HSE PRIMARY CARE
REIMBURSEMENT SERVICE

REIMBURSEMENT LIST OF
WOUND CARE PRODUCTS

GUIDELINES FOR MANUFACTURERS/DISTRIBUTORS

1.0 INTRODUCTION

1.1 These Guidelines have been prepared by the HSE National Expert Group for the information of Manufacturers /Distributors of Wound Care Products. Additions to the Reimbursable List will be considered in compliance with the Health (Pricing and Supply of Medical Goods) Act, 2013.

1.2 There are two types of Application Forms for products:

Type 1-New Products

Type 2-Existing Products

1.3 These Guidelines are applicable to both Type 1 and Type 2 products.

1.4 It will be a matter for the professional judgement of the National Expert Group to determine whether the evidence / supporting documentation / samples provided with the application meet the criteria and level of performance specified in these Guidelines and are suitable for the intended clinical use.

1.5 Products must be cost effective. It will be a matter for the National Expert Group to determine whether a product application is cost effective. The HSE reserves the right to request a mini Health Technology Assessment (HTA) on any product application received.

1.6 Applicants should note that samples of products and/or packaging for Type 2 applications **may** be requested by the HSE following initial review of the application.

1.7 Applicants should note that samples of products and/or packaging for Type 1 applications **will** be requested by the HSE following initial review of the application.

1.8 Products used on the body, or inserted into the body, must not cause adverse or toxic reactions.

1.9 Products must be suitable for administration under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use.

1.10 Applicants will be required to submit additional supporting documentation if requested to do so by the HSE in order to evaluate the cost effectiveness of a product. Examples of this additional documentation may include reports of reducing wastage; comparisons with similar products; value for money initiatives etc.

1.11 Products must not be advertised or promoted to the public in everyday magazines / newspapers / TV / radio. However, marketing activity which is aimed primarily at healthcare professionals is acceptable. Claims for patient outcome improvement should be supported by clinical evidence. Online advertising can present difficulties where claims for patient outcome improvement are made without the clinical evidence to support the claim.

Advertising in journals which are aimed at healthcare professionals is acceptable. Advertising through social media campaigns or journals which have no relevance for healthcare professionals is not.

1.12 The list of Wound Care Products reimbursable under the GMS and Community Drugs Schemes will be maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013.

Applicants should note that the interchangeability or substitution clause in the Act is intended for those medicinal products deemed interchangeable by the Health Products Regulatory Authority (HPRA) and it is not intended to be applied to medical devices.

1.13 The classifications of products listed may be subject to change from time to time.

1.14 The HSE operates a strict no price increase policy in relation to contract and reimbursement prices for goods and services. The reimbursement prices will remain in place unless otherwise agreed between the HSE and the Applicant.

1.15 The HSE intends to review the reimbursement pricing on an annual basis after go-live. The review will be based on the published pricing rules and will seek to ensure that the reimbursement prices continue to underpin the availability of quality products and services for eligible patients while delivering affordability and value for money for the Irish State. Applicants will be informed in advance of each pending review and may submit additional data to the HSE at the time for the review in order to provide supplementary evidence in relation to their pricing arrangements.

1.16 Application Fees will be applied in line with the Health (Reimbursement List) (Application Fees) Regulations 2016. When approval is granted, the fee must be paid prior to publication on the Reimbursement List. A confirmation of payment and final artwork must be submitted to the HSE Primary Care Reimbursement Service (PCRS) prior to publication on the Reimbursement List.

1.17 All Wound Care product application forms are to be submitted to:

reimbursement.applications@hse.ie

2.0 APPLICATION PROCESS – TYPE 1

2.1 This process should be followed by Applicants when they wish to have a new product added to the list of Wound Dressings on the PCRS reimbursement list.

2.2 Applicants should complete the Type 1 Application Form (Appendix 1) for each new product they wish to have included on the PCRS Reimbursement List. A signed copy of the Type 1 Application Form, along with appropriate backup material/Clinical Evidence should be sent electronically to the HSE at the email address on the Application Form.

2.3 (a) A single Application Form and supporting documents should be submitted to cover each new product.

(b) A single Application Form and supporting documents should be submitted for each size of a new product.

(c) Each Application Form and supporting documents should be submitted in a separate email.

(d) The HSE will issue an acknowledgement email containing a unique reference number for the application.

2.4 The HSE will conduct an initial review of the electronic application to ensure that all necessary documentation has been submitted. Once the required documentation is confirmed the HSE will request the Applicant to submit samples and packaging of the proposed new products.

2.5 Product samples should be identical to the final product, though not necessarily from a production run if this is impractical. The text of the proposed labelling / artwork should be final although it may be presented in mock up form if the finally produced version is not available.

2.6 As part of their Application Form, Applicants will be required to identity the appropriate Product Classification from the Product Classifications list in Appendix 3 which best matches their product. This should be based on identifying which Product Classification offers an equivalent technical solution and/or an equivalent level of clinical care for patients.

2.7 In the event that the product requires a new classification, the Applicant should identify this fact on the application form and submit their reasons for the new classification in the appropriate section.

2.8 Once all of the required documentation and product samples/packaging has been received by the HSE, the application will be assessed by the National Expert Group at their next scheduled review meeting.

2.9 The National Expert Group will assess each product application, including samples and supporting documentation from a clinical and technical perspective in the first instance. This will determine whether the evidence provided justifies the product being included on the Reimbursement list.

2.10 For those products which are approved by the National Expert Group, the reimbursement price will be agreed in accordance with the pricing rules in Section 9.0 of this document.

2.11 The HSE will aim to ensure that the reimbursement price of the new product is equivalent to products already listed in the appropriate product classification, having regard to difference in sizes etc. Where an Applicant is requesting a price premium for their new product, they are required to outline in their application the factors which they believe justify the premium.

2.12 The National Expert Group shall be authorised to make the final recommendation to the HSE for the inclusion or otherwise of products on the PCRS Reimbursement List.

2.13 Where an Applicant is not satisfied with the decision of the National Expert Group on a product application, for example in relation to the inclusion or rejection of a product or the proposed reimbursement price, they may submit a representation to the HSE on the matter together with relevant additional information. The National Expert Group will assess the additional information provided with the representation at their next scheduled review meeting to determine whether the decision should be changed.

3.0 APPLICATION PROCESS – TYPE 2

3.1 The application process for Type 2 should be followed by Applicants when they wish to notify the HSE of a discontinuation or minor change to an existing product on the list of Wound Dressings on the HSE Reimbursement List.

3.2 Applicants should complete the Type 2 Application Form (Appendix 2) for each existing product when wishing to notify the HSE of the discontinuation or minor change. A signed copy of the Type 2 Application Form should be sent electronically to the HSE at

Reimbursement.applications@hse.ie

3.3 Examples of minor changes to existing products would be, product name change, a change in Manufacturer/Distributor of the product, a change in packaging (including product reference codes), a change in product specification.

3.4 (a) A single Application Form and supporting documents should be submitted to cover each Type 2 Application

(b) Each Application Form and supporting documents should be submitted in a separate email.

(c) The HSE will issue an acknowledgement email containing a unique reference number for the application.

3.5 The HSE will conduct an initial review of the electronic Type 2 Application Form to ensure that sufficient information has been provided. The HSE reserves the right to request additional documentation and/or product samples/packaging from the Applicant prior to consideration of the application.

3.6 Once all of the required documentation has been received by the HSE, the application will be assessed by the National Expert Group at their next scheduled review meeting.

3.7 The National Expert Group will assess each application, and determine whether the continuation/ discontinuation/ minor change can be accepted by the HSE.

3.8 Products that are approved for discontinuation from the Reimbursement List shall remain live on the reimbursement list for a period of at least 12 months to allow for patient transition to an alternative product if required.

4.0 GENERAL CRITERIA FOR ALL WOUND CARE PRODUCTS

The following General Criteria applies to all Wound Care Products submitted for inclusion on the PCRS Reimbursement List.

4.1 The presentation and ranges of sizes offered must be suitable for use in a community setting.

4.2 All products must demonstrate compliance with Directive 93/42/EEC, with each product carrying the CE marking. This Directive is implemented in Ireland via the European Communities (Medical Devices) Regulations 1994 (S.I. No.252 of 1994)

4.3 All products must be free of toxins.

4.4 Use of latex in either the product itself or packaging must be clearly identified.

4.5 Where clinically required, all products must be available in a variety of formats and sizes.

5.0 SPECIFIC CRITERIA FOR WOUND DRESSINGS

In addition to the General Criteria for All Wound Care Products (ref: Section 4.0), the following additional criteria are required for **all** Wound Dressings.

5.0.1 Any inserts and instructions for dressings must be available in the English language.

5.0.2 All dressings must provide an effective level of thermal insulation and mechanical protection and satisfactorily maintain, where applicable, the pH of the wound.

5.0.3 All dressings must produce minimal pain as a result of adherence to the wound surface:

(a) On application.

(b) Non-adherent to wound bed.

(c) Upon removal.

5.0.4 All dressings must maintain contact with wound bed on application and during wear-time.

5.0.5 All dressings must not release particles or non-biodegradable fibres into the wound.

5.0.6 All dressings must satisfactorily donate to / maintain the wound and the surrounding skin in an optimum state of hydration (this implies the ability to function effectively under compression).

5.0.7 All dressings must be capable of being left in place safely for 3 to 7 days (where clinically appropriate) without causing trauma to the Wound or surrounding skin upon removal.

5.0.8 All dressings must not break up upon removal.

In addition to the General Criteria for All Wound Care Products (ref: Section 4.0), and the additional criteria required for **all** Wound Dressings (ref: sections 5.0.1 to 5.0.8), the product classifications listed in this section have additional specific criteria.

Product classifications which are not listed in this section do not have any additional specific criteria. Please refer to Appendix 3 for the full list of product classifications.

5.3 Alginate Dressings

5.3.1 The product must possess haemostatic activity.

5.4 Anti-Microbial Dressings

5.4.1 Dialkylcarbamoyl

5.4.1.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.2 Iodine – Cadoxemer

5.4.2.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.2.2 The product must exhibit effective wound cleansing (debriding) activity.

5.4.2.3 The product should have high absorption properties.

5.4.2.4 The product must have the ability to sustain antimicrobial activity over a minimum of 72 hours.

5.4.3 Iodine – Povidone

5.4.3.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.3.2 The product must not impede or damage granulation tissue and must be of a tight weave.

5.4.3.3 The product must contain 10 % Povidone – Iodine.

5.4.4 PHMB

5.4.4.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection

5.4.4.2 The product must have high absorption properties

5.4.5 Honey Dressings

5.4.5.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection

5.4.5.2 The product must exhibit effective wound debriding activity.

5.4.5.3 The product must provide effective protection to the periwound skin from potentially irritant wound exudate and excess moisture.

5.4.5.4 The product must possess effective odour absorbing/combating properties.

5.4.5.5 The product must have the ability to remove or inactivate proteolytic enzymes in chronic wound fluid.

5.4.5.6 The product must not impede or damage granulation tissue.

5.4.6 Silver Foams

5.4.6.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.6.2 The product must have high absorption properties.

5.4.6.3 The adhesive silver foam dressings must have silicone borders.

5.4.7 Silver Fibre Alginates

5.4.7.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.7.2 The product must have high absorption properties.

5.4.8 Silver Hydrofibres

5.4.8.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.8.2 The product must have high absorption properties

5.4.8.3 The product must be threaded.

5.4.9 Silver Sheets

5.4.9.1 The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.5 Film Dressings

5.5.1 The product must have a high Moisture Vapour Transmission Rate (MVTR).

5.5.2 The product, if self-adhesive, must form an effective water-resistant seal to the periwound skin, but must be easily removed without causing trauma or skin stripping.

5.6 Foam Dressings

5.6.1 The product must have high absorption properties.

5.6.2 The product must provide effective protection to the periwound skin from potentially irritant wound exudate and excess moisture.

5.6.3 The product must be capable of sufficiently conforming to any wound.

5.6.4 The product, if self-adhesive, must form an effective water-resistant seal to the periwound skin, and be easily removed without causing trauma or skin stripping.

5.7 Hydrocolloid Dressings

5.7.1 The product must provide effective protection to the periwound skin from potentially irritant wound exudate and excess moisture.

5.7.2 The product, if self-adhesive, must form an effective water-resistant seal to the periwound skin, and must be easily removed without causing trauma or skin stripping.

5.7.3 The product must exhibit effective wound cleansing (debriding) activity.

5.8 Hydrofibre Dressings

5.8.1 The product must have high absorption properties.

5.8.2 The product must have vertical wicking capabilities.

5.8.3 The product must be threaded.

5.8.4 The product must provide effective protection to the periwound skin from potentially irritant wound exudate and excess moisture.

5.8.5 The product must exhibit effective wound cleansing (debriding) activity.

5.9 Hydrogel Dressings

5.9.1 The product must exhibit effective wound cleansing (debriding) activity.

5.9.2 Details of how much absorption is from the dressing and how must moisture it delivers must be provided

5.11 Protease Modulator

5.11.1 The product must have the ability to inactivate and remove proteolytic enzymes in chronic wound fluid.

5.12 Wound Contact Layer

5.12.1 The product must not impede or damage granulation tissue and must be of tight weave.

6.0 SPECIFIC CRITERIA FOR BANDAGES & ADHESIVES

In addition to the General Criteria for All Wound Care Products (ref: Section 4.0), the following additional criteria are required for **all** Bandages & Adhesives.

6.0.1 All Bandages & Adhesives must comply with the relevant regulatory quality standards, i.e. CE Mark and any other standard specific to the Bandages & Adhesives.

6.0.2 The manufacturing companies of Bandages & Adhesives must comply with the relevant regulatory quality standards, i.e. ISO 9000-2000 or above, ISO 13485 and any other standard specific to the design and manufacture of the Bandages & Adhesives products.

6.0.3 All Bandages & Adhesives must have a minimum shelf life period of 6 months from the date of delivery. For sterile products, the minimum shelf life must be as per the relevant sterilisation method standards which in any case must not be less than 6 months.

6.0.4 All Bandages & Adhesives must be easy to apply, easy to use and where appropriate must include clear instructions outlining application.

6.0.5 All Bandages & Adhesives must not break up upon removal.

6.0.6 All Bandages & Adhesives must not release particles or non-biodegradable fibres into the wound.

In addition to the General Criteria for All Wound Care Products (ref: Section 4.0), and the additional criteria required for **all** Bandages & Adhesives (ref: sections 6.0.1 to 6.0.6), the product classifications listed in this section have additional specific criteria.

Product classifications which are not listed in this section do not have any additional specific criteria. Please refer to Appendix 3 for the full list of product classifications.

6.1 Compression Bandages

6.1.1 Elastic compression bandages must be capable of remaining safely in place for up to 7 days and must maintain clinical levels of full compression when the patient is mobile.

6.1.2 Short stretch full compression bandages must be capable of maintaining clinical levels of compression of 35 to 40mmHg for up to 7 days when the patient is mobile.

6.1.3 Short stretch light compression bandages must capable of maintaining clinical levels of compression up to 25mmHg for up to 7 days when the patient is mobile.

6.1.4 Multilayer long stretch full compression bandages must be capable of maintaining clinical levels of compression of 35 to 40mmHg on a 24 hours basis for up to 7 days when the patient is mobile.

6.1.5 Multilayer long stretch light compression bandages must be capable of maintaining clinical levels of compression up to 25mmHg on a 24 hour basis for up to 7 days when the patient is mobile.

6.1.6 The product must have effective non-slip properties.

6.2 Medicated Bandages

6.2.1 The product must be capable of remaining safely in place for up to 7 days.

6.4 Elasticised Adhesive Bandages

6.4.1 The product must be capable of being removed without causing pain or trauma to the wound or surrounding tissue.

6.4.2 The product must have adequate adhesive properties and must adhere effectively.

6.5 Lightweight Conforming Bandage

6.5.1 The product must have effective non-slip properties.

6.5.2 The product must have effective non-roll properties.

6.5.3 The product must be tightly woven, and must not become loose when worn and must have durable characteristics.

6.6 Tubular bandage

6.6.1 The product must have effective non-slip properties.

6.6.2 The product must have effective non-roll properties.

6.6.3 The product must be tightly woven, and must not become loose when worn and must have durable characteristics.

6.9 Surgical Adhesive Tapes

6.9.1 That product must be easy to remove without causing trauma or skin stripping.

6.9.2 The product must have effective adhesive properties and must adhere effectively.

6.9.3 Silk tape must have water resistant properties.

6.10 Adhesive Island Dressings

6.10.1 The product must be easy to remove without causing trauma or skin stripping.

6.10.2 The product must have adequate adhesive properties and must adhere effectively.

6.11 Skin Closure Strips

6.11.1 The product must be capable of remaining safely in place for a minimum of 7 days.

611.2 The product must have adequate adhesive properties and must adhere effectively.

6.11.3 The product must be easy to remove removed without causing trauma or skin stripping.

6.11.4 The product must form an effective water-resistant seal to the periwound skin.

6.13 Non-Woven / Filmated Swabs (Sterile)

6.13.1 The product must be easy to open and must allow effective distribution of the swab portion.

6.14 Non-Woven / Filmated Swabs (Non Sterile)

6.14.1 The product must be easy to open and must allow effective distribution of the swab portion.

7.0 SPECIFIC CRITERIA FOR COMPRESSION HOS

In addition to the General Criteria specified in Section 4.0, the Wound Dressings listed in this section have additional specific criteria.

Graduated Compression Hosiery

7.0.1 The product must be suitably durable for use in community and acute settings.

7.0.2 The product must be capable of maintaining an effective level of elasticity.

7.0.3 The product must have effective non-slip properties.

7.0.4 The product must have effective non-roll properties.

7.0.5 The product must be easy to apply and clear instructions for application must be provided with each product.

7.0.6 The product must provide graduated compression in accordance with patient specific prescription.

8.0 GUIDELINES FOR CLINICAL TRIALS OF WOUND CARE PRODUCTS

8.1 This section is applicable to Type 1 - New Products only where the requirement for Clinical Trials is identified as part of the supporting documentation required under the application process. Please refer to Appendix 3 for the list of Wound Care Products which require Clinical Trials.

8.2 An Applicant is required to submit the published report on a minimum of 3 Clinical Trials for each product being submitted as a Type 1 application. The reports must have been published in a peer review journal.

8.3 The Clinical Trial must be pertinent to the product classification nominated by the Applicant for the product.

8.4 It is not a prerequisite that the Clinical Trial must have been conducted in Ireland.

8.5 The Clinical Trials submitted must be 'in vivo' and not 'in vitro' only. 'In vitro' trials are acceptable but not without accompanying data from an 'in vivo' trial.

8.6 A Clinical Trial should ideally have been conducted by an appropriately qualified medical or nursing person who had no direct or indirect association with the manufacturer or proposed Irish distributor of the product. If there was any link between the manufacturer or proposed Irish distributor and the person who conducted the trial, this link should be declared on the Type 1 Application Form. This is a transparency requirement. A link will not automatically exclude either the product or the medical person, but if a link exists it must be declared on the Type 1 Application Form.

8.7 A minimum of 3 Clinical Trials must have been conducted at not less than 3 centres, with a minimum of at least 20 participants in each of the trials..

8.8 Each participant in the Clinical Trial must have been fully informed of the trial procedures and their written consent must have been obtained. This is a self certification requirement. Applications must confirm with the Clinical Trial evidence that consent has been obtained. The HSE reserves the right to request records if necessary.

8.9 Each product on trial must have been assessed on its own merit and without the benefit of any additional product, irrespective of whether the additional product is on the approved HSE reimbursable list of products. Each product has to have its own evidence presented rather than relying on the evidence available for a similar product or category of products.

8.10 A trial participant may have been withdrawn from the Clinical Trial at any time at the discretion of the person who conducted the trial or at the participant's own request.

8.11 The final report shall set out at a minimum the length of the Clinical Trial, the patient cohort, the products and/or range of products used, the clinical outcomes achieved and any other relevant information.

8.12 Where a Clinical Trial is not required (ref: Appendix 3) the Applicant must submit a minimum of 2 x written testimonials for each product being submitted. The written testimonials must be signed by an appropriate qualified clinical user which confirms the satisfactory "use in practice" of the product.

9.0 PRICING RULES HSE WILL APPLY TO ALL WOUND DRESSINGS APPLICATIONS.

9.1 In the first instance, each Type 1 product application will be assessed from a clinical and technical perspective to determine whether the evidence provided justifies the product being included on the reimbursement list.

9.2 For Type 1 products which are approved and for all Type 2 products, the reimbursement price will be equivalent to the reimbursement price for the relevant product classification, having regard to differences to sizes etc.

9.3 The reimbursement price for each product classification will be determined on the basis of whichever is the lowest of:

9.3.1 UK adjusted price (at 12 month average exchange rate), or;

9.3.2 Average of the lowest three European countries submitted, or;

9.3.3 Price proposed to the HSE

for the lowest price agreed for any product included in the relevant classification, having regard to differences in sizes, presentation etc.

9.4 The UK adjusted price will be based on the average rate of exchange over 12 months up to date of application, having regard to the prices quoted in the following:

9.4.1 C&D (the most current edition available at the time of pricing);

9.4.2 BNF (the most current edition available), if C&D unavailable;

9.4.3 Submitted UK Price, if C&D and BNF not available.

9.5 It will be a matter for the Applicant to supply sufficient supporting evidence to justify a premium above the proposed reimbursement price for the product classification.

9.6 In the event that a product requires a new classification, the reimbursement price will be determined using the same criteria as outline above. The HSE shall in all cases have the final say in relation to the inclusion or otherwise of a premium for new/innovative products.

9.7 The new Reimbursement List will be made available to patients, clinicians and suppliers via the PCRS section of the HSE website.

9.8 The HSE reserves the right to offer a reimbursement price which will be benchmarked against the prices(s) available to the HSE, for products that, in the opinion of the HSE Expert Group, offer an equivalent technical solution and/or an equivalent level of clinical care for patients.

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 1

TYPE 1 - NEW PRODUCT APPLICATION FORM:

New Wound Care 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:	
Summary Details of Clinical Trial No. 3:	
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 (Prices should be quoted per unit)

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	€

[1] Please refer to Section 8.0 of this document for Guidelines for Clinical Trials of Wound Care Products

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

Country	€	Country	€
Country	€	Country	€
Country	€	Country	€
Average of the three lowest European Countries			
Country	Country	Country	Average
€	€	€	€

- 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.

European Pricing Footnotes:

Name and Address of Key Contact for Application:

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

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 2

TYPE 2 - EXISTING PRODUCT NOTIFICATION FORM:

Existing Wound Care Products on the HSE list of Reimbursable items.

This form has been prepared to enable manufacturers/distributors to inform the HSE of any of the following in relation to existing Wound Care Products on the HSE List of Reimbursable Items.

a) Intention to Discontinue Wound Care Products on the HSE Reimbursement List

b) Minor Changes of Wound Care Products on the HSE Reimbursement List

Note: This form must be completed for each product / GMS code on the existing HSE Reimbursement List irrespective of whether the notification concerns a discontinuation or minor change.

1. Product Details

GMS Code:	
Manufacturer:	
Distributor to HSE Customers:	
Product Name:	
Product Description:	
Product Pack Size:	
Product Reference Code:	
Product Classification: (See Appendix 3)	
All certification is up to date and valid:	
In the event of any changes to the above, the HSE will be notified immediately in writing:	

Current HSE Reimbursement Price:	**€**
Proposed HSE Reimbursement Price:	**€**
Basis for requested change in HSE Reimbursement Price:	

Applicants should note that the HSE will employ the pricing rules set out in Section 7 of this Guidelines document to determine the actual reimbursement price for the product.

(a) Intention to <u>Discontinue</u> Wound Care Products on the HSE Reimbursement List

Applicants should complete this section if they wish to notify the HSE of their intention to discontinue the listing of a Wound Care Product on the HSE Reimbursement List.

In the interest of maintaining an uninterrupted supply of Wound Care Products to patients, it is a requirement that products that are approved for discontinuation from the Reimbursement List shall remain live on the reimbursement list for a period of at least 12 months to allow for patient transition to an alternative product if required

Proposed date for product discontinuation:	
Date (month and year) when it is estimated that stocks of product will be depleted:	
Where the product discontinuation is of a particular pack size within a range of products provide details of those products that will continue to remain available:	
Give reasons for the proposed product discontinuation of the product (s) with appropriate substantiating information:	
If there is a reimbursed alternative to the product being discontinued please provide details:	
Provide an evaluation of likely impact that the proposed discontinuation will have on the quality of patient care, including an estimate of the number of patients it will affect:	
Provide details of the current status and availability of the product in the various Member States of the European Union:	
A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the discontinuation of the product.	

(b) Minor Changes of Wound Care Products on the HSE Reimbursement List

Applicants should complete this section if they wish to notify the HSE of a proposed Minor Change to a Wound Care Product on the HSE Reimbursement List.

Changes to the product can include, for example.

Packaging of product (including pack size); Product Specification; Name of product; Manufacturer /Distributor of the product; Product Reference Code;

Details of Proposed Minor Change:	
Proposed date for Minor Change:	
Date (month and year) when it is estimated that stocks of currently listed product will be depleted:	
A copy of any letter(s) sent or proposed to be sent to Health Care Professionals in relation to the minor change of the product:	

NOTE: For ALL Minor Change notifications, an electronic copy of the outer packaging artwork, CE certification and patient information leaflet for currently listed product AND proposed minor change product must be submitted with the application.

Name and Address of Key Contact for Application:

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 information should be submitted to:

reimbursement.applications@hse.ie

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX 3

PRODUCT CLASSIFICATIONS

5.0	WOUND DRESSINGS	EVIDENCE REQUIRED
5.1	Absorbent Dressings	Clinical Trials x 3
5.2	Super Absorbent Dressings	Clinical Trials x 3
5.3	Alginate Dressings	Clinical Trials x 3
5.4	Antimicrobial Dressings – 5.4.1 Dialkylcarbamoyl 5.4.2 Iodine – Cadexomer 5.4.3 Iodine – Povidone 5.4.4 PHMB 5.4.5 Honey 5.4.6 Sliver Foam 5.4.7 Silver Fibre Alginates 5.4.8 Silver Hydrofibres 5.4.9 Silver Sheets	Clinical Trials x 3
5.5	Film Dressings	Clinical Trials x 3
5.6	Foam Dressings	Clinical Trials x 3
5.7	Hydrocolloid Dressings	Clinical Trials x 3
5.8	Hydrofibre Dressings	Clinical Trials x 3
5.9	Hydrogel Dressings	Clinical Trials x 3
5.10	Odour Control Dressings	Clinical Trials x 3

5.11	Protease Modulator Dressings	Clinical Trials x 3
5.12	Wound Contact Layer	Clinical Trials x 3
5.13	Monofilament Pad	Clinical Trials x 3
5.14	Antiseptic PHMB Solution	Clinical Trials x 3
5.15	Skin Protectors	Clinical Trials x 3
5.16	Topical Haemoglobin Spray	Clinical Trials x 3
6.0	**BANDAGES & ADHESIVES**	**EVIDENCE REQUIRED**
6.1	Compression Bandages	Clinical Trials x 3
6.2	Medicated Bandages	Clinical Trials x 3
6.3	Cohesive Bandages	Clinical Trials x 3
6.4	Elasticised Adhesive Bandages	Clinical Trials x 3
6.5	Lightweight Conforming Bandages	Written Testimonials x 2
6.6	Tubular Bandages	Written Testimonials x 2
6.7	Cotton Net Tubular Bandage	Written Testimonials x 2
6.8	Crepe Bandages	Written Testimonials x 2
6.9	Surgical Adhesive Tapes	Written Testimonials x 2
6.10	Adhesive Island Dressings	Clinical Trials x 3
6.11	Skin Closure Strips	Clinical Trials x 3
6.12	Lint Absorbent	Written Testimonials x 2
6.13	Non-Woven/Filimated Swabs (Sterile)	Written Testimonials x 2

6.14	Non-Woven/Filimated Swabs (Non Sterile)	Written Testimonials x 2
6.15	Triangular Bandage	Written Testimonials x 2
6.16	White Open Wove bandage	Written Testimonials x 2
6.17	Absorbent Wool Roll	Written Testimonials x 2

7.0	**COMPRESSION HOSIERY**	**EVIDENCE REQUIRED**
7.1	Graduated Compression Hosiery	Clinical Trials x 3