HSE Primary Care Reimbursement Service (PCRS) Urinary and Ostomy Guidelines for Manufacturers/Distributors/Suppliers

Policy ☐ Procedure ☐ Protocol ☐ Guideline ☒ Clinical Guideline ☐

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[1] Details the senior management roles involved in the development of the document.

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HSE Primary Care Reimbursement Service (PCRS) Urinary/Ostomy Product Reimbursement Guidelines for Manufacturers/Distributors/Suppliers. Non-drug reimbursement guidelines Urinary and Ostomy consumables underpinned by the Health (Pricing and Supply of Medical Goods) Act 2013.
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These Guidelines have been prepared by the HSE for the information of Manufacturers /Distributors in relation to reimbursement of Urinary and Ostomy consumable Products. The list of Urinary and Ostomy Products reimbursable under the GMS and Community Drug Schemes will be maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013.

[3] Details the version number and section numbers with updated content.

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HSE
Primary Care Reimbursement Service

Urinary and Ostomy Products

Guidelines for Suppliers/Manufacturers/Distributors

Index

1. 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 Urinary and Ostomy products (the "**Products**"). These Guidelines have been prepared by the HSE for the information of Suppliers[5] 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.[6]

By way of example, additional documentation may be requested to assess the cost-effectiveness 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.

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[5] 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.

[6] 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[7]. 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.[8] 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.

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[7] 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).

[8] 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."*

(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.

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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.

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) 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.

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. 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.[9]

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.

[9] 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.[10]

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 Reimbursement Service ("**PCRS**") 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.[11]

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.

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

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

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).

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[12] 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).

[12] 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.*"

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”.

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.[13]

[13] 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.

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:-

  (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.[14]

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

[14] 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.

- 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 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 URINARY PRODUCTS

5.1 Incontinence Sheaths/External Catheters

Incontinence Sheaths/External Catheters may be: (a) one piece or two piece; (b) adhesive or non-adhesive.

5.1.1. Sheaths must be manufactured from material that is non-abrasive to the skin and is impermeable to water (but allows air to permeate).

5.1.2. Each sheath must have a universal connector to allow connection to a urinary drainage or leg bag.

5.1.3. Sheaths must be available in a variety of sizes: 18mm - 40mm, the minimum range must be 25mm - 35mm.

5.1.4. Adhesive/adhesive strips must not cause any skin reaction and/or breakdown.

5.1.5. Both one-piece and two-piece systems must have adequate adhesive to ensure that the Product remains in place under normal circumstances for a minimum wear time of twelve hours.

5.1.6. Sheaths must be easily removed, without causing skin trauma.

5.1.7. Adhesive must be easily removed, without causing skin trauma.

5.1.8. Sheaths must be individually wrapped and packed in boxes of 30 and in the case of a two piece system must contain an adhesive strip.

5.1.9. A measuring guide must be available for correct fitting and must be included in each box or made available to patients as required.

5.1.10. Each box of sheaths must be clearly marked to allow for easy identification.

5.1.11. Each box of sheaths must contain a leaflet with application directions – this must be easily understood by the patient and include illustrations for ease of comprehension.

5.2 Leg Bags and Straps/Sleeves

Leg Bags

5.2.1 Leg bags must be available either (a) sterilised (for use with indwelling catheters); or (b) unsterilised (for use with incontinence sheaths).

5.2.2 All sterilised bags must have:-

(a) a non-return valve at the top of the bag.

(b) a needle-free sampling port.

5.2.3 Leg bags must be available in packs of not greater than 10. Each pack must contain a minimum of 1 set of leg straps. Upon request, additional leg straps must be made available free of charge ("**FOC**").

5.2.4 Leg bags must be available in varying capacities, from 250ml to 1500ml.

5.2.5 Each box must contain a leaflet with instructions for use stating minimum wear time (e.g., one week under normal circumstances).

5.2.6 When in contact with the skin, leg bags must not cause skin irritation.

5.2.7 A smaller bag (250mls) may be required for intermittent urinary leaks or dribbling.

Tubing

5.2.8 Leg bag and tubing must be sold as one unit.

5.2.9 Leg bags must be available in a variety of tubing lengths. The minimum length must be direct, i.e. connects directly to the sheath/catheter.

5.2.10 Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routing.

5.2.11 Connectors on leg bag must be universal.

5.2.12 The tap must be easily opened and closed (i.e. user-friendly and must not pose a hazard when left in an open position (i.e. when the leg bag is used in conjunction with a night drainage bags))

Straps & Sleeves

5.2.13 Straps must be elasticated and/or adjustable. The fastening must be sufficient to ensure that the leg bag is held in place when the bag is full. When in contact with the skin, the strap must not cause skin irritation.

5.2.14 A sleeve will be acceptable as an alternative to straps.

5.2.15 Sleeves should be available in a variety of sizes (small, medium, large & extra large).

5.2.16 The sleeve should be machine washable or disposable.

5.2.17 The sleeve should ensure that the leg bag is held in place when the bag is full.

5.2.18 The sleeve should not cause skin irritation when in contact with skin

5.2.19 The sleeve should last for a minimum of 1 week.

5.3 Overnight Drainage Bags

5.3.1 Drainage bags may be (a) drainable; or (b) non-drainage.

5.3.2 Drainable bags must be available: (a) sterilised (for use with indwelling catheters); or (b) unsterilised (for use with incontinence sheaths).

5.3.3 All sterilised bags must have:-

(a) a non-return valve at the top of the bag.

(b) a needle-free sampling port.

5.3.4 Sterilised bags must be available singly and unsterilised bags must be available in packs of 10 to 30.

5.3.5 Each box must contain a leaflet with instructions for use, stating minimum wear time under normal circumstances in the case of-

(a) Drainable – one week. Drainable bags for use with catheters should be sterile when used, and discarded when disconnected, max use for 7 days if on continuous drainage.

(b) Non-drainable – 12-24 hours. Non-drainable bags to be discarded when ¾ full (12-24 hrs).

5.3.6 The length of tubing must be approximately 1,000mm.

5.3.7 Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routeing.

5.3.8 Connectors must be universal.

5.3.9 In the case of drainage bags the tap must be easily opened and closed, i.e. user-friendly.

5.3.10 A smaller bag (250 mls) may be required for intermittent urinary leaks or dribbling 250 mls.

5.3.11 Bed/floor bag holder(s) should be provided FOC by the Supplier, as required by the patient.

5.4 Urinary Catheters

5.4.1 Catheters may be:-

(a) **Indwelling catheters for short term use** – minimum wear time of 7 days under normal circumstances.

(b) **Indwelling catheters for long term use** suitable for urethral and suprapubic – maximum wear time of 12 weeks under normal circumstances.

(c) **Indwelling catheters for medium term use** – wear time 4 weeks or as per manufacturer's instructions.

(d) **Intermittent self-catheterisation catheters** –

- Nelaton – single use only.
- Hydrophilic or coated – single use only.
- Incorporating drainage bags.
- Compact/discreet.

- Catheters, Dilatation without Drainage Eyes.
- Catheters with Balloon Dilators.

5.4.2 Catheters must be composed of silicone, non silicone, latex coated or non coated: or other suitable material in the case of:

a) indwelling short term

b) indwelling long term

c) indwelling medium term

d) intermittent self catheterisation.

5.4.3 Catheters must be smooth and free from surface irregularities – they must appear clean and free from extraneous matter when examined by normal or corrected vision.

5.4.4 Indwelling catheters must be sterile, with the expiry date of sterility clearly marked on both the inner and outer packaging. It is recommended to come with two removable stickers, detailing size, batch expiry date etc.

5.4.5 Intermittent catheters must be sterile, with the expiry date of sterility clearly marked.

5.4.6 A recognised mark of sterilisation must be visible on each unit of packaging.

5.4.7 In the case of indwelling catheters each catheter must have a universal connector, to allow connection to a drainage system without the use of a separate connector.

5.4.8 Catheters must be available in female length (22cm. approximately) and standard length (40cm. approximately).

5.4.9 Intermittent female catheters available in a wide range of compact/discreet lengths (e.g. from 3.5cm to the normal size 20cm).

5.4.10 Intermittent male catheters should also be available in a wide range of compact/discreet sizes (e.g. from 10Ch to 18Ch), compact or standard.

5.4.11 Option of collecting bag attached with intermittent catheters to be available.

5.4.12 State if for single use or reusable.

5.4.13 Catheters should be available in a wide range of Charriére sizes (e.g. 10Ch. to 30Ch). And intermittent catheters should also be available in a wide range of Charriére sizes (e.g. 8Ch. to 18Ch).

5.4.14 Catheters for paediatric use should be available in a wide range of sizes (e.g. 6Ch. to 10Ch) – the length of paediatric catheters must be 25cm approximately.

5.4.15 Indwelling catheters should be available in a wide range of balloon sizes (e.g. ranging from 3ml (paed) to 30ml). The volume required to inflate the balloon must be clearly marked on the packaging. The standard balloon size is 10mls.

5.4.16 In the case of indwelling catheters, Charriére size and balloon size must be detailed on the packaging and on the universal connector of each catheter.

5.4.17 Indwelling and intermittent catheters may be available with varying tips, e.g. Round, Couvelaire, Dulour, Le Guillon, Nelaton and Tiemann tip.

5.4.18 Intermittent catheters may be self-lubricating e.g. with Polyvinylpyrrolidone (P.V.P.) hydrophilic coating or lubricant on the surface of the catheter. Any lubricant used must be sterile, non-toxic and certified as such by a recognised body.

5.4.19 In the case of:

a) indwelling catheters short term – pack sizes must not exceed 10.
b) indwelling catheters long term – individually wrapped sterilised within pack.
c) indwelling catheters medium term - must not exceed 5.
d) indwelling catheters can come as a complete kit.
e) intermittent catheters (i) Nelaton – pack sizes must not exceed 30-50
(ii) Lubricated – pack sizes must not exceed 30.

5.4.20 It is preferable that intermittent catheters would have universal colour coding for size purposes for the client and the Pharmacist for order purposes.

5.4.21 In the case of intermittent catheters, each box should contain a leaflet with instructions for use and care after use.

5.4.22 Outer packaging must be durable to avoid damage to products during transport and/or storage with easy to identify Charrière size, type of catheter and length.

5.4.23 Instructions for storage must be given to Pharmacist and client by the supplier, e.g. avoid kinking of catheter, avoid direct sunlight, avoid damp conditions, store flat, etc.,

5.5 Catheter Valves

5.5.1 The materials used in manufacturing valves must be smooth and free from surface irregularities.

5.5.2 Catheter valves must have a universal inlet connector. This connector should be non-slip and secure.

5.5.3 Each catheter valve must have an outlet connector which is universal. This allows for the use of a drainage system either leg or overnight drainage bag.

5.5.4 Catheter valves must have an opening mechanism which is easy to use (i.e. user-friendly and minimising the risk of hand contamination).

5.5.5 The tap must have the facility to be left in an open or closed position. The tap must not pose a hazard when left in the open position, i.e. when used in conjunction with leg or overnight drainage bag.

5.5.6 All catheter valves must be sterile. A recognised mark of sterilisation and expiry date of same must be clearly marked on inner and outer packaging.

5.5.7 Each catheter valve must be individually wrapped sterilised.

5.5.8 Each box of catheter valves must contain a leaflet with directions for use, which must be easily understood by the patient and include illustration for ease of comprehension. Instructions must state minimum wear time (e.g. 7 days under normal circumstances).

5.6 Retracted Penile Continence System

5.6.1 **Plastic**

(a) Must be of good quality and be odour proof.
(b) Must be flexible and comfortable.
(c) Must be discreet and unobtrusive.
(d) Must be quiet film.

5.6.2 **Bag (with tap)**

(a) Bags must be available in boxes of not greater than 10.
(b) Each box of bags must contain a leaflet with application directions – this must be easily understood by the patient and include illustrations for ease of comprehension. Instructions must clearly state minimum wear time, i.e. 1-3 days under normal circumstances.

5.6.3 **Adhesive**

(a) Must be easy to apply and remove.
(b) Must be secure.
(c) Must be comfortable.
(d) Must incorporate a skin protective.
(e) If the appliance incorporates an adhesive tape, the tape must be non-allergic.

5.6.4 **Taps**

(a) The tap must be easily opened and closed (i.e. user-friendly and must not pose a hazard when left in an open position).

5.6.5 **Connectors**

(a) Connectors on retracted penile continence system bags must be universal to facilitate easy attachment to night drainage and/or leg bags.

5.7 Nephrostomy Drainage

5.7.1 Nephrostomy bags must be available in a variety of capacities, from 350ml-500ml.

5.7.2 Nephrostomy bags must be sterile.

5.7.3 Nephrostomy bags must have a non-return valve at the top of the bag.

5.7.4 Should be available in packs not greater than 10.

5.7.5 Each box must contain a leaflet with instructions for use stating minimum wear time (i.e. one week under normal circumstances).

5.7.6 When in contact with the skin, nephrostomy bags must not cause skin irritation.

5.7.7 Nephrostomy bags must be available in a variety of tubing lengths. The minimum length must be direct.

5.7.8 Nephrostomy bag and tubing must be sold as one unit.

5.7.9 Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routing.

5.7.10 The tap must be easily opened and closed.

5.7.11 There may be a requirement for a connector to connect nephrostomy bag to a night drainage bag.

5.7.12 Straps must be elasticated and/or adjustable. The fastening must be sufficient to ensure that the nephrostomy bag is held in place when the bag is full. When in contact with the skin, the strap must not cause skin irritation. Straps must be included in the nephrostomy bag pack.

5.8 Catheter Securement

5.8.1 Comfortable to wear to prevent traction / movement or pulling on the catheter.

5.8.2 Easy to apply and remove that doesn't cause skin damage.

5.8.3 Fits any size catheter.

5.8.4 Each box of devices must contain application directions – this must be easily understood by the patient and include illustrations for ease of comprehension. Instructions must clearly state minimum wear time (i.e. 3-5 days under normal circumstances).

5.8.5 When in contact with the skin, they must not cause skin irritation.

5.8.6 May be single use or machine washable.

5.9 Spigots

5.9.1 Spigots should be sterile.

5.9.2 Spigots should be of durable plastic.

5.10 Urinary Clamps/Dribble Stops

5.10.1 Applies pressure to penis without skin damage.

5.10.2 Discreet and comfortable to wear.

5.10.3 Adjustable for the individual.

5.10.4 Available singly.

5.10.5 Each box of bags must contain a leaflet with application directions – this must be easily understood by the patient and include illustrations for ease of comprehension.

Instructions must clearly state minimum wear time (i.e. 24 hour bladder control under normal circumstances).

5.11 Catheter Maintenance Solutions ("CMS")

5.11.1 The materials used in manufacturing of CMS must be compatible with the connectors.

5.11.2 Catheter solutions must have a universal inlet connector, suitable to attach to all catheters.

5.11.3 This connector should be non-slip and secure.

5.11.4 CMS must have an opening mechanism which is easy to use (i.e. user-friendly and minimising the risk of hand contamination).

5.11.5 CMS must have the facility to be left in an open or closed position.

5.11.6 All CMS must be sterile. A recognised mark of sterilisation and expiry date of same must be clearly marked on inner and outer packaging.

5.11.7 Each CMS must be individually wrapped and available in boxes of 10.

5.11.8 Each box of CMS must contain a leaflet with directions for use, which must be easily understood by the patient and include illustration for ease of comprehension. Instructions must state frequency of use.

5.11.9 Each box must include instruction on disposal of waste.

5.12 Trans Anal Irrigation

5.12.1 Pump/control unit /water holder and rectal catheters may be separate.

5.12.2 Supplies of rectal catheters must be available in boxes of not greater than 10-15.

5.12.3 Rectal Catheters must be smooth and free from surface irregularities – they must appear clean and free from extraneous matter when examined by normal or corrected vision.

5.12.4 Rectal catheters may be available in different sizes.

5.12.5 Rectal catheters may be self-lubricating or any lubricant used must be non-toxic and certified as such by a recognised body.

5.12.6 Pump system should be easily filled.

5.12.7 Each box should state if rectal catheters are for single use.

5.12.8 Each box must contain a leaflet with directions – this must be easily understood by the patient and include illustrations for ease of comprehension. Instructions must clearly state how often this should be used.

5.12.9 Information on disposable of waste in every pack (e.g., catheters do/do not flush down the toilet).

6. SPECIFIC CRITERIA FOR OSTOMY PRODUCTS

6.1. Ostomy Collection Pouches

6.1.1. **Size (All Pouches)**

(a) All pouches except Fistula must be available in a wide range of gasket sizes.

(b) Fistula pouches must be available as a standard "cut to fit".

6.1.2. **Plastic (All Pouches)**

(a) The plastic must be of good quality and be odour proof.

(b) Must be flexible and comfortable.

(c) Must be discreet and unobtrusive.

(d) Must be quiet film.

6.1.3. **Pouch (All Pouches)**

(a) The pouch must have a soft, absorbent backing and be available in clear (including split cover variants) and opaque presentations.

(b) Each box of pouches must be packed in box sizes ranging 10 – 30 units.

(c) In the case of two-piece systems, shelf containers and preferably unit and inner containers, must contain a statement as to which pouches and flanges will couple together.

(d) Each box of pouches must contain a leaflet with application directions. Directions must be easily understood by the patient and include illustrations for ease of comprehension.

(e) A measuring guide must be available for correct fitting and must be included in each box or be available upon request. In the case of fistula pouches a template must be included.

6.1.4. **Adhesive (All Pouches and Flanges)**

(a) Must be easy to apply and remove.

(b) Must be secure.

(c) Must be comfortable.

(d) Must incorporate a skin protective.

(e) If the appliance incorporates an adhesive tape, the tape must be non-allergenic.

6.1.5. **Filters**

(a) Filters must be discreet and effective (i.e. odour or faecal material should not leak from the filter, they should prevent ballooning, designed to avoid blockage of the filter, waterproof in shower/bath or filter covers should be included in box of products).

6.1.6. **Pouch Closures (Drainable, Fistula and Post-Op. Pouches)**

(a) Pouch closures should be integrated into the pouch.

(b) Pouch closures should be easy to clean and allow for repeated opening and closing.

(c) If a soft wire tie is the method of closure, a minimum of one tie per pouch must be included.

(d) If a bung type closure is the method of closure the bung should be securely attached to the pouch.

(e) Standard clip – 1 clip per ten pouches is acceptable.

6.1.7. **Convexity**

(a) Convex products should identify the degree of convexity e.g. shallow or deep or more preferably the depth of convexity in millimetres (mm). This should be displayed on outer box.

(b) Literature included with the pouch should outline appropriate use of and precautions required when using convexity. (e.g., should be used under the supervision of a medical healthcare professional such as a stoma clinical nurse)

6.1.8. **Taps (Urostomy)**

(a) The tap must be easily opened and closed (i.e. user-friendly and must not pose a hazard when left in an open position (i.e. when the pouch is used in conjunction with leg and night drainage bag)).

6.1.9. **Non-Return Valve (Urostomy)**

(a) Urostomy pouches must have a non-return valve.

6.1.10. **Connectors (Urostomy)**

(a) Connectors on urostomy pouches must be universal to facilitate easy attachment to leg and night drainage pouches.

(b) One connector per pack of 10 pouches is acceptable.

6.1.11. **Urostomy Drain Tubing**

(a) Tubing must be constructed in material with anti-kink properties, yet must be sufficiently flexible to allow easy manipulation and routeing.

6.1.12. **Drainage Bags**

(a) Faecal ostomy pouch free drainage bags must:

i. Contain an instruction leaflet;
ii. Have a capacity between 2 and 3 litres;
iii. Be made from a good quality plastic;

iv. Have volume measuring markings on bag;
v. Have a durable and secure emptying tap/device;
vi. Have universal eyelets to attach bag to a stand; and
vii. Be available in pack sizes between 10-30 units.

(b) Drainage bags for use with urostomy pouches must comply with applicable criteria for urinary incontinence products as set out in these Guidelines.

6.1.13. **Flanges**

(a) Two Piece pouches must be easy to attach to flanges.

(b) In the case of two-piece systems, shelf containers and preferably unit and inner containers must contain a statement as to which pouches and flanges will couple together within a range.

(c) There may be instances where a patient may not achieve the minimum wear time. Consequently, users should be advised that the minimum wear time is conditional (e.g. on there being no leakage from under the flange or an adverse skin reaction occurring).

6.2. Adhesive Removers

6.2.1. Must include clear patient instructions (e.g., wash skin following use).

6.2.2. Must not damage skin.

6.2.3. Must not cause pain on application.

6.2.4. Contents must be clearly marked.

6.2.5. Must be easy to use.

6.2.6. Must not compromise the adhesion of the new pouch being applied.

6.3. Belts

6.3.1. Must include clear patient instructions.

6.3.2. Must be comfortable next to skin (e.g., plastic tabs).

6.3.3. Must be of washable fabric.

6.3.4. Must be compatible with pouches.

6.3.5. Must be easy to adjust.

6.4. Deodorants/Air Freshener

6.4.1. Must include clear patient instructions i.e. if applicable not to be sprayed on or near stoma.

6.4.2. Must be ozone friendly.

6.5. Irrigation/Plug Devices

6.5.1. **Irrigation/Plug Appliances**

(a) Appliances must contain clear instructions with illustrations for patient use.

(b) Appliances must clearly state approximate length of time for which it can be used (i.e., Pouch, Tubing, Cone - not less than 1 year).

(c) Sleeves must be packed in boxes of 10-50 units.

(d) Cones must be packed singly.

6.5.2. **Irrigation Pouch**

(a) Plastic must be of good quality.

(b) Capacity must be 1000mls. to 2000mls.

(c) Volume capacity must be clearly labelled and easily read.

(d) Pouch must incorporate a good quality holder/handle.

6.5.3. **Irrigation Tubing**

(a) Must be of good quality plastic.

(b) Must have anti-kink properties.

(c) Must be flexible and easy to use.

(d) Must incorporate a water controlling device which is easy to use.

6.5.4. **Cone/Catheter**

(a) Material must be of good quality.

(b) Must be soft.

(c) Tip must be rounded for comfortable insertion and removal, without causing damage to the stoma or rectum.

(d) Must be easy to remove from the tubing for easy cleaning.

6.5.5. **Sleeves (One Piece)**

(a) Plastic material must be of good quality.

(b) Adhesive must be easy to apply and remove from skin.

(c) Sleeves must contain security clip (e.g., for when the patient wishes to walk around during the procedure).

(d) Instructions must state length of time each sleeve can be used for (i.e., single use).

6.5.6. **Sleeves (Two Piece)**

(a) Plastic material must be of good quality.

(b) Sleeve must be easy to apply to and remove from belt flange.

(c) Sleeves must contain security clip i.e. for when the patient wishes to walk around during the procedure.

(d) Instructions must state length of time each sleeve can be used for (i.e., single use).

(e) Must state approximate length of time each belt can be used for (i.e. minimum of 6 months).

6.5.7. **Plugs (One Piece)**

(a) Material must be of good quality.

(b) Material must be soft and comfortable.

(c) Must be discreet and unobtrusive.

(d) Must be easy to insert and remove without traumatising the stoma or peristomal skin.

(e) Must incorporate an effective filter.

(f) Must be available in a selection of sizes.

(g) Must contain clear instructions and illustrations for use and disposal.

(h) Must be packed in boxes of 10-30 units.

(i) Adhesive must be secure, easy to apply and remove from skin.

(j) Adhesive must incorporate a skin protective.

6.5.8. **Plugs (Two Piece)**

(a) Base plate must be soft and comfortable.

(b) Must be discreet and unobtrusive.

(c) Adhesive must be secure, easy to apply and remove from skin.

(d) Adhesive must incorporate a skin protective.

(e) Must incorporate an effective filter.

(f) Plug must be easy to attach and remove from base plate.

(g) Must be packed in boxes of 10-30 units.

(h) Must contain clear instructions and illustrations for use and disposal.

(i) Must be available in a selection of sizes.

(j) Plug must be easy to insert and remove without traumatising the stoma or peristomal skin.

6.6. Skin Fillers and Protectives (Sprays, Powders, Pastes and Wipes)

6.6.1. Contents must be clearly labelled.

6.6.2. Instructions must be clearly stated.

6.6.3. Must be easy to apply to and remove from skin.

6.6.4. Must not cause pain on application.

6.6.5. Must not cause damage to skin.

6.7. Skin Protectors (Seals/Rings)

6.7.1. Must adhere to moist skin.

6.7.2. Must be comfortable on skin.

6.7.3. Must be flexible on skin.

6.7.4. Must be available in a variety of sizes i.e. rings.

6.7.5. Must be easy to apply to and remove from skin.

6.7.6. Must contain instructions.

6.8. High Output Pouches

6.8.1. Must have a bung type closure to allow for connection to free drainage if required.

6.8.2. Must have an adhesive resistant to corrosive effluent.

6.8.3. Convex high output pouches must have an option of attaching a belt.

6.8.4. Must have a larger than average pouch capacity.

6.9. Anal Plugs

6.9.1. Contents must be clearly labelled.

6.9.2. Instructions must be clearly stated.

6.9.3. Must be available in a variety of sizes.

6.9.4. Must be easy to apply to and remove from skin.

6.9.5. Must be individually wrapped.

7. REVIEW OF CLINICAL DATA

7.1. This section is applicable only to **Category 1** applications (New Products).

7.2. 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:-

7.2.1. CE Certification;

7.2.2. Quality and safety data;

7.2.3. the published report on a minimum of two peer reviewed clinical investigations for each Product being submitted as a Category 1 application.

- 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, the minimum dataset referred to in **Appendix C**, and any other relevant information.

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

7.4. Each clinical investigation must have been conducted in at least three centres, with a minimum of at least 20 participants in total across the three centres.

7.5. 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.

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

7.6.1. 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.

7.6.2. 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.

7.7. 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. However, the Supplier must have supplied the necessary items that allowed a Product to have been used effectively (e.g., set of straps to have been used with leg bags).

7.8. 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.

7.9. Each Supplier who initiated a clinical investigation must have appointed a person who would have been responsible for coordinating each clinical investigation. The duties of a coordinator 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.

7.10. Permission to carry out the clinical investigation must have been obtained by the coordinator conducting the clinical investigation from the relevant authority.

7.11. 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.

(d) Participants must have been participated in the trial for the period of time outlined in the table below on the type of product under trial.

7.12 **Exclusions:-**

- Participants who were found to have had a skin assessment rating of 2, 3, or 4 must have be cleared by medical advice if they were included in the Clinical Trial:-

0 = Normal intact skin,
1 = Patchy redness,
2 = Extensive redness,
3 = Reddened blistered but not broken,
4 = reddened with open areas of skin.

- Participants who were undergoing Radiotherapy or Chemotherapy treatment must also have been excluded from the trial.
- Products excluded from Clinical Trials are Post-op and Fistula pouches (Ostomy Products).

7.13 The following must have been compiled with when conducting a Clinical Trial:-

- **Length of Trial –** The minimum length of trial period must have been set for each specific product as indicated hereunder-

Urinary Products

Product Classification	Clinical Investigation Period
Incontinence Sheath/External Catheters	7 Days
Leg Bags & Overnight Drainage Bags	7 Days
Straps/Sleeves	28 Days
Urinary Catheters	
(a) Indwelling Long Term	3 Months
(b) Intermittent Self Catheterisation	7 Days
(c) Indwelling Short/Medium Term	1 Month
Catheter Valves	14 Days
Retracted Penile Continence System	14 Days
Nephrostomy Drainage	7 days
Catheter Securement	7 days
Spigots	7 days
Urinary Clamps/Dribble Stops	7 days
Catheter maintenance solutions	7 days
Trans Anal Irrigation.	14 days

Ostomy Products

Product Classification	Clinical Investigation Period
One/Two Piece Closed Pouches	10-12 Days
One/Two Piece Open Pouches	18-20 Days
Urostomy Pouches	18-20 Days
Adhesive Remover	To be determined by the type of pouch being worn
Pouch Closures·.	18-20 Days
Belts	To be determined by the type of pouch being worn
Deodorant/ Air Freshener	To be determined by the type

	of pouch being worn
Filters	10-12 Days
Irrigation /Plug Appliances(Pouch/Tubing/Cone/Sleeve)	28 Days
Skin Fillers & Protectives	To be determined by the type of pouch being worn
Skin Protectors	To be determined by the type of pouch being worn
Anal Plugs	28 days

- The minimum wear time for Pouches/Flanges under trial will have been the participants normal wear time for this type of product.

7.14 Where a Clinical Trial is not required **(ref: Appendix C)**, the Applicant must submit a minimum of two written testimonials, from 2 different centres, for each product being submitted. The written testimonials must be on hospital headed paper signed by an appropriate qualified clinical user which confirms the satisfactory "use in practice" of the product.

8. TRIAL MINIMUM DATASET

URINARY PRODUCTS

A questionnaire for each product on trial must have been provided by the Co-ordinator to the person who conducted the trial and this must have been completed by the trial participant.

8.1 **Incontinence Sheath**

- 7.1.1 Security.
- 7.1.2 Comfort.
- 7.1.3 Ease of application.
- 7.1.4 Ease of removal.
- 7.1.5 Adhesive residue.
- 7.1.6 Frequency of change – durability.
- 7.1.7 Wear time/Reasons for change.

8.2 **Leg Bags & Overnight Drainage Bags**

- 8.2.1 Sterilised.
- 8.2.2 Unsterilised.
- 8.2.3 Effectiveness of non-return valve.
- 8.2.4 Effectiveness of needle-free sampling port.
- 8.2.5 Ease of use of needle-free sampling port.
- 8.2.6 Effectiveness of tap.
- 8.2.7 Ease of opening of tap.
- 8.2.8 Tubing anti-kink properties.
- 8.2.9 Flexibility of tubing.
- 8.2.10 Ease of attachment to Night Drainage/Leg Bag.
- 8.2.11 Ease of removal from Night Drainage/Leg Bag.

8.3 **Straps/Sleeves**

- 8.3.1 Clear instructions.
- 8.3.2 Ease of application.
- 8.3.3 Comfort.
- 8.3.4 Effectiveness.
- 8.3.5 Skin health.

8.4 **Urinary Catheters**

- 8.4.1 Sterility mark.
- 8.4.2 Universal connector.
- 8.4.3 Balloon size.
- 8.4.4 Non-toxic.
- 8.4.5 Ease of opening
- 8.4.6 Ease of insertion
- 8.4.7 Ease of removal
- 8.4.8 Lubrication
- 8.4.9 Ease of handling

8.5 **Catheter Valves**

- 8.5.1 Connectors – Ease of attachment.
- 8.5.2 Connectors – Ease of removal.
- 8.5.3 Ease of opening of tap.
- 8.5.4 Ease of closing of tap.
- 8.5.5 Clear instructions.

8.6 **Retracted Penile Continence System**

- 8.6.1 Security.
- 8.6.2 Comfort.
- 8.6.3 Odour proof material.
- 8.6.4 Discreet.
- 8.6.5 Unobtrusive.
- 8.6.6 Noise/rustle factor.
- 8.6.7 Ease of application.
- 8.6.8 Ease of removal.
- 8.6.9 Adhesive effectiveness.
- 8.6.10 Skin health.
- 8.6.11 Effectiveness of tap.
- 8.6.12 Ease of opening of tap.
- 8.6.13 Ease of closing of tap.
- 8.6.14 Connectors – ease of attachment.

8.7 **Nephrostomy Drainage**

- 8.7.1 Sterilised.
- 8.7.2 Unsterilised.
- 8.7.3 Effectiveness of non-return valve.
- 8.7.4 Effectiveness of needle-free sampling port.
- 8.7.5 Effectiveness of tap.
- 8.7.6 Ease of opening of tap.
- 8.7.7 Tubing anti-kink properties.
- 8.7.8 Flexibility of tubing.

8.8 **Catheter Securement**

- 8.8.1 Clear instructions.
- 8.8.2 Ease of application.
- 8.8.3 Comfort.
- 8.8.4 Effectiveness.
- 8.8.5 Skin health.

8.9 **Spigots**

- 8.9.1 Sterilised.
- 8.9.2 Durability.

OSTOMY PRODUCTS

A questionnaire for each product on trial must have been provided by the Co-ordinator to the person who conducted the trial and this must have been completed by the trial participant.

8.10 **Pouches: One Piece Closed/Open**

8.10.1 Security.

8.10.2 Comfort.

8.10.3 Odour proof material.

8.10.4 Noise/Rustle factor.

8.10.5 Aesthetic appearance.

8.10.6 Filter performance.

8.10.7 Ease of application.

8.10.8 Ease of removal.

8.10.9 Adhesive residue.

8.10.10 Backing paper - ease of removal.

8.10.11 Flexibility.

8.10.12 Capacity adequacy.

8.10.13 Frequency of change - durability.

8.10.14 Visibility/Profile.

8.10.15 Assessment of backing material -Comfort,
-Ability to absorb perspiration.

8.10.16 Wear time/Reasons for change.

8.10.17 Daily activities - Showering/bathing- Ease of drying,
-Filter performance,
-Adhesive performance.

8.10.18 Status of peristomal skin at final assessment.

8.11 **Pouches: Two Piece System**

In addition to points referred to under 8.10 above, the following must have been included in the Questionnaire-

8.11.1 Ease of attachment of flange to pouch.

8.11.2 Ease of removal of flange from pouch.

8.11.3 Incidence of "pop-off' occurrence.

8.11.4 Flanges - Flexible,

- Inflexible.

8.12 **Urostomy Pouches**

In addition to points referred to under 8.1 above, the following must have been included in the questionnaire-

8.12.1 Effectiveness of non-reflux valve.

8.12.2 Effectiveness or tap, security.

8.12.3 Ease of opening.

8.12.4 Ease of closing.

8.12.5 Ease of attachment to Night Drainage Bag/Leg Bag.

8.12.6 Ease of removal from Night Drainage Bag/Leg Bag.

8.12.7 Connectors - Ease of attachment,

- Ease of removal,

- Security.

8.13 **Adhesive Removers**

8.13.1 Clear instructions.

8.13.2 Damage to skin.

8.13.3 Pain on application.

8.13.4 Ease of application.

8.13.5 Compromising pouch adhesion.

8.14 **Pouch Closures**

8.14.1 Ease of application.

8.14.2 Ease of opening.

8.14.3 Ease of removal.

8.14.4 Security.

8.14.5 Ease of cleaning.

8.14.6 Comfort.

8.14.7 Discreet.

8.15 **Belts**

8.15.1 Clear instructions.

8.15.2 Ease of application.

8.15.3 Ease of removal.

8.15.4 Ease of belt adjustment.

8.15.5 Discreet.

8.15.6 Comfort.

8.15.7 Washable.

8.16 **Deodorants/Air Fresheners**

8.16.1 Clear instructions.

8.16.2 Effectiveness.

8.16.3 Ease of Usage.

8.16.4 Acceptability of perfume.

8.17 **Filters**

8.17.1 Visibility profile.

8.17.2 Effectiveness.

8.17.3 Acceptable wear time.

8.17.4 Leakage through filter.

8.18 **Irrigation/Plug Appliances**

8.18.1 Clear instructions.

8.18.2 Ease of storage/carriage.

8.19 **Irrigation Bag**

8.19.1 Plastic - Durability.

8.19.2 Capacity.

8.19.3 Labelling.

8.19.4 Holder - quality,

- effectiveness.

8.20 **Irrigation Tubing**

8.20.1 Anti-kinking.

8.20.2 Ease of handling.

8.20.3 Flexibility.

8.20.4 Water controlling device - ease of usage,

- effectiveness.

8.20.5 Ease of removal from cone.

8.21 **Cone/Catheter**

8.21.1 Ease of insertion/removal.

8.21.2 Comfortable.

8.21.3 Ease of removal from tubing.

8.21.4 Ease of cleaning.

8.22 **Sleeves**

8.22.1	Ease of application.	(1-Piece)
8.22.2	Ease of removal.	(1-Piece)
8.22.3	Comfortable.	(1-Piece)
8.22.4	Ease of usage.	(Security clip)
8.22.5	Effectiveness.	(Security clip)
8.22.6	Ease of application of flange to belt.	(2-Piece)
8.22.7	Ease of removal of flange from belt.	(2-Piece)
8.22.8	Comfortable.	(2-Piece)

8.23 **Skin Fillers & Protectives (Sprays Powders Pastes & Wipes)**

8.23.1 Clear instructions

8.23.2 Ease of application

8.23.3 Adherence to moist skin

8.23.4 Ease of removal where appropriate

8.23.5 Effectiveness

8.24 **Skin Protectives (Seals/Rings)**

8.24.1 Clear instructions

8.24.2 Ease of application

8.24.3 Adherence to moist skin

8.24.4 Ease of removal

8.24.5 Effectiveness

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 PCRS 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

Request for New Urinary or Ostomy 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 Investigation/User Evaluation Data

Summary Details of Clinical Investigation/User Evaluation Data/Accuracy Data No. 1:	
Summary Details of Clinical Investigation/User Evaluation Data/Accuracy Data No. 2:	
CE Certificate Submitted[15]:	
Please provide details of any relationship / link between the manufacturer or proposed Irish	

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

distributor and the person who conducted the clinical investigation	

3. Product Samples

See Sections 3.3, 3.4 and 4.3 of this Guidelines document for information of submission of Product samples.

4. Proposed Prices (All prices provided must be per single unit and not pack price)

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.

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

APPENDIX B

CATEGORY 2 - EXISTING PRODUCT APPLICATION FORM

Existing Urinary or Ostomy 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.

- 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

APPENDIX C

PRODUCT CLASSIFICATIONS

URINARY PRODUCTS

URINARY	EVIDENCE REQUIRED
Catheter Maintenance Solutions	Clinical Trial x 2
Catheter Securement	User Evaluation Data
Catheter Valves	User Evaluation Data
Catheters Non Silicone - Indwelling (Long Term)	Clinical Trial x 2
Catheters Non Silicone - Indwelling (Medium Term)	Clinical Trial x 2
Catheters Non Silicone - Indwelling (Short Term)	Clinical Trial x 2
Catheters Non Silicone - Isc (Lubricated)	Clinical Trial x 2
Catheters Non Silicone - Isc (Lubricated) Incorporating Drainage Bag	Clinical Trial x 2
Catheters Non Silicone - Isc (Nelaton)	Clinical Trial x 2
Catheters Silicone - Indwelling (Long Term)	Clinical Trial x 2

Catheters Silicone - Isc (Lubricated)	Clinical Trial x 2
Dilatation Catheters	Clinical Trial x 2
Drainage Bags	User Evaluation Data
Incontinence Sheaths	Clinical Trial x 2
Intermittent Catheter Lubricated - Gms	Clinical Trial x 2
Leg Bag Holder	User Evaluation data
Leg Bags	User Evaluation Data
Nephrostomy Drainage	User Evaluation Data
Retracted Penile Continence System	User Evaluation Data
Trans Anal Irrigation	Clinical Trial x 2
Spigots	User Evaluation Data
Urinary Clamps/Dribble Stops	Clinical Trial x 1 User Evaluation Data

OSTOMY PRODUCTS

OSTOMY	EVIDENCE REQUIRED
Absorbents	Clinical Trial x 2
Adhesive Hydrocolloid Barrier Extension	Clinical Trial x 2
Adhesive Removers	Clinical Trial x 2
Bag Closures	User Evaluation Data
Belts	Clinical Trial x 2
Colostomy Bags	Clinical Trial x 2
Deodorants/Air Fresheners	Clinical Trial x 2
Filters	Clinical Trial x 2
Fistula Bags	Clinical Trial x 2
High Output Pouches	Clinical Trial x 2
Ileostomy (Drainable) Bags	Clinical Trial x 2
Irrigation/Plug Appliances	Clinical Trial x 2

Post-Op. Bags	Clinical Trial x 2
Skin Fillers & Protectives (Barrier)	Clinical Trial x 2
Skin Protectors (Wafers, Washers)	Clinical Trial x 2
Stoma Caps	Clinical Trial x 2
Tubing	User Evaluation Data
Two Piece Ostomy Systems	Clinical Trial x 2
Urostomy Bags	Clinical Trial x 2

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),

(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.