Response

Medicines and Healthcare products Regulatory Agency

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

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For enquiries regarding this response please contact office@thecca.org.uk

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About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. The CCA membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate around 5,500 pharmacies, which represents nearly half of the market. CCA members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year. The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public.

Consultation questions

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

   Agree

   We agree with the MHRAs assessment that Codeine Linctus is frequently misused, presenting a direct or indirect threat to human health. We also recognise that codeine linctus is addictive and has the potential to be abused or used illegally. Recognising the limited therapeutic value of codeine linctus, the vast majority of CCA pharmacies do not stock codeine linctus.

   The community pharmacy sector has shown previously that they are able to manage risks around pharmacy supply of medicines which have the potential to cause harm. For example, when concerns were raised about pseudoephedrine, the sector adapted and implemented measures to restrict the sale of large quantities that could be used for illicit purposes. This included new processes and training for all team members.

   Whilst we support this reclassification on the balance of risks and benefits, we wish to be clear that we do not usually support the reclassification of P-meds to POM. This reduces access and choice for patients – and potentially leads to worsening health outcomes. At a time when all the NHS, in particular general practice, is under immense pressure, having a broad range of therapeutic tools available for community pharmacists is invaluable.

   In addition, the NHS Delivery Plan for Recovering Access to Primary Care states that the MHRA, DHSC and NHS England will work together to identify medicines which could be reclassified from POM to P-meds. We support this ambition which will improve patient choice and accessibility, as well as releasing pressure from other parts of the NHS.

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

   Agree.

   Changing codeine linctus from a P-med to a POM may reduce incidents where patients present at multiple pharmacies or attend a pharmacy multiple times when

different pharmacists are working, to obtain more supplies than would usually be necessary or permitted by a pharmacist.

However, we would caution that the reclassification may result in more patients seeking codeine linctus from unscrupulous or unregulated online pharmacies or other vendors. The GPhC have already taken regulatory action against several pharmacy premises for unusually high sales of codeine linctus, and work should be undertaken with the GPhC to ensure that this reclassification does not increase sales on the unregulated market.

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?**

   Not sure.

   Under current rules, codeine linctus may only be sold or supplied (including those issued against a prescription) under the direct supervision of a pharmacist. We would expect that pharmacists are already monitoring the use of codeine in patients. The only benefit we have identified would be pharmacists having a record of patients' prescriptions through the PMR (with potentially additional records through electronic prescribing in England), which would allow pharmacists to ensure that patients are not taking codeine linctus for longer than intended or taking larger doses than prescribed. Moving the medicine to a POM may also enable prescriber audits, allowing patient use to be reviewed - independent of the patient's pharmacy of choice.

   In addition, pharmacists should be providing patients with information relating to the risks, side effects and potential for adverse reactions when any codeine drugs are sold or supplied. We do not see how the re-classification as a POM would change or enhance these interactions.

   If a proportion of patients move to an unregulated market that is flouting guidance or legislation, then there may be reduced scrutiny. However, the challenge of online, unlicensed sales of medicines extends beyond any one medicine.

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

   Not sure.

   As above.

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)?**

   No.

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

Agree.