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

23 September 2025

Dear Healthcare Professionals,

**FDA Responds to Evidence of Possible Association Between Autism and Acetaminophen
(Paracetamol) Use During Pregnancy**

Your attention is drawn to the following United States Food and Administration's (FDA) announcement that the process for a label change for acetaminophen (paracetamol) to reflect evidence suggesting that the use of acetaminophen by pregnant women may be associated with an increased risk of neurological conditions such as autism and attention deficit hyperactivity disorder (ADHD) in children is initiated. The agency also issued a related letter alerting physicians nationwide.

"The FDA is taking action to make parents and doctors aware of a considerable body of evidence about potential risks associated with acetaminophen," said FDA Commissioner Marty Makary, M.D., M.P.H. "Even with this body of evidence, the choice still belongs with parents. The precautionary principle may lead many to avoid using acetaminophen during pregnancy, especially since most low-grade fevers don't require treatment. It remains reasonable, however, for pregnant women to use acetaminophen in certain scenarios."

Evidence in recent years has suggested a correlation between acetaminophen use during pregnancy and subsequent diagnosis of conditions like autism and ADHD. Multiple large-scale cohort studies, including the Nurses' Health Study II and the Boston Birth Cohort, find this association. Some studies have described that the risk may be most pronounced when acetaminophen is taken chronically throughout pregnancy.

It is important to note that while an association between acetaminophen and neurological conditions has been described in many studies, a causal relationship has not been established and there are contrary studies in the scientific literature. It is also noted that acetaminophen is the only over-the-counter drug approved for use to treat fevers during pregnancy, and high fevers in pregnant women can pose a risk to their children. Additionally, aspirin and ibuprofen have well-documented adverse impacts on the fetus.

Please refer to the following website in FDA for details:

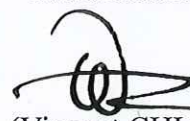
<https://www.fda.gov/news-events/press-announcements/fda-responds-evidence-possible-association-between-autism-and-acetaminophen-use-during-pregnancy>

In Hong Kong, there are 707 registered pharmaceutical products containing paracetamol (acetaminophen). So far, with regard to paracetamol, the Department of Health (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. In light of the above FDA's announcement, the DH will remain vigilant on any safety update of the drug issued by other overseas drug regulatory authorities.

Please note that this letter serves as a mean for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Clinical Trials and Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



(Vincent CHIANG)

for Assistant Director (Drug)