REPUBLIC OF KENYA

MINISTRY OF MEDICAL SERVICES

PHARMACY AND POISONS BOARD

Telegram: "MINHEALTH" Nairobi
Telephone: 020-2716905/6, 020-3562107
Cellphone: 0733-884411/0720 608811
Fax: 2713409
E-mail: info@pharmacyboardkenya.org

When replying please quote

PHARMACY AND POISONS BOARD HOUSE
LENANA ROAD
P.O Box 27663-00506
NAIROBI

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All Market Authorization Holders

Re: Suspension of Registrations of Hydroethyl Starch (HES)- containing Solutions

Hydroxyethyl starch (HES) solutions are used for the treatment of hypovolemia (low blood volume) when plasma volume expansion is desired. Recent data have associated the use of these products with an increased risk of severe adverse events when used in certain patient populations.

Preliminary recommendation in the review of HES solutions for infusion carried out by the Pharmacovigilance Risk Assessment Committee (PRAC) concluded that the risk of HES products outweigh the benefits. This was published on the European Medicines Agency's website on 14th June 2013. The recommendations were made based on studies that show that patients with severe sepsis treated with HES products were more likely to receive renal replacement therapy and also patients treated with HES products were at a greater risk of mortality.

FDA has also completed the analysis of data from the RCTs, meta-analyses and observational studies indicating increased mortality and renal injury requiring RRT in critically ill adult patients, including patients with sepsis and those admitted to the ICU who are treated with HES solutions.

Based on the above, the Board has suspended registration of all HES containing solutions and orders that they all be withdrawn from the market immediately. This will remain so until the Board receives any new information.

DR. KIPKERICH C. KOSKEI, OGW
REGISTRAR

Cc: Chief Executive Officer
Kenya Medical Supplies Agency
Nairobi