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本署檔號 OUR REF.:

(來函請註明此檔案號碼) DH DO DIMC/7-30/1
(IN REPLY PLEASE QUOTE THIS FILE REF.)

26 September 2025

Dear Healthcare Professionals,

Announcements on the use of Paracetamol (also known as Acetaminophen) during pregnancy released by the World Health Organization and overseas drug regulatory authorities

The Department of Health (“DH”) noted that the World Health Organization (“WHO”) had issued a statement¹ on 24 September 2025 indicating that there is currently insufficient scientific evidence to conclude that paracetamol (also known as acetaminophen) use during pregnancy causes autism or other neurodevelopmental disorders in children, or that there is any association between the two. Furthermore, several drug regulatory authorities subsequently made announcement or advices including those in the European Union², the United Kingdom³, Australia⁴, and Canada⁵, emphasised that based on rigorous assessments of existing scientific data, paracetamol remains an important option for pregnant women to relieve pain or fever when clinically indicated and under medical advice. Some authorities specifically noted that studies suggesting a potential link between the two exhibit significant limitations and in fact failed to establish a causal relationship. Conversely, the medical community has long confirmed through more rigorous large-scale studies that there is no association between paracetamol use during pregnancy and autism or attention deficit/hyperactivity disorder (ADHD).

Based on current scientific evidence, claims that taking paracetamol during pregnancy causes autism or other neurodevelopmental disorders in children lack sufficient supporting evidence.

¹ <https://www.who.int/news/item/24-09-2025-who-statement-on-autism-related-issues>

² <https://www.ema.europa.eu/en/news/use-paracetamol-during-pregnancy-unchanged-eu>

³ <https://www.gov.uk/drug-safety-update/paracetamol-and-pregnancy-reminder-that-taking-paracetamol-during-pregnancy-remains-safe>

⁴ <https://www.tga.gov.au/news/media-releases/paracetamol-use-pregnancy>

⁵ <https://recalls-rappels.canada.ca/en/alert-recall/acetaminophen-recommended-treatment-fever-and-pain-during-pregnancy>

In Hong Kong, there are 707 registered pharmaceutical products containing paracetamol (acetaminophen). So far, with regard to paracetamol, the DH has received 59 cases of adverse drug reaction, but these cases were not related to autism and ADHD in children associated with pregnancy use.

The DH will continue to closely monitor safety recommendations and research findings from other international health authorities and drug regulatory authorities regarding the use of paracetamol containing products, and to take appropriate follow-up actions as necessary.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Vincent CHANG', written over a horizontal line.

(Vincent CHANG)

for Assistant Director (Drug)