NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

9 September 2015

Decision to list Respiratory Devices

PHARMAC is pleased to announce the approval of the agreements with Apex Medical and EBOS Healthcare to list peak flow meters, spacer devices and a paediatric mask for use with spacer devices.

These agreements were the subject of a consultation letter dated 6 July 2015 available on PHARMAC's website at: http://www.pharmac.health.nz/news/consultation-2015-07-06-respiratory-devices/

In summary, the effect of the decision is that the following products will be listed in Section B and Part III of Section H of the Pharmaceutical Schedule from 1 November 2015:

- Apex Medical's e-chamber Turbo 220 ml (single patient) spacer
- Apex Medical's e-chamber La Grande 510 ml (single patient) spacer
- Apex Medical's e-chamber Mask (paediatric) for use with spacer devices
- EBOS' Mini-Wright AFS Low Range (30-400 L/min) peak flow meter, and
- EBOS' Mini-Wright Standard (60-800 L/min) peak flow meter.

From 1 February 2016, the following products will be delisted from Section B and Part III of Section H of the Pharmaceutical Schedule:

- Space Chamber Plus 230 ml (single patient) spacer
- Space Chamber 230 ml (autoclavable) spacer
- EZ-fit Paediatric Mask, mask for spacer device, size 2
- Breath-Alert, Peak flow meter, low range
- Breath-Alert, Peak flow meter, normal range.

For the avoidance of doubt, no changes will be made as a result of this decision to the listing of the Volumatic 800 ml Spacer device (supplied by GlaxoSmithKline) in Section B and Part III of Section H of the Pharmaceutical Schedule.

Details of the decision, and a summary of the feedback received in response to consultation, are set out on the following pages

Details of the decision

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From 1 November 2015, the following products will be listed in the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excl GST) under the terms and conditions of an agreement between PHARMAC and Apex Medical:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Spacer device	220 ml (single patient)	e-chamber Turbo	1	$2.95
Spacer device	510 ml (single patient)	e-chamber La Grande	1	$5.12
Mask for spacer device	Small	e-chamber Mask	1	$2.20

- e-chamber Turbo will be listed in Section B of the Pharmaceutical Schedule with Sole Supply Status from 1 February 2016 to 30 June 2018.
- e-chamber Turbo will be listed in Part III of Section H of the Pharmaceutical Schedule and have price and delisting protection until 30 June 2018.
- e-chamber La Grande will be listed in Section B of the Pharmaceutical Schedule with subsidy and delisting protection until 30 June 2018.
- e-chamber La Grande will be listed in Part III of Section H of the Pharmaceutical Schedule and have price and delisting protection until 30 June 2018.
- e-chamber Mask will be listed in Section B of the Pharmaceutical Schedule with Sole Supply Status from 1 February 2016 to 30 June 2018.
- e-chamber Mask will be listed in Part III of Section H of the Pharmaceutical Schedule and have price and delisting protection until 30 June 2018.
- Space Chamber Plus, the currently listed brand of spacer device, 230 ml (single patient) will be delisted from Section B and Part III of Section H of the Pharmaceutical Schedule from 1 February 2016.
- EZ-fit Paediatric Mask, the currently listed brand of mask for spacer device, size 2 will be delisted from Section B and Part III of Section H of the Pharmaceutical Schedule from 1 February 2016.
- Space Chamber, the currently listed autoclavable 230 ml spacer device will be delisted from Section B of the Pharmaceutical Schedule from 1 February 2016.

For the avoidance of doubt, no changes will be made as a result of this decision to the listing of the Volumatic 800 ml Spacer device (supplied by GlaxoSmithKline) in Section B and Part III of Section H of the Pharmaceutical Schedule.

From 1 November 2015 the following products will be listed in the Pharmaceutical Schedule at the following prices and subsidies (ex-manufacturer, excl GST) under the terms and conditions of an agreement between PHARMAC and EBOS Healthcare:

Chemical	Presentation	Brand	Pack size	Price and subsidy
Peak flow meter	Low range (30-400 L/min)	Mini-Wright AFS Low Range	1	$9.54
Peak flow meter	Normal range (60-800 L/min)	Mini-Wright Standard	1	$9.54

- Mini-Wright AFS Low Range will be listed in Section B of the Pharmaceutical Schedule with Sole Supply Status from 1 February 2016 to 30 June 2018.

- Mini-Wright AFS Low Range will be listed in Part III of Section H of the Pharmaceutical Schedule and have price and delisting protection until 30 June 2018.

- Mini-Wright Standard will be listed in Section B of the Pharmaceutical Schedule with Sole Supply Status from 1 February 2016 to 30 June 2018.

- Mini-Wright Standard will be listed in Part III of Section H of the Pharmaceutical Schedule and have price and delisting protection until 30 June 2018.

- Breath-Alert, the currently listed brand of Peak flow meter, low range will be delisted from Section B and Part III of Section H of the Pharmaceutical Schedule with effect from 1 February 2016.

- Breath-Alert, the currently listed brand of Peak flow meter, normal range will be delisted from Section B and Part III of Section H of the Pharmaceutical Schedule with effect from 1 February 2016.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 21 July 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
The anti-static properties of the spacers will avoid the need for priming which is good for patients.	Noted
Clarification on any costs that the patient may incur.	Spacers, masks and peak flow meters will remain on PSO and there will be no charge to patients.
Concern that putting a used spacer device into household recycling collections will potentially expose recycling workers to prescription medicine residues and respiratory pathogens.	PHARMAC is not aware of any evidence that recycling spacers would lead to any appreciable safety risks.

Theme	Comment
Are DHBs are able to continue to using a cheaper peak flow meter?	Peak flow meters are listed in the "Optional Pharmaceuticals" section of Section H of the Pharmaceutical Schedule. There is no Hospital Supply Status awarded to the peak flow meters listed as a result of this decision, so DHB hospitals are able to purchase other brands if they prefer to. Advice we received from Respiratory Physicians was that meters capable of measuring both low range (up to 450 L per minute) and normal range (up to 800 L per minute) were required.
Are disposable mouthpieces available to go with the peak flow meters?	Disposable mouthpieces are not included in the Agreement with EBOS. The Mini-Wright peak flow are listed for single patient use however, the universal mouthpiece may be autoclaved or used with disposable mouthpieces if the intention is for them to be used for a number of patients.
DHBs use various sizes of paediatric masks for different aged children as one size does not fit all. Are they able to continue to use them and will all masks fit the new spacers?	As with the peak flow meters, the masks are also listed in the "Optional Pharmaceuticals" section of Section H of the Pharmaceutical Schedule without Hospital Supply Status and DHB hospitals are able to purchase other brands if they wish. The masks are shaped for an effective seal and are designed to fit infants and children so should be suitable for different aged children to use.
Concern about level of market exposure to this product to prove its efficacy, robustness and acceptability to consumers.	These products have been available on private market in New Zealand and have received positive feedback from patients. PHARMAC has been advised that these devices have been widely used in the hospital market in Australia.

Theme	Comment
A supplier raised concerns about the spacers clinical effectiveness and safety, in particular whether: • the lung deposition is above or equal to other spacers available. • the lack of exhaust valve will mean that air will be freely inhaled through the exhaust openings reducing the efficacy of the drug delivery. • the exhaust vents would direct exhaled breath onto the face around the mouth and fine drug particles (that have not settled in the lungs) would be exhaled and impact the face and maybe the eyes. • the turbo mouthpiece could trap saliva and therefore trap bacteria and respiratory pathogens. • the swing gate valve on the e-chamber spacer was adequately secure. • The oval opening will be difficult to use with inhalers with round ends, which could be frustrating for users.	As with any change, it is advisable that patients and their healthcare professionals are aware that there may be a slight difference and monitor symptoms accordingly. PHARMAC reviewed and sought specialist clinical advice on in vitro deposition testing conducted by an independent laboratory in Australia. This evidence supports the efficacy of the proposed e-chamber Turbo spacer and demonstrates non-inferiority to the currently subsidised Space Chamber Plus. In vitro deposition testing procedures are designed to mimic actual breathing patterns and a possible small inflow of air through these openings would be accounted for in the testing. Results obtained in testing support the efficacy of the proposed e-chamber Turbo spacer. PHARMAC has not seen any substantiated evidence that particle deposition on the face would occur. Washing weekly and disposal of the device after 12 months as per the instructions will appropriately minimise potential for any significant bacterial contamination. The supplier of the e-chamber spacer has had no reported incidences from overseas use. PHARMAC has received anecdotal reports of issues with swing gate valves for the incumbent devices but no reports of valve pieces being extracted from devices have been received Whilst insertion and removal may be more difficult than with the more conventional MDI shape, the design of the Turbo spacer is not prohibitive for use with a round inhaler mouthpiece.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz.