SFDA SAFTEY COMMUNICATION

October 28th, 2013

Subject: The use of hydroxyethyl starch and risk of kidney injury and mortality in certain patient populations

The Saudi Food and Drug Authority (SFDA) would like to inform healthcare providers that following safety review of hydroxyethyl starch (HES), it has been found that the use of this product is associated with increased risk of renal injury and mortality in certain patient populations. Therefore, the following recommendations should be considered before using this product:

1- HES may be used in patients with hypovolaemia caused by acute blood loss where treatment with alternative infusions solutions known as crystalloids alone is not considered to be sufficient. In these patients, HES solutions should not be used for more than 24 hours and kidney function should be monitored for at least 90 days.

2- Hydroxyethyl starch **should not be used (i.e. contraindicated)** in the following conditions:

- In critically ill adult patients including those with sepsis, burn injuries and those admitted to the ICU.
- In patients with pre-existing kidney and/or liver injury.
- In patients undergoing open heart surgery in association with cardiopulmonary bypass due to excess bleeding.

3- HES should be discontinued at the first sign of renal injury.

4- HES should be discontinued at the first sign of coagulopathy.

For further information please contact us using the following information:

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You are also encouraged to report any adverse events through this link:

http://ade.sfda.gov.sa