IAPEN
Advancing Nutrition Care in India

The Society for Clinical Nutrition and Metabolism

APPLICATION FOR PRODUCTS TO BE APPROVED FOR INCLUSION IN IAPEN - DIRECTORY OF CLINICAL NUTRITION PRODUCTS AND SUPPLEMENTS

NOTE:

When making an application, the Information Notes / Application MUST be downloaded in its entirety and used as a template with the statements supporting an application appearing under the relevant paragraph.

Applicants must respond to each and every requirement as indicated and provide a statement that the requirement either can or cannot be met along with brief supporting evidence

1. **CATEGORISATION OF CLINICAL NUTRITION PRODUCTS AND SUPPLEMENTS** (All applications)

See Appendix 1 for further information (See Page 11)

Category 1: Infant Nutrition Products
Category 2: Enteral Nutrition Product
Category 3: Parenteral Nutrition Products
Category 4: Supplements
Category 5: Other products and equipments which are not suitable in above categories

NOTE: **While a degree of choice of all the above items may be important to facilitate compliance, it is not intended that an infinite variety of broadly similar products should be available on prescription. Other factors being equal, normally price will be an important determinant for inclusion on the reimbursable list.**

2. **TYPE OF SUBMISSION** (All applications)

Type 1 New formulations which the Applicant perceives to have well characterised and substantiated advantages in terms of nutritional composition and patient tolerance / acceptability

Type 2 Formulations which are broadly similar in composition to existing products already on the market and which could be considered to be suitable alternatives

Type 3 Existing product in the directory with minor changes

Type 4 Any other existing products in the market not suitable in first three types (Example: Equipments like feeding tubes etc..).

Note: Suppose if any equipment is to be listed, please directly go to Step 5.4 after filling the step 3.

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3. FOOD AND SAFETY AUTHORITIES OF INDIA OR CENTRAL DRUGS STANDARD CONTROL ORGANIZATION OR SIMILAR GOVERNMENT ORGANIZATIONS

Submissions must include evidence that the products have been notified to the Food Safety and Standards Authority of India (FSSAI) or Central Drugs Standard Control Organization or similar government organizations and that at the time of this notification there were no concerns with the placing of the product on the Indian market.

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4. FORMULATION (Type 1, Type 2 and relevant Type 3 applications)

4.1 Ingredients and Nutritional Information

4.1.1 A **complete** quantitative formulation must be provided including a full list of ingredients, additives and potential allergens together with confirmation that these comply with all relevant legislation. In addition the unique identifiers

4.1.2 An information / data sheet about the product must be provided.

4.1.3 If the product is to be reconstituted, diluted or otherwise altered, information will be required in respect of the nutritional composition as fed.

4.1.4 A statement must be provided, signed and dated by an appropriately competent and authorised individual describing their status and accepting legal responsibility for the accuracy of all the above declarations on behalf of the Applicant.

4.2 Nutritional Composition

The following information must be provided in addition:

4.2.1 Composition, percentage and source of nitrogen, sub-groups of sugars, fibres and sub-groups of fats.

4.2.2 Information about any protein hydrolysis including:
- whole protein source
- degree of hydrolysis i.e. chain lengths
- source of enzymes used for hydrolysis
- proportion as free amino acids
- whether there is any trace of enzyme or whole protein remaining in the product

4.2.3 Information about any carbohydrate hydrolysis including:
- carbohydrate source
- source of enzymes used for hydrolysis
- whether there is any trace of enzyme remaining in the product

4.2.4 Nutrient composition should be provided in mmols (SI / Système Internationale) units as well as in milligrams, SI being the standard unit of clinical measurement. This applies specifically to the electrolyte composition and the expectation is that mmols will eventually be stated on the label to improve patient safety.

NOTE: Electrolytes in this context include sodium, potassium, chloride, calcium, phosphate and magnesium

4.2.5 Nutritional composition per 100ml or per 100gm and per container must be given.

4.2.6 Potential renal solute load.

4.2.7 Osmolality / Osmolarity

4.2.8 Fatty acids.
- the total amounts of poly-unsaturated and saturated fatty acids and the ratio between them
- source and ratio of n6 : n3 fatty acids
- amount (g) of long chain polyunsaturated fatty acids where added
- amount (g) of medium chain triglycerides where added

NOTE: If the standard data sheet does not contain the above information, it must be provided separately.

4.3 Manufacturing Process and Quality Control Mechanisms

A full manufacturing statement must be provided with reference to appropriate external certification which is recognised by the Indian.
This statement must be signed and dated by an appropriately competent and authorised individual describing their status and accepting legal responsibility for the accuracy of this declaration on behalf of the Applicant.

NOTE: If any part of the manufacturing process takes place outside the India, companies must confirm that manufacturing and quality

standards continue to comply with the relevant Indian legislation and that equivalent manufacturing accreditations and testing methodologies are in place.

There must also be an absence of pathogenic bacteria in all liquid products, specifically E Coli and Salmonella. While sterility cannot be guaranteed, all powdered products must be free from E Coli and Salmonella.

4.4 Special instructions

4.4.1 All powdered products must include a scoop and instructions for reconstitution either using a specified scoop (which must be included) for measuring loose powder, or a given weight of powder in a sachet. The size and weight of powder contained in the scoop must be stated. There must also be instructions for safe storage after reconstitution.

NOTE: Dietary Foods for Special Medical Purposes require that instructions are provided for appropriate preparation, use/disposal and storage of the products

4.4.2 Standard recipes / baking instructions must be provided if appropriate

4.5 Shelf life

Information must be provided about the maximum length of time after which the product must not be used.

Directions must also be provided about the product storage conditions in opened, prepared for use and unopened states.

4.6 Terminology

4.6.1 For a product to be considered “nutritionally complete”, it must be able to provide the sole source of nourishment (with safe and appropriate levels of all macro / micronutrients) for each 24 hours for the person for whom it is intended when used in accordance with the Applicant’s instructions; no additions will be necessary to maintain optimal nutritional status.

If an Applicant claims that a product is “nutritionally complete” and can be used as the sole source of nutrition, the following information must appear on the product data sheet:

- The dietary values must be referenced to a recognised international standard

– Estimated requirements for, energy, protein, electrolytes, vitamins’ and minerals for an adult male must be stated as a comparator.

– The volume within which the product meets these requirements and is therefore promoted as being nutritionally complete (rounded up or down to the nearest 50 ml) must be stated.

The following additional statements will be viewed by the Foods Review Group as helpful:

- these amounts may need to be modified according to the age and clinical condition of the patient

- assessment by a dietician is always recommended when there is any doubt about an individual patient's nutritional requirements

4.6.2 Ingredient listings must use the common name and, where relevant, the unique identifiers for each substance. These are the regulated international non-proprietary names (INN) and the Chemical Abstracts Service (CAS) registry numbers if available. This means that the full chemical name and not just the trade name must be given.

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5. **<u>EVIDENCE OF CLINICAL EFFICACY</u>** (According to the type of application (Type 1, Type 2 and relevant Type 3 & Type 4)

NOTE: **Correspondence must be conducted via e-mail, through the Secretariat. This is to ensure transparency and a clear audit trail**. **Companies can call to IAPEN for further information and clarifications.**

5.1 **Type 1 applications** will require detailed reports of completed clinical trials of the product which demonstrate its therapeutic usefulness in the management of disease in the community for the indications sought.

NOTE: **One full copy of two key reference papers must be provided as supporting evidence together with an abstract and full reference to directly relevant papers from peer reviewed journals.**

Any evidence of health economic benefits of a product will be welcomed.

General statements of support from healthcare professionals or others will not be considered by the IAPEN.

5.2 **Type 2 applications** will require evidence from any available studies of products which are broadly similar in composition (and which could be considered to be suitable alternatives) demonstrating their therapeutic usefulness in the management of disease in the community for the indications sought. Acceptability information will also be required

NOTE: **One full copy of two key reference papers must be provided as supporting evidence together with an abstract and full reference to directly relevant papers from peer reviewed journals.**

Any evidence of health economic benefits of a product will be welcomed by the IAPEN.

General statements of support from healthcare professionals or others will not be considered by the IAPEN.

5.3 **Type 3 applications** will require the following evidence of efficacy

5.3.1 If the proposed change relates to minor macronutrient content modification i.e. nitrogen, fat or carbohydrate (or any component of these), micronutrient content or concentration, the rationale must be provided and this should be based on clinical studies wherever possible.

5.3.2 If the proposed change relates to changes in the corporate strategy, manufacturing process, ingredient availability, presentation, labelling, patient acceptability or cost, the rationale must be provided.

5.3.3 If compositional changes are in response to either INDIAN legislation, then this must be referenced

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5.3.4 If the location in which the product or any component of the product is manufactured is changed, then the following will be required:

5.3.4.1 Within India – a statement advising of the new location and confirming that the source of manufacturing has changed and advising of the new location but that all existing Indian legislation continues to apply

5.3.4.2 Outside India – a statement confirming that manufacturing and quality standards continue to comply with the relevant Indian legislation and that equivalent manufacturing accreditations and testing methodologies are in place will be required. Appropriate external certification (recognised by the Indian authorities) must also be submitted.

NOTE: The changes identified in a Type 3 application are normally considered by the IAPEN to be "minor changes" and, as such, will not require a complete application.

5.4: Type 4: If the product to be listed is equipment then the design or drawing or photo and equipment specifications, usage and product description should be submitted.

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6. **<u>Administration To The Patient</u>** (Type 1, Type 2 and relevant Type 3 & Type 4 applications)

6.1 Where appropriate, dosage, timing and / or frequency of administration for adults, infants and children must be given.

6.2 Methods and routes of administration must be described i.e. whether for oral consumption and / or to be administered via a tube.

6.3 Any requirements for reconstitution of the product before administration to the patient must be stated.

6.4 Suppose, if equipment is present, photos or video showing how to administrator to the patient should be submitted.

NOTE: This information should be provided on the packaging, data sheet and any technical healthcare professional / patient literature.

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7. <u>Contra - Indications And Precautions</u> (Type 1, Type 2 and relevant Type 3 & Type 4 applications)

Details of warnings, contraindications, side effects, potential interactions with medicines (both general and, if known, specific), adverse reactions and guidance on clinical monitoring must be given.

NOTES: This information must be provided on both the data sheet and any technical healthcare professional / patient literature.

Appropriate guidance should be given if the product is not suitable for use by particular cultures and must be provided on both the data sheet and any other relevant technical healthcare professional / patient literature. This information should also appear on the label if possible.

Specific guidance must be provided if relevant, about the following:

- **use during pregnancy / lactation**
- **use for infants and children**
- **any potential for overdosing**

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8. <u>PRESENTATION</u> (Type 1, Type 2 and relevant Type 3 and Type 4 applications)

The following will be required;

8.1 Description of the appearance and form of the product e.g. solid, powder, liquid, pasta, bread, biscuit

8.2 Whether it will be sold in a bag, bottle, tin, tub etc.

8.3 Net weight / volume of each unit as set out above

8.4 Secondary / cluster package size and weight / number of units

8.5 Whether any additional giving or measuring devices are included. The size / volume and weight of product per device must be stated.

NOTE: All this information can be provided on the data sheet.

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9. <u>Labelling, Packaging & Samples</u> (Type 1, Type 2 and relevant Type 3 & Type 4 applications)

9.1 Details of labels / packaging or proposed labels /packaging for all unit sizes for products to be reimbursed must be provided, including labelling for secondary / cluster packaging.

Any changes to existing labelling required for the Indian market must be submitted to the IAPEN. A statement must be provided confirming that all labelling complies with Indian regulations. This statement must be signed and dated by an appropriately competent and authorised individual describing their status and accepting legal responsibility for the accuracy of this declaration on behalf of the Applicant.

Note: Applicants must provide a sample of "actual size" labels. Electronic versions will not be acceptable.

9.2 Samples of the product must be provided for the IAPEN inspection (one sample of each product being submitted will suffice).

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10. <u>DESCRIPTIVE LITERATURE</u> (Type 1, Type 2 and relevant Type 3 & Type 4 applications)

A statement about how the product will be promoted, e.g. whether it will also be promoted as being lactose free, cow's milk protein free, gluten free, soya free etc, must be provided.

Any literature intended for patients **must** be provided at the time of submission.

NOTES: Medicinal claims (i.e. claims to treat, prevent or cure) are *never allowed*.
For certain products statements are required to indicate suitability of use*.

Reference to IAPEN approval for inclusion should only be made in technical information specifically designed for the advice of healthcare professionals. This includes:

- **entries in the Food Authority of India or any similar authority**
- **articles in peer reviewed journals**
- **the standard company data sheet**
- **any such information on company websites (which must be password protected)**

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* Under Indian Food Legislation

Any such reference must only be made for the condition for which the product has been approved and not imply that the product has other characteristics which may be beneficial and which the IAPEN may therefore have also approved by default.

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11. PROMOTIONAL POLICY (Type 1, Type 2 and relevant Type 3 & Type 4 applications only if relevant)

A statement must be provided confirming that the product will be advertised solely to healthcare professionals.

NOTES: Any IAPEN approved products placed on the market must comply with current Indian food legislation regarding health claims. Any breach of this provision will result in the product being recommended for de-listing.

12. MARKET AVAILABILITY (All application Types : Type 1, Type 2 and relevant Type 3 & Type 4)

12.1 Applicants must state the dispensing unit / pack size

12.2 Applicants must 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.

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13. PRICE TO THE IAPEN (All application Types: Type 1, Type 2 and relevant Type 3 & Type 4)

13.1 A statement of the proposed total price of the product to the IAPEN Members must be provided. The IAPEN will accept applications for products which satisfy the published criteria.

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14. IAPEN MEETINGS

All applicants of submissions are advised that it would be in their interests for a named representative of the Applicant to be available to respond to any queries which may arise when products are considered at a meeting of the IAPEN. This will help to ensure that product submissions can be expedited efficiently.

NOTE: It will not be normal practice to invite representatives of the Applicants to attend the actual meetings of the IAPEN.

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15. DURATION OF IAPEN APPROVAL FOR PRODUCTS (All applications)

Approval for any product to be directly will be valid for a **maximum** of 1 years. In the case of all listed products, the IAPEN reserves the right to request a company to conduct a new trial at any time if additional research produces information which may challenge its clinical efficacy. In exceptional circumstances e.g. information / instruction from the Department of Health Children or the Food Safety Authority of India, the IAPEN reserves the right to delete any product from the directory with immediate effect.

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16. The IAPEN will review the product at the end of this period and **may** request resubmission. Products will not automatically be de-listed other than where no prescriptions have been issued for one calendar years.

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17. All products currently listed at the implementation date of guidelines will be subject to initial review before launch of the final list of items for 2013.

NOTES: **Product review is necessary to reflect current trends including**

- **changes in clinical practise**
- **changes in marketing direction**
- **the prescriptions issued in respect of individual products over a period of time**

The review process will apply to all existing products in the first instance as well as to new ones. After that, a rolling programme of reviews will occur year on year.

Further to the initial review of existing products, Companies will be advised when their products are due to be reviewed again. They will have the option of providing supplementary information at this time if they choose to do so.

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18. Indicate YES/NO that your product will come under the purview of Infant laws in India (Brest feeding promotional network of India).

Appendix 1

IAPEN Products Classification

1. **Infant Nutrition Products**
   - 1.2 Milk-based Formulas
   - 1.3 Soy-based Formulas
   - 1.4 Elemental Formulas
   - 1.5 Premature Formulas
   - 1.6 Lactose-free Formulas
   - 1.7 Follow-Up Formulas
   - 1.8 Other Specialized Formulas
   - 1.9 New Developments
   - 1.10 Organic Infant Formula
   - 1.11 Probiotic/Prebiotic Infant Formula
   - 1.12 Algae-derived Omega-3 Fatty Acid DHA Infant Formula
   - 1.13 Allergy Management and Hydrolysated Protein Infant Formulas
   - 1.14 Equipments or other products
2. **Enteral Nutrition Products**
   - 2.1. Non - disease specific enteral tube feeds
     - 2.1.1. Protein and Energy Products (≥1.0kcal/ ml and <5.0g protein/100ml)
       - 2.1.1.1. Standard Tube Feed with Fibre.
       - 2.1.1.2. Standard Tube Feed without Fibre.
       - 2.1.1.3. Standard Tube Formula for Children with Fibre.
       - 2.1.1.4. Standard Tube Formula for Children without Fibre.
       - 2.1.1.5. Energy Enriched Formula for Infants: Suitable from birth to 18 months.
     - 2.1.2. Protein and Energy Rich Products
       - 2.1.2.1. Standard Energy, Increased Protein Tube Feed with Fibre.
       - 2.1.2.2. Standard Energy, Increased Protein Tube Feed without Fibre.
       - 2.1.2.3. Standard Energy, High Protein Tube Feed +/- Fibre.
       - 2.1.2.4. High Energy Increased Protein Tube Feed with Fibre.
       - 2.1.2.5. High Energy, Increased Protein Tube Feed without Fibre.
       - 2.1.2.6. High Energy High Protein Tube Feed.
       - 2.1.2.7. High Energy Tube Formula for Children, with Fibre.
       - 2.1.2.8. High Energy Tube Formula for Children without Fibre.
     - 2.1.3. Protein and Energy Reduced Products
     - 2.1.4. Equipments
   - 2.2. Non - disease specific oral nutritional supplements
     - 2.2.1. Protein and Energy Products (≥1.0kcal/ ml and <5.0g protein/100ml)
       - 2.2.1.1. Standard Sip Feeds for Children with Fibre.
       - 2.2.1.2. Standard Sip Feeds for Children without Fibre.
       - 2.2.1.3. Enriched Energy Formula (ONS): Suitable for Infants from birth to 18 months.
     - 2.2.2. Protein and Energy Rich Products
       - 2.2.2.1. Non-Milk Tasting Sip Feed.
       - 2.2.2.2. Powered Milkshake Style ONS.
       - 2.2.2.3. Protein and/or Energy Rich Sip Feeds with Fibre.
       - 2.2.2.4. Protein and/or Energy Rich Sip Feeds without Fibre.
       - 2.2.2.5. Enhanced Protein Liquid.
       - 2.2.2.6. Semi-Solid.
       - 2.2.2.7. Protein and/or Energy Rich Sip Feeds for Children with Fibre.
       - 2.2.2.8. Protein and/or Energy Rich Sip Feeds for Children without Fibre.
       - 2.2.2.9. Protein Concentrate Powder.
       - 2.2.2.10. Other
     - 2.2.3. Protein and Energy Reduced Products
     - 2.2.4. Equipments
   - 2.3. Nutritional products for specific clinical conditions

2.3.1. Diabetes Specific Products
2.3.1.1. Diabetes Specific Sip Feed.
2.3.1.2. Diabetes Specific Tube Feed.
2.3.2. Cancer Specific (EPA enriched) Products
2.3.2.1. Cancer Specific (EPA enriched) Sip Feed.
2.3.2.2. Cancer Specific (EPA enriched) Tube Feed.
2.3.3. Milk Substitute
2.3.4. Other
2.3.5. Equipments
2.4. Nutritional products designed for the specific management of inherited metabolic disorders
2.4.1. Inherited Metabolic Disorders
2.4.2. Other products
2.5. Staple food products designed to optimise nutritional status as part of the clinical management of formally diagnosed chronic disease states
2.5.1. Gluten Modified Foods
2.5.2. Low Protein Foods
2.6. Nutritional products designed to enhance the safety and / or acceptability of foods or feeds which are prescribable in any of the above categories
2.6.1. Thickeners
2.6.2. Flavourings
2.6.3. Equipments

3. Parenteral Nutrition Products
3.1 Amino Acids
3.2 Dextrose
3.3 Fats
3.4 Nutritional Additives
3.5 Equipments

4. Supplements and related equipments.

The IAPEN would like to acknowledge the assistance the Executive Members of the Governing Council of IAPEN for support in developing this application.