



# **PDA's response to the Medicines and Healthcare products Regulatory Agency (MHRA): Public Consultation on proposal to make Codeine linctus and Codeine Oral Solutions available as a prescription-only medicine (POM)**

Copy of the response submitted via email in August 2023

## Summary

The Medicines and Healthcare products Regulatory Agency (MHRA) recently published a consultation to make Codeine linctus and Codeine Oral Solutions prescription only medicines (POMs).

Responses could only be submitted via the online survey. The questions and the PDA responses are copied below.

## Consultation questions

1. Do you agree that Codeine Linctus should only be available as a Prescription Only (POM) medicine?

Agree ✓  
Disagree  
Not Sure

Please provide any comments or evidence to support your response.

The MHRA consultation document notes the increase in the number of deaths recorded involving codeine from 88 in 2011 to 200 in 2021. The consultation also notes the significant increase in reports to the MHRA around illegal activities involving codeine linctus and the risk that this poses not only to patients or users but also to pharmacists who face the risk of violence (if refused a sale) from repeat buyers of codeine linctus.

In light of the evidence collected by the MHRA and published in the consultation document the PDA agrees with the proposal to make these items POM.

Please also see our answer to question 14.

2. Do you agree that the proposal to reclassify to POM would limit the potential for recreational use or use for illegal purposes?

Agree ✓  
Disagree  
Not Sure

Please provide any comments or evidence to support your response.

We agree that reclassification may create a further barrier for recreational use or use for illegal purposes.

3. Do you agree that the proposal to reclassify to POM would help the pharmacist to monitor use in patients who would benefit from the prescription of codeine linctus?

Agree

Disagree ✓

Not Sure

Please provide any comments or evidence to support your response.

Pharmacists cannot access the full clinical records of patients. At present pharmacists can access limited information, usually contained within the Summary Care Record. Many patients choose not to have this SCR (there is an opt-out provision for any patient that does not wish their record to be shared).

There is no evidence to support the hypothesis that reclassification would “help” the pharmacist monitor use in patients who have been prescribed codeine linctus. This is especially the case for online purchases where a private online prescribing service provides a prescription (or prescribes and supplies) without passing this information on to the patient’s GP.

4. Do you agree that pharmacist training materials would help to educate pharmacists and patients

Agree

Disagree ✓

Not Sure

Please provide any comments or evidence to support your response.

Pharmacists are level 7 educated healthcare professionals who have to be registered with a UK regulator to practice in the UK. In general, it is not appropriate to suggest that pharmacists need “educating” around the risk of opioid misuse and addiction.

However, it will be essential that the government puts into place a well-resourced and well-executed public awareness campaign to inform people/patients if this change was put into place.

The MHRA working with relevant other parties needs to ensure that the risks around inappropriate advertising, packaging and communications outside of the pharmacy focus on educating the public around the risks of illegal/inappropriate opioid use and how the public may be able to spot signs of illegal/inappropriate use by friends or family. This is especially important as solid dose products containing codeine in combination with other pharmaceuticals will continue to be available.

There may be an increased in the risk of inappropriate use of these solid dose products, for example some users simply substituting codeine combination products for codeine linctus and the risk of harm of excess paracetamol intake.

5. Do you think that the proposal could risk impacting people differently, or could impact adversely on any of the protected characteristics (covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998)?

Agree

Disagree

Not Sure

Please provide any comments or evidence to support your response.

A 2021 paper published by Cork Institute of Technology looked at age and gender characteristics which may be a factor for those seeking to access codeine based products. The paper can be accessed [here](#).

6. Do you agree that the proposal to reclassify would have little impact on primary care?

Agree

Disagree

Not Sure

Please provide any comments or evidence to support your response.

Patient / user behaviours are difficult to predict. In general, pharmacists are well versed in suggesting suitable alternative or similar products for many clinical conditions so there may not be a significant impact on primary care (which we presume in this context means GP practices). We would expect that all prescribers in primary care settings would be part of the awareness raising campaign alert that we suggest.

7. The MHRA may publish consultation responses. Do you want your response to remain confidential?

\*If partially, please indicate below which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Yes

No

Partially

We do not object to any part of our response being published.

## Please tell us a little bit about you so that we can ensure we have a balanced pool of responses

8. Are you?

Public/Patient

Patient Representative organisation

A Healthcare Professional

A Trade/Professional organisation/association

Personally experienced in the effects of codeine linctus

Other (please specify)

We are the largest independent UK wide organisation, with over 37,000 members, representing pharmacists and students studying for a pharmacy degree and for foundation year pharmacist trainees.

9. Where do you live, or if you represent an organisation, tell us the geographical area you cover?

UK

England

Scotland

Wales

Northern Ireland

Other (please specify)

We are a UK wide organisation.

10. What is your ethnic group?

Our members are from a widely varying ethnic groups. We also have a number of EDI membership groups.

11. Age group

Our members (including student members) are from the age of 18 upwards.

## Satisfaction survey - give feedback on participating

12. It was easy to participate in this opportunity

Strongly Agree

Agree

Neither agree or disagree

Disagree

Strongly Disagree

13. The supporting information was understandable

Strongly Agree

Agree

Neither agree or disagree ✓

Disagree

Strongly Disagree

14. What could we do better?

The consultation paper could have provided better and broader context.

The MHRA could also have engaged with relevant stakeholders such as the PDA which is the largest UK-wide membership body representing pharmacists. Our experience in providing support to members over 5,000 incidents within the past year provides us with unequalled insight on risks and risk mitigation within pharmacy practice. We also campaigned extensively around violence and abuse experienced by pharmacists. Our policy department also suggests policy positions around pharmacy practice taking into consideration a complex and diverse range of factors.

It is in that context we have made this submission. The issue around opioid addiction is hugely complex. Besides codeine linctus and codeine oral solutions there are solid dose preparations which contain codeine or dihydrocodeine and which are also available to purchase without prescription.

We note that there is no context provided about the impact of these solid dose preparations and the harm caused by their misuse even though there are significant concerns over some products (for example combination products which contain ibuprofen and codeine).

The UK Government is aware of the impact of all non-prescription codeine based products (solid dose and liquid) and this consultation may have been better served if all codeine based products were considered holistically

<https://www.gov.uk/drug-safety-update/over-the-counter-painkillers-containing-codeine-or-dihydrocodeine>

The Pharmaceutical Society of Ireland introduced specific guidelines for the sale of non-prescription preparations containing codeine. This followed from legislative changes in Ireland in 2008 which required specific supervision by a pharmacist for codeine-based products.

Some background can be found [here](#) and its especially relevant to contrast the prohibition of advertising any product containing codeine in Ireland when compared to how such products can be advertised in the UK <https://www.gov.uk/guidance/advertise-your-medicines>.

Whilst, given on the evidence presented by the MHRA, the PDA agrees to the reclassification of liquid codeine based products to the POM category, the PDA also believes that there are wider concerns around all opioid products that can be purchased without a prescription and that these also require consideration.

## About the Pharmacists' Defence Association

The Pharmacists' Defence Association (PDA) is a not-for profit defence association and trade union for pharmacists. It is the only organisation that exclusively looks after the interests of employee and locum pharmacists across all sectors of pharmacy. Currently with a membership of more than 37,000, the PDA is the largest representative membership body for pharmacists in the UK and this membership continues to grow.

Delivering more than 5,000 episodes of support provided to members who have found themselves in a critical incident situation in the last year alone, provides the PDA with a rich vein of up-to-date experiences which have informed policies and future strategy.

This experience has recently been informed by the very considerable number of Covid-19 related issues being faced by members. The practical experience gained in supporting member issues from the coal face is further enhanced by regular member surveys and focus group interactions. The information in this document is largely built upon the experience of our members.

The primary aims of the PDA are to:

- Support pharmacists in their legal, practice and employment needs
- Represent the individual or collective concerns of pharmacists in the most appropriate manner
- Proactively seek to influence the professional, practice and employment agenda to support members
- Lead and support initiatives designed to improve the knowledge and skills of pharmacists in managing risk and safe practices, so improving patient care
- Work with like-minded organisations to further improve the membership benefits to individual pharmacists
- Arrange insurance cover for individual pharmacists to safeguard and defend their reputation.