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DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

Dear Healthcare Professionals,

Ambroxol- and bromhexine-containing medicines – risk of severe allergic reactions

Your attention is drawn to the European Medicines Agency's (EMA) announcement regarding the risk of severe allergic reactions in patients treated with ambroxol or bromhexine.

The EMA's Pharmacovigilance Risk Assessment Committee (PRAC) has completed a review of medicines containing ambroxol or bromhexine. The PRAC considers that the risk of allergic reactions is small, but has recommended the product information for these medicines should be updated with further information on severe allergic reactions. Severe skin reactions (SCARs) such as erythema multiforme and Stevens-Johnson syndrome should be introduced as a side effect, together with advice to discontinue treatment immediately if symptoms of SCARs occur. The PRAC recommendation will now be forwarded to the Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh), which will adopt a final position.

Please refer to EMA's website for details:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2015/01/news_detail_002248.jsp&mid=WC0b01ac058004d5c1

In Hong Kong, ambroxol- and bromhexine-containing medicines are registered pharmaceutical products indicated as secretolytic in acute and chronic bronchopulmonary diseases associated with abnormal mucus secretion and impaired mucus transport. News related to the review of ambroxol- and bromhexine-containing medicines conducted by the EMA was posted on the Drug Office website on 12 April 2014. So far, the Department of Health has not received any adverse drug reaction report in connection with the drugs. In view of the EMA's announcement, the matter will be discussed in the meeting of the Registration Committee of the Pharmacy and Poisons Board. 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 Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 2186 9845 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,

(Grant NG)
for Assistant Director (Drug)