13 October 2010

Proposal to list various oral suspending agents, products used in compounding oral liquid mixtures and galenicals

PHARMAC is seeking feedback on a proposal to:

- fund the oral suspending agents Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend and Ora-Blend SF;
- fund the following products for use in compounding of oral liquid mixtures: methyl hydroxybenzoate BP (Midwest), propylene glycol USP (Midwest) and sodium bicarbonate BP (Midwest); and
- fund two galenicals: menthol (Midwest) and sulphur (Midwest),

all through a provisional agreement with Midwest Pharmaceutics NZ Limited.

Further details of this proposal, including how to provide feedback and background information, can be found below and on the following pages. It is proposed that all changes would be implemented on 1 December 2010.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by Thursday, 28 October 2010 to:

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Therapeutic Group Manager
PHARMAC
Email: Greg.Williams@pharmac.govt.nz
Fax: 04 460 4995
Post: PO Box 10 254, Wellington 6143

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

Oral suspending agents

- Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend, Ora-Blend SF (the “Ora-products”) would be listed in Section C and in Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excluding GST):
Chemical Presentation Brand Pack size Proposed price and subsidy

Methylcellulose with glycerin and sucrose Suspension Ora-Blend 473 ml OP $38.00

Methylcellulose with glycerin and sodium saccharin Suspension Ora-Blend SF 473 ml OP $38.00

Methylcellulose Suspension Ora-Plus 473 ml OP $38.00

Glycerin with sucrose Suspension Ora-Sweet 473 ml OP $38.00

Glycerin with sodium saccharin Suspension Ora-Sweet SF 473 ml OP $38.00

• All of the Ora-products except Ora-Sweet and Ora-Sweet SF would be subject to the following restrictions:
  
  Only in extemporaneously compounded oral formulations
  Only in combination

• Ora-Sweet and Ora-Sweet SF would be subject to the following restrictions:
  
  Only in extemporaneously compounded oral formulations
  Only in combination with Ora-Plus

• The price of the Ora-products would be reduced, and would thereafter remain at the reduced price, if the volume of the Ora-product purchased during any six month period reached a trigger volume as follows (ex-manufacturer, excluding GST):

<table>
<thead>
<tr>
<th>6-monthly trigger volume for price and subsidy reduction (packs of 473 ml suspension)</th>
<th>Proposed adjusted price for Ora-products</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,501</td>
<td>$36.80 per Pack</td>
</tr>
<tr>
<td>2,501</td>
<td>$35.50 per Pack</td>
</tr>
<tr>
<td>5,001</td>
<td>$32.50 per Pack</td>
</tr>
</tbody>
</table>

• All of the Ora-products would have subsidy and delisting protection until 1 July 2013.

• The explanatory notes in Section C of the Pharmaceutical Schedule would be amended as follows (additions in bold, deletions in strikethrough):
Oral liquid mixtures

Oral liquid mixtures are subsidised for patients unable to swallow subsidised solid oral dose forms where no suitable alternative proprietary formulation is subsidised. Suitable alternatives include dispersible and sublingual formulations, oral liquid formulations or rectal formulations. Before extemporaneously compounding an oral liquid mixture, other alternatives such as dispersing the solid dose form (if appropriate) or crushing the solid dose form in jam, honey or soft foods such as yoghurt should be explored.

The Emixt website [www.pharminfotech.co.nz/manual/Formulation/mixtures/index.htm](http://www.pharminfotech.co.nz/manual/Formulation/mixtures/index.htm) has evidence-based formulations which are intended to standardise compounded oral liquids within New Zealand. The Emixt website also provides stability and expiry data for compounded products. We understand that for the majority of products compounded with Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend or Ora-Blend SF, a four week expiry would be clinically acceptable.

Subsidy for extemporaneously compounded oral liquid mixtures is based on:

<table>
<thead>
<tr>
<th>Solid dose form qs</th>
<th>or</th>
<th>Solid-dose form qs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preservative qs</td>
<td></td>
<td>Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend or Ora-Blend SF</td>
</tr>
<tr>
<td>Suspending agent qs</td>
<td></td>
<td>Ora-Blend SF to 100%</td>
</tr>
<tr>
<td>Water to 100%</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Prescribers may prescribe, and/or pharmacists may add, extra non-subsidised ingredients such as flavouring and colouring agents, but these extra ingredients will not be reimbursed. The subsidised ingredients in the formula will be reimbursed and a compounding fee paid.

The majority of extemporaneously compounded oral liquid mixtures should contain a preservative and suspending agent.

- **Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend or Ora-Blend SF** when used in compounding are considered to be appropriate preservative and suspending agents.
- Methylcellulose 3% is considered a suitable suspending agent and compounded hydroxybenzoate solution or methyl hydroxybenzoate 10% solution are considered to be suitable preservatives. Usually 1 ml of these preservative solutions is added to 100 ml of oral liquid mixture.

Some oral solid-dose forms are not considered appropriate for compounding into oral liquid mixtures and, therefore, should not be used for extemporaneously compounded oral liquid mixtures. These include long-acting solid-dose formulations, enteric coated tablets or capsules, sugar-coated tablets, hard gelatin capsules and chemotherapeutic agents.

The following practices will not be subsidised:

- **Where a Standard Formula exists in the Pharmaceutical Schedule for any solid-dose form,** compounding the solid dose form in Ora-Sweet, Ora-Sweet SF, Ora-Plus, Ora-Blend or Ora-Blend SF.
- Mixing one or more proprietary oral liquids (e.g. an antihistamine with pholcodine linctus).
- Extemporaneously compounding an oral liquid with more than one solid dose chemical.
- Mixing more than one extemporaneously compounded oral liquid mixture.
- Mixing one or more extemporaneously compounded oral liquid mixtures with one or more proprietary oral liquids.
- The addition of a chemical/powder/agent/solution to a proprietary oral liquid or extemporaneously compounded oral mixture.
Products for use in compounding of oral liquid mixtures and galenicals:

- Menthol and sulphur would be listed in Section B, and methyl hydroxybenzoate, propylene glycol and sodium bicarbonate would be listed in Section C, of the Pharmaceutical Schedule as follows (prices and subsidies expressed ex-manufacturer, excluding GST):

<table>
<thead>
<tr>
<th>Chemical</th>
<th>Presentation</th>
<th>Brand</th>
<th>Pack size</th>
<th>Proposed price and subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Menthol Crystals</td>
<td>Midwest</td>
<td>25 g</td>
<td>$6.92</td>
<td></td>
</tr>
<tr>
<td>Methyl hydroxybenzoate</td>
<td>Powder Midwest</td>
<td>25 g</td>
<td>$8.98</td>
<td></td>
</tr>
<tr>
<td>Propylene glycol Liquid</td>
<td>Midwest</td>
<td>500 ml</td>
<td>$11.25</td>
<td></td>
</tr>
<tr>
<td>Sodium bicarbonate Powder BP</td>
<td>Midwest</td>
<td>500 g</td>
<td>$8.95</td>
<td></td>
</tr>
<tr>
<td>Sulphur Precipitated</td>
<td>Midwest</td>
<td>100 g</td>
<td>$6.35</td>
<td></td>
</tr>
</tbody>
</table>

- All of the above products would have subsidy and delisting protection until 1 January 2012.

- Menthol crystals would be added to the list of dermatological galenicals.

Background

PHARMAC convened a working group with representatives from the New Zealand Hospital Pharmacist Association (NZHPA) and David Woods (consultant pharmacist with national and international expertise in practical aspects of paediatric formulation) to review oral liquid compounding in New Zealand hospitals and community pharmacies (using community claims data). The working group noted that there was a wide variance in compounding formulae in different hospitals, and community pharmacy compounding formulations also appeared to vary considerably across different pharmacies.

The major differences that were identified were:

- concentration of final preparation;
- suspending agents used; and
- expiry date on the final compounded oral liquid product.

The working group is formalising a final recommendation of formulae using evidence-based compounding stability data. The intent is that this list would be available at no cost to community and hospital pharmacists in New Zealand on the Emixt website. The formulae would provide evidence-based information on which suspending agents to use (including appropriate products to suspend using the Ora-products), the expiry date and a standardised concentration of the final preparation. It is likely that the process of uploading the monographs to the Emixt website would take 8 months; however, it is anticipated that if the current proposal is approved, information relating to the Ora-products would be available from 1 December 2010.

PHARMAC notes that this list would not be a list of Standard Formulae (as defined in the Pharmaceutical Schedule) rather, the intention is to provide community and hospital pharmacists with evidence-based formulae to use when compounding an oral liquid formulation in situations other than those where a Standard Formula exists in the Pharmaceutical Schedule.