

衛生署藥物辦公室
藥物註冊及進出口管制部



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(IN REPLY PLEASE QUOTE THIS FILE REF.)

Dr. Raymond LIANG

President

Hong Kong Academy of Medicine

(Fax Number: 2505 5577)

Dear Dr. LIANG,

**MHRA: Do not use intravenous hypotonic saline solution
in children except in specialist settings under expert supervision**

Your attention is drawn to that the Medicines and Healthcare products Regulatory Agency (MHRA) reminded healthcare professionals not to use intravenous hypotonic saline (0.18% saline/4% glucose solution) in children aged 16 years or less, unless it is in a specialist setting and under expert supervision. In general, hypotonic saline is given to patients intravenously in a hospital to maintain or replace their fluid and salt requirements.

A review of the risks and benefits of hypotonic saline when used in children was undertaken by the MHRA and the Commission on Human Medicines (CHM). The review followed the restart of an inquiry into the deaths of four children in the UK who died from cerebral oedema caused by dangerously hyponatraemia after receiving intravenous hypotonic saline. On the basis of the evidence from this review, the CHM recommended that intravenous hypotonic saline should not be used in children except those treated by experts in paediatric specialist settings, such as kidney, heart, liver, high dependency and intensive care units.

Please refer to MHRA's website for details:

<http://www.mhra.gov.uk/Safetyinformation/Safetywarningsalertsandrecalls/Safetywarningsandmessagesformedicines/CON199554>

In Hong Kong, there are four registered injectable pharmaceutical products containing 0.18% saline, namely 0.18% Sodium Chloride 4.3% Dextrose Injection (HK-12411), 0.18% Sodium Chloride & 4.3% Glucose Injection (HK-28206), 0.18% Sodium Chloride and 4.3% Dextrose Injection (Thai Otsuka) (HK-55595) and 0.18% Sodium Chloride and 4.3% Glucose Intravenous Infusion (PT Otsuka) (HK-56868). So far, Department of Health has not received any related adverse drug reactions of the products. Healthcare professionals are advised to balance the risk of possible adverse effects related to the use of 0.18% saline/4% glucose solution against the benefit of treatment. Moreover, healthcare professionals should be aware and promptly recognize signs and symptoms of hyponatraemia (headache, nausea, seizures, lethargy, coma cerebral oedema) in children receiving hypotonic intravenous fluids.

Please encourage your members to report any adverse events caused by the drugs to the Pharmacovigilance Unit of Department of Health (tel. no.: 2319 2920, fax: 3904 1225 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 drug safety digest of drug safety news and information issued by Drug Office.

Yours sincerely,

(Ms. Pamela LI)
for Assistant Director (Drug)

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