



## IRISH MEDICINES BOARD

### **Paracetamol – Available evidence does not support a causal relationship with asthma in children after exposure in pregnancy or use in early infancy**

Paracetamol was first introduced into clinical practice in the 1950s, and has become one of the most widely used analgesic-antipyretics. Due to its safety profile, when used within therapeutic doses, it is considered the analgesic of choice in pregnancy and in children. In the paediatric population in particular, paracetamol has displaced the use of aspirin after the association with Reye syndrome was established.

A possible association between paracetamol and childhood asthma was initially postulated based on the observation that the displacement of paediatric aspirin use in favour of paracetamol had coincided with an increased prevalence of asthma in Western countries.<sup>1</sup> In 2008 the Pharmacovigilance Working Party (PhVWP) of the European Medicines Agency considered the available data and concluded that a causal association between paracetamol and asthma after exposure in utero or in early infancy could not be established.

Since then a number of new epidemiological studies investigating this possibility have been published and a further review was undertaken to evaluate the results of these studies.<sup>2-10</sup> (see the PhVWP Monthly report for further information: [http://www.ema.europa.eu/docs/en\\_GB/document\\_library/Report/2011/02/WC500102322.pdf](http://www.ema.europa.eu/docs/en_GB/document_library/Report/2011/02/WC500102322.pdf))

To date, most of the studies conducted to investigate the possible causal association between paracetamol and asthma after exposure in pregnancy or early infancy were cross-sectional surveys which had limitations in their design.<sup>11-18</sup> More recent

studies,<sup>2-10</sup> including birth cohort studies, have reported conflicting results. Evaluation of these studies has highlighted the difficulties surrounding the issue due to possible confounding by indication, as paracetamol is commonly used to treat symptoms of febrile illness/respiratory infections, which may be associated with an increased risk of asthma.

The most recent PhVWP review has therefore concluded that a causal association between paracetamol exposure in utero and in early infancy and asthma has not been established from the studies available to date.

The PhVWP noted the lack of therapeutic alternatives to paracetamol for use during pregnancy and in children. Considering the uncertainties surrounding the current evidence, no regulatory action is considered necessary. Any newly emerging data will be carefully reviewed. As with other medicines, paracetamol should only be used during pregnancy or in children if clearly necessary.

#### **Key message**

The available evidence does not support a causal relationship between paracetamol and asthma in children after exposure in pregnancy or use in early infancy.

As with other medicines, paracetamol should only be used during pregnancy or in children if clearly necessary.

*A list of references is available from the Irish Medicines Board on request.*

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