

TYPE 1 - NEW PRODUCT APPLICATION FORM

New Urinary & Ostomy Products to be added to HSE Reimbursement List

1. General Information

Applicant Company Name:	
Product Name:	
Product Description:	
Product Pack Size:	
Product Reference Code:	
Product Specification:	
Manufacturer:	
Distributor to HSE Customers:	
Launch Date for Product in Ireland:	
Identify appropriate product classification (ref: Appendix 3)	
If no product classification is suitable, please provide justification for creation of a new classification:	
GMS Code of nearest comparator product:	
Proposed method of distribution for making the product available to HSE contractors (i.e. GPs or Pharmacists)	
Previous use of the product in hospital or community areas in Ireland. Provide details of location, duration of use and average annual usage.	

2. Clinical Trials ¹

Summary Details of Clinical Trial No. 1:	
Summary Details of Clinical Trial No. 2:	
CE Certificate Submitted ² :	
Please provide details of any link between the manufacturer or proposed Irish distributor and the person who conducted the trial	

3. Product Samples

See Section 2.5 and 2.6 of this Guidelines document for information of submission of product samples.

4. Proposed Prices

Reimbursement Price Proposed to HSE	€		
United Kingdom Equivalent			
C&D (the most current edition available at time of application)	£		
BNF (if C&D price is not available) (the most current edition available at time of application)	£		
European Pricing			
United Kingdom	£	Country	€
Country	€	Country	€
Country	€	Country	€
Country	€	Country	€

¹ Please refer to Section 7 of this document for Guidelines for Clinical Trials of Urinary & Ostomy Products and Sections 8 & 9 Trial Minimum Datasets

² An electronic copy of a valid CE certificate for the product must be submitted with the application.

Country	€	Country	€
Average of the three lowest European Countries			
Country	Country	Country	Country
€	€	€	€
<ul style="list-style-type: none"> • United Kingdom price should be quoted in Pound Sterling. • State the European Country and Reimbursement Price in Euro where this product is marketed and reimbursed under the country's Schemes/Insurance System. • HSE will require independent validation of the European prices submitted which must accompany this form. Where this information is not available, please provide explanatory footnote/s in the table provided below. • If this product is not available, specify N.A. 			
Reason for Price Submitted:			

<u>Name and Address of Key Contact for Application:</u>	
Name:	
Position:	
Address:	
I confirm that the information provided in this application is correct.	
Signature: _____	Date: _____
Telephone No: _____	E-mail: _____

The completed form along with application information should be submitted to:
reimbursement.applications@hse.ie