**TYPE 3 – MINOR CHANGE**

This form has been prepared to enable manufacturers/distributors to inform the HSE of any of the following in relation to existing Clinical Nutritional Products on the HSE List of Reimbursable Items:

1. Intention to Discontinue Clinical Nutritional Products on the HSE Reimbursement List:
2. Minor Changes of Clinical Nutritional Products on the HSE Reimbursement List.

**1. Product Details**

|  |  |
| --- | --- |
| **Applicant Company Name:** |  |
| **GMS Code:** |  |
| **Manufacturer:** |  |
| **Distributor to HSE Customers:** |  |

|  |  |
| --- | --- |
| **Product Name:** |  |
| **Product Description:** |  |
| **Product Pack Size:** |  |
| **Product Reference Code:** |  |
| **Product Category/Sub Categories: (See Appendix D):** |  |

**2. Notification**

1. **Intention to Discontinue Nutritional Products on the HSE Reimbursement List**

Applicants should complete this section if they wish to notify the HSE of their intention to discontinue the listing of a Clinical Nutritional Product on the HSE Reimbursement List.

In the interest of maintaining an uninterrupted supply of Clinical Nutritional Products to patients, it is a requirement that products that are approved for discontinuation from the HSE 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) of expiry of last batch** |  |
| **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:** |  |
| **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 Irish Health Care Professionals in relation to the discontinuation of the product (Confirmation that same is enclosed):** |  |

1. **Minor Changes of Clinical Nutritional Products on the HSE Reimbursement List**

Applicants should complete this section if they wish to notify the HSE of a proposed Minor Change to a Clinical Nutritional Product on the HSE Reimbursement List.

Note: Examples of Minor Changes to the product are set out in Section 7 of this Guidelines document.

|  |  |
| --- | --- |
| **Applicant Company Name:** |  |
| **GMS Code** |  |
| **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 discontinuation of the product (Confirmation that same is enclosed):** |  |

NOTE: For ALL Minor Change notifications, an electronic copy of the outer packaging artwork, CE certification and patient information leaflet for currently listed product AND proposed minor change product must be submitted with the application

|  |
| --- |
| **Name and Address in Block Capitals 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:**

NonDrugReimbursement.Applications@hse.ie