HSE National Patient Safety Alert

Date of Issue: 26 Sept 2022
Unique ID: HSENPSA 0001/2022

PRIORITY 2 –Warning

Risk of Harm from Codeine-Containing Products

Who needs to take action on this safety issue?

This HSE National Patient Safety Alert (NPSA) is for action by all Health Service personnel involved in caring for patients suspected to have experienced harm arising from dependence on codeine-containing products, including toxicities associated with the analgesic component of combination products.

What is the safety issue?

Regular or prolonged use of codeine-containing products may produce psychological and physical dependence. For combination products, use of higher doses and/or for a longer duration than that recommended, can also lead to serious adverse clinical outcomes arising from exposure to the analgesic component (e.g. paracetamol or ibuprofen). These include hepatotoxicity, gastrointestinal and renal toxicities, such as gastrointestinal haemorrhage and perforation and renal failure[1].

What action is required?

1. Circulate this NPSA to all clinical staff who provide care for patients who may be impacted by the use of codeine-containing products, particularly in the specialities of Gastroenterology, Nephrology, Gynaecology, General Practice, Pharmacy and Psychiatry and Addiction Services.

2. Staff should report cases of suspected harm (past or current) to the Health Products Regulatory Authority (HPRA) via the HPRA's online adverse reaction report form available at: *https://www.hpra.ie/homepage/about-us/report-an-issue/human-adverse-reaction-form* or by phone on 01 676 4971.
   - It is not necessary to complete all fields of the online form, however, as much information as is known should be provided. Include the brand name(s) of the suspect medicine(s), or if unknown, state all active ingredient(s) (e.g. ibuprofen codeine combination product). Provide a summary of available information on the circumstances of use (e.g. if use was prescribed and/or accessed over the counter 'OTC', duration and quantity), details of any suspected dependence or misuse, and any associated suspected reactions (i.e. adverse clinical outcomes).

When does the action need to be completed by?

Please circulate this HSE NPSA to relevant staff by 21 Oct 2022.

Why is this action required?

The HPRA are the competent authority in Ireland for pharmacovigilance and operate a system through which suspected adverse reactions can be reported by health care professionals. A small number of cases describing significant harm relating to the analgesic component of codeine-containing combination products, in the context of dependency to codeine, have recently been reported to the HPRA via the national adverse reaction reporting system. As the system is voluntary, there may be under-reporting of such cases. The HPRA are therefore encouraging reporting of any similar cases that you may be aware of for pharmacovigilance monitoring purposes.

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What evidence supports the issuing of this HSE NPSA?

Available data suggest regular usage of codeine-containing products in Ireland, including those available 'over-the-counter'.[1,2,3,4] Given the known risk of dependence as well as the potential for harm associated with the additional analgesic component in combination products (e.g. paracetamol or ibuprofen), it is important that relevant cases are reported to the HPRA.

The devastating personal impact of dependency cannot be overstated as is outlined in a recently reported Irish example[5], and a lived experience report on codeine dependency[6].

Where can I get further information?

For queries on patient safety alerts in general please email patientsafetytogether@hse.ie

For any queries on reporting to the HPRA or to discuss any other potentially relevant data sources with the HPRA, please contact medsafety@hpra.ie

What stakeholders were involved in issuing this HSE NPSA?

A coordinated approach was undertaken to endorse reporting of relevant data to the HPRA to inform pharmacovigilance monitoring and risk management on this patient safety issue.

This alert has been developed collaboratively by the following groups:

- National Quality and Patient Safety Directorate, HSE
- National Clinical Advisors and Group Leads (NCAGL), HSE
- HSE Addiction Services
- Irish Medication Safety Network
- Health Products Regulatory Authority (HPRA)
- National Patient Safety Office (NPSO), Department of Health

References

1. Carney et al., 2018. "A comparative analysis of pharmacists' perspectives on codeine use and misuse – a three country survey." Substance Abuse Treatment, Prevention, and Policy, 13 (12). https://doi.org/10.1186/s13011-018-0149-2
2. "Rates of reported codeine-related poisonings and codeine prescribing following new national guidance in Ireland" https://www.drugsandalcohol.ie/30636/
3. "Non-Prescription Medicinal Products containing Codeine: Guidance for pharmacists on safe supply to patients." PSI guidance document Version 4 2019.
4. Richards, et al., 2022. "Sales of Over-the-Counter Products Containing Codeine in 31 Countries, 2013-2019: A Retrospective Observational Study." Drug safety, 45(3) 237-247. https://doi.org/10.1007/s40264-021-01143-2
5. https://www.rte.ie/news/ireland/2022/0203/1277601-mother-medication-addiction/
6. Van Hout et al., 2018. "'Codeine is my companion': Misuse and dependence on codeine containing medicines in Ireland." Irish Journal of Psychological Medicine, 35(4), 275-288. https://doi.org/10.1017/ipm.2015.60