NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

**29 November 2012**

# Proposal involving Voluven and Volulyte 6% approved

PHARMAC is pleased to announce the approval of the agreement with Fresenius Kabi New Zealand Limited regarding Voluven and Volulyte 6%. This was the subject of a consultation letter dated 1 November 2012. In summary, the effect of the decision is that:

- Volulyte 6% (hydroxyethyl starch 130/0.4 with sodium chloride, sodium acetate, potassium chloride and magnesium chloride) will be listed in Section H of the Pharmaceutical Schedule from 1 January 2013; and

- Both Volulyte 6% and Voluven (hydroxyethyl starch 130/0.4 with sodium chloride) will be included on the National Preferred Medicines List when it is implemented from 1 July 2013.

## Details of the decision

- From 1 January 2013, Volulyte 6% will be listed in Part II of Section H of the Pharmaceutical Schedule at the following price (expressed ex-manufacturer, excluding GST) and the chemical description for Voluven will be altered as set out below (additions in **bold**):

| Chemical | Presentation | Brand | Pack size | Price |
|---|---|---|---|---|
| Hydroxyethyl starch 130/0.4 with magnesium chloride, potassium chloride, sodium acetate and sodium chloride | Inj 6% with magnesium chloride 0.03%, potassium chloride 0.03%, sodium acetate 0.463% and sodium chloride 0.6%, 500 ml | Volulyte 6% | 20 | $198.00 |
| Hydroxyethyl starch **130/0.4 with sodium chloride** | Inj 6% **with sodium chloride 0.9%, 500 ml** | Voluven | 20 | $198.00 |

- Volulyte 6% and Voluven will be listed in the national Preferred Medicine List (PML) in Section H of the Pharmaceutical Schedule from the date of its implementation (currently estimated to be 1 July 2013).

## Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 15 November 2012 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal with the following issues being raised in relation to specific aspects of the proposal:



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| Theme | Comment |
|---|---|
| Results from the CHEST and 6S studies which were published in the New England Journal of Medicine recently highlighted that that hydroxyethyl starches can no longer be recommended for intensive care patients due to the increased risk of renal injury. | Inclusion of these hydroxyethyl starches on the PML provides clinicians the option of using hydroxyethyl starches if they consider it clinically appropriate in the circumstances.<br>Because other consultation response highlighted that there is still a place in therapy for these starches in the perioperative setting we consider that inclusion on the PML would be appropriate. |
| Despite the results from the CHEST and 6S studies, Voluven and Volulyte should still be included in the PML because there is still a place in therapy for these agents in the perioperative setting.<br><br>Any colloid needs to be used judiciously. There are only two classes of colloid available that are not derived from blood products – hydroxyethyl starch and gelatin. Hydroxyethyl starch is the more effective colloid and gelatin is associated with its own issues and is therefore used infrequently. If hydroxyethyl starch is not available for perioperative use, there would be a significant increase in the use of blood-product derived colloids such as albumin which has financial and supply implications. | Information noted. |

**More information**

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.