**14.2 SALBUTAMOL**

**200 microgram inhalation: powder for, 128 capsules; Ventolin® Rotacaps®; GlaxoSmithKline Australia Pty Ltd.**

1. **Purpose of Application**
   1. The submission requestedPBSlisting of a new pack size of 128 salbutamol capsules to replace the current listing of salbutamol 100 capsule pack size. As a result of the existing maximum quantity (200 capsules) not being divisible by the new pack size (128), the existing maximum quantity and number of repeats needed to be amended to provide an approximately equivalent amount of therapy as the current listing of 200 capsules and 5 repeats.
2. **Summary of submission**
   1. The submission requested listing a new pack size presentation (and therefore an amendment to the maximum quantity was required) after advising of supply difficulties with the 100 capsules pack size. The new pack size would replace the old pack size.
   2. The submission requested an equivalent price based on the per milligram price of the currently listed pack of 100 capsules.
   3. The submission did not present an estimate of PBS usage and financial implications but estimated that approximately 70 units of the currently PBS listed *Ventolin Rotacaps* are dispensed on a weekly basis.
   4. The submission proposed that the new pack size be listed at a quantity of 2 packs with 4 repeats (total prescription would provide a patient with 1,280 capsules) in place of the currently listed 2 packs with 5 repeats (total prescription would provide a patient with 1,200 capsules). This was considered appropriate by the PBAC.
   5. The PBAC considered that inclusion of the new pack size of salbutamol capsules on the PBS would have no net financial implications as this new pack size will replace the currently PBS listed pack size of 100 capsules.
3. **PBAC Outcome**
   1. The PBAC recommended out-of-session an unrestricted benefit listing for Ventolin Rotacaps 200 microgram, 128 capsules, on a cost-minimisation basis with the currently listed pack of 100 capsules.
   2. The PBAC recommended that the maximum quantity of 200 units (2 packs) be amended to 256 units (2 packs), and, the number of repeats be amended from 5 repeats to 4 repeats.
   3. The PBAC advised that the new presentation is suitable for inclusion in the PBS medicines for prescribing by nurse practitioners within collaborative arrangements.
   4. The Safety Net 20 Day Rule should not apply.

**Outcome:**

Recommended

1. **Recommended listing**
   1. Amend listing to read as follows:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Name, Restriction,  Manner of administration and form | Max. Qty (Packs) | Max. Qty (Units) | №.of  Rpts | Proprietary Name and Manufacturer | |
| Salbutamol  200 microgram inhalation: powder for, ~~100~~ ***128*** capsules | 2 | ~~200~~  ***256*** | ~~5~~ ***4*** | Ventolin® Rotacaps® | GK | |

Unrestricted benefit

1. **Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

1. **Sponsor’s Comment**

The sponsor had no comment.