

Codeine ban in children considered

NEIL BRAMWELL

CODEINE should not be used in children under 12 years, a committee of the European Medicines Agency (EMA) has recommended.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended a series of measures to address safety concerns about the use of codeine-containing medicines in children.

It said the drug should not be used at all in children under 18 years who undergo surgery for the removal of the tonsils or adenoids to treat obstructive sleep apnoea (OSA) because they are more susceptible to respiratory problems.

It also proposed the prescribing information carry a warning that

children with conditions associated with respiratory problems should not use codeine.

The minimum age for use of codeine in Australia is seven years.

A spokesperson for the TGA said it was aware of the issue and was "continuing to review the available information to determine whether any action is required in Australia".

The TGA previously stated that, while some labels indicated codeine was unsuitable for children, others included dosing instructions for those over seven years.

Europe's PRAC reviewed reports of children who developed serious adverse effects or died after taking codeine. Most of the cases occurred after surgical removal of the tonsils or adenoids for OSA.

The children had evidence of

being ultra-rapid metabolisers of codeine, whereby the drug is converted to morphine by the CYP2D6 enzyme at a faster than normal rate causing possible toxic effects such as respiratory depression.

The PRAC said codeine should only be used in children over 12 to treat acute moderate pain that cannot be relieved by other painkillers such as paracetamol or ibuprofen.

It further recommended that, as the risk of side effects with codeine may apply to adults, it should not be used by people of any age who are known to be ultra-rapid metabolisers, or breastfeeding mothers.

The PRAC recommendations were to be considered by the Coordination Group for Mutual Recognition and Decentralised Procedures – Human this week.

