**CATEGORY 1 - NEW PRODUCT APPLICATION FORM**

**New Diabetes Consumable 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.** |  |

1. **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[[1]](#footnote-1):** |  |
| **Please provide details of any relationship / link between the manufacturer or proposed Irish distributor and the person who conducted the clinical investigation** |  |

1. **Product Samples**

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

1. **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:** |
|  |

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| --- |
| **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:NonDrugReimbursement.Applications@hse.ie)

1. An electronic copy of a valid CE certificate for the product must be submitted with the application. [↑](#footnote-ref-1)