

10 June 2009

Proposal to list Hypertonic Saline (7% sodium chloride solution) in the Pharmaceutical Schedule for use in Cystic Fibrosis

Proposal Summary

PHARMAC is seeking feedback on a proposal to list hypertonic saline (7% sodium chloride solution) in Sections B and H of the Pharmaceutical Schedule from 1 August 2009 for use in a nebuliser for patients with cystic fibrosis. In summary, the proposal involves:

- listing 7% sodium chloride solution (500 ml bag) in Sections B and H of the Pharmaceutical Schedule; and,
- awarding Biomed Sole Supply Status for 7% sodium chloride solution in a 200 ml to a 500 ml bag in Section B of the Pharmaceutical Schedule until 30 June 2011..

If this proposal is approved by the PHARMAC Board (or Chief Executive under Delegated Authority), guidelines for the use of a bag of 7% sodium chloride solution would be developed in association with the Cystic Fibrosis Advisory Panel and the Cystic Fibrosis Association of New Zealand.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5pm, 29 June 2009** to:

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 PHARMAC
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 Wellington 6143

Email: kyle.reid@pharmac.govt.nz

Fax: 04 460 4995

All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

Details of the proposal

It is proposed that from 1 August 2009, a 500 ml bag of 7% sodium chloride solution would be listed in Sections B and H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, exclusive of GST):

<i>Chemical</i>	<i>Strength</i>	<i>Brand</i>	<i>Form</i>	<i>Pack Size</i>	<i>Price and Subsidy</i>
Sodium chloride	7%	Biomed	Bag	500 ml	\$23.90

Biomed would have Sole Supply Status of 7% sodium chloride solution in any pack size from 200 ml to 500 ml in Section B of the Pharmaceutical Schedule until 30 June 2011.

Background to the Proposal

The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Cystic Fibrosis Advisory Panel, both recommend that hypertonic saline (sodium chloride 7% solution) is listed on the Pharmaceutical Schedule for use in a nebuliser by cystic fibrosis patients.

Nebulised hypertonic saline improves mucociliary clearance, improves lung function and reduces the number and severity of exacerbations in patients with cystic fibrosis.

Methods to obtain 7% hypertonic saline for nebulisation include:

- mixing sodium chloride with sterile water,
- breaking a 23.4% glass vial of sodium chloride solution and diluting it with sterile water, or;
- using a 7% bag of sodium chloride solution.

Of the above methods the Cystic Fibrosis Advisory Panel recommends the use of a bag of 7% sodium chloride (as detailed below)..

Accordingly, PHARMAC issued a Request for Proposals for the Sole Supply of 7% sodium chloride solution in Section B of the Pharmaceutical Schedule. This proposal is the result of that process.

Use of a 7% sodium chloride bag for nebulisation in Cystic Fibrosis

A spike with a clear-link valve is attached to the bag of 7% sodium chloride solution and a luer-lock syringe is used to withdraw a dose as required (as illustrated below).



To reduce the possibility of contamination the syringe remains attached to the valve and bag at all times (thus creating a closed circuit) and fluid is withdrawn only.