Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

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.

NOTE:

For ALL Minor Change

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:	

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