1. **Proposed Listing on the Stoma Appliance Scheme**
The applicant, Omnigon, sought an increase to the current list price of the Welland Flair 2 Two-Piece Flat Baseplate (SAS Code 9994B; eight variants) to the benchmark price for Subgroup 4(d) of the Stoma Appliance Scheme (SAS) Schedule – $5.232.

2. **Comparator**
The application was for listing at the benchmark price, based on the presence of attributes as defined for products in Subgroup 4(d).

3. **Background**
This application was incorrectly considered as an application for new listing at the Stoma Product Assessment Panel (SPAP) meeting in November 2012, leading to the duplication of the product on the 1 April 2013 SAS Schedule (and subsequent removal of the invalid duplicate listing via the release of an erratum). The application was therefore referred back to the Panel in July 2013 for correct consideration of the applicant’s request for an increase to benchmark pricing for this product. The product is currently listed in Subgroup 4(d) at the ‘under benchmark’ unit price of $5.005, with a maximum monthly quantity of 30 units.

The Panel’s November 2012 recommendation in relation to this application stated that the product should be listed in subgroup 4(a) of the SAS Schedule (Two-Piece Flat Baseplate with Mechanical Coupling), at the lower commensurate benchmark unit price than that set for subgroup 4(d) (Two-Piece Flat Baseplate with Adhesive Coupling). The applicant has subsequently contested this categorisation. In view of the necessary reconsideration of this application, the Panel was requested to simultaneously revisit the question of the nature of the product’s coupling mechanism, and through it make a definitive determination as to the correct categorisation of all Flair 2 products.

4. **Clinical Place for the Product**
The product is a flat baseplate suitable for use as part of a two-piece ostomy appliance system with an attaching pouch.

5. **SPAP Comment**

   **Clinical Analysis**
The applicant contended that the product satisfies all feature requirements for a benchmark listing in Subgroup 4(d), and offers a unique ‘Dual-Security’ coupling system with both adhesive and mechanical features. This coupling system, along with the product’s ‘skin friendly’ Hyperflex hydrocolloid baseplate material, is claimed to provide clinical benefits to patients regardless of whether the baseplate used is flat or convex.

It was reaffirmed by the Panel that the product’s primary coupling mechanism is mechanical, with the adhesive strip forming an additional security layer. The reasons for this determination (with application to all Flair 2 products) were as follows:

- attachment of the appropriate pouch to this baseplate primarily requires mechanical force (of a degree that makes the product unsuitable for use in post-operative patients) to achieve a ‘click’ connection. Mechanical connection is required before the adhesive can be used.
coupling cannot be achieved by placement of the fingers behind the ‘landing zone’ of the baseplate to achieve a ‘stick’ connection (the normal method used for adhesive systems); and

- if the adhesive strip covers on the baseplate are not removed, the pouch will still attach – ie. the primary (mechanical) coupling mechanism will still function.

The Panel was satisfied that the product contains all the attributes of the notional benchmark product in Subgroup 4(a) of the SAS Schedule, and that under the existing SAS Pricing Guidelines there is therefore no justification for the list price to remain below that of the benchmark for products listed in Subgroup 4(a) ($4.141).

It was noted that the supplementary clinical data presented were of a very low quality and therefore not informative. The evaluation relied on nurse (as opposed to patient) rating of the product’s performance, versus comparator products previously used and according to assessment criteria relating to both baseplate and pouch. Minimal description was provided, and the opinions of the stomal therapy nurses surveyed related to only 11 patients.

In order for any future recommendation to list the product at the benchmark price in Subgroup 4(d) to be made, the Panel would require evidence substantiating the product’s superiority to a Subgroup 4(a) – and status as ‘no worse than’ a Subgroup 4(d) – product. Information relating to the product’s performance against a Subgroup 4(d) comparator would be required at a higher evidence quality than that provided within the current submission. In the absence of such evidence, the primary/dominant coupling mechanism must be the default determinant of correct categorisation.

**Economic Analysis**

As the product contains the features of the notional benchmark product in Subgroup 4(a) of the SAS Schedule, the Panel agreed to recommend listing on a cost-minimisation basis.

**Financial Analysis**

As the product is currently listed in Subgroup 4(d) at a higher price than that of the benchmark set for Subgroup 4(a), rescheduling the product to Subgroup 4(a) would result in a cost reduction to Government.

6. **SPAP Recommendation**

The SPAP recommended that the Welland Flair 2 Two-Piece Flat Baseplate (SAS code 9994B; eight variants) be transferred to Subgroup 4(a) of the SAS Schedule and priced at the commensurate benchmark unit price of $4.141, with a monthly maximum quantity of 30 units.

Furthermore, the Panel recommended that all Welland Flair 2 products currently listed in adhesive coupling subgroups on the SAS Schedule be transferred to the appropriate mechanical coupling subcategories, with commensurate benchmark list prices and maximum monthly quantities.

7. **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. An SPAP decision not to recommend listing or not to recommend 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.
8. Applicant’s Comment
Omnigon accepts the SPAP’s decision at this time.