contain codeine, such as honey and lemon mixtures and cough sweets are equally effective at helping a patient with short-term dry cough. The National Institute for Health and Care excellence (NICE) consider that codeine should not be used for short-term cough.

A pharmacist is able to advise patients of alternative self-care treatments.

However, patients with persistent cough lasting longer than 8 weeks, may benefit from the treatment with Codeine linctus. If a patient has persistent cough, they are usually examined by a doctor to try to diagnose why this is happening and the doctor can advise on appropriate treatment. Therefore, a change in availability from pharmacy to prescription is unlikely to have a significant impact on healthcare practice.

Codeine can be used to suppress coughing and reduce the number of times a person will cough although is unlikely to eliminate it altogether.

Codeine is an opioid and will breakdown in the body to form morphine. The effectiveness of codeine to suppress cough depends on the ability of the individual to breakdown codeine into morphine, which is thought to provide the main activity. As an opioid, it is an addictive medicine, therefore patients should only take it for short periods of time.

Codeine linctus is currently available without prescription under the supervision of a pharmacist (P).

### **What is in Codeine linctus?**

Codeine linctus is an oral solution containing either 15mg/5ml codeine or 7mg/5 ml codeine.

### **What is Codeine linctus used for?**

Codeine linctus has a number of indications, including:

- Recommended as an anti-tussive (cough-suppressant) for a non-productive cough by oral administration.
- Codeine is indicated in adults for relief of the symptoms of dry or irritating coughs.
- Codeine is indicated in adults for the relief of an unproductive dry cough.
- Codeine linctus is indicated for a dry or painful cough.

Overall, Codeine linctus is indicated for the treatment of dry and painful cough in adults and adolescents aged 12 – 18 years without breathing problems.

The CHM has advised that the proposal to reclassify on safety grounds could be granted.

This consultation outlines the background to this decision.

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### **3. Proposal to make Codeine linctus available as a Prescription Only (POM) medicine**

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#### **Who has made the proposal?**

The MHRA made the proposal to reclassify Codeine linctus to prescription only status.

#### **What is the view of the Commission on Human Medicines?**

The CHM has advised that Codeine linctus should only be available by prescription, otherwise known as a Prescription Only Medicine (POM) due to concerns over addiction and diversion of supply. Views were also obtained from stakeholders across government in England and devolved countries, and professional bodies on the proposal and on risk minimisation measures. The views were summarised and provided for CHM when they considered the proposal. The proposed changes would apply throughout the United Kingdom.

#### **Proposed terms of reclassification**

##### **What are the details of this change?**

As a result of a review of the safety of codeine linctus and the risk of addiction through recreational use and increasing reports of diversion, the CHM considered that Codeine linctus should be controlled by prescription.

### **4. How was the proposal assessed for Codeine Linctus being available as a Prescription Only medicine?**

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A medicine will be non-prescription unless it fulfils the criteria for prescription control (POM criteria) as set out below. POM status is required if any of the following criterion apply:

1. A direct or indirect danger exists to human health, even when used correctly, if used without medical supervision.
2. There is frequently incorrect use which could lead to direct or indirect danger to human health.
3. Further investigation of activity and/or side-effects is required.
4. The product is normally prescribed for parenteral administration (by injection).

In the UK, these criteria are laid down in the Human Medicines Regulations 2012, regulation 62(3)<sup>1</sup>.

The MHRA, advised by the CHM, therefore considered lack of evidence of the benefit of treatment in short-term cough, and evidence of the risks associated with the misuse and abuse of codeine linctus.

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<sup>1</sup> <sup>4</sup> The Human Medicines Regulations 2012. <http://www.legislation.gov.uk/uksi/2012/1916/contents/made>

The assessment of the proposal against each POM criteria is provided below.

#### **4.1 POM Criterion 1 – *The product is likely to present a direct or indirect danger to human health, even when used correctly, if used without medical supervision***

The main criterion that must be considered in the classification of Codeine linctus as a pharmacy status, is that it does not present a direct or indirect danger to human health if used, even correctly, without the supervision of a doctor. A direct danger may be present if the product causes adverse reactions that are important because of their seriousness, severity, or frequency.

A danger may also be present if the reaction is one for which there is no suitable preventative action such as being able to identify the group of patients who are at risk if they use the product without medical supervision so that they can be excluded from using the pharmacy product. Direct danger may arise from drug interactions with commonly used medicines. For the product to be suitable for pharmacy status the drug interactions would need to be preventable.

##### **4.1.1 Direct danger to human health**

###### **Adverse reactions**

Codeine was first discovered in the 1800s and is a prodrug of morphine. This means that codeine breaks down in the body to form morphine, which is considered to provide the beneficial effects of the medicine. Patient exposure to Codeine linctus has been extensive since originally authorised. It is a well-established product for which the safety profile is well known.

Post-marketing reports of adverse events with codeine are in keeping with those listed in the Summary of Product Characteristics (SmPC). The SmPC is a legal document that is the basis of information for healthcare professionals on how to use a medicine.

Many adverse events reported for Codeine linctus reflect the method of action of this medicine and are common to all drugs known as opioids. Adverse events (side effects) include constipation and associated disorders of the gut; dry mouth; psychiatric disorders such as euphoria, dysphoria (unhappiness), confusion; nervous system disorders such as dizziness, seizures, addiction, dependence, sleep disturbances; heart disorders; muscle rigidity; urinary retention, decreased libido, and skin or sensitivity disorders such as skin rashes, hives, itching and sweating.

Adverse events associated with Codeine linctus as a pharmacy medicine are currently managed through the product information (SmPC, PIL and label).

###### **Drug interactions**

The classes of medicines which have potential to interact with codeine are stated in the SmPC for Codeine linctus. Corresponding detailed information is provided for the patient in the PIL and the label (outer carton) advises the patient to speak to the pharmacist if they are taking any other medicines. Pharmacy training materials could provide comprehensive information concerning drug interactions with codeine.

###### **Medicines metabolised by the same/similar route to codeine**

Codeine is metabolised (broken down by the body) by an enzyme in the liver known as CYP 2D6. Taking medicines that enhance the activity of this enzyme (e.g., rifampicin) at the same time as codeine can reduce blood levels of codeine, although raise blood levels of morphine, and potential side effects. Similarly, medicines that inhibit the activity of this enzyme, prevent metabolism, although will not remove potential for side effects from codeine (e.g., cimetidine).



All drug interactions with Codeine linctus are currently managed through the product information. However, not all product information is consistent.

#### 4.1.2 Indirect danger to human health

The potential for indirect danger occurring from non-prescription use of a medicine arises mainly from the use of the medicine without medical supervision in groups of patients that are not suitable. In these circumstances, danger can arise from mistaken diagnosis, or exclusions that are deliberately or inadvertently not heeded.

The following potential indirect dangers have been identified for pharmacy supply of Codeine Linctus:

##### **Intentional misuse – risk of non-prescription ‘off-label’ use (use outside the terms of the marketing authorisation)**

- It is possible that some excluded categories of people with persistent cough may try to purchase Codeine linctus in the pharmacy.

##### **Indirect Danger resulting from missed underlying risk factors and conditions**

The symptoms of dry cough are considered suitable for self-assessment by patients, supplemented by advice from a pharmacist, although if symptoms of cough exist alongside additional breathing symptoms, the possibility of other underlying conditions being present is greater. Groups of patients who may experience serious risk associated with opioid medicines, including Codeine linctus are:

- Patients suspected of drug abuse.
- Patients with kidney or liver disease; as codeine may accumulate.
- Patient with asthma or bronchitis.
- In children below the age of 12 years; due to an increased risk of developing serious and life-threatening adverse reactions.
- In women during breastfeeding (as codeine and morphine may be present in breast milk).
- In a rare group of patients who can digest codeine very quickly into morphine.

##### **Duration of treatment**

It is possible in certain situations that a patient may suffer a worsened outcome as a result of unsupervised use of non-prescription codeine if they continue to use Codeine linctus in circumstances where alternative treatments might have been more suitable.

The maximum duration of treatment with Codeine linctus has not been set. If a patient continues to take Codeine linctus for prolonged periods of time, then they have the potential to become tolerant to the beneficial effects and feel they need more to gain the same effect. Guidance is provided to patients taking codeine tablets, that if symptoms do not improve after 3 days, then they should seek the advice of a doctor. A similar direction can be made for Codeine linctus.

An acute dry cough (lasting less than 3 weeks) and a subacute cough (lasting between 3 – 8 weeks) would generally resolve itself. However, if cough becomes persistent then the patient would be seeking care from a physician to manage their symptoms, who would be able to prescribe Codeine linctus if it was beneficial for the patient.

##### **Overall conclusion on POM criterion 1 (The product is likely to present a direct or indirect danger to human health, even when used correctly, if used without medical supervision.)**

This criterion is not completely fulfilled, as product information may be improved to minimise risks to patients when used correctly. Pharmacists are able to discuss with individuals about their cough to determine if they have any underlying risk factors or conditions. They are also



able to advise the individual with a dry cough on suitable treatment and to seek advice from their GP if their cough does not improve after a period of time. Pharmacists may be able to recognise a repeat buyer and direct them to their GP for further assessment. However, this does not prevent the individual from purchasing Codeine linctus from an alternative pharmacy or waiting until there is a change in shifts between pharmacists at the pharmacy and does not prevent a patient suspected of drug abuse from using the medicine recreationally or becoming addicted (see under criterion 2)

#### **4.2 POM Criterion 2 – The product is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health**

The ways that Codeine Linctus could be used incorrectly:

- Misuse/abuse
- Overdose
- addiction
- for illegal purposes

#### **Risk of medicinal misuse / abuse**

The risk of misuse and abuse of opioid medicines such as codeine is well-known. This is a particular risk for Codeine linctus as an oral solution with the strength of solution (15mg/5ml and 7mg/5ml) intended for use as a cough medicine available as a pharmacy medicine. It has been observed in other countries, that Codeine linctus is being drunk straight from the bottle by people addicted to codeine. The product information for Codeine linctus contains a warning against use in patients with history of drug or substance abuse although is not consistent and prone to confusion.

Codeine linctus is being used recreationally to make a drink known as 'Purple Drank', 'Lean', 'Dirty Sprite' or 'Sizzurp' (herein collectively referred to as Purple Drank). Purple Drank is a mix of Codeine linctus, promethazine (an antihistamine) and fizzy drinks, sometimes with boiled sweets to take away the bitterness of the linctus. Codeine provides the euphoria sought by users and the antihistamine is added to counteract any sensitivity reactions to codeine however promethazine is also a sedative, can make you sleepy and lose track of how much codeine has been consumed. Purple Drank is made at home in unmeasured amounts, therefore there is always the risk of overdose. Also, as a recreational drink, people may not be aware of how much codeine they are taking and this can have serious risks, especially if taken with alcohol. Concomitant use with a central nervous system (CNS) depressant (for example sedatives, anti-anxiety medicines, cough suppressants or other opioids), illicit drugs, or alcohol, will increase the risk of breathing problems, becoming unconscious and death.

Purple Drank is widely mentioned in social media with the false impression that there are few safety issues. Recreational users of Purple drank are at risk of becoming addicted to codeine.

It is difficult to determine the total background use, incidence of adverse reports, degree of harm, or fatalities from the recreational use of Purple Drank, as it has many names, is identified through logos and emojis and its components are frequently obtained illegally. Similarly, adverse events related to the use of Purple Drank will be significantly under-reported to the Yellow Card scheme as it is non-medical use.

However, recreational activity has prompted safety warnings, both within local regions of concern (schools), police notices and generally through professional healthcare best practice guidance. Charities are beginning to raise more awareness about the effects of Purple Drank/Lean, as use of it in the UK has been particularly linked to young people. In 2018, the

UK Association for Forensic Nurses and Paramedics also published an alert raising awareness of the drink with their members.

Regulatory actions have also been taken in other countries world-wide either to reclassify Codeine linctus to POM or remove it from the market owing to its use in Purple Drank and the risks of addiction.

### **Overdose**

The risk of significant overdose with Codeine linctus is mitigated by the low strength (15 mg/5ml) however a maximum pack size has not been set. The majority of all sales of Codeine linctus are in pack sizes of 200ml (600mg).

A toxic dose of 2.5mg/kg body weight has been reported and a lethal dose of codeine is anywhere between 500mg to 1000mg, depending on how long a patient has been exposed to codeine and tolerant they are to its effects. Therefore, if a patient were to drink the 200ml bottle at once, it may be fatal. Data obtained from the Office of National Statistics, revealed that from 2011-2021 deaths involving codeine, not from a compound formulation in the UK, increased from 88 to 200 although there is no information available about prescription status in these fatal events.

The primary effects of codeine in overdose are an exaggeration of the known adverse effects of the drug, based on the opioid method of action.

The PIL and label for Codeine linctus warn against taking too much of the product, for example on the label for Care Codeine linctus, it states, 'Do not exceed the stated dose' and 'a lower dose may be more suitable'. In the PIL for an alternative Codeine linctus, advice is provided to the patient on what to do if they take too much (tell a doctor and take the pack to show what medicine has been taken).

Other opioids will contain more detailed information on the possible effects of overdose and provide advice to people who have discovered a patient who may have overdosed on an opioid, (coma, slow breathing, pinpoint pupils) however this information is not in the Codeine linctus product information.

### **Addiction**

The risk of addiction to codeine medicines was reviewed by CHM in 2005, 2009 and 2019. At each stage, it has been observed that previous risk minimisation actions, including increased and improved warnings in product information and labelling, have been insufficient to minimise risk and addiction continues to be a problem. In 2019, CHM recommended updates to the SmPC, PIL and labels for all prescribed opioids. The labels inform patients that Codeine linctus contains an opioid and can cause addiction.

Pharmacy staff can intercept regular purchasers of Codeine linctus should this be attempted and refer them to their GP for assessment of their symptoms. However, pharmacists have experienced some violent aggression from repeat buyers.

Medicines on prescription can be logged in a patients' summary care record. This enables pharmacists within the community to see how much and how often a patient has provided a prescription and when it was dispensed. At the current time with a non-prescription medicine only available from the pharmacist, this potential risk minimisation is not available.

### **Use for illegal purposes**

The MHRA has received a surge of referrals since 2018 from law enforcement and within the supply chain. Over the past 18 months, approximately 3 referrals per month have been received and suggest that use in the UK community is widespread and increasing. This includes wholesale purchase malpractice (for which the General Pharmaceutical Council have taken action), theft from wholesalers and delivery vehicles, and bribery.

This is a growing concern not only to the patient / user, but also to the pharmacist and staff at wholesalers.

Sales of Codeine linctus from illegal websites are also at greatly inflated prices, purporting to be at bargain prices, although are considerably higher than through the pharmacy. Therefore, this gives the repeat user the illusion that they are buying cheaper codeine online, whilst it is much cheaper to obtain at the pharmacy or on prescription.

Ready-made combination solutions of codeine and the antihistamine, promethazine, as a concentrate of purple drank, are not authorised medicines. These combination solutions are also available to buy on illegal websites and do not always contain what the person expects and can be toxic.

**Overall conclusion on POM criterion 2 (The product is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health.)**

The second POM criterion is considered to be fulfilled for Codeine linctus because the risks of direct or indirect danger to human health from incorrect use. This takes into account that Codeine linctus may present, if incorrectly used;

*(i) a substantial risk of medicinal abuse,*

*(ii) to lead to addiction, or*

*(iii) to be used for illegal purposes*

Moving Codeine linctus to POM would not remove potential for recreational use, however, it would form an additional barrier for the repeat purchaser to overcome. Prescription would also enable the pharmacist to monitor the patient's usage through their summary care record and the doctor to manage symptoms of diagnosed persistent cough and counsel on the risks of addiction and dependence. If the patient was diagnosed as addicted, then referral could be made to a dependence unit for help to stop using it.

**4.3 POM Criterion 3 – The product contains substances or preparations of substances of which the activity requires, or the side effects require, further investigation**

Codeine linctus is a well-established product having been widely used in the UK for a number of years. Its efficacy and safety profile are well known, and there are no issues requiring further investigation.

**Overall conclusion on POM criterion 3**

The third POM criterion is not considered to be fulfilled for Codeine linctus.

**4.4 POM Criterion 4 – The product is normally prescribed by a doctor for parenteral administration (that is, by injection).**

Codeine linctus is a solution intended for oral administration only.

**Overall conclusion on POM criterion 4**

The fourth POM criterion is not considered to be fulfilled for Codeine Linctus.

## **5. Further details on the proposed reclassification**

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### **5.1 Monitoring of the safety concerns**

The safety concerns associated with Codeine linctus are monitored through the routine activities that pharmaceutical companies have to undertake legally to monitor their products (routine pharmacovigilance). The MHRA also undertake regular reviews of safety concerns in line with the Human Medicines Regulations 2012.

## **5.2 Minimising the safety concerns**

The risk of all safety concerns and adverse events for Codeine linctus are minimised through routine measures including the product information (SmPC, PIL & label) and classification of the medicine.

The safety concerns for the supply of Codeine linctus in the pharmacy could be minimised further through an additional risk minimisation measure of pharmacist training materials. These will highlight the important potential risks of Codeine linctus and ensure that pharmacists know how to identify relevant conditions and advise and manage patients appropriately, including when referral to a doctor is necessary. Acute and sub-acute cough are self-limiting conditions, for which there are alternative cough syrups of which a pharmacist can advise if the cough is irritating.

A patient with a persistent cough will need to be fully diagnosed by a doctor to obtain a prescription before the pharmacist can dispense the medicine. This enables the pharmacist to have better control on the amount an individual will receive, will provide pharmacists in alternating shifts to view the patient's summary care record as an indication of the patient's usage, and improve overall record keeping preventing over-ordering for the pharmacy as a whole. This also minimises the risk that a person could make repeat purchases from a single pharmacy when the pharmacists change shifts.

## **5.3 Pharmacy support materials**

Support materials could be provided to pharmacists to give to patients highlighting the risks of recreational use, a description of Purple Drank, the effects and risks and the potential symptoms of overdose and how to recognise if you are addicted. Additional advice can be provided on how to recognise potential overdose and what to do.

The support materials could also provide links to addiction services and helplines, e.g. [FRANK](#).

An example leaflet highlighting potential for addiction to opioid medicines is available at:

[OPIOID MEDICINES AND THE RISK OF ADDICTION \(publishing.service.gov.uk\)](#)

## **5.4 Label and leaflet**

As codeine is an opioid medicine, warnings are on the label as recommended by CHM in 2019, to state "contains opioid" and "can cause addiction" in a rectangle on the front face of the carton. This should also appear on the bottle label.

As a prescription medicine, further warnings and guidance can be included in the PIL to highlight the risk of overdose, what to do if you have overdosed or if you observe a person who has overdosed, explain what it means to be addicted and how to recognise addiction.

Similar warnings can be added to PIL in line with the MHRA patient leaflet warning patients about the risks of addiction to opioids. [Opioid medicines and the risk of addiction - GOV.UK \(www.gov.uk\)](#)

## **5.5 Summary of Product Characteristics**

The Summary of Product Characteristics (SmPC) for the Codeine linctus medicines are inconsistent. This document is a description of the properties of Codeine linctus and the conditions attached to its use. It is used as a reference by healthcare professionals.

The product name for some products does not contain the strength per dose. This is not in line with the Human Medicines Regulations 2012 Schedule 8, regulation 24, and therefore should be included.

The risks associated with metabolism and the potential for toxicity in children led CHM in 2010 to consider that codeine should not be used in children under the age of 18 years. One Codeine linctus product contains an indication for use in adolescents without compromised respiratory function (breathing difficulties). Given that cough is linked with breathing difficulties, it would follow that Codeine linctus should not be used in patients below the age of 18 years.

As a prescription medicine, further warnings and guidance can be included to highlight the risk of overdose, what to do if you have overdosed or observed a person who has overdosed or explain what it means to be addicted and how to recognise addiction.

## **6. Consultation with stakeholders**

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CHM considered the views of a roundtable that had been convened to consider the risk of the recreational use of Codeine linctus and further steps that could be taken to minimise the risk. The roundtable included representation from individual pharmacists, professional bodies (Royal Pharmaceutical Society, General Pharmaceutical Council, Healthcare Distribution Association, General Medical Council), health policy officials (Department of Health and Social Care, Department of Health Northern Ireland, Scottish Government), the National Crime Agency and a representative from the Advisory Council on the Misuse of Drugs.

The roundtable considered that actions could be taken by all stakeholders. The roundtable considered that control by prescription would provide a further barrier and could aid pharmacists when faced with repeat buyers. However, the roundtable also recognised the professionalism of pharmacists and agreed that they would be able to identify repeat buyers and endorsed the need for further communication between pharmacies.

Further risk minimisation measures were also discussed, such as keeping Codeine linctus out of sight to prevent self-selection. Controls have been set on the sales of Codeine linctus to pharmacists from warehouses, although this has not prevented criminal activity. Proposals were put forward on limitations and restrictions of sales to the public, and prevention of sales together with promethazine.

These views were taken into consideration by the CHM when considering the suitability of Codeine linctus for use without medical supervision and the conditions under which Codeine linctus should be controlled.

## **7. Summary**

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- Codeine linctus 15mg/5ml and 7mg/5ml is a medicine for treatment of unproductive dry cough in adults and adolescents aged 12–18 years without breathing problems.
- The active ingredient of Codeine linctus is currently available without prescription under the supervision of a pharmacist.
- Codeine is an opioid and can cause addiction
- The number of registered deaths in England and Wales involving codeine (not from compound formulation) has increased from 88 in 2011 to 200 in 2021.
- Codeine is used to make the recreational drink Purple drank in unmeasured amounts with users running the risk of overdose and death.

- Codeine linctus is also associated with criminal activity and sold on illegal websites at inflated prices.
- Regulatory activity has already been taken in other countries to reclassify or remove Codeine linctus from the market.

## **8. What do you think?**

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- The MHRA is proposing that Codeine linctus should be further controlled through reclassification to POM to limit the risks from recreational use, potential for addiction, overdose and use for illegal purposes.
  - The CHM has advised that Codeine linctus could be controlled by prescription, therefore should only be available upon presentation of a prescription
  - The CHM considered that this would not have an impact on primary or secondary care, as those who benefit from Codeine linctus (individuals with persistent cough) are already under clinical care.
- [Tell us what you think about this proposed change](#). The deadline for comments is 15<sup>th</sup> August 2023.

