HSE Primary Care Eligibility & Reimbursement Service

Wound Care Products

Guidelines for Suppliers

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Seirbhís Sláinte Níos Fearr á Forbairt | Building a Better Health Service

Index

INTRODUCTION

1.1. Scope of the Guidelines

1.1.1. The HSE maintains a Reimbursement List pursuant to the Health (Pricing and Supply of Medical Goods) Act 2013 (the "**2013 Act**"), which includes a listing of Wound Care Products (the "**Products**"). These Guidelines have been prepared by the HSE for the information of Suppliers[1] of the Products.

1.1.2. These Guidelines are applicable to both new and existing Products.

- The process for submitting an application to have a new Product added to the Reimbursement List is referred to as the "**Category 1**" application process (set out at Section 3 of these Guidelines).

- The process for submitting an application in respect of an existing Product is governed by the "**Category 2**" application process (set out at Section 4 of these Guidelines).

1.1.3. Nothing contained in these Guidelines shall be construed as legal advice, nor should you regard these Guidelines as a substitute for legal advice in any circumstances.

1.2. Legal Framework / Principles Applicable to All Applications

1.2.1. **Applications.**

(a) Section 18(1) of the 2013 Act provides the legal basis for Suppliers of Products to make an application to the HSE requesting that the HSE add a Product to the Reimbursement List. All applications will be assessed in line with the terms of the 2013 Act.

(b) Applications may be submitted at any time. However, the National Expert Group will hold review meetings twice yearly and make recommendations to the appropriate delegated authority in relation to each application.

(c) Where the HSE receives an application but is unable to make a decision whether to add or refuse to add an item to the Reimbursement List in line with section 18 of the 2013 Act, the HSE will give notice in writing to the applicant specifying the additional information it requires from the applicant in order to determine the application.[2]

By way of example, additional documentation may be requested to assess the costeffectiveness of a Product and may include but is not limited to reports of reducing wastage, comparisons of the Product with similar Products, value for money initiatives, etc.

[1] The term "**Supplier**" refers to a company that submits an application to the HSE under these Guidelines and may include a manufacturer, distributor or agent for the Product.

[2] See 2013 Act at section 18(3).

(d) A supplier who has made an application to add a Product to the Reimbursement List may withdraw the application (without prejudice to his or her right to make, at a later date, another application in respect of that Product) by providing written notice to the HSE at any time before a determination is made under section 18(2) of the 2013 Act.

1.2.2. **Cost Effectiveness.**

(a) The HSE will have regard to the cost effectiveness of a Product when determining whether to add the Product to the Reimbursement List[3]. It will be a matter for the HSE to consider whether the reimbursement price proposed for a Product is cost effective.

(b) However, the National Expert Group may request that the Health Technology Assessment Group ("**HTAG**") conduct a mini Health Technology Assessment ("**HTA**") on any Product application received and shall have regard to any HTA guidelines published by the Health Information and Quality Authority ("**HIQA**") that appear to the HSE to be relevant to the relevant decision. Where a mini HTA review is conducted on a Product, the HTAG will produce and forward an Advice Note to the applicant and to the HSE.

1.2.3. **Application Fees.**

The **Health (Reimbursement List) (Application Fees) Regulations 2016 (S.I. No. 576/2016)** set out the fees payable by a supplier to the HSE in respect of an application submitted under section 18(1) of the 2013 Act**.** The relevant prescribed fee must be paid to the HSE before an application will be considered by the National Expert Group.

1.2.4. **Marketing.**

(a) Products must not be advertised or promoted to the public.[4] For the avoidance of doubt, the following activities are prohibited:-

- Direct marketing to patients via everyday magazines, newspapers, TV or radio;
- Direct marketing via canvassing activity to patients; and
- Advertising through social media campaigns or journals which have no relevance for healthcare professionals.

(b) Marketing activity which is aimed primarily at healthcare professionals is acceptable. For example, it would be acceptable for a Product supplier to advertise in journals which are aimed at healthcare professionals.

(c) All claims for patient outcome improvement should be supported by clinical evidence.

[3] Section 19 of the 2013 Act provides that where the HSE makes a relevant decision under section 18 (e.g., to add an item to the Reimbursement List or refuse to add an item to the Reimbursement List) HSE shall make such relevant decision in accordance with criteria specified in Schedule 3 to the 2013 Act that apply to the item or listed item. Part 3 of Schedule 3 includes General Criteria to which the HSE shall have regard, and includes, *inter alia,* the "*cost effectiveness of meeting health needs by supplying the item concerned rather than providing other health services*". See also section 20 of the 2013 Act (regarding attaching conditions to listed items in the interest of cost-effectiveness).

[4] See Schedule 3, Part 2 (Criteria Applicable to Medical Devices, Foodstuffs for Particular Nutritional Uses and Dietary Foods for Special Medical Purposes), section 1(b) states that, "*The medical device . . . subject to paragraph 2, must not be advertised or promoted to the public*". Section 2 states that, "*The Executive may disapply the criterion referred to in paragraph 1(b) in the case of a particular medical device . . . if it is satisfied that to disapply that criterion in that case is in the interests of (a) patient safety, or (b) public health."*

(d) Please note that products which are not included on the Reimbursement List do not fall within the scope of this clause.

2. MANDATORY CRITERIA

2.1. Before any application under the 2013 Act to add a Product to the Reimbursement List will be accepted, Suppliers must certify that the Product (the subject of the application) complies with:-

(a) applicable national standards and European Commission standards; and

(b) the criteria set out in these Guidelines; and

(c) all applicable laws.

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

2.3. For **Category 1** Applications in respect of which a clinical investigation is required, the application should demonstrate that the Product is acceptable for use by patients by presenting such clinical investigation results to the HSE (which ideally should have been conducted independently of the Supplier).

2.4. All Products must demonstrate compliance with applicable European and domestic laws in relation to medical devices.

2.5. Each Product must carry a CE marking.

2.6. All Products must be free of toxins.

2.7. Use of latex in either a Product or packaging of a Product must be clearly identified.

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

3. APPLICATION PROCESS – CATEGORY 1 (NEW PRODUCTS)

3.1. The Application

3.1.1. The Category 1 Application Process should be followed by Suppliers when they wish to have a new Product added to the Reimbursement List.

3.1.2. Suppliers should complete the Category 1 Application Form (**Appendix A**) for each new Product they wish to have included on the Reimbursement List. A signed copy of the Category 1 Application Form, along with appropriate backup material, should be sent electronically to the HSE at: NonDrugReimbursement.Applications@hse.ie

3.1.3. Please note that:-

(a) A separate Application Form and supporting documents should be submitted in respect of each new Product.

(b) A separate Application Form and supporting documents should be submitted in respect of each size of a new Product.

(c) Each Application Form and supporting documents should be submitted by the Supplier to the HSE in a separate email.

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

(e) The HSE will notify the Supplier when their application is in order and will then request that the Supplier pay the relevant application fee by EFT. The Supplier must submit a copy of the receipt (demonstrating that the relevant fee has been paid in respect of their application) to NonDrugReimbursement.Applications@hse.ie within 10 working days of the notification. The relevant fee must be paid to the HSE before the application will be considered by the National Expert Group.

3.1.4. **Product Classification**

(a) As part of their Application Form, Suppliers will be required to identify the appropriate Product Classification for their Product from the list at **Appendix C.** Suppliers should identify the appropriate Product Classification as those which offer an equivalent technical solution and/or an equivalent level of clinical care for patients.

(b) Product Classifications are subject to change by the HSE from time to time.

(c) In the event that the Product does not fit within any of the classifications listed at **Appendix C**, Suppliers should identify this fact on the Application Form and may submit reasons why the addition of a new classification category would be appropriate for their Product.

3.2. Initial Review

The HSE will conduct an initial review of the electronic application to ensure that all necessary documentation has been submitted.

3.3. Samples and Packaging

3.3.1. Once the required documentation (including confirmation that the relevant prescribed fee(s) have been paid) is confirmed, the HSE will request the Supplier to submit samples and packaging of the proposed new Products.

3.3.2. Any inserts and instructions for use of the Product must be included in English and be clear and easy to understand by patients.

3.3.3. Product samples should be identical to the final Product (though not necessarily from a production run if this is impractical).

3.3.4. The text of the proposed labelling / artwork should be final (though it may be presented in mock-up form if the finally produced version is not available). However, an item will not be added to the Reimbursement List until the HSE has received final copies of the Product labelling/artwork.

3.4. Review by the National Expert Group.

3.4.1. Once all of the required documentation (including confirmation that the relevant prescribed fee(s) have been paid) and Product samples/packaging have been received by the HSE, the application will be assessed by the National Expert Group at its next scheduled review meeting.

3.4.2. The National Expert Group will review each Product application, including samples and supporting documentation from a clinical and technical perspective in the first instance. The National Expert Group will have regard to the applicable criteria specified in Schedule 3 of the 2013 Act (*Criteria Applicable to Items and Listed Items for Purposes of Executive Making Relevant Decision under section 18)* (as may be amended). Excerpts from Schedule 3 of the 2013 Act in its current form are set out in **Appendix D** hereto.

3.4.3. If the National Expert Group is unable to make a recommendation whether to add or refuse to add an item to the Reimbursement List, the National Expert Group will give notice in writing to the applicant specifying the additional information it requires from the applicant. The statutory timeline for processing the application will be suspended unless and until the applicant gives the National Expert Group the additional information that it requires.[5]

3.4.4. If the National Expert Group is of the view that a Product should be added to the Reimbursement List from a clinical and technical perspective, the National Expert Group will attempt to provisionally agree a price with the supplier.

[5] See Section 18(3) of the 2013 Act.

3.4.5. The National Expert Group shall, when considering the proposed relevant price submitted by the supplier, take into account:-

(a) the equivalent relevant prices (if practicably available) of the item in all other Member States where the item is marketed,

(b) the relevant prices of therapeutically similar listed items,

(c) the potential therapeutic benefits of the item for patients likely to use the item if it were to become a listed item,

(d) the potential budget impact of the item if it were to become a listed item,

(e) the ability of suppliers of the item to meet patient demand for the item if it were to become a listed item,

(f) the resources available to the Executive, and

(g) the terms of any agreement in place (whether entered into before, on or after the commencement of this section) between the Executive and any representative body of the suppliers of drugs, medicines or medicinal or surgical appliances where the agreement relates, whether directly or indirectly, to the price of the item.[6]

3.4.6. Where Suppliers request a price for their Product that is higher than the relevant prices of therapeutically similar listed items already on the Reimbursement List, the supplier should outline in their application the factors which they believe justify the higher price.

3.4.7. At the conclusion of the review by National Expert Group of all relevant materials, the National Expert Group will make a recommendation regarding whether the Product should be added to the Reimbursement List to the appropriate delegated authority, as follows:-

(a) In circumstances where the HSE's costs in relation to the Product are estimated to be less than €10 million per annum, the appropriate delegated authority is the Assistant National Director of the Primary Care Eligibility & Reimbursement Service ("**PCERS**") and the Head of Procurement; or

(b) In circumstances where the HSE's costs in relation to the Product are estimated to be less than €10 million per annum, the appropriate delegated authority is the HSE Board.[7]

3.5. Proposed Decision

3.5.1. The appropriate delegated authority will review the recommendation from the National Expert Group, and, in accordance with the 2013 Act, proceed to make a proposed decision.

3.5.2. Part 2 of Schedule 1 of the 2013 Act provides that where the HSE proposes to make a decision under section 18 of the 2013 Act (e.g., to add or to refuse to add a Product to the Reimbursement List), the HSE (through the appropriate delegated authority) shall give notice in writing of the proposal to the supplier of the Product (the subject of the proposal).

[6] Section 21(2) of the 2013 Act.

[7] See Health Service Executive (Governance) Act, 2019 (No. 17 of 2019).

3.5.3. The notice of the proposed decision shall include:-

(a) A statement of the proposal of the HSE;

(b) A statement setting out the reasons on which the proposal of the HSE is based;

(c) A statement that the supplier of the Product (the subject of the proposal) has the right to make representations in writing (i.e., "**relevant representations**") to the HSE with respect to the proposal within a period of 28 days after the supplier received the notice (or such longer period as the HSE permits in any particular case); and

(d) A statement that, if such supplier so wishes, he or she may give the HSE a notice in writing, within the period referred to in *subparagraph (c)*, stating that he or she will not be making any relevant representations.

3.5.4. If the Supplier opts to make representations in relation to the proposed decision (as referred to in paragraph 3.5.3(c), above), the Supplier may at that time request that the Health Technology Assessment Group ("**HTAG**") conduct a mini Health Technology Assessment ("**HTA**") (if a mini HTA has not already been done). Where a mini HTA review is conducted on a Product, the HTAG will produce and forward an Advice Note to both the applicant and to the HSE. The Advice Note will be reviewed by the appropriate delegated authority as part of the Supplier's representations.

3.6. Decision

3.6.1. The HSE (acting through the appropriate delegated authority) shall, after considering the relevant representations (if any), including the Advice Note produced on foot of a mini-HTA (if applicable), or after being given a written notice that the supplier will not be making any relevant representations:-

(a) implement the proposal without modification;

(b) subject to paragraph 4 of Part 2 of Schedule 1 of the 2013 Act[8] propose modifications to the proposal; or

(c) decline to implement the proposal.

3.6.2. The HSE will, as soon as practicable after making a decision give notice in writing of the decision, together with its reasons for the decision, to the supplier of the Product (the subject of the decision).

3.6.3. Section 27 of the 2013 Act provides that certain "relevant persons" who are aggrieved by a "relevant decision" may appeal to the High Court against the relevant decision within 30 days from the date on which the "relevant person" was given the "relevant notification".

[8] Paragraph 4 of Part 2 of Schedule 1 of the 2013 Act provides that, "*If the Executive, after considering the relevant representations wishes to propose modifications to the proposal (including any proposal to which this paragraph has previously applied), then this Part shall have effect with respect to the proposal as modified by the Executive as it has effective with respect to the proposal before modification.*"

4. APPLICATION PROCESS – CATEGORY 2 (EXISTING PRODUCTS)

4.1. General Rules

4.1.1. The Category 2 Application Process should be followed by Suppliers when they wish to notify the HSE of a discontinuation or minor change to an existing Product on the Reimbursement List.

4.1.2. Suppliers should complete the Category 2 Application Form (**Appendix B**) for each existing Product when wishing to notify the HSE of a discontinuation or minor change. A signed copy of the Category 2 Application Form, along with appropriate backup material, should be sent electronically to the HSE at NonDrugReimbursement.Applications@hse.ie .

4.1.3. Please note that:-

(a) A separate Application Form and supporting documents should be submitted in respect of each Category 2 application.

(b) Each Application Form and supporting documents should be submitted by the Supplier to the HSE in a separate email.

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

(d) The HSE will notify the Supplier when their application is in order and will then request that the Supplier pay the relevant application fee by EFT. The Supplier must submit a copy of the receipt (demonstrating that the relevant fee has been paid in respect of their application) to NonDrugReimbursement.Applications@hse.ie within 10 working days of the notification. The relevant fee must be paid to the HSE before the application will be considered by the National Expert Group.

4.1.4. **Applications in respect of removing a Product from the Reimbursement List**

- For Suppliers seeking to have a Product removed from the Reimbursement List, the HSE requests that Suppliers provide at least 12 months' advance written notice of such request for removal in order to allow for patient transition to an alternative Product, if required.
- In circumstances where the Product will permanently cease to be marketed in the State, the HSE requests that Suppliers notify the HSE of the anticipated date of cessation as soon as reasonably practicable.[9]

4.1.5. **Applications in respect of minor changes to Products on the Reimbursement List**

- Examples of minor changes to existing Products may include but are not limited to changes to:-

[9] Section 18(6) of the 2013 Act provides that the HSE shall remove a Product from the Reimbursement List which it is satisfied has permanently ceased to be marketed in the State.

(a) the packaging of Product (including pack size);
(b) the Product specification;
(c) the name of Product;
(d) the supplier of the Product; (e) the Product reference code; or (f) a Price reduction offer.

- The HSE may assess reasonable fees for to effecting minor changes to Products on the Reimbursement List.

4.2. Initial Review

4.2.1. The HSE will conduct an initial review of the electronic Category 2 Application Form to ensure that sufficient information has been provided.

4.3. Samples and Packaging

4.3.1. The HSE reserves the right to request additional documentation and/or Product samples/packaging from the Applicant prior to consideration of an application for a minor change.

4.4. Review by the National Expert Group

4.4.1. Once all required documentation (including confirmation that the relevant prescribed fee(s) have been paid) and Product samples/packaging (if required) has been received by the HSE, the application will be assessed by the National Expert Group at its next scheduled review meeting.

4.4.2. **Applications in respect of removing a Product from the Reimbursement List**

- Products (the subject of an application from a Supplier seeking to have the Product removed from the Reimbursement List) will generally be removed from the Reimbursement List on the expiry of 12 months from the date that the application was submitted to the HSE or at such other time as the HSE and the Supplier agree or as is required by law.[10]

4.4.3. **Applications in respect of minor changes to Products on the Reimbursement List**

- The National Expert Group will assess each Product application and determine whether the minor change will be accepted by the HSE.

- If the minor change is not accepted by the HSE, the National Expert Group will notify the Supplier of the reasons that the minor change is not being accepted. The National Expert Group may also, at its discretion, request any additional documents or information that may, in its view, assist in allowing the minor change to be accepted by it.

- If the Supplier submits a Category 2 application for a “minor change” but the National

[10] Please note that Section 18(6) of the 2013 Act provides that the HSE shall remove a Product from the Reimbursement List which it is satisfied has permanently ceased to be marketed in the State.

Expert Group is of the view that the request is not “minor”, the National Expert Group will notify the Supplier of its view and recommended next steps.

5. SPECIFIC CRITERIA FOR WOUND DRESSINGS

5.1. Criteria for all Wound Dressings

In addition to the Mandatory Criteria at Section 2, the following criteria also apply in relation to all Wound Dressings.

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

5.1.2. Dressings must produce as little pain as possible as a result of adherence to the wound surface on application and on removal. The dressing must be non-adherent to the wound bed.

5.1.3. Dressings must maintain contact with wound bed on application and during wear-time.

5.1.4. Dressings must not release particles or non-biodegradable fibres into the wound.

5.1.5. 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).

5.1.6. 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.

5.1.7. Dressings must not break up upon removal.

5.2. Criteria for Specific Categories of Wound Dressings

5.2.1. In addition to the Mandatory Criteria at Section 2, and the criteria for all wound dressings at section 5.1, further criteria apply in relation to the product classifications listed below.

5.2.2. Wound Dressing Product classifications which are not listed in this section 5 do not have any additional specific criteria. Please refer to **Appendix C** 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**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.

5.4.2. **Iodine – Cadoxemer**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.
(b) The product must exhibit effective wound cleansing (debriding) activity.
(c) The product should have high absorption properties.
(d) The product must have the ability to sustain antimicrobial activity over a minimum of 72 hours.

5.4.3. **Iodine – Povidone**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.
(b) The product must not impede or damage granulation tissue and must be of a tight weave. (c) The product must contain 10 % Povidone – Iodine.

5.4.4. **PHMB**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection
(b) The product must have high absorption properties

5.4.5. **Honey Dressings**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection
(b) The product must exhibit effective wound debriding activity.
(c) The product must provide effective protection to the periwound skin from potentially irritant wound exudate and excess moisture.
(d) The product must possess effective odour absorbing/combating properties.
(e) The product must have the ability to remove or inactivate proteolytic enzymes in chronic wound fluid.
(f) The product must not impede or damage granulation tissue.

5.4.6. **Silver Foams**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.
(b) The product must have high absorption properties.
(c) The adhesive silver foam dressings must have silicone borders.

5.4.7. **Silver Fibre Alginates**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.
(b) The product must have high absorption properties.

5.4.8. **Silver Hydrofibres**

(a) The product must possess broad spectrum antimicrobial activity - capable of combating localised infection.
(b) The product must have high absorption properties (c) The product must be threaded.

5.4.9. **Silver Sheets**

(a) 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

5.10. Protease Modulator

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

5.11. Wound Contact Layer

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

5.12. Wound Debridement

5.12.1. The product should exhibit effective wound cleansing and debridement properties

5.13. Skin Protectors

5.13.1. The product should protect both intact and broken skin from bodily fluids.

6. SPECIFIC CRITERIA FOR BANDAGES & ADHESIVE PRODUCTS

6.1. Criteria for all Bandages & Adhesive Products

In addition to the Mandatory Criteria at Section 2, the following criteria also apply in relation to all Bandages and Adhesive Products.

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

6.1.2. 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.

6.1.3. 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.

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

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

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

6.2. Criteria for Specific Categories of Bandages & Adhesive Products

6.2.1. In addition to the Mandatory Criteria at Section 2, and the criteria for all bandages and adhesive products at section 6.1, further criteria apply in relation to the product classifications listed below.

6.2.2. Bandages and Adhesive Product classifications which are not listed in this section 6 do not have any additional specific criteria. Please refer to **Appendix C** for the full list of product classifications.

6.3. Compression Bandages

6.3.1. 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.

6.3.2. 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.

6.3.3. 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.

6.3.4. 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.

6.3.5. 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.

6.3.6. The product must have effective non-slip properties.

6.4. Medicated Bandages

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

6.5. Elasticised Adhesive Bandages

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

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

6.6. Lightweight Conforming Bandage

6.4.1 The product must have effective non-slip properties.

6.4.2 The product must have effective non-roll properties.

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

6.7. Tubular 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.

6.8. Surgical Adhesive Tapes

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

6.6.2 The product must have effective adhesive properties and must adher effectively.

6.6.3 Silk tape must have water resistant properties.

6.9. Adhesive Island Dressings

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

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

6.10. Skin Closure Strips

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

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

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

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

6.11. Non-Woven / Filmated Swabs (Sterile)

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

6.12. Non-Woven / Filmated Swabs (Non Sterile)

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

7. SPECIFIC CRITERIA FOR COMPRESSION HOSIERY

7.1. Criteria for Compression Hosiery

7.1.1. In addition to the Mandatory Criteria at Section 2, further criteria apply in relation to the Products listed at sections 7.2, below.

7.1.2. Compression Hosiery Product classifications which are not listed in this section 7 do not have any additional specific criteria. Please refer to **Appendix C** for the full list of product classifications.

7.2. Graduated Compression Hosiery

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

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

7.2.3. The product must have effective non-slip properties.

7.2.4. The product must have effective non-roll properties.

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

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

8. REVIEW OF CLINICAL DATA

8.1. This section is applicable to Category 1 (New Products) where the requirement for clinical trials is identified as part of the supporting documentation required under the application process. Please refer to **Appendix C** for the list of Wound Care Products which require clinical trials.

8.2. In addition to any other requirements set out in these Guidelines or at law, a Supplier submitting a **Category 1** application is required to submit:-

8.2.1. CE Certification;

8.2.2. Quality and safety data;

8.2.3. the published report on a minimum of three peer reviewed clinical investigations for each Product being submitted as a Category 1 application (conducted at not less than 3 centres with a minimum of 20 participants each), where required (see **Appendix C**).

- The reports must have been published in a peer review journal and available in English.
- The reports shall have set out, at a minimum, the length of the clinical investigation, the patient cohort, the number of Products used, the clinical outcomes achieved and any other relevant information.
- The clinical investigations 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.

8.3. The clinical investigation need not have been conducted in Ireland.

8.4. A clinical investigation should ideally have been conducted by an appropriately qualified health professional who is independent of the Supplier of the Product. If there was any connection between the Supplier and the person who conducted the investigation, this connection should be declared on the Category 1 Application Form.

8.5. Financial or other interests between investigators and the manufacturer of the Product should be clearly described.

8.5.1. Where an independent investigation (not sponsored by the Supplier) is cited as support, full details of any linkages, competing interests or conflicts of interest between any of the authors and the Product Supplier (or related companies) must be disclosed.

8.5.2. A suggested form of disclosure would be to use the criteria identified in the International Committee of Medical Journal Editors (“**ICMJE**”) Uniform Disclosure Form for potential conflicts of interest. http://www.icmje.org/coi_disclosure.pdf

Note: The data generated by any investigation should *inter alia* properly reflect the objectives of the investigation. The HSE is not responsible for the design of any investigation or any component thereof.

8.6. Each Product 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 Reimbursement List.

8.7. A clinical investigation participant may have been withdrawn from the clinical investigation at any time at the discretion of the person who conducted the investigation. However, the reasons for that the participant(s) withdrew should be documented and made available to the HSE.

8.8. Each Supplier who initiated a clinical investigation must have appointed a person who would have been responsible for co-ordinating each clinical investigation. The duties of a Co-ordinator should have included:-

(a) Preparing information booklets containing correct procedures,
(b) Formulating a questionnaire,
(c) Distributing the above documentation,
(d) Collecting the questionnaires, (e) Collating the data, (f) Presenting the results.

8.9. Permission to carry out the clinical investigation must have been obtained by the Co-ordinator conducting the clinical investigation.

8.10. The following were prerequisites for participation in a clinical investigation:-

(a) Participants must have been willing to use the Product.
(b) Participants must have provided informed consent.
(c) Participants must have been able to comprehend and complete the questionnaire provided.

The HSE reserves the right to request records if necessary.

8.11. Where a clinical investigation is not required (see **Appendix C**) the Applicant must submit a minimum of two 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.

8.12. Each Product must have its own evidence presented rather than relying on the evidence available for a similar Product or category of Products.

9. PRICING

9.1. The HSE has a statutory obligation under the Health Act, 2004 to use the resources available to it in the most beneficial, effective and efficient manner to improve, promote and protect the health and welfare of the public.

9.2. In accordance with the 2013 Act, the HSE shall have regard to the factors set out in section 21(2) of the Act when considering the proposed relevant price of a Product by the Supplier (which includes but is not limited to the relevant price of therapeutically similar listed items).

9.3. In considering the resources available to the HSE, and subject to the factors listed at section 21(2) of the Act, the reimbursement price for each Product classification will be determined on the basis 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 available to the HSE, or

9.3.4. Price proposed to the HSE or entity funded by the HSE, or

9.3.5. The lowest price of any Product included in the relevant Product classification, having regard to differences to sizes 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. Drug Tariff (the most current edition available at the time of pricing);

9.4.2. C&D (the most current edition available) if Drug Tariff not available;

9.4.3. BNF (the most current edition available), if Drug Tariff & C&D not available; or

9.4.4. Submitted UK Price, if all the above are not available.

9.5. The reimbursement price for each Product is inclusive of all costs associated with delivery of the Products (i.e. wholesaler or distribution costs)

9.6. It will be a matter for the Supplier to supply sufficient supporting evidence to justify a premium above the proposed reimbursement price for the Product classification.

9.7. In the event that a Product requires a new classification, the reimbursement price will be determined using the same criteria as outlined 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.

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

9.9. Adjustments to Pricing

9.9.1. The HSE operates a strict no price increase policy in relation to contract and reimbursement prices for goods and services.

9.9.2. Prices may be reduced in line with the 2013 Act.

9.9.3. The HSE will review the prices of the Products in line with the 2013 Act. Suppliers will be informed of any proposed changes in price following each pricing review and be given an opportunity to make representations in advance of a final decision being made in accordance with the 2013 Act.

9.9.4. Please refer to the 2013 Act for detailed information regarding the setting, reviewing and altering of the relevant prices of Products.

APPENDIX A

CATEGORY 1 - NEW PRODUCT APPLICATION FORM

New Wound Care Products to be added to HSE Reimbursement List

1. General Information

Supplier 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 C)	
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 [11]

Summary Details of Clinical Trial No. 1:	
Summary Details of Clinical Trial No. 2:	
Summary Details of Clinical Trial No. 3:	

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

CE Certificate Submitted[12]:	
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			
Drug Tariff (the most current edition available at the time of pricing)	£		
C&D (if Drug Tariff is not available) (the most current edition available)	£		
BNF (if Drug Tariff is not available) (the most current edition available)	£		
European Pricing			
United Kingdom	£	Country	€
Country	€	Country	€
Country	€	Country	€
Country	€	Country	€
Average of the three lowest European Countries			
Country	Country	Country	Country
€	€	€	€

- 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 may 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.

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

Reason for Price Submitted:

Name and Address of Key Contact for Application:

Name:

Position:

Address:

I confirm that the information provided in this application is correct and certify that the Product (the subject of the application) complies with:-

(a) applicable national standards and European Commission standards;
(b) the criteria set out in these Guidelines; and (c) all applicable laws.

Signature: _____ **Date:** _____

Telephone: _____ **E-mail:** _____

The completed form along with all required supporting documentation should be submitted to:

NonDrugReimbursement.Applications@hse.ie

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APPENDIX B

CATEGORY 2 - EXISTING PRODUCT APPLICATION FORM

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

1. Purpose

This form should be used by suppliers to:-

(a) Request that a Product be removed from the Reimbursement List; or

(b) Request a minor change in relation to a Product on the Reimbursement List.

Note: Suppliers should complete this form for each existing Product when wishing to notify the HSE of a discontinuation or minor change. A separate Application Form and supporting documents should be submitted in respect of each Category 2 application.

2. Product Details

GMS Code:	
Manufacturer:	
Distributor:	
Product Name:	
Product Description:	
Product Pack Size:	
Product Reference Code:	
Product Classification: *(See Appendix C)*	

3. Request to Discontinue Product

Suppliers should complete this section if they wish to remove the listing of a Product that is on the Reimbursement List.

Products (the subject of an application under this section) will generally be removed from the Reimbursement List on the expiry of 12 months from the date that the application was submitted to the HSE or at such other time as the HSE and the Supplier agree or as is required by law.

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.	

4. Request for Minor Change to Product

Suppliers should complete this section if they wish to request that the HSE make a minor change to a Product on the Reimbursement List.

Changes to the Product may include, for example: Packaging of the Product (including pack size); Product Specification; Name of Product; Supplier of the Product; Product Reference Code; Price Reduction offer.

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 requests, a copy of the outer packaging artwork, CE certification, Product samples and/or patient information leaflet for (both before the minor change and after the proposed minor change) may be requested by the HSE following receipt of the electronic application.

- The HSE may assess reasonable fees for to effecting minor changes to Products on the Reimbursement List.

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• A decision made in respect of a Category 2 application is not a “relevant decision” for purposes of the 2013 Act.

Name and Address of Key Contact for Application:

Name:

Position:

Address:

I confirm that the information provided in this application is correct and certify that the Product (the subject of the application) complies with:-

(a) applicable national standards and European Commission standards;

(b) the criteria set out in these Guidelines; and (c) all applicable laws.

Signature: _____ **Date:** _____

Telephone: _____ **E-mail:** _____

The completed form along with all required supporting documentation should be submitted to:

NonDrugReimbursement.Applications@hse.ie

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APPENDIX C

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 – 5.6.1 Foam Dressing 5.6.2 Moisturising Surfactant Foams	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	Wound Debridement 5.13.1 Debridement Dressings 5.13.2 Ancillaries	Clinical Trials x 3
5.14	Skin Protectors	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 7.1.1 Stocking / Tights 7.1.2 Wraps	Clinical Trials x 3

APPENDIX D

Excerpts from Schedule 3 of the 2013 Act *(Criteria Applicable to Items and Listed Items for Purposes of Executive Making Relevant Decision under section 18)*

Part 2 (*Criteria Applicable to Medical Devices, Foodstuffs for Particular Nutritional Use and Dietary Foods for Special Medical Purposes*)

1. *The medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose –*
   - *(a) Must be suitable for use under the supervision of a general medical practitioner or other relevant health professional and not be restricted to hospital or medical specialist use,*
   - *(b) Subject to paragraph 2, must not be advertised or promoted to the public, and*
   - *(c) Must not be for the purpose of obtaining a cosmetic effect.*
2. *The Executive may disapply the criterion referred to in paragraph 1(b) in the case of a particular medical device, foodstuff for a particular nutritional use or dietary food for a special medical purpose if it is satisfied that to disapply that criterion in that case is in the interest of –*
   - *(a) Patient safety, or*
   - *(b) Public health*

Part 3 (*General Criteria*)

The Executive shall have regard to –

- *(a) The health needs of the public,*
- *(b) The cost-effectiveness of meeting health needs by supplying the item concerned rather than providing other health services,*
- *(c) The availability and suitability of items for supply or reimbursement, or both, under section 59 of the Health Act, 1970 (as amended),*

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(d) The proposed costs, benefits and risks of the item or listed item relative to therapeutically similar items or listed items provided in other health service settings and the level of certainty in relation to the evidence of those costs, benefits and risks,

(e) The potential or actual budget impact of the item or listed item,

(f) The clinical need for the item or listed item

(g) The appropriate level of clinical supervision required in relation to the item to ensure public safety,

(h) The efficacy (performance in trial), effectiveness (performance in real situations) and added therapeutic benefit against existing standards of treatment (how much better it treats a condition than existing therapies), and

(i) The resources available to the Executive.