REPUBLIC OF NAMIBIA

Ministry of Health and Social Services

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Enquiry: Ms. A M Shimbulu

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OFFICE OF THE REGISTRAR OF MEDICINES

Dear Healthcare Professional Communication on Safe Use of Hydroxyethyl-Starch (HES) Containing Products

Dear Healthcare Professional,

Background

The European Medical Agency's (EMA) Pharmacovigilance Risk Assessment Committee (PRAC) has recommended the suspension of the marketing authorisations for hydroxyethyl-starch (HES) solutions for infusion across the European Union.

These products are used as plasma volume replacement following acute blood loss, where treatment with the alternative products, crystalloids, alone is not considered to be sufficient. Some examples of HES products registered in Namibia includes; Voluven® 6%, Sabax Pentastarch® 6%, Sabax Hetastarch® 6%, VitaHES®, Vitafusal® 6%, Tetraspan® 10%, Tetraspan® 6%, Hemohes® 10% and Hemohes® 6%.

Two drug utilisation studies which indicated that HES solutions were being used in critically ill patients as well as those with sepsis and kidney injury triggered a review by PRAC. The review assessed the results of the drug utilisation studies, together with the currently available data on benefits and risks from clinical trials and observational studies and feedback received from stakeholders and experts. Based on this review, the PRAC concluded that restrictions introduced in 2013 for the use of HES products have not been sufficiently effective.

The restrictions included that HES should no longer be used to treat critically ill patients or patients with sepsis, because of an increased risk of kidney injury and mortality seen in clinical trials.

Namibia Medicines Regulatory Council's decision

The NMRC has decided to keep this product on the market as there are currently no drug utilisation studies done suggesting non-adherence to the restrictions in Namibia.

The Namibia Medicines Regulatory Council would however like to re- emphasise that healthcare providers adhere to the restrictions associated with the use of HES-containing products to ensure rational and safe use of these products.

The following are the restrictions in the use of HES-containing products:

- HES-containing products may be used solely for the treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient.
- HES-containing products should be used in the lowest effective dose for the shortest period of time. The treatment should be guided by continuous haemodynamic monitoring so that the infusion is stopped as soon as the appropriate haemodynamic goals have been achieved.
- HES-containing products are contraindicated in:
  - Sepsis
  - Burns
  - Renal impairment or renal replacement therapy
  - Intracranial or cerebral haemorrhage
  - Critically ill patients (typically admitted to the ICU)
  - Hyperhydrated patients, including patients with pulmonary oedema
  - Dehydrated patients
  - Severe coagulopathy
  - Severely impaired hepatic function
- There is lack of robust long-term safety data in patients undergoing surgical procedures and in patients with trauma. The expected treatment benefits should be carefully weighed against the uncertainties with regard to long-term safety and other available treatment options should be considered.
- Large randomised clinical trials have reported an increased risk of renal dysfunction in the critically ill, including patients with sepsis. Therefore, HES should no longer be used in these patients.
- Monitoring of renal function in patients receiving HES is recommended and HES must be discontinued at the first sign of renal injury.

Call to report adverse medicine reactions

Healthcare professionals should report all suspected adverse reactions associated with use of HES to the Therapeutics Information and Pharmacovigilance Centre (TIPC) of the NMRC using the Adverse Medicines Reaction form (Safety Yellow Form).

Please see below the contact details for TIPC:

Tel: 061 203 2406
Fax: 086 451 8283
Email: info.TIPC@mhss.gov.na

Yours sincerely,

REGISTRAR OF MEDICINES
REPUBLIC OF NAMIBIA

MR. JOHANNES GAESEB
REGISTRAR OF MEDICINES