PUBLIC SUMMARY DOCUMENT

Product: Omnigon Flexima Uro Silk **Applicant:** Omnigon **Date of SPAP Meeting:** 22 October 2019

1. Proposed Deletion on the Stoma Appliance Scheme

The applicant, Omnigon, sought the deletion of five variants no longer available, from the current listing of the Omnigon Flexima Uro Silk (SAS Code 9826E) in subgroup 3(b), of the Stoma Appliance Scheme (SAS) Schedule. The product, including 10 variants, is currently listed at a unit price of \$6.373, with a maximum monthly quantity of 30 units.

2. Substitute products

The nominated substitute products are variants in the Omnigon Flexima Uro Silk (SAS Code 9826E) range. The product, including 10 variants, is currently listed in subgroup 3(b), of the SAS Schedule at a unit price of \$6.373, with a maximum monthly quantity of 30 units.

variants to be deleted	
Product Code	Description
44916	Medium, 640ml, polygon, CTF 15mm-25mm
44918	Medium, 230ml, hexagon, pre-cut 20mm
44921	Medium, 640ml, polygon, pre-cut 25mm
44923	Medium, 640ml, polygon, pre-cut 30mm
44936	Extra small, 230ml, hexagon, pre-cut 35mm

Variants to be deleted

Nominated substitute – SAS Code 9826E - Omnigon Flexima Uro Silk

Product Code	Description
44919	Non-return valve single chamber, beige with fabric backing, extra small, 230ml, adapter for connection to drainage bag, tap closure, belt loops on baseplate, hydrocolloid baseplate, shallow convexity, rigid convex ring, hydrocolloid self- adhesive, standard wear, polygon, cut-to-fit, 12mm, 35mm,
44915	Non-return valve single chamber, transparent with fabric backing, extra small, 230ml, tap closure, adapter for connection to drainage bag, belt loops on baseplate, hydrocolloid baseplate, shallow convexity, rigid convex ring, hydrocolloid self-adhesive, standard wear, polygon, cut-to- fit, 12mm, 25mm,
44917	Non-return valve single chamber, transparent with fabric backing, extra small, 230ml, tap closure, adapter for connection to drainage bag, belt loops on baseplate, hydrocolloid baseplate, shallow convexity, rigid convex ring, hydrocolloid self-adhesive, standard wear, polygon, cut-to- fit, 12mm, 35mm,

3. Background

This product was first listed on the SAS Schedule in April 2011.

4. Clinical Place for the Product

The proposed substitute product provides an alternative for users requiring a one-piece urostomy with convex baseplate

Financial Analysis

The deletion of five variants is recommended. Substitute products are currently listed in subgroup 3(b) of the SAS Schedule at the same cost and maximum monthly quantity. It is therefore unlikely that there would be any budgetary impact for the SAS as a consequence of deleting this product.

5. SPAP Recommendation

The SPAP recommended the deletion of five variants from the product range for Omnigon Flexima Uro Silk (SAS Code 9826E) listed in subgroup 3(b), of the SAS Schedule at the unit price of \$6.373, with a maximum monthly quantity of 30 units.

The SPAP also noted that Omnigon is to advise Stoma Associations, ostomates, Stomal Therapy Nurses and ACSA of the deletion. A period of approximately six months from the SPAP recommended date (22 October 2019) should be given to allow users of the product to seek a suitable alternative and to enable Stoma Associations to manage their stock levels.

6. Context for Decision

The SPAP helps decide whether stoma products should be subsidised and, if so, the conditions of their subsidisation in Australia. It considers submissions in this context. A SPAP decision not to recommend listing or changes to a listing does not represent a final SPAP view about the merits of a particular stoma product. A company can resubmit to the SPAP following a decision not to recommend listing or changes to a listing. The SPAP is an advisory committee and as such its recommendations are non-binding on Government. All SPAP recommendations are subject to Cabinet/Ministerial approval.

7. Applicant's Comment

Omnigon agrees with the SPAP's recommendation.