

衛生署藥物辦公室
藥物註冊及進出口管制部

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Dear Healthcare Professionals,

Bromocriptine - restriction on use for stopping breast milk production

The EMA has completed an EU-wide review of bromocriptine-containing medicines at the request of the French medicines authority (ANSM) following concerns in France over increased reports of rare but potentially serious or fatal side effects, particularly cardiovascular side effects (such as heart attack and stroke), neurological side effects such as seizures (fits) and psychiatric side effects (such as hallucinations and manic episodes). The available evidence confirmed that bromocriptine was effective in preventing or suppressing lactation after childbirth but an association between bromocriptine treatment and events such as heart attack, stroke, fits, and psychiatric disorders could not be ruled out. The Agency's Pharmacovigilance Risk Assessment Committee (PRAC) has recommended that the medicines should only be used for this purpose (in strengths up to 2.5 mg) when there are compelling medical reasons for stopping lactation, such as to avoid further distress after loss of the baby during or just after childbirth, or in mothers with HIV infection, who should not breastfeed. Bromocriptine should not be used routinely for preventing or stopping milk production, nor to relieve symptoms of pain or swelling of the breasts after childbirth. Such symptoms can be managed by measures such as breast support or applying ice, and the use of painkillers if needed. The PRAC recommendation will be forwarded to the Coordination Group for Mutual Recognition and Decentralised Procedures – Human (CMDh) which will adopt a final position.

The Committee also concluded that bromocriptine must not be used in women at increased risk of serious side effects, including women with disorders that increase blood pressure or severe psychiatric disorders.

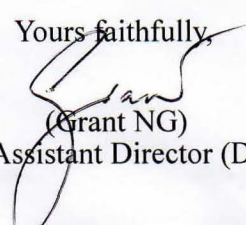
Please refer to the EMA's website for details:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/referrals/Bromocriptine-containing_medicinal_medicines_indicated_in_the_prevention_or_suppression_of_physiological_lactation_post-partum/human_referral_prac_000031.jsp&mid=WC0b01ac05805c516

In Hong Kong, there are seven registered pharmaceutical products containing bromocriptine which are prescription-only medicines. So far, the Department of Health (DH) has not received any local adverse drug reaction report related to the drug. The DH will remain vigilant on any safety updates of the drug and actions taken by overseas regulatory authorities and the final legally binding decision by the European Commission for further consideration. 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)

*We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority*