

## COMMUNICATION TO STAKEHOLDERS

Issue No.: CLINPR01-2024/25

30 July 2024

# RESTRICTION ON CODEINE USE IN CHILDREN, PREGNANT AND/OR BREASTFEEDING MOTHERS

## INTRODUCTION

This document is intended to provide communication to The Holder of Certificate of Registration for Codeine containing products.

The Advisory Clinical Committee (ACC) reviewed data submitted by HCRs to support the continued use of codeine in children under 12 years and concluded that, there is evidence indicating that codeine-containing medicines are associated with respiratory complications when used in children under the age of 12 years. There have been several publications including PSURS and PBRERs indicating an unacceptable risk, including fatal outcomes when codeine-containing medicines have been administered to children.

Accordingly, in line with the European Medicine Agency (EMA) and USA-Food and Drug Administration (FDA), SAHPRA concluded that the safety restrictions be implemented in paediatric population. Thus, SAHPRA instructs HCRs of codeine-containing medicines to include a contraindication for use in children under the age of 12 years. Similar considerations apply to breastfeeding women as there are similar outcomes in infants of breastfeeding mothers who have taken codeine-containing products. Further adverse events have been reported in neonates born to mothers who have recently ingested codeine-containing products.

In consideration of the deliberations on this matter, the Authority recommends that HCRs of codeine-containing products amend their PI and PILs as follows:

### ***Contraindications:***

1. Children under the age of 12 years.
2. Women who are breastfeeding their infants and women in the third trimester of pregnancy.
3. Codeine should not be used at all in children (aged below 18 years) who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea, as these patients are more susceptible to respiratory problems.

***Special warnings and precautions for use:***

1. Include a warning that children with conditions associated with respiratory problems should not use codeine.
2. The PIL to be aligned accordingly.

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SIGNIFLOW

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