

TYPE 2 - PRODUCT APPLICATION FORM:

New Nutritional Products to be added to HSE Reimbursement List

A.1 General Information

Applicant 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 Category/Sub Categories (ref: Appendix D):	
If no product Category/Sub Categories is suitable, please provide justification for creation of a new Category/Sub Categories:	
GMS Code of nearest comparator product:	
Proposed method of distribution for making the product available to HSE Pharmacy contractors:	
Previous use of the product in hospital or community areas in Ireland. Provide	

details of location, duration of use and average annual usage:	
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A.2 Reference Papers ¹

Please confirm (tick) that details of Reference paper No. 1 have been provided (See Section 6.1)	
Please confirm (tick) that details of Reference Paper 2 have been provided (See Section 6.1)	
Please confirm (tick) that details of the Acceptability Studies have been provided. (See Section 6.5)	
CE Certificate Submitted ² :	

A.3 General Criteria for all Nutritional Products

A3.1	Please confirm that the product has been notified to the FSAI. (Section 2) (Evidence of same must be provided and cross referenced to this question)	
A3.2	Please confirm that the product complies with all relevant aspects of Food Law. (Section 2)	
A3.3	Please confirm that the product complies with the specific rules for food products covered by the Reimbursement Scheme. (Section 2)	
A3.4	Please confirm that the product complies with the Legislation applicable to all foods (Section 2)	
A3.5	Please confirm that the product complies with Legislation covering /Foods for Specific Groups and Foods for Special Medical Purposes (Section 2)	

¹ Please refer to Sections 4 , 6 & 8 of this document for Guidelines for Clinical Trials of Nutritional Products

² An electronic copy of a valid CE certificate for the product must be submitted with the application.

A3.6	<p>Please confirm that a complete quantitative formulation has been provided (Section 2.12.1)</p> <p>(Please provide as an Addendum and cross reference to this question)</p>	
A3.7	<p>Where applicable, please confirm that the unique identifiers (Ref: Section 2.17, Terminology) have been provided. (Section 2.12.1)</p> <p>(Please provide as an Addendum and cross reference to this question)</p>	
A3.8	<p>Please confirm that an information / data sheet about the product has been provided. (Section 2.12.2)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.9	<p>Please confirm that information has been provided in respect of the nutritional composition as fed, if the product is to be reconstituted, diluted or otherwise altered. (Section 2.12.3)</p> <p>(If so, Please provide an Addendum and cross reference to this question)</p>	
A3.10	<p>Please confirm that a statement signed by an authorised person accepting legal responsibility for the accuracy of the declarations on behalf of the Applicant has been provided. (Section 2.12.4)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.11	<p>Please confirm that the information in relation to the Nutritional Composition of the product has been provided. (Section 2.13)</p> <p>(Please note that if the standard data sheet does not contain any of the information required, it must be provided separately as an Addendum and cross referenced to the relevant question)</p>	
A3.12	<p>Please confirm that a full manufacturing statement has been provided. (Section 2.14)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.13	<p>Please confirm that the requirements in relation to Special Instructions have been provided. (Section 2.15)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.14	<p>Please confirm that the requirements in relation to Shelf Life have been provided. (Section 2.16)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.15		

	<p>Please confirm that the requirements in relation to Terminology have been provided. (Section 2.17)</p> <p>(Please provide an Addendum and cross reference to this question)</p>	
A3.16	<p>Please confirm that the requirements in relation to administration of the product to the Patient have been provided. (Section 2.18)</p> <p>(Evidence of same must be provided and cross referenced to this question)</p>	
A3.17	<p>Please confirm that the requirements in relation to Contraindications and Precautions have been provided. (Section 2.19)</p> <p>(Evidence of same must be provided and cross referenced to this question)</p>	
A3.18	<p>Please confirm that the requirements in relation to presentation of the product have been provided. (Section 2.20)</p> <p>(Evidence of same must be provided and cross referenced to this question)</p>	
A3.19	<p>Please confirm that the requirements in relation to the Labelling, Packaging and Descriptive Literature have been provided. (Section 2.21 – 2.22)</p> <p>(Evidence of same must be provided and cross referenced to this question)</p>	
A3.20	<p>Please confirm that the requirements in relation to Promotional Policy have been provided. (Section 2.23)</p> <p>(Evidence of same must be provided and cross referenced to this question)</p>	
A3.21	<p>Please state the Dispensing Unit/Pack size of the product. (Section 2.24.1)</p>	
A3.22	<p>Please state what arrangements are in place to enable approved products to be dispensed by a pharmacist against a prescription. If distribution arrangements are not sufficient to ensure continuity of supply, the product will be recommended for de-listing. (Section 2.24.2)</p>	

A4. Product Samples

See Sections 2.21, 3.3, 5.4 and 7.5 of this Guidelines document for information of submission of product samples when requested.

A5. Proposed Price

Reimbursement Price Proposed to HSE Please specify Pack Size, Unit Price and VAT		€	
United Kingdom Equivalent			
Chemist & Druggists (the most current edition available at time of application)	£		
BNF (if C&D price is not available) (the most current edition available at time of application)	£		
European Pricing			
United Kingdom	£	Country:	€
Country:	€	Country:	€
Country:	€	Country:	€
Country:	€	Country:	€
Country	€	Country	€
Average of the three lowest European Countries			
Country:	Country:	Country:	Average
€	€	€	€
<ul style="list-style-type: none">• 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 will 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 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 application information should be submitted to:

Sabrina.phelan@hse.ie