

15 November 2011

Sole supply of Respiratory Devices (peak flow meters, spacer devices, paediatric masks)

PHARMAC is pleased to announce the approval of proposals with Air Flow Products Limited and GlaxoSmithKline NZ Limited for the sole supply of a number of respiratory devices. The proposals were the subject of a consultation letter dated 14 October 2011 which can be found at <http://www.pharmac.govt.nz/2011/10/14/Respiratory%20Devices.pdf>.

In summary, the effect of the decision is that the following products will have Community Sole Supply Status until 30 June 2015.

- GlaxoSmithKline's Volumatic brand of spacer device, 800 ml – this will remain fully subsidised at the current price.
- Air Flow Ltd's paediatric mask for use with spacer devices – this will remain fully subsidised at a lower price/subsidy.
- Air Flow Ltd's 230 ml spacer device (single patient) - this will remain fully subsidised at a lower price/subsidy.
- Air Flow's low and normal range peak flow meters – these will remain fully subsidised at a lower price/subsidy.

The above products will also be listed in Part II of the Pharmaceutical Schedule:

Finally, the chemical heading for the listing of the 230 ml (autoclavable) spacer device will be amended and the quantity available on a PSO reduced from 20 to 5.

Details of the proposal

Mask for Spacer device and Peak Flow Meters

The paediatric mask for spacer device and peak flow meters will have price and subsidy reductions in Section B of the Pharmaceutical Schedule, and will be listed in Part II of Section H of the Pharmaceutical Schedule, from 1 December 2011 as follows (ex-manufacturer, excluding GST)

Product	Presentation	Brand	Pack Size	Current price and subsidy	Price and subsidy from 1 Dec 2011
Mask for spacer device	Size 2	EZ-fit Paediatric mask*	1	\$3.28	\$2.99
Peak Flow Meter	Low range	Breath-Alert	1	\$13.75	\$11.44
Peak Flow Meter	Normal Range	Breath-Alert	1	\$13.75	\$11.44

NB: *there has been a name change for the paediatric mask from Foremount Child's Silicone mask to EZ-fit paediatric mask. There is no change to the product itself and the pharmacode will remain the same.

Spacer Devices

GSK's Spacer device will continue to be listed in Section B and Part II of Section H of the Pharmaceutical Budget as follows (ex-manufacturer, excl GST):

Product	Presentation	Brand	Pack Size	Current price and subsidy	Price and subsidy from 1 Dec 2011
Spacer Device	800 ml	Volumatic	1	\$8.50	\$8.50

Air Flow Products Limited new "Space Chamber Plus" 230 ml Spacer Device will be listed in Section B and Part II of Section H of the Pharmaceutical Schedule from 1 December 2011 (ex-manufacturer, excl GST). This will replace the current "Space Chamber" brand which will have a price and subsidy reduction from 1 December 2011 and will be delisted from 1 February 2012 (ex-manufacturer, excl GST).

Product	Presentation	Brand	Pack Size	Current price and subsidy	Price and subsidy from 1 Dec 2011
Spacer Device	230 ml (single patient)	Space Chamber Plus	1	Not listed	\$4.72
Spacer Device	230 ml (single patient)	Space Chamber	1	\$8.38	\$4.72

Air Flow Products Ltd Space Chamber Plus differs from its current Space Chamber in the valve design and the dimensions. The supplier states that these modifications will lead to improved drug delivery with an increase in the weight of drug exiting the device as shown in the table below. Members of the Respiratory Subcommittee of PTAC considered the new spacer device appropriate and noted that while the increased dose would not impact on the majority of patients some may experience increased side effects. They considered that clinicians, respiratory nurses and patients should be informed of the changes if implemented.

Anderson Cascade Impactor Test Results (performed by the Aerosols Group of the School of Paediatrics and child Health at the University of Western Australia)

Device		Weight of drug per actuation (µg)		MMAD* (µm)
		Exiting Device	Particles <4.7µm	
Space Chamber	Mean	19.8	18.3	2.36
	SD	4.4	4.4	0.11
Space Chamber Plus	Mean	36.2	32.7	2.42
	SD	8.3	7.5	0.23
Volumatic Spacer	Mean	40.9	37.5	2.57
	SD	5.3	5.0	0.01

*MMAD Mass median aerodynamic diameter.

PHARMAC and Air Flow Products Limited will provide implementation material.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 2 November 2011 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal. The following issues were raised in relation to specific aspects of the proposal:

Theme	PHARMAC Comment
One responder expressed concern that there were no masks for adults listed on the Pharmaceutical Schedule.	Adult masks have never been listed on the Pharmaceutical Schedule. PHARMAC would be happy to receive an application for their funding including information regarding the clinical benefit that they would provide.
One responder was concerned that the implementation time frames were too short and recommended that there be a crossover of subsidy for the masks and space chambers.	The masks and peak flow meters are the same as those currently listed and are supplied by the incumbent supplier. The only product that is changing is the Spacer. PHARMAC understands that due to the large volume of the spacers, pharmacies do not tend to hold significant stock of these items.
<p>One responder commented that they supported better access to the 230ml spacer device as it leads to better compliance for children and men due to the smaller size.</p> <p>The same responder opposed the reduction in the number of 230 ml spacers available on a PSO.</p> <p>The same responder considered the contract period was too long and would lock out potential innovation and cost reduction.</p>	<p>There will be no change in accessibility to the 230 ml spacer. The reduction in the number obtainable on a PSO is only in relation to the considerably more expensive autoclavable spacer which is designed to be used by multiple patients. It appears to be being provided to individual patients as demonstrated by the increase in usage following the change from WSO to a PSO.</p> <p>The length of the agreement takes into account the likelihood of better and cheaper products becoming available while also providing sufficient incentive for suppliers to reduce their pricing.</p>

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.