## CATEGORY 2 - EXISTING PRODUCT APPLICATION FORM

#### Existing Diabetes Consumable on the HSE List of Reimbursable Items

1. **Purpose**

This form should be used by suppliers to:-

* 1. Request that a Product be removed from the Reimbursement List; or
  2. 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.

#### Product Details

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

1. **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.** |  |

#### 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:-**

1. **applicable national standards and European Commission standards;**
2. **the criteria set out in these Guidelines; and**
3. **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**](mailto:reimbursement.applications@hse.ie)