

4 August 2015

Decision to list Rex Medical's respiratory aerosol inhalers

PHARMAC is pleased to announce the approval of an agreement with Rex Medical Limited to list a range of generic respiratory products. This was the subject of a consultation letter dated 16 February 2015 available on PHARMAC's website at <http://www.pharmac.health.nz/news/consultation-2015-02-16-rex-medical/>

In summary, the effect of the decision is that the following products will be listed, fully funded, in Section B and Part II of Section H (the Hospital Medicines List) from 1 October 2015:

- Floair (fluticasone) aerosol inhaler 50 mcg, aerosol inhaler 125 mcg and aerosol inhaler 250 mcg;
- RexAir (fluticasone with salmeterol) aerosol inhaler 50 mcg fluticasone with 25 mcg salmeterol, and aerosol inhaler 125 mcg fluticasone with 25 mcg salmeterol;
- Meterol (salmeterol) aerosol inhaler 25 mcg; and
- SalAir (salbutamol) aerosol inhaler 100 mcg.

Details of the decision

From 1 October 2015 the following products will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer and ex-GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy 1 October 2015
Fluticasone	aerosol inhaler 50 mcg	Floair	120 dose OP	\$7.50
Fluticasone	aerosol inhaler 125 mcg	Floair	120 dose OP	\$13.60
Fluticasone	aerosol inhaler 250 mcg	Floair	120 dose OP	\$27.20
Fluticasone with salmeterol	aerosol inhaler 50 mcg with 25 mcg salmeterol	RexAir	120 dose OP	\$37.48
Fluticasone with salmeterol	aerosol inhaler 125 mcg with 25 mcg salmeterol	RexAir	120 dose OP	\$49.69
Salbutamol	aerosol inhaler 100 mcg	SalAir	200 dose OP	\$3.80
Salmeterol	aerosol inhaler 25 mcg	Meterol	120 dose OP	\$26.46

- A confidential rebate, ending on 31 May 2017, will apply to Floair, RexAir and Meterol which will reduce the net price of those treatments to the Funder.
- From 1 June 2017 the prices and subsidies for Floair, RexAir and Meterol will reduce (i.e. the net price and the list price will be the same).
- Floair, RexAir, SalAir and Meterol will have subsidy and delisting protection until 1 February 2019.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by the 2nd of March 2015 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
<p>Some responders acknowledged that there is benefit in having a range of brands of inhaled medications available but all wanted assurance that there is good evidence of device testing, bioequivalence and patient acceptability.</p>	<p>Rex Medical has conducted clinical research in New Zealand with its devices over a three year period, assessing bioequivalence and usability.</p> <p>Medsafe assesses such matters as part of the registration process.</p> <p>The canisters, actuators and valves used in the products are manufactured by specialist companies.</p> <p>Rex Medical currently supplies a salbutamol with ipratropium bromide aerosol inhaler (Duolin HFA) and this has been funded in New Zealand since February 2011.</p> <p>Duolin HFA is manufactured by Cipla and is dispensed to ~36,000 patients in New Zealand every year with no complaints having been forwarded to PHARMAC. Floair, RexAir, SalAir and Meterol are also manufactured by Cipla.</p>

Theme	Comment
<p>Some responders were concerned that there could be patient confusion as a result of this proposal, whether the inhaler would fit the spacer devices, whether there are dose counters on the combination inhaler and raised concerns regarding introducing new inhalers due to the past experience with the Salamol inhalers.</p>	<p>Patients will not be required to change their inhalers as a result of this decision. The GSK branded products will remain listed on the Pharmaceutical Schedule.</p> <p>It is expected that the combination inhalers will have dose counters as these are being assessed by Medsafe. The inhalers are identical in shape to inhalers currently available on the market and will fit the spacer devices in the same way.</p> <p>PHARMAC is aware of the issues that surrounded the introduction of Salamol and will closely monitor any reports of malfunctions. Floair, RexAir, SalAir and Meterol are from the same manufacturer as Duolin HFA and, as mentioned above, PHARMAC has received no negative feedback following its listing in 2011.</p>

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.