1. **Proposed Listing on the Stoma Appliance Scheme**
   The applicant, Omnigon, sought listing of the Welland Aurum One-Piece Urostomy Flat Pouch in Subgroup 3(a) of the Stoma Appliance Scheme (SAS) Schedule. The product, including eighteen variants, was proposed for listing at the benchmark unit price of $4.674, with a maximum monthly quantity of 60 units.

2. **Comparator**
   The application was for listing at the benchmark price, based on the presence of attributes as defined for products in Subgroup 3(a).

3. **Background**
   This was the Stoma Product Assessment Panel (SPAP)’s first consideration of this product.

4. **Clinical Place for the Product**
   The product is a one-piece urostomy pouch with a flat baseplate, suitable for use by people with a urinary stoma – for example an ileal conduit. It features the thicker and more robust baseplate required in appliances designed for the collection of urinary output.

5. **SPAP Comment**

   **Clinical Analysis**
   The SPAP noted that the product contains the attributes of the notional benchmark product in Subgroup 3(a) of the SAS Schedule, and would meet the requirements of the SAS without the addition of Manuka honey to the hydrocolloid in the baseplate.

   Clinical papers submitted by the applicant refer to the use of honey in wound care, where the honey offers a moist wound environment for healing. The SPAP noted that this may not be of benefit in the context of stoma care, where poorer baseplate function due to hydration is a conceivable secondary outcome of the addition of this new ingredient. As honey is a hydroscopic substance, the absorption of moisture in the peristomal area could potentially reduce baseplate adhesion resulting in leakage.

   The Panel noted the clinical data provided by the applicant to confirm that there had been no adverse changes to peristomal skin condition as a result of using a hydrocolloid baseplate infused with Manuka honey, but concluded that these studies were not informative. Of the ten percent of participants in the user evaluation conducted in November 2012 who reported a change in skin condition, half reported improvement while just under half reported deterioration. This represented a doubling of participants whose skin condition had deteriorated during the trial period (from four to eight percent). It was also noted that a trial period of two weeks for any one product is insufficient for the observance and monitoring of any skin conditions that may arise.

   Further, the Panel noted the conclusion of the 2013 Cochrane Review into the use of honey in wound care: ‘there is insufficient evidence to guide clinical practice in other types of wounds [beyond venous leg ulcers, burns and cutaneous Leishmaniasis where results on the
effect of honey are equivocal] and health services may wish to consider avoiding routine use of honey dressings until sufficient evidence of effect is available.'

The Panel therefore concluded that there is no evidence of any clinical benefit provided by the addition of Manuka honey to the baseplate of a stoma appliance, while the potential for detrimental effects on patient outcomes has not been addressed by the applicant.

Economic Analysis
Not undertaken.

Financial Analysis
Listing of this product would be on a cost-minimisation basis compared with the notional benchmark product in Subgroup 3(a) of the SAS Schedule. There would therefore be no budgetary impact for the SAS as a consequence of listing this product under the conditions requested by the applicant.

6. SPAP Recommendation
In view of the potential of the inclusion of honey in the baseplate of this product to impact skin integrity and appliance adhesion, the SPAP recommended that listing of the product be deferred pending provision by the applicant of acceptable data pertaining to the patient-relevant outcomes of skin condition/integrity, baseplate adhesion and leakage. Any study conducted in order to obtain such data should ideally run for a period of no less than four weeks.

In addition, the SPAP requested evidence of conformity with Australian and European safety standards, including the results of biocompatibility tests – for example compliance with ISO-10993.

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.