

Australian Government Department of Health and Aged Care

Application to List Stoma Related Products on the Stoma Appliance Scheme Groups 8 to 11

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, in Groups 8 to 11.

A product used in the management of a stoma may be considered for a listing in a subgroup of Groups 8 to 11 on the SAS Schedule if it meets the conditions outlined in the SAS Application and Assessment Guidelines (Guidelines).

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 full assessment of their application by the Stoma Product Assessment Panel (SPAP).

Please ensure all sections of the application are complete before submitting the application to the Department of Health and Aged Care (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>



Department of Health and Aged Care

Section 1 – Applicant Details

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

Application Details of Sponsor		
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



Department of Health and Aged Care

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	
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	



^{*} Department of Health and Aged Care

Product Features

This table should be used to specify the product features for products in Groups 8 to 11. If this is an application to list a product range, please use a separate row for each new product within the product range. If more than 10 product codes are required, please attach the additional codes on a separate document with the supporting documentation.

Product Code	Product Description

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.



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Section 3 – Clinical Assessment Information

Please attach all clinical assessment information with your application.

The purpose of this section is to obtain all relevant clinical 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.

Applications for benchmark listing will be assessed on a cost minimisation basis.

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.

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.



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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	
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	