Australian Government Department of Health and Aged Care

Application to List Stoma Related Products on the Stoma Appliance Scheme

Price Premium Products

About this form

This form should be used by sponsors of stoma-related products seeking to add a listing to the Stoma Appliance Scheme (SAS) Schedule, or to add an additional variant to an existing SAS code and product range listed on the SAS Schedule.

A product used in the management of a stoma may be considered for a price premium listing on the SAS Schedule if it meets the conditions outlined in the SAS Application and Assessment Guidelines (Guidelines).

The price premium is set by the Department of Health and Aged Care (the Department) following advice from the Stoma Product Assessment Panel (SPAP).

This form must be completed with reference to the Guidelines. The Guidelines are available on the SAS webpage under 'Resources' or at www.health.gov.au/resources/publications/stoma-appliance-scheme-application-and-assessment-guidelines.

A separate form must be used for products to be listed under each SAS code.

It is the responsibility of the sponsor to provide sufficient information relevant to each of the sections for a full assessment of their application by the SPAP.

Please ensure all sections of the application are complete before submitting the application to the Department. A checklist has been provided for your assistance.

Completed applications and supporting material should be sent to the Department using the contact details listed below:

Contact Details for the SPAP Secretariat:

Address: Stoma Appliance Scheme GPO Box 9848 CANBERRA ACT 2601 Phone: (02) 6289 2308 Email: <u>stoma@health.gov.au</u> Web: <u>www.health.gov.au/stoma</u>



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Section 1 – Applicant Details

The applicant must be the sponsor of the stoma-related product in Australia.

Application Details of S	ponsor
Company	
ABN	
Address	
City	
State/Postcode	
Contact Name	
Position	
Phone	
Email	

Applicant Declaration

I declare that the information provided on this form and any attachments is true and correct to the best of my knowledge.

I accept that this application and/or its contents will be made available to the Stoma Product Assessment Panel which will consider it for the purpose of making recommendations to the Department of Health and Aged Care.

Applicant Signature

Date



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Section 2

Product Information

The purpose of this section is to obtain information about the product which is the subject of the application as well as the nominated comparator product for the application.

Product Information	Product Details
Group	
Subgroup	
Group ID	
Product Name	
Product Code	
SAS Code (for existing product ranges only)	
Product Pack Size	
Number of Variants	
Proposed Unit Price (\$)	
Proposed Monthly/Annual Maximum Quantity	
ARTG ID	
Comparator Product Information	Comparator Product Details:
Comparator Group	
Comparator Subgroup	
Comparator Product Name	
Comparator SAS Code	
Comparator Unit Price	

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Product Features

This table should be used to specify the product features for Groups 1 to 7. If this is an application to list a product range with multiple variants, use the Microsoft Excel Product Features Table to add additional variants within the same product range to an 'Application to list a product - Benchmark Groups 1 to 7' or 'Application to list a product - Price Premium Products'. Only fill out the fields in the table for features that are relevant to the product.

Product Features	Description/size
Pouch Type	
Pouch Filter	
Pouch Construction Material	
Pouch Volume (ml)	
Pouch Size	
Pouch closure	
Valves	
Belt Loops	
Night Drainage	□Yes □No
Headspace	
Baseplate Type	
Baseplate Material	
Baseplate Thickness (mm)	
Baseplate Shape	
Baseplate Skin Adhesion	
Baseplate Wear Time	
Baseplate Opening Type	
Baseplate Opening Size (mm)	
Release Tabs	□Yes
	□No



Has the Microsoft Excel product features table been used for additional variants?

 \Box Yes – attach the table when you submit your application.

🗆 No

Product Samples

Applicants should provide 3 product samples.

Please ensure all product samples are labelled correctly with the product code and product description on each product included in the application. If there are multiple products in the product range, please separate the products and label correctly.

Product Photo

Please attach an image of the product which is the subject of the application with the supporting documents in the application.



Section 3 – Clinical Assessment Information

Please attach all clinical information with your application.

The purpose of this section is to obtain all relevant clinical assessment information about the product to enable it to be fully assessed against the appropriate comparator. Information provided under this section will be used to assess the products clinical effectiveness and safety.

Refer to section 3 of the Guidelines for more information on clinical assessment evidence the SPAP will consider.

Section 4 – Economic Assessment Information

Please attach all economic assessment information with your application.

Applicants requesting a price premium should provide evidence demonstrating the product offers improved health outcome over the appropriate benchmark comparator, and that the higher cost can be justified.

The purpose of this section is to obtain relevant economic information, if available, about the product, to allow the cost and cost effectiveness of the product to be assessed in relation to the nominated comparator or other relevant products. This will enable SPAP to determine whether the product is likely to represent value in terms of expenditure on healthcare in Australia.

Refer to section 4 of the Guidelines for more information on economic assessment information the SPAP will consider.

Section 5 – Financial Assessment Information

Please attach all financial assessment information with your application.

The purpose of this section is to seek information about the proposed price, the proposed monthly or annual maximum quantity and the potential utilisation of the product which is the subject of the application. For a price premium product, evidence provided should demonstrate that the product has improved quality of life and/or survival provided by the product in comparison to a benchmark product.

Refer to section 5 of the Guidelines for more information on financial assessment information the SPAP will consider.

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Section 6 – Additional Information

The purpose of this section is to allow any further information to be provided which may be relevant to the application and has not been included in the previous sections. Any confidential information in the application should also be identified here. Please attach a separate page for additional information if required.



Section 7 – Supporting Documentation

All attachments relating to this application should be correctly labelled and indicate the relevant section in the application they refer to in the table below (attach a separate page/s if additional space is required)

File title	Relevant Section in Application

Application Checklist

Information	Included
Section 1 – Application Details and Declaration	
Section 2 – Product information, comparator product information and product features	
Section 2 – Product photo (attachment), Product samples (labelled)	
Section 3 – Clinical Assessment Information (attachment)	
Section 4 – Economic Assessment Information (attachment)	
Section 5 – Financial Assessment Information (attachment)	
Section 6 – Additional Information including confidential information	
Section 7 – Supporting Documentation & Checklist	