衞生署藥物辦公室
藥物資訊及警戒科
香港九龍觀塘巧明街 100 號
Landmark East 友邦九龍大樓
20 樓 2002-05 室

電話號碼 Tel. No.: 3974 4175
詢問處 Enquiries: (852) 3974 4175
傳真號碼 Faxline No.: (852) 2803 4962
本署檔號 OUR REF.:

DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG INFORMATION AND PHARMACOVIGILANCE DIVISION
Suites 2002-05, 20/F, AIA Kowloon Tower,
Landmark East, 100 How Ming Street,
Kwun Tong, Kowloon, Hong Kong

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

13 Jul 2022

Dear Healthcare Professionals,

Australia: First-generation oral sedating antihistamines - do not use in children

Your attention is drawn to the Therapeutic Goods Administration's (TGA) announcement that with the arrival of winter and flu season in Australia, consumers and health professionals are reminded that first-generation oral sedating antihistamines, including those available over-the-counter (OTC), should not be used for the treatment of cough, cold and flu symptoms in children under 6 years. First-generation oral sedating antihistamines should not be given to children under 2 years of age for any indication. These medicines can cause children serious harm, or even death, and there is little if any evidence that they are effective in treating cough, cold and flu symptoms.

Since 1 September 2020, all OTC products containing first-generation oral sedating antihistamines have been required to carry warnings that state 'Do not give to children under 2 years of age'. Oral preparations for coughs, cold or flu must also carry warnings stating: 'Do not give to children under 6 years of age' and 'should only be given to children aged 6 to 11 years on the advice of a doctor, pharmacist or nurse practitioner'.

The TGA's independent Advisory Committee on Medicines (ACM) has advised that there is minimal if any evidence supporting efficacy of first-generation oral sedating antihistamines for allergic rhinitis and cough and cold symptoms in children.

The committee reinforced the importance of health professionals providing thoughtful diagnosis, advice and treatment of allergy, cold and flu symptoms in children. They also reiterated that it is inappropriate to use antihistamines for sleep and behaviour disturbance, especially in children and adolescents.

To 24 May 2022, 226 cases involving use of first-generation oral sedating antihistamines in newborns, infants and children were reported to the TGA. The reports included a range of adverse events, including hypersensitivity reactions, vomiting, hallucination, tremor and abnormal movement. Of the 226 cases, 20 related to off-label use, misuse or overdose in children 4 years and under.

First-generation oral sedating antihistamines include products containing the following active ingredients:

- alimemazine (trimeprazine)
- brompheniramine
- chlorphenamine
- dexchlorpheniramine
- diphenydramine
- doxylamine
- pheniramine
- promethazine
- triprolidine

These products are indicated for multiple conditions, including the treatment of symptoms for cold, flu, cough and allergy.

Please refer to the following website in TGA for details:
https://www.tga.gov.au/publication-issue/first-generation-oral-sedating-antihistamines-do-not-use-children

In Hong Kong, there are registered oral pharmaceutical products containing brompheniramine (103 products), chlorphenamine (788 products), dexchlorpheniramine (106 products), diphenydramine (61 products), doxylamine (2 products), pheniramine (2 products), promethazine (237 products) and triprolidine (43 products). They are all non-prescription medicines, except doxylamine which is a prescription-only medicine. There is no registered pharmaceutical product containing alimemazine (trimeprazine).

So far, the Department of Health (DH) has received one adverse drug reaction report related to brompheniramine for children under 2 years of age, which involved abnormal movement of the eyeball. In light of the above TGA's announcement, the DH will remain vigilant on any safety update of the drugs issued by other overseas drug regulatory authorities for consideration of any action deemed necessary.

Please note that this letter serves as a means 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 Adverse Drug Reaction 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,

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(Terence MAN)
for Assistant Director (Drug)