HSE PRIMARY CARE

REIMBURSEMENT SERVICE

REIMBURSEMENT LIST OF

PERSONAL DIAGNOSTIC, MONITORING & DELIVERY DEVICES

GUIDELINES FOR SUPPLIERS/MANUFACTURERS/DISTRIBUTORS

Version 2.0 March 2018

1. INTRODUCTION

1.1. These guidelines have been prepared by the HSE National Expert Group for the information of Suppliers[1] of Personal Diagnostic, Monitoring & Delivery devices (hereafter "Products[2]"). Additions to the Reimbursable List will be considered in compliance with the Health (Supply and Pricing of Medical Goods) Act, 2013.

1.2. There are two Categories of submission for Products:

Category 1 - New Products

Category 2 - Existing Products

1.3. These guidelines are applicable to both Category 1 and Category 2 Products.

1.4. Please note that samples of Products and/or packaging for Category 1 applications **will** be requested by the HSE following initial review of the application.

1.5. Please note that samples of Products and/or packaging for Category 2 applications **may** be requested by the HSE following initial review of the application.

1.6. Products used on the body, or inserted into the body, must not cause an adverse or toxic reaction.

1.7. Products (excluding Continuous / Flash Glucose Monitoring Systems) 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.

1.8. Continuous / Flash Glucose Monitoring Systems must be suitable for self administration use under the supervision of a relevant specialist hospital clinic.

1.9. Products must be cost effective[3]. It will be a matter for the National Expert Group to determine whether a product application is cost effective. The HSE reserves the right to request a mini Health Technology Assessment (HTA) on any product application received.

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

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[1] The term Suppliers refers to the Applicant companies who submit the Products for reimbursement. An Applicant company may be a Manufacturer, Distributor or Agent for the product.

[2] Products does not include equipment (e.g. Glucometers, Insulin Pumps, Urinalysis Machines, CGM Smart Device/Monitor) as these are not a consumable device and have a shelf life of greater than one month.

3 'Cost-effectiveness refers to meeting health needs by supplying the item concerned rather than providing other health services'. Please refer to Section 21 (Chapter 3) of the Health (Pricing and Supply of Medicinal Goods) Act 2013.

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

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

Direct marketing and canvassing activity to patients is prohibited.

Please note that Products which are not included on the Reimbursement List for Personal Diagnostic, Monitoring & Delivery Devices (e.g. pumps & meters) do not fall within the scope of this clause.

1.12 The list of Personal Diagnostic, Monitoring & Delivery Devices reimbursable under the GMS and Community Drugs Schemes will be maintained in compliance with the Health (Pricing and Supply of Medical Goods) Act 2013.

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

1.13 The Classifications of Products listed may be subject to change from time to time.

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

Prices may be reduced in line with the Health (Pricing & Supply of Medical Goods 2013) Act.

1.15 The HSE intends to review the reimbursement pricing in line with each Application Process. The review will be based on the published pricing rules and will seek to ensure that the reimbursement prices continue to underpin the availability of quality Products and services for eligible patients while delivering affordability and value for money for the Irish State. Suppliers will be informed of the outcome of each pricing review and may submit additional data to the HSE at the time of the review in order to provide supplementary evidence in relation to their pricing arrangements.

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

1.17 Suppliers wishing to submit an application for consideration at the first review meeting of the National Expert Group for Personal Diagnostic, Monitoring & Delivery Devices (scheduled for early August 2017) must submit the relevant Application Form by close of business Friday 30th June 2017.

1.18 Applications can be submitted on an ongoing basis at any time after the closing date for applications for the first review. Applications received after the closing date for the first

review will be considered at the next scheduled review meeting in October 2017. It is proposed that review meetings will take place on a twice yearly basis thereafter.

1.19 All product application forms are to be submitted to:

reimbursement.applications@hse.ie

2. APPLICATION PROCESS – CATEGORY 1 (NEW PRODUCTS)

2.1. This process should be followed by Suppliers when they wish to have a new product added to the list of Personal Diagnostic, Monitoring & Delivery Devices on the PCRS Reimbursement List.

2.2. Suppliers should complete the Category 1 Application Form (Appendix A) for each new product they wish to have included on the PCRS Reimbursement List. A signed copy of the Category 1 Application Form, along with appropriate backup material, should be sent electronically to the HSE at:

reimbursement.applications@hse.ie

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

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

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

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

2.4. The HSE will conduct an initial review of the electronic application to ensure that all necessary documentation has been submitted. Once the required documentation is confirmed the HSE will request the Supplier to submit samples and packaging of the proposed new Products. Instructions for use of the product must be included in English and be clear and easy to understand by the patient.

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

2.6. As part of their Application Form, Suppliers will be required to identify the appropriate Product Classification from the list at Appendix C for their product. 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.

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

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

2.9. The National Expert Group will assess each product application, including samples and supporting documentation from a clinical and technical perspective in the first instance.

This will determine whether the evidence provided justifies the product being included on the Reimbursement List.

2.10. For those Products which are approved by the National Expert Group, the reimbursement price will be agreed in accordance with the pricing rules in Section 7 of this document.

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

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

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

3. APPLICATION PROCESS – CATEGORY 2 (EXISTING PRODUCTS)

3.1. The application process for Category 2 should be followed by Suppliers when they wish to notify the HSE of a discontinuation or minor change to an existing product on the list of Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List.

3.2. 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 should be sent electronically to the HSE at

reimbursement.applications@hse.ie

3.3. Examples of minor changes to existing Products would be, Packaging of product (including pack size); Product Specification; Name of product; Supplier of the product; Product Reference Code; Price Reduction offer

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

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

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

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

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

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

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

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

4. MANDATORY CRITERIA FOR PERSONAL DIAGNOSTIC, MONITORING & DELIVERY DEVICES

4.1. In order to have an application accepted, Suppliers must demonstrate that :-

4.1.1 The proposed product complies with applicable national standards, incorporating EC Standards, including Medical Devices 93/42/EC (as amended) with each product carrying the CE marking;
And

4.1.2 The proposed product complies with the criteria set out in these guidelines;
And

4.1.3 For Category 1 Applications only, the application demonstrates User Acceptability by the presentation of Clinical Trial results (where applicable), which should ideally have been conducted independently of the Supplier.

4.1.4 Comply with best practice covering;

- Free access to glucometers in Hospital Clinics, GPs working through an integrated care programme or relevant healthcare professional involved in the management of patients with diabetes
- Provision of education to healthcare professionals so that they can counsel patients effectively on the use of the product/device.

5. PRODUCT CLASSIFICATIONS FOR PERSONAL DIAGNOSTIC, MONITORING & DELIVERY DEVICES

5.1 BLOOD GLUCOSE TEST STRIPS

5.1.1 Must comply with ISO15197:2013
5.1.2 Packaged to minimise contamination and influence from external factors such as air and moisture
5.1.3 Small sample volume required (e.g. 0.3 µL to 1 µL)
5.1.4 Fill strip (e.g. top/tip/end) to automatically draw up blood
5.1.5 Confirmation of sample fill (e.g. reaction commences when sufficient blood sample has been applied)
5.1.6 Test time approximately 5/10 seconds
5.1.7 Single use
5.1.8 For self-testing

5.2 KETONE STRIPS (Blood analysis)

5.2.1 Packaged to minimise contamination and influence from external factors such as air and moisture
5.2.2 Small sample volume required
5.2.3 Designed to automatically draw up blood
5.2.4 Confirmation of sample fill (e.g. reaction commences when sufficient sample has been applied)
5.2.5 Short test time
5.2.6 Single use
5.2.7 For self-testing

5.3 URINALYSIS TEST STRIPS

5.3.1 Packaged to minimise contamination and influence from external factors such as air and moisture
5.3.2 Dry reagent strip, used for the point of care testing of urine
5.3.3 Reagent pads attached to inert plastic strips
5.3.4 Change colour due to reaction with various constituents requiring measurement
5.3.5 Timed and easy to interpret results
5.3.6 Single use
5.3.7 For self-testing

(Urinalysis test strips include multi-parameter tests for the detection of Bilirubin, Urbilinogen, Albumin, Blood, Creatinine, Glucose, Ketone, Leukocyte Esterase, Specific Gravity, Nitrite, pH, and Protein. This list is not exhaustive)

5.4 LANCETS

5.4.1 Small, sharp device used to prick the skin to obtain blood sample/draw blood
5.4.2 May be operated by a click button device
5.4.3 Can include different depth settings
5.4.4 Various sizes (i.e. adult and paediatric)
5.4.5 Single use
5.4.6 For self-testing

5.5 SELF-INJECTING SYSTEMS (Syringes and Needles)

5.5.1 Safe, reliable and easy to handle

5.5.2 Needles include a range of lengths and gauges adapted to user requirements

5.5.3 Syringes feature easy-to-read scale markings for accuracy

5.5.4 Designed for easy compatibility

5.5.5 Sterile, single use

5.6 INSULIN INFUSION SETS/RESERVOIRS/CARTRIDGES

5.6.1 Disposable infusion sets that work with insulin pumps to administer insulin to the body through the infusion site

5.6.2 Plastic tubing with soft, flexible cannula or stainless steel needle for subcutaneous insertion

5.6.3 Cannula and tubing available in various different lengths

5.6.4 Easy to use and comfortable (adapts to the body's movements), allowing for different insertion angles

5.6.5 Easy to connect and disconnect

5.6.6 Optimum insulin absorption

5.6.7 Reservoirs/Cartridges should be ready to use and fit neatly into the insulin vial

5.6.8 Reservoirs/Cartridges should have an integrated seal to reduce leakage or spillage

5.6.9 Reservoirs/Cartridges should be available in a number of sizes to meet daily insulin needs

5.7 CONTINUOUS GLUCOSE MONITORING (CGM)

5.7.1 Continuous glucose monitoring (CGM) systems using a small discrete sensor inserted under the skin to measure glucose levels in tissue fluid

5.7.2 Continuous Glucose Monitoring Sensor remains in place for up to 7 days before replacement

5.7.3 Sensor can detect and alert the patient when glucose levels are reaching a high or low limit

5.7.4 A compatible/integrated transmitter to enable real-time glucose readings to be transmitted from the sensor to a smart device/monitor (e.g. compatible smart device and Bluetooth wireless technology).

5.7.5 Data can be stored, downloaded and shared from the smart device/monitor. (Note: smart device/monitors are not a reimbursable item)

5.8 FLASH GLUCOSE MONITORING (FGM)

5.8.1 Flash glucose monitoring (FGM) systems using a small discrete sensor inserted under the skin to measure glucose levels in tissue fluid

5.8.2 Flash Glucose Monitoring Sensor remains in place for up to 14 days before replacement

5.8.3 A compatible/integrated transmitter to enable real-time glucose readings to be transmitted from the sensor to a smart device/monitor (e.g. compatible smart device and Bluetooth wireless technology).

5.8.4 Data can be stored, downloaded and shared from the smart device/monitor. (Note: smart device/monitors are not a reimbursable item)

6. GUIDELINES FOR CLINICAL TRIALS OF PERSONAL DIAGNOSTIC, MONITORING & DELIVERY DEVICES

6.1 This is applicable to Category 1 – New Products only.

6.2 A Supplier is required to submit CE Certification, Quality and Safety Data Sheets.

6.3 A Supplier is required to submit the published report on a minimum of **two** peer reviewed Clinical Trials for each product being submitted as a Category 1 application (see Appendix C). The reports must have been published in a peer review journal and available in English.

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

6.5 A Clinical Trial should ideally have been conducted by an appropriately qualified health professional who is independent of the Supplier of the product. If there was any link between the Supplier and the person who conducted the trial, this link should be declared on the Category 1 Application Form.

6.6 Each product on trial must have been assessed on its own merit and without the benefit of any additional product, irrespective of whether the additional product is on the approved HSE reimbursable list of Products.

6.7 A trial participant may have been withdrawn from the Clinical Trial at any time at the discretion of the person who conducted the trial.

6.8 The final report shall have set out at a minimum the length of the Clinical Trial, the patient cohort, the number of Products used, the clinical outcomes achieved and any other relevant information.

6.9 Each Supplier who initiated a Clinical Trial must have appointed a person who would have been responsible for co-ordinating each trial. The duties of a Co-ordinator should have included:-

- Preparing information booklets containing correct trial procedures,
- Formulating a questionnaire,
- Distributing the above documentation,
- Collecting the questionnaires,
- Collating the data,
- Presenting the results.

6.10 Permission to carry out the trial must have been obtained by the Co-ordinator conducting the trial

6.11 The following were prerequisites for participation in a Clinical Trial:-

- Participants must have been willing to use the product on trial.
- Participants must have provided informed consent.
- Participants must have been able to comprehend and complete the questionnaire provided.

6.12 Financial or other interests between trial investigators and the manufacturer of the product should be clearly described.

6.12.1 Where an independent trial (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.

6.12.2 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 Trial should properly reflect the objectives of the Trial and this list is not exhaustive. The HSE cannot be responsible for the design of any Trial or any component thereof.

6.13 Where a Clinical Trial is not required (ref: Appendix C), the Supplier must submit User Evaluation Data for each product being submitted. Applications for ketone strips and urinalysis test strips require submission of Accuracy Data in addition to the User Evaluation Data.

6.14 The user evaluation reports must be signed by an appropriate qualified health professional which confirms the satisfactory "use in practice" of the product and also evidence that no quality defects have been reported within the past 2 years, if applicable.

7. PRICING RULES APPLYING TO ALL APPLICATIONS

7.1 In the first instance, each Category 1 product application will be assessed from a clinical and technical perspective to determine whether the evidence provided justifies the product being included on the Reimbursement List.

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

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

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

7.3.2 Average of the lowest three European countries submitted, or

7.3.3 Price proposed to the HSE.

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

7.4 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;

7.4.1 Drug Tariff (the most current edition available at the time of pricing)

7.4.2 C&D (the most current edition available) if Drug Tariff not available

7.4.3 BNF (the most current edition available), if Drug Tariff & C&D not available

7.4.4 Submitted UK Price, if all the above are not available

7.5 The reimbursement price for each product must be inclusive of all costs associated with delivery of the Products (i.e. wholesaler or distribution costs)

7.6 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.

7.7 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.

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

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

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX A

CATEGORY 1 - NEW PRODUCT APPLICATION FORM

New Personal Diagnostic, Monitoring & Delivery Devices 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/User Evaluation Data

Summary Details of Clinical Trial/User Evaluation Data/Accuracy Data No. 1:	
Summary Details of Clinical Trial No. 2:	
CE Certificate Submitted[4]:	
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 2.4 and 2.5 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	€

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

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

Signature: _____ **Date:** _____

Telephone No: _____ **E-mail:** _____

The completed form along with application information should be submitted to:

reimbursement.applications@hse.ie

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Health Service Executive

APPENDIX B

CATEGORY 2 - EXISTING PRODUCT NOTIFICATION FORM

Existing Personal Diagnostic, Monitoring & Delivery Devices on the HSE List of Reimbursable Items.

This form has been prepared to enable Suppliers to inform the HSE of any of the following in relation to existing Personal Diagnostic, Monitoring & Delivery Devices on the HSE List of Reimbursable Items.

a) Intention to Discontinue Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List

b) Minor Changes of Personal Diagnostic, Monitoring & Delivery Devices

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

1. Product Details

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

2. Notification

(a) Intention to Discontinue Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List

Suppliers should complete this section if they wish to notify the HSE of their intention to discontinue the listing of a Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List.

In the interest of maintaining an uninterrupted supply of Personal Diagnostic, Monitoring & Delivery Devices to patients, it is a requirement that Products that are approved for discontinuation from the Reimbursement List shall remain live on the Reimbursement List for a period of at least 12 months to allow for patient transition to an alternative product if required

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

(b) Minor Changes of Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List

Suppliers should complete this section if they wish to notify the HSE of a proposed Minor Change to a Personal Diagnostic, Monitoring & Delivery Devices on the HSE Reimbursement List.

Changes to the product can include, for example:
Packaging of 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 notifications, a copy of the outer packaging artwork, CE certification, product samples and/or patient information leaflet for currently listed product AND proposed minor change product may be requested by the HSE following receipt of the electronic application.

Name and Address of Key Contact for Application:

Name:

Position:

Address:

I confirm that the information provided in this application is correct.

Signature: _____ **Date:** _____

Telephone No: _____ **E-mail:** _____

The completed form along with information should be submitted to:

reimbursement.applications@hse.ie

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

APPENDIX C

PRODUCT CLASSIFICATIONS

	PRODUCT CLASSIFICATIONS	EVIDENCE REQUIRED
1	Blood Glucose Test Strips	User Evaluation Data (See Section 6.13)
2	Ketone Strips	User Evaluation Data Accuracy Data (See Section 6.13)
3	Urinalysis Test Strips	User Evaluation Data Accuracy Data (See Section 6.13)
4	Lancets	User Evaluation Data (See Section 6.13)
5	Self-Injecting Systems	User Evaluation Data (See Section 6.13)
6	Insulin Infusion Sets	Clinical Trial x 2 (See Section 6)
7	Continuous Glucose Monitoring (CGM) Systems	Clinical Trial x 2 (See Section 6)
8	Flash Glucose Monitoring (FGM) Systems	Clinical Trial x 2 (See Section 6)