HealthShare Victoria

Invitation to Supply

Issue Date: 6 July 2021 for Industry Briefing

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Please carefully read all ITS documents once formally released. Please refer to HSV website for further information

Healthsharevic.org.au

ITS Number:	HSVITS2022-018
ITS Name:	Enteral Feeding and Oral Nutrition Support
Closing Date and Time:	18 August 2021 14:00 AEST/AEDT

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PART 4: STATEMENT OF REQUIREMENTS

1. Participating Health Services

a. The Participating Health Services for this ITS are

(i) All 'Public Health Services' (as legislatively defined) referred to in Schedule 1 and Schedule 5 of the *Health Services Act 1988*; and

(ii) Other relevant participating health and health related organisations as follows:

- Department of Health (DH) Needle and Syringe Program

2. Scope

a. The scope of this ITS includes:

(i) Enteral Feeding and Oral Nutrition Support products used in most clinical settings, including:

- all critical care areas, from neonate to adult

(ii) general wards, aged care and departments

(iii) Products that are compatible with a range of equipment systems, including:

- Volumetric Enteral Feeding Pump
- Syringe Driver Enteral Feeding Pump

b. The scope of this ITS does not include:

(i) infant formulae & special paediatric formulae;
(ii) integrated Enteral Feeding System
(iii) nasogastric tube
.

3. Product Categories

a. A complete range of Enteral Feeding and Oral Nutrition Support products is required for treatment of patients across Victorian Public Health Services

b. The categories required include:

CATEGORY NUMBER	CATEGORY NAME
1	ENTERAL FORMULA PRODUCTS
2	ORAL NUTRITION SUPPORT PRODUCTS
3	THICKENED BEVERAGES

CATEGORY NUMBER	CATEGORY NAME
4	THICKENING AGENTS
5	MODULAR PRODUCTS
6	ENTERAL FEED ADMINISTRATION SETS, FEEDING BAGS AND ACCESSORIES
7	ENTERAL FEEDING PUMPS
8	NUTRITIONAL MEAL REPLACEMENT PRODUCTS
9	ENTERAL SYRINGES AND ACCESSORIES

c. The Respondent may offer products in one, some or all categories.

d. HSV reserves the right not to consider any additional products offered.

e. For a full list of product categories and subcategories, refer to Appendix 1 - Product List.

4. Product Offering

a. Respondents are to list a direct match to the part and part number listed on the Response Worksheet.

b. If a direct match is not possible, list alternative or best match with the alternate part number.

c. HPV may not consider any product that is subject to a current HPV Agreement, other than those listed below:

   (i) HPVC2016-018 Enteral Feeding and Oral Nutrition Support

d. Respondents will ensure that each product is offered in only one subcategory. It is the Respondent's responsibility to ensure that each product is submitted in the most appropriate subcategory.

5. Clinical Trials

a. Participating Health Services may, at their discretion, research or trial new technology or use non-contracted products to perform clinical trials at any time during the Term of any resulting Agreement.

Product Requirements

6. Standards and Compliance

a. All items offered must comply with relevant Australian Standards, Orders, Legislation and Regulations (collectively 'Compliance Requirements'), or their equivalent International Compliance Requirements. Refer to Appendix 2 – Compliance Requirements for a list of the minimum Compliance Requirements.

b. All therapeutic goods offered must be approved by the Australian Therapeutic Goods Administration (TGA), unless exempt. The Respondent must provide evidence of this (i.e. ARTG certificates) in its response. HSV recommends the use of products in accordance with TGA registered indications.

c. The successful Respondent must provide evidence of ARTG certification to Participating Health Services upon request.

7. Packaging and Labelling

a. Sterile products will be packaged in a manner that protects the contents from contamination during transportation, storage and handling.

b. All labels must comply with the *Therapeutic Goods Act* 1989 and the *Therapeutic Goods (Medical Devices) Regulations* 2002.

c. Items will be delivered in accordance with the manufacturer's instructions.

d. It is desirable for individual product packaging to include (where applicable):

(i) whether the product is sterile;

(ii) whether the product is MRI compatible (implantable products);

(iii) whether the product (or packaging) contains latex or is latex-free; and

8. Infection Control

a. Where applicable, all items must meet the requirements of the *Australian Guidelines for the Prevention and Control of Infection in Healthcare* (2019) and for reusable items must meet the disinfection standard of AS/NZS 4187.

b. Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products.

9. Substances of Concern

a. Preference will be given to products (including their accompanying packaging) that are latex-free, unless otherwise stated.

b. Preference will be given to products that are free of diethylhexyl phthalate (DEHP).

10. Product Information

a. The Respondent will submit a copy of relevant product diagrams, specifications or brochures to assist in accurately identifying products offered.

b. Where research papers or relevant scientific information is available, this should be submitted with the Response.

c. All product information submitted should:

(i) be in electronic format

(ii) be in English

(iii) be specific to the product offered

(iv) contain the Respondent's company name

(v) include the product code

(vi) include a detailed specification of the product

(vii) include clear diagrams/pictures of the product.

d. To assist in managing this material, all product information submitted should be labelled with the relevant HSV category and subcategory number.

e. Electronic copies should include the HSV Category and subcategory numbers in the filename or identifying metadata.

f. HSV may not consider unlabelled submissions.

g. Product information will not be evaluated but is necessary to assist in accurately identifying products offered.

h. HSV reserves the right to exclude products from evaluation when the product is unidentifiable and provided information is:

(i) Not labelled as per clause d above; or

(ii) Is incomplete as to clause c.

i. Product samples are not to be provided unless specifically requested by HSV, as per Part 2 clause **Error! Reference source not found. Error! Reference source not found.**.

j. The Respondent should not submit information relating to products that are not called for in this ITS.

11. Warranty

a. All products covered in this ITS are to be issued a warranty for twelve (12) months from the delivery date for normal use.

b. Upon request, the successful Respondent will provide information (printed or electronic) explaining product warranty.

c. The repair or replacement of any item under warranty will be at no cost to the Participating Health Service.

d. The cost of any pickup or delivery associated with a repair or replacement under warranty will be borne by the successful Respondent.

e. It is highly desirable that the successful Respondent provides Participating Health Services with a replacement or suitable loan item at no cost until the repaired item is returned.

12. Recall Process

a. All recalls must be managed in line with the *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019).

b. Within three (3) months of agreement commencement, all recalls and/or hazard alerts will be completed using GS1 Recall OR Recall Health.

c. Class 1 recalls (as defined by the TGA's *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019) must also meet the requirements under section Part 5 clause 6 Warranty, where applicable.

13. Price review

a. Except where detailed in Item 9 of the Supply Schedule, the Unit Prices must remain fixed for the Term of this Agreement and no further adjustment of the Unit Prices shall take place.

b. If the parties do agree to a change in the Unit Prices of the Goods, such agreement must be in writing.

Delivery

14. Electronic Data Interchange

a. The Participating Health Services prefer to exchange orders, payments, acknowledgements, invoices, remittance notices and other records (Data) electronically, in place of tangible documents. Successful Respondents are required to work with the Participating Health Services to achieve this outcome.

15. Delivery

a. Products awarded in this agreement will be delivered to the location(s) specified by Participating Health Services within the shortest possible timeframe; however, this must not exceed three (3) Business Days from receipt of order unless otherwise agreed with the Participating Health Service.

b. The delivery timeframe will also apply to the delivery of products under the Participating Health Services Home Enteral Nutrition program.

c. All deliveries are bound as per the Deed of Standing Offer Agreement, Part 5 clause 9 Acceptance and Rejection of Deliverables.

16. Urgent Deliveries

a. For the purposes of this section, urgent deliveries refer to urgent requests placed by an individual Participating Health Service and does not include state-wide emergency situations.

b. The Respondent should be able to receive and action urgent delivery requests 24 hours a day, 7 days a week.

c. Urgent deliveries should be received by Participating Health Services within 24 hours from receipt of order.

d. The delivery timeframe will also apply to the urgent delivery of products under the Participating Health Services Home Enteral Nutrition program.

Support

17. Training

a. Upon request by a Participating Health Service, successful Respondents will deliver a training package and/or training materials to facilitate the introduction of their ITS to clinicians in their operating environment.

b. Training requirements may include (but are not limited to):

   (i) face-to-face training at Participating Health Service sites (i.e., in-service training)

   (ii) online training

   (iii) off-site study days for clinicians

   (iv) updates and refresher training on new products and/or equipment and surgical techniques

   (v) training materials.

18. Customer Service and Support

a. The successful Respondent must be able to provide customer service and support to Participating Health Services, either directly or via a third party, during business hours

b. The successful Respondent will provide Participating Health Services with representatives that are:

   (i) inherently familiar with the contracted products

   (ii) appropriately qualified

   (iii) technically/clinically knowledgeable about the contracted products

   (iv) available to respond to Participating Health Services' queries 24 hours a day or during business hours.

c. It is desirable that nominated Representatives have a clinical background or experience.

d. The level of customer service and support required of Representatives is expected to include (but is not limited to):

   (i) liaising with clinicians to recommend products and solutions.

   (ii) promptly answering clinicians' queries (including after hours)

   (iii) liaising with various hospital departments (for example: operating theatre, Nurse Unit Managers)

   (iv) providing on-site clinical support during cases (if requested)

   (v) providing informational materials

   (vi) providing education and in-service training upon request.

e. Representatives must comply with Participating Health Services' local policies regarding engagement with Participating Health Service staff.

Award

19. Conditional Acceptance

a. Products may be designated as 'Conditionally Accepted' for the following reasons:

   (i) Where products offered are not 'known and accepted' but represent value for money; or

   (ii) Where products are inactive and have not been in use for at least 12 months.

   (iii) Where minimum data information is not provided e.g., UNSPSC code.

b. Clause 3.10 of the Draft Deed of Standing Offer Agreement sets out terms relating to Conditionally Accepted Deliverables.

c. Products designated as 'Conditionally Accepted' may be subject to desktop and functional evaluation by health services.

d. "Acceptance for use" is confirmed by issuing a product acceptance certificate or any other form signed by an appropriate clinical representative of a Participating Health Service

e. Pricing will be as per response position and cannot be amended post Agreement acceptance.

20. Key Performance Indicators

a. Refer to Part 5 Draft Deed of Standing Offer Agreement clause 5 and Schedule 1 – Supply Schedule, Item 17.

21. Service Level Agreement

a. Participating Health Services may enter into a Service Level Agreement (SLA) with the successful Respondent(s). The SLA may cover arrangements including, but not limited to:

   (i) the provision of products on consignment

   (ii) requirements for stock management and rotation

   (iii) arrangements for ordering, invoicing and delivery

   (iv) clinical support, including attendance requirements for Representatives in relation to education and training.

   (v) communication arrangements for product recalls and safety alerts (refer to Part 4 clause 12 Recall Process).

b. The SLA will be in addition to the Agreement between the successful Respondent(s) and HSV and will not alter any terms of the Agreement.

c. HSV will not be responsible for monitoring compliance with any SLA. This is a matter of agreement between the parties to the SLA.

d. Successful Respondent(s) will provide a copy of all Service Level Agreements to HSV within 1 week of being finalised.

Category 1 – Enteral Formula Products

A full range of enteral formula is required to meet clinical needs. This includes:

(i) for in-patients and as part of the Home Enteral Nutrition (HEN) program;
(ii) for adult and paediatric patients;
(iii) to suit all clinical conditions;
(iv) a full range of energy levels;
(v) liquid, powder, 'ready to use' and 'ready to hang' formulas;
(vi) low, standard and high protein formulas;
(vii) with and without added fibre; and
(viii) low sodium, low carbohydrate, peptide and amino acid-based products.
(ix) Respondents to consider offering formulas incorporating real food/natural ingredients

b Where enteral formula products claim to be nutritionally complete they shall provide 100% RDI for a male of 31-50 years in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" as endorsed by the National Health and Medical Research Council on 9 September 2005.

c Where enteral formula products are tendered specifically for paediatric use and claim to be nutritionally complete, they shall provide 100% RDI for a child of 4-8 years of age in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" as endorsed by the National Health and Medical Research Council on 9 September 2005.

d Respondents are advised to refer to **Error! Reference source not found.Error! Reference so urce not found.**.

e Where products are presented in a powdered form, response information regarding nutritional content shall be based on the standard dilution and state the standard dilution volume in millilitres.

f For all enteral formula products offered, Respondents shall provide the following information in the product description on the Tender Response Worksheet:

(i) brand name;
(ii) volume in millilitres;
(iii) weight in grams;
(iv) percentage of dilution;
(v) weight of scoop measure in grams (where applicable); and
(vi) product packaging type i.e. ready to hang, glass, plastic, tetrapak, can.

g For all enteral formula products offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) kilojoules provided per 100 ml of feed and per unit;
(ii) the volume and cost per day to achieve 100% recommended daily intake (RDI) as described in Category 1, clauses 1b and 1c;
(iii) the price per kilojoule for each presentation, calculated on the base price tendered;
(iv) protein content, as a percentage of total energy provided, in grams per Litre and per unit;
(v) carbohydrate content, as a percentage of total energy provided, and in grams per unit and in grams per Litre;
(vi) electrolyte content of sodium and potassium, in milligrams per Litre;

(vii) water in millilitres per litre;
(viii) fibre content, in grams per Litre and type of fibre;
(ix) where enteral formula products are offered for consumption by patients with specific medical conditions, list other specific nutrients in milligrams per Litre, required for the medical condition;
(x) osmolality, in milliosmoles per kilogram water;
(xi) presence or absence of:

- lactose;
- gluten;

(xii) presence of FODMAPs, specifically:

- Fructose, Fructans, Raffinose;
- Inulin;
- Polyols-sorbitol, Xylitol;

(xiii) glycaemic index, where available;
(xiv) whether the product is nutritionally complete;
(xv) Kosher compliant;
(xvi) Halal compliant; and
(xvii) suitability for individuals on a vegan diet.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) a complete nutritional composition profile for each product;
(ii) an ingredient composition list which identifies as a minimum, the source(s) of protein, fats, carbohydrate and fibre included in each product; and
(iii) a list of deficiencies where enteral formula products are not nutritionally complete.
(iv) For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 2 – Oral Nutrition Support Products

a A range of oral nutrition support products is required to meet clinical needs for nutritional supplementation. This includes:

(i) for in-patients and as part of the Home Enteral Nutrition (HEN) program;
(ii) for adult and paediatric patients;
(iii) a full range of:

I. energy levels; and
II. flavours;

(iv) a full range of liquids, powders, puddings and bars which includes:

I. milky type and non-milk varieties;
II. peptide based; and
III. with and without added fibre;

b Where the thickness of oral nutrition support products has been modified to facilitate consumption by patients with swallowing difficulties, Respondents are advised to offer these products in Category 3 - Thickened Beverages.

c Where oral nutrition support products are claimed to be nutritionally complete they shall provide 100% RDI for a male of 31-50 years of age in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" endorsed by the National Health and Medical Research Council on 9 September 2005.

d Where oral nutrition support products are tendered specifically for paediatric use and are claimed to be nutritionally complete, they shall provide 100% RDI for a child of 4-8 years of age in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" as endorsed by the National Health and Medical Research Council on 9 September 2005.

e Where oral nutrition support products are presented in a powdered form, response information regarding nutritional content shall be based on the standard dilution and state the standard dilution volume in millilitres.

f For all oral nutrition support products offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) presentation type i.e. ready to drink, powder, concentrate, pudding, bar;
(iii) product packaging type i.e. glass bottle, plastic bottle, plastic wrap, tetrapak, can, plastic cup;
(iv) volume in millilitres; or
(v) weight in grams;
(vi) weight of scoop measure in grams (where applicable); and
(vii) flavour;

g For all oral nutrition support products offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) kilojoules provided per 100 ml or 100 grams of supplement and per unit;

(ii) the volume and cost per day to achieve 100% recommended daily intake (RDI) as described in clauses Category 2 - clauses b and c;
(iii) the price per kilojoule for each presentation, calculated on the base price tendered;
(iv) protein content, as a percentage of total energy provided, in grams per litre and per unit;
(v) carbohydrate content, as a percentage of total energy provided, in grams per unit, and grams per Litre;
(vi) electrolyte content of sodium and potassium in milligrams per Litre;
(vii) fibre content, in grams per litre and type of fibre;
(viii) where oral nutrition support products are offered for consumption by patients with specific medical conditions, list other specific nutrients in milligrams per Litre, required for the medical condition;
(ix) osmolality, in milliosmoles per kilogram water;
(x) presence or absence of:

I. lactose;
II. gluten;

(xi) presence of FODMAPs, specifically:

I. Fructose, Fructans, Raffinose;
II. Inulin;
III. Polyols-sorbitol, Xylitol;

(xii) glycaemic index, where available;
(xiii) whether the product is nutritionally complete;
(xiv) Kosher compliant;
(xv) Halal compliant;
(xvi) suitability for individuals on a vegan diet; and
(xvii) if packaging is resealable.

(xviii) Provide allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) a complete nutritional composition profile for each product;
(ii) an ingredient composition list which identifies as a minimum, the source/s of protein, fats, carbohydrate and fibre included in each product; and
(iii) where oral nutrition support products are not nutritionally complete, list the deficiencies.
(iv) For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 3 – Thickened Beverage

a A range of pre-packed, ready-to-use thickened beverages is required for consumption by patients with swallowing difficulties. This includes:

(v) for in-patients and as part of a Home Enteral Nutrition (HEN) program;
(vi) for nutritional supplementation and hydration;
(vii) a full range of thicknesses;
(viii) recommended temperature range to be specified for consumption of beverages
(ix) a full range of flavours; and
(x) a range of bases including water, cordial, fruit juice, milk-type, tea, coffee and other.

b Thickened beverages are sought under the following levels:

(i) Mildly thick fluid – IDDSI Level 2, colour code Green, (previously Level 150);
(ii) Moderately thick fluid – IDDSI Level 3 colour code Yellow, (previously Level 400); and
(iii) Extremely thick fluid – IDDSI Level 4 colour code Pink, (previously Level 900).

Preference will be given for product with IDDSI guideline level number and colour code on packaging of thickened product of pre-packed/ready-made beverages.

Products range submitted under each level will be required to provide thickness test report using both the IDDSI flow test and the Bostwick viscosity test (cm/30s) from a third-party test organisation. Temperature of product to be specified during tests.

c All tendered thickened beverages shall comply with Australian New Zealand Food Standards Code 1.2.9: Legibility Requirements.

d Where thickened beverages are claimed to be nutritionally complete they shall provide 100% RDI for a male of 31-50 years of age in a defined volume, as described in Nutrient Reference Values for Australia and New Zealand endorsed by the National Health and Medical Research Council on 9 September 2005.

e Where oral nutrition support products are tendered specifically for paediatric use and are claimed to be nutritionally complete, they shall provide 100% RDI for a child of 4-8 years of age in a defined volume, as described in Nutrient Reference Values for Australia and New Zealand as endorsed by the National Health and Medical Research Council on 9 September 2005.

f For all thickened beverages offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet.

(i) brand name;
(ii) volume in millilitres;
(iii) level of thickness e.g. Level 150;
(iv) colour code of pack e.g. green;
(v) size of the font for the level of thickness in millimetres e.g. 3mm;
(vi) type of base e.g. water, fruit juice;
(vii) flavour; and
(viii) product packaging type i.e. plastic bottle, plastic cup, tetrapak, can.

g For all thickened beverages offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet.

(i) kilojoules provided per 100 ml of thickened beverage and per unit;
(ii) the volume and cost per day to achieve 100% recommended daily intake (RDI) as described in Category 3 - clauses e and f;
(iii) price per kilojoule for each presentation, calculated on the base price tendered;
(iv) whether the product is nutritionally complete;
(v) protein content, as a percentage of total energy provided, in grams per unit and grams per Litre;
(vi) carbohydrate content, as a percentage of total energy provided, in grams per unit, and grams per Litre;
(vii) electrolyte content of sodium and potassium in milligrams per Litre;
(viii) active ingredient used to thicken the beverage
(ix) fibre content, in grams per litre and type of fibre;
(x) the presence or absence of:

I. lactose;
II. gluten;

(xi) presence of FODMAPs, specifically:

I. Fructose, Fructans, Raffinose;
II. Inulin;
III. Polyols-sorbitol, Xylitol;

(xii) glycaemic index, where available;
(xiii) Kosher compliant;
(xiv) Halal compliant;
(xv) suitability for individuals on a vegan diet; and
(xvi) if packaging is resealable.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) a complete nutritional composition profile for each product; and
(ii) an ingredient composition list that identifies at a minimum, the source/s of protein, fats, carbohydrate and fibre included in each product.
(iii) For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 4 – Thickening Agents

a Thickening agents are required to modify the consistency of oral fluids for consumption by patients with swallowing difficulties. This includes:

(iv) for in-patients and as part of a Home Enteral Nutrition (HEN) program; and
(v) a full range of packaging sizes.

b When thickening agents are used in accordance with the manufacturer's instructions, the modified fluid shall retain a stable consistency i.e. within the consistency range to which it was prepared, over a 24 hour period.

c Thickening agents shall incorporate clear instructions for use including:

(i) the type of fluids to which the thickening agent can be added;
(ii) IDDSI name, thickness level and colour code of thickened product on the instructions for thickening powder
(iii) the dosage levels required to achieve different consistency levels across the range of fluids;
(iv) cost to achieve different consistency levels across the range of fluids; and
(v) the mode of preparation e.g. blender.

d For all thickening agents offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) presentation e.g. powder or liquid;
(iii) volume in millilitres; or
(iv) weight in grams; and
(v) weight of the scoop measure in grams (where applicable).

e For all thickening agents offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) kilojoules provided per 100 ml of thickened beverage;
(ii) carbohydrate content is per 100 grams;
(iii) active ingredient used to thicken the beverage
(iv) fibre content, in grams per litre and type of fibre;
(v) the presence or absence of:

I. lactose;
II. gluten;

(vi) presence of FODMAPs, specifically:

I. Fructose, Fructans, Raffinose;
II. Inulin;
III. Polyols-sorbitol, Xylitol;

(vii) Kosher compliant;
(viii) Halal compliant; and
(ix) suitability for individuals on a vegan diet.
(x) if packaging is resealable.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) an ingredient composition list which identifies at a minimum, the source/s of the thickening agent.

b For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 5 – Modular Products

a A full range of modular products is required to meet clinical needs. This includes:

(i) for both in-patients and as part of Home Enteral Nutrition (HEN) program;
(ii) glucose polymers including liquid and powder presentations;
(iii) fibre powder; and
(iv) fat emulsions, including medium and long chain triglyceride oil;
(v) protein powder;
(vi) combination products including for example glucose polymer/fat.

c For all modular products offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) presentation e.g. liquid or powder;
(iii) volume in millilitres, or
(iv) weight in grams;
(v) flavour, where applicable;
(vi) the weight of the scoop measure in grams (where applicable); and
(vii) percentage dilution.

d For any glucose polymer offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) the energy level in kilojoules per 100 grams or kilojoules per 100 millilitres;
(ii) the carbohydrate content in grams per 100 grams or grams per 100 millilitres; and
(iii) the protein content in grams per 100 grams or grams per 100 millilitres.

e For any fibre powder offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) the energy level in kilojoules per 100 grams or kilojoules per 100 millilitres;
(ii) the fibre content in grams per 100 grams; and
(iii) the fibre sources.

f For any fat emulsions offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) the energy level in kilojoules per 100 grams or kilojoules per 100 millilitres;
(ii) the carbohydrate content in grams per 100 grams or grams per 100 millilitres;
(iii) the type/s of fat; and
(iv) the percentage of each type of fat as total fat content.

g For any protein powder offered, Respondents shall provide the following information on the Tender Response worksheet:

(i) the energy level in kilojoules per 100 grams or kilojoules per 100 millilitres;
(ii) the protein content in grams per 100 grams; and
(iii) the protein sources.

h For any combination products offered, Respondents shall provide the following information on the Tender Response worksheet:

(i) the energy level in kilojoules per 100 grams or kilojoules per 100 millilitres;
(ii) the glucose polymer/fat content in grams per 100 grams; and
(iii) the glucose polymer/fat source.

i For all modular products offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) the presence or absence of:

I. lactose;
II. gluten;

(ii) presence of FODMAPs, specifically:

I. Fructose, Fructans, Raffinose;
II. Inulin;
III. Polyols-sorbitol, Xylitol;

(iii) Kosher compliant;
(iv) Halal compliant; and
(v) suitability for individuals on a vegan diet.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) a complete nutritional composition profile for each product;
(ii) an ingredient composition list which identifies as a minimum, the source/s of protein, fats, carbohydrate and fibre included in each product; and
(iii) where oral nutrition support products are not nutritionally complete, list the deficiencies.
(iv) For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 6 – Enteral Feed Administration Sets, Feeding Bags and Accessories

a A range of enteral feeding equipment is necessary to meet requirements in the hospital and home setting. This includes:

(v) pump-driven and gravity-driven administration sets;
(vi) feeding bags with and without integral administration sets;
(vii) connectors and adaptors including universal adaptors; and
(viii) accessories to facilitate the provision of enteral feed administration.

b Enteral feed administration sets shall incorporate at a minimum:

(i) a distal connector to allow connection with commercially available ready-to-hang enteral feeds or feeding containers;
(ii) kink resistant tubing; and
(iii) a proximal connector at the patient end to allow connection with the patient feeding tube.

c Enteral administration feed sets shall *not* be compatible with intravenous or hypodermic access devices.

Provision of Enteral Feed Administration Sets

a Enteral feed administration sets shall be offered under the following pricing model in the Tender Response Worksheet:

(i) whether sets are compatible to specific pump manufacturers;
(ii) outright purchase of pump: for use where the customer owns the enteral feeding pumps with which the sets are to be used; and
(iii) pump provided ‘free-on-loan’: for use where enteral feeding pumps are being provided without charge for use by the associated sets.

Additional Information:

a The following information shall be readily available to all contract users via hard copy and electronic means:

(i) a description and/or diagram of each pump set offered which identifies all features including roller clamps, 3-way taps and Y-sites; and
(ii) a list detailing the compatibility of each enteral feed administration set offered with the range of ‘Ready To Hang’ nutritional feeds and feed bags available in Australia.

Category 7 – Enteral Feeding Pumps

a A range of enteral feeding pumps is required to facilitate the delivery of enteral feeds in both the hospital environment or as part of a Home Enteral Nutrition (HEN) program.

b Enteral feeding pumps can be either:

(i) Volumetric enteral feeding pumps; utilising either a rotary or linear peristaltic pumping mechanisms to administer feed
(ii) Enteral syringe driver feeding pumps; feed delivery via a syringe with the pump advancing the syringe plunger

Provision of Pumps

c Enteral feeding pumps shall be offered under the following arrangements only:
(i) outright purchase of pump: for use where the customer owns the enteral feeding pumps with which the sets are to be used;
(ii) volumetric pumps provided 'free-on-loan': for use where enteral feeding pumps are being provided without charge for use with the associated sets;
(iii) enteral syringe pumps provided 'free-on-loan': for use where enteral feeding pumps are being provided without charge based on associated spend;
(iv) Suppliers should specify a list of compatible syringes.

e Where enteral feeding pumps are provided 'free on loan':
(i) they shall remain the property and responsibility of the Respondent;
(ii) the responsibility for service, maintenance and recall management shall be retained by the Respondent
(iii) Respondents shall fully detail the arrangement by which pumps are received and maintained. This includes:
I. the minimum requirements for the hospital to access pumps both at commencement of the agreement and throughout the life of the agreement;
II. arrangements for pump delivery and acceptance testing;
III. arrangements for preventive inspection/maintenance service and repair including timing for replacement of defective or ageing equipment and to indicate if these services are done on-site or off-site;
IV. the process by which enteral feeding pumps are tracked while in active use within the hospitals and as part of a HEN program;
V. management and reporting of pump inventory provided to the hospitals or health services;
VI. the responsibility and any costs where pumps are inadvertently damaged or lost. This should take into account the age of the pump and depreciation in value across the life of the contract; and
VII. provision of essential accessories i.e. external power supplies and pole clamps.

f For all enteral feeding pumps offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) the overall physical dimensions in centimetres;
(iii) the gross mass including battery in kg;
(iv) the net mass excluding charger (where present) in kg; and
(v) GMDNS (Global Medical Device Nomenclature System) preferred product title.

g For all enteral feeding pumps offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) the ambient operating temperature range;
(ii) the maximum operating altitude;
(iii) is the enteral feed pump and accessories hyperbaric approved from the manufacturer to withstand elevated atmospheric pressure to at least 2.8 ATA absolute;
(iv) the type of pumping mechanism e.g. peristaltic, piston;
(v) the minimum and maximum flow rate for continuous feed indicating the percentage of accuracy of the pump based on industry standard feed of 1.0 Kcal per millilitre; specifying what fluid and viscosities the flow rate is based on;
(vi) if the pump is recommended for ambulatory use;
(vii) if the positioning of the pump in other than an upright position, adversely affects the capacity and accuracy of the pumping mechanism;
(viii) any known contraindications to use;
(ix) the recommended useful life of the enteral feeding pump, as suggested by the manufacturer; and
(x) Pole Clamp – integral/detachable (if detachable does it require a tool to unlock).

Standards and Compliance

a All enteral feeding pumps must be approved by the Australian Therapeutic Goods Administration (TGA), i.e., ARTG number must be submitted for each enteral feeding pump.

b Suppliers of enteral feeding pumps must be compliant with AS ISO 13485.

c Manufacturer of enteral feeding pump must be compliant with AS ISO 14971.

d Enteral feeding pumps must not cause electromagnetic interference to other medical devices.

(i) Tendered product must comply with a relevant Electromagnetic Compatibility standard/s.

e If enteral feeding pump can connect to the hospital's IT network infrastructure, or connect directly to the internet (via i.e., public Wi-Fi, mobile 4G/5G network, etc.) then Respondents must:

(i) include the Manufacturer Disclosure Statement for Medical Device Security (MDS2) form (the latest version of form at time of tender, version ANSI/NEMA HN 1:2019) for each enteral feeding pump with their submission, and
(ii) Specify any broadcasting features used on both wired and wireless networks including; broadcast, multicast and unicast.
(iii) submit a list of Software Bill of Materials (SBoM) for each enteral feeding pump, and
(iv) provide (i) and (ii) to Participating Health Services upon their request.

Power Supply

a All enteral feeding pumps shall be both battery and mains powered.

Mains Powered

b Enteral feeding pumps shall comply with the requirements of this specification when operated within the power supply range of 240 volts +/- 10%, 50Hz.

c The power supply system shall be immune to the effects of common power surges and power fluctuations.

d External power supplies that fit squarely and firmly in a typical power outlet and mid-length style power supplies may be used where the weight does not exceed 300 grams. External power supplies must isolate extra low voltage and incorporate over temperature and short circuit protection.

e A minimum 10% of the external power supplies and power supply cables that are faulty or damaged shall be replaced at no cost to health services. Faulty cables include those cables which have intermittent loss of power.

Battery Powered

f Enteral feeding pumps shall incorporate:

(i) a battery system that will maintain power to fully operate the pump in the event of the removal of the mains supply; and

(ii) an indicator that clearly identifies that the pump is running on battery power.

g The battery shall be continuously charged from a mains power supply, even if the power control switch of the pump is turned off.

h A clear visual indication and audible alarm must be given to warn that the battery power is nearly exhausted.

i Enteral feeding pumps shall start up and continue to operate accurately on mains power despite a fully discharged battery is being connected.

j Please specify the battery chemistry e.g. SLA, Lithum-iln. Preference may be given to products provided with rechargeable batteries that do not require cycling to maintain capacity.

k Preference will be given to preventative maintenance programs that include replacement of re-chargable batteries. Please specify battery replacement frequencies. The average rechargeable battery life must be at least one (1) year, with tolerance to partial charging.

l Tenders shall provide the following information on the Tender Response Worksheet:

(i) the life expectancy of the battery (in years);
(ii) the time required (in minutes) to fully charge a fully discharged battery;
(iii) the period of time (in hours) for which a fully charged battery can operate a pump when set at a rate of 100-125 millilitres per hour; and
(iv) the time duration that the pump will continue to run after battery low alarm first sounds.

j The minimum battery life (in hours); preference will be given to pumps that can operate as described in Category 7 – Battery Powered clause “l (iii)” above for a minimum of six (6) hours.

Construction Quality

a All pumps shall:

(i) be of robust construction of the casing and to provide the primary material detail e.g. polycarbonate;
(ii) be protected against fluid spills due to breakage or disconnection of feed containers. Patient safety shall not be compromised, and pump operation shall not be adversely affected by fluid spills. If fluid penetrates the electronic circuitry, the pump shall fail safely
(iii) have no rough or sharp edges;
(iv) have switches, knobs, and other controls that are designed for conditions of heavy use; and
(v) have an attachment point for a pole clamp (if not fixed).

b All pumps tendered must be capable of being cleaned with the following cleaning or disinfectant agents without causing any degradation to the pump:

(i) Neutral Detergent, pH 6 -8 in either an aqueous solution or impregnated wipe, and
(ii) 70-90% Alcohol, and
(iii) At least, one of the following hospital grade disinfectant categories:
I. Chlorine and chlorine compounds, or
II. - Hydrogen peroxide, or
III. - Quaternary ammonium compounds, or
IV. - Phenolic disinfectants.

Performance

c During the delivery cycle, the flow rate shall remain as continuous as possible.

d It is desirable that there is no interruption when changing flow settings but shall not exceed 10 seconds in flow interruption.

e Enteral feeding pumps should have patient lockout capabilities.

f Volumetric Enteral feeding pumps must have:

(i) an accuracy of selected rate and volume of ±10%;
(ii) a maximum flow rate of at least 300ml/hr;
(iii) a flow rate range of 1 ml/hr to at least 50 ml/hr in 1ml increments and thereafter, in increments of up to 5 ml;
(iv) the cassette shall be easily loaded into the pump; and
(v) the pump shall sense an upstream (fluid side) occlusion and downstream occlusion (flow restriction)

e Enteral Syringe feeding pumps must have:

(i) an accuracy of selected rate and volume of ±10%;
(ii) flow rate range of 0.1 to 99.9 mL/hr in increments of 0.1mL/hr for neonates or children.

Ease of Use

g Enteral feeding pumps should be easy to set up, prime and be simple to use;

h Controls shall be easy to set and logically arranged;

i Labels and displays shall clearly and concisely identify the functions of all switches, controls, monitors and displays;

j The control setting values shall be easy to read and determine;

k The external housing of the pump shall be easy to clean; and

l A brief set of instructions and important precautions shall be permanently and prominently displayed on the device.

Displays

a Displays shall be easily read at one (1) metre from the pump in day and night-time conditions.

b LCD displays shall have a backlight facility.

c An indicator on the display shall be present that indicates:

(i) an infusion is in progress;
(ii) the pump is running on battery or mains power; and
(iii) amount of battery life remaining.

d Respondents shall advise the parameters displayed by the pump on the Tender Response Worksheet. These shall include as a minimum:

(i) infusion rate;
(ii) total volume to be infused; and
(iii) volume delivered;

e Preference may be given if additional parameters are displayed by the pump for example on the following:

(i) dose limit;
(ii) intermittent flushing mode; and
(iii) bolus feeding option.

Alarms

a Enteral feeding pumps shall have the following clearly audible and visual alarms as a minimum:

(i) set dislodgement/free-flow detection;
(ii) empty bag /container /infusion complete detection;
(iii) occlusion alarm:
(iv) Low battery alarm; and
(v) battery depleted alarm;

b The cause of each alarm condition shall be readily identifiable by the user.

c Respondents shall advise on the Tender Response Worksheet if:

(i) the volume of the pump alarm is adjustable (must remain sufficient to hear in presence of moderate ambient noise (65dB).
(ii) the alarm can be switched off; and
(iii) the alarm can be disabled.

Network Connectivity

a Successful Respondent must inform Participating Health Services, HealthShare Victoria, and Department of Health (Digital Health team) within 72 hours, if it has intelligence reports of a cybersecurity vulnerability being actively exploited by threat actors.

b Successful Respondents must have a programme in place that informs Participating Health Services of cybersecurity vulnerabilities to the tendered device throughout its life cycle.

c Any pc or server 'like' tendered product that can connect onto the hospital's IT network, whether physical or virtual, must:
(i) have unique user login credentials (both generic and group logins must not be used), and
(ii) user level of privileges managed, and
(iii) have strong user login authentication protocols.

d Tendered products installed with an Operating System (OS), the OS must be supported and patchable.
(i) OS patch updates must be installed in affected tendered product within 30 days from patch being released from OS provider.

e Tendered product software program (app) must have a patch update installed within 90 days upon an app vulnerability having been identified.

f Where a vulnerability whether in the OS, or the app of tendered device is being actively exploited by threat actors, the Successful Respondents must provide Participating Health Services:
(i) advice on introducing compensating control measures in avoiding vulnerability being exploited, and
(ii) a patch update within 48 hours rectifying the vulnerability.

g Endpoint protection solutions (anti-malware, application control, multi-factor authentication, etc.) must be permitted to be enabled and/or installed on tendered products.
(i) all endpoint protection solutions for the tendered product must be listed in the Product Catalogue,
(ii) endpoint protection event log should feed into Participating Health Service's cybersecurity system (i.e., SIEM),
(iii) details of the endpoint protection event log must be listed in the Product Catalogue
(iv) endpoint protection event logs should include:
I. a log of valid and invalid logins and logoffs
II. all security type processes

h All communication ports must be disabled by default, and only the ports required in specific install base to be activated via a secure login by the Participating Health Service's IT Department.

i Tendered product should have the capability to utilise multiple security certificates to hospital's IT network infrastructure.

j Tendered products must **not** have hardcoded or default passwords.

k Participating Health Services must be permitted to control the use of administrative level privileges on tendered products, if applicable.

l Remote Access to any tendered product must:

(i) be through a secure environment, and
(ii) be time-limited; access should time out after after 30 minutes, and
(iii) be encrypted, and
(iv) have unique user login credentials (both generic and group logins must not be used), and
(v) use strong user login authentication protocols, and
(vi) use the Participating Health Service's existing remote access gateway.

m Tendered devices that connect onto Participating Health Service's IT network, should have UL 2900 certification.

(i) If so, date when certification was acquired for tendered device?

Marking Information

a Each enteral feeding pump offered shall be marked legibly and permanently with:

(i) manufacturer's name or registered trademark;
(ii) model number or name specific to the particular design;
(iii) equipment serial number;
(iv) supply voltage, frequency and the current or power rating;
(v) fuse type and ratings;
(vi) control function labels, connector function labels;
(vii) hazard warnings (if applicable); and
(viii) electrical safety classifications.

Enteral Feeding Pumps Training Requirements

Operator Training

a Respondents shall provide the following information in their response.

(iii) full details of the operator training program including the duration and content

(iv) training package and training materials to facilitate the introduction may be offered electronically (e.g. online or CD/DVD) in addition to face-to-face.

b Training shall:

(i) be provided by personnel experienced in training;
(ii) include all aspects required for safe and effective pump operation including set-up and operation, troubleshooting, any safety and emergency procedures, and equipment cleaning;
(iii) occur on-site at the relevant hospital or health service;
(iv) other care settings including homes and community; and
(v) accommodate all relevant staff over a number of shifts.

c Successful Respondents shall ensure that service and/or educational personnel do not discuss or suggest other products or devices, other than those products or devices that they have been requested to support.

d Successful Respondents are expected to provide training to Participating Health Service users for the effective life of the equipment. This is to ensure that new employees have access to the manufacturers' level of training.

Training of Hospital Biomedical Engineers

e Respondents shall provide in their response:

(vi) full details, including curriculum and costs, of a recognised and approved manufacturer's technical training course on the pump/s offered.

f The training courses shall be of a recognised and approved manufacturer's technical training course (both state and national) on the pump/s offered and shall be equal to the course/s that the manufacturer's biomedical engineering staff is required to undertake.

g This training shall include, but not be limited to:

(vii) equipment operation;
(viii) inspection;
(ix) preventative maintenance and calibration;
(x) troubleshooting; and
(xi) corrective maintenance.

h Respondents shall provide the following information in their response:

(xii) the availability of loan pumps to cover extended repairs; and
(xiii) all costs and responsibilities associated with the provision of enteral feed pumps including spare parts, and specialist tools/equipment.

Software Updates

a In the event of a software update, the Respondent shall:

(i) provide such updates at no cost;
(ii) perform supplementary in-service training at no cost in the event that the software updates changes the operation or servicing of any equipment;

Service and Parts

a Respondents shall provide the following information in their response:

(i) the details of a full comprehensive service & maintenance contract including all costs;
(ii) the recommended frequency of preventive inspection/maintenance required to ensure quality control.

b A written report shall be provided to the relevant hospital representative for all services undertaken; details of test results must be available to PHS on request.

c Respondents shall guarantee the supply of all necessary spare parts, special tools and instruments, revised and tested software and all other technical data:

(i) for the duration of any resulting contract; and
(ii) for a minimum of five (5) years from the date that manufacturing is ceased for any tendered enteral feeding pump.

Successful Respondents must notify HPV and Participating Health Services of 'end of support' for all pumps and associated consumables and semi-consumables by the last date of manufacture. If an upgrade is required to ensure continuing support, the cost of this upgrade should not be more than 50% of the cost of a new replacement device (if the upgrade cost exceeds this amount, the device will be considered to be no longer supported).

Successful Respondents must notify HPV and Participating Health Services of 'end of manufacture' date for all pumps and associated consumables and semi-consumables at least twelve (12) months before the last date of manufacture.

d Where provided, diagnostic software shall:

(i) be supplied in the appropriate form e.g. compact discs, flash drives, together with one (1) copy of a user manual for such software;
(ii) not be copy-protected and shall be identical in all aspects with the software used by the manufacturer's field service personnel; and
(iii) be the latest updated and tested version available at the time of delivery.

e Any sets required for calibration or performance testing of enteral feeding pumps and accessories shall be supplied to Health Services at no cost regardless if the pumps are purchase outright or free-on-loan.

Warranty

a Enteral feeding pumps shall have a minimum warranty period of twelve (12) months.

b The Respondent shall provide the following information in their response:

(i) the period and extent of the warranty period, including all terms and conditions;
(ii) details of any preventative maintenance to be undertaken at the Respondent's expense during the warranty period, including frequency of service and nature of work; and
(iii) details of corrective maintenance undertaken at the Respondent's expense during the warranty period

Operating Manuals

Operator User Manuals

b For each type of enteral feeding pump offered, successful Respondents shall provide one complete copy of all operator user manuals for retention by hospital or health service based Biomedical Engineering services.

c Operating user manuals shall be in English and shall include but not be limited to:

(i) the comprehensive operating instructions;
(ii) all information necessary to operate the equipment in accordance with specifications and without exceeding safety limits;
(iii) recommended procedures for cleaning, battery charging, etc;
(iv) all error messages and troubleshooting procedures; and
(v) safety requirements and precautions.

d Enteral feeding pumps that are expected to be used in the home will come with training documentation for each device purchased. This level of documentation is to be aimed at the home user level.

Technical Maintenance Manual

d For each type of pump offered, successful Respondents shall provide one complete copy of all technical maintenance information necessary to carry out preventive inspection / preventative maintenance, and corrective maintenance to repair faulty or damaged pump. The technical documentation shall contain all details available to the manufacturer's service staff including tools required, available spare parts and costs for retention by hospital or health service based Biomedical Engineering services.

Acceptance Testing

a Successful Respondents shall provide the following information in their response:

(i) an overview of equipment acceptance/performance testing procedures carried out on pumps prior to delivery to the customer; and
(ii) any requirements and the availability of specialised, pump specific equipment required for testing the system, for the period of installation and acceptance testing.

Additional Information

e The following information shall be readily available for all contract users as hard and electronic copy:

(i) service and maintenance information including:
I. location and capability of the repair/service facility;
II. location and availability of spare parts and consumable items and their pricing;
III. the work address, telephone/fax numbers including mobile and e-mail contact, for service or maintenance; and
IV. the process for handling repairs/equipment breakdown.

(ii) Where applicable, all items must meet the requirements of the Australian Guidelines for the Prevention and Control of Infection in Healthcare (2010).
(iii) Upon request by Participating Health Services, successful Respondents must provide cleaning details for all reusable products prior to shipping the goods.
(iv) Upon request by Participating Health Services, successful Respondents must provide a full list of suitable cleaning products approved for use in Australia (TGA registered), including cleaning products maximum permissible concentration levels.
(v) Upon request by Participating Health Services, successful Respondents must provide a full list of non-suitable cleaning products.

Category 8 – Nutritional Meal Replacement Products

a A range of nutritional meal replacement products is required to meet clinical needs. This includes:

(i) for in-patients and as part of the Home Enteral Nutrition (HEN) program;
(ii) for adult and paediatric patients;
(iii) a full range of:

I. energy levels; and
II. flavours;

(iv) a full range of liquids, powders, puddings, bars and others which includes:

I. milk and non-milk type; and
II. with and without added fibre;

b Where the thickness of nutritional meal replacement products has been modified to facilitate consumption by patients with swallowing difficulties, Respondents are advised to offer these products in Category 3 - Thickened Beverages.

c IDDSI guideline levels and colour code on the packaging of thickened product on pre packed / ready made drinks and on the instructions for thickening powder

d Where nutrition meal replacement products are claimed to be nutritionally complete they shall provide 100% RDI for a male of 31-50 years of age in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" endorsed by the National Health and Medical Research Council on 9 September 2005.

e Where nutrition meal replacement products are tendered specifically for paediatric use and are claimed to be nutritionally complete, they shall provide 100% RDI for a child of 4-8 years of age in a defined volume, as described in "Nutrient Reference Values for Australia and New Zealand" as endorsed by the National Health and Medical Research Council on 9 September 2005.

f Where nutrition meal replacement products are presented in a powdered form, response information regarding nutritional content shall be based on the standard dilution and state the standard dilution volume in millilitres.

g For all nutrition meal replacement products offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) presentation type i.e. ready to drink, powder, concentrate, pudding, bar and others;
(iii) pack type i.e. glass bottle, plastic bottle, plastic wrap, tetrapak, can, plastic cup;
(iv) volume in millilitres; or
(v) weight in grams;
(vi) weight of scoop measure in grams (where applicable); and
(vii) flavour;

h For all nutrition meal replacement products offered, Respondents shall provide the following information on the Tender Response Worksheet:

(i) kilojoules provided per 100 ml or 100 grams of supplement and per unit;
(ii) the volume and cost per day to achieve 100% recommended daily intake (RDI) as described in clauses Category 8 - clauses b and c;

(iii) the price per kilojoule for each presentation, calculated on the base price tendered;
(iv) protein content, as a percentage of total energy provided, in grams per Litre and per unit;
(v) carbohydrate content, as a percentage of total energy provided, in grams per unit, and grams per Litre;
(vi) electrolyte content of sodium and potassium in milligrams per litre;
(vii) fibre content, in grams per litre and type of fibre;
(viii) where oral nutrition support products are offered for consumption by patients with specific medical conditions, list other specific nutrients in milligrams per Litre, required for the medical condition;
(ix) osmolality, in milliosmoles per kilogram water;
(x) presence or absence of:

I. lactose;
II. gluten.

(xi) presence of FODMAPs, specifically:

I. Fructose, Fructans, Raffinose;
II. Inulin;
III. Polyols-sorbitol, Xylitol.

(xii) glycaemic index, where available;
(xiii) whether the product is nutritionally complete;
(xiv) Kosher compliant;
(xv) Halal compliant;
(xvi) suitability for individuals on a vegan diet; and
(xvii) if packaging is resealable.

Additional Information

a The following information shall be available to all contract users via hard copy and electronic means:

(i) a complete nutritional composition profile for each product;
(ii) an ingredient composition list which identifies as a minimum, the source/s of protein, fats, carbohydrate and fibre included in each product; and
(iii) where oral nutrition support products are not nutritionally complete, list the deficiencies.
(iv) For each applicable product, provide a list of allergen type code, an allergen statement and allergen specification agency e.g. AM, AX, AY, ML – GSI – contain soy oil, milk proteins, soy lecithin etc.

Category 9 – Enteral Syringes and Accessories

a A full range of plastic enteral syringes (oral and tube) and tip caps is required to meet clinical needs. If the product is ENFit compatible, this should be stated on the product and/or packet. This includes:

(i) a full range of:
  I. sizes and volumes for adult and paediatric e.g. 0.5 - 100 millilitres;
  II. dead space volumes of low dose syringes;
  III. packaging sizing options e.g. box of 10, single individual packs, bulk packs;
  IV. clear and coloured plungers and clear and coloured barrels;
  V. non-sterile and sterile
  VI. ENFit and non ENFit products to be submitted in the appropriate subcategory

b All enteral syringes shall have:
(i) a tip configuration that is not compatible with a luer connection i.e. hypodermic needle or needleless IV access port;
(ii) bold scale graduations for easy visualisation that resist removal.

c All enteral syringes shall not have fractionated teaspoon measurements on the syringe barrel as the only scale of measurement.

d For each enteral syringe offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:
(i) brand name;
(ii) single use or multi-days use (to specify number of days)
(iii) volume in millilitres;
(iv) dead space volume of low dose syringes in millilitres;
(v) the scale of graduations e.g. 0.1 ml;
(vi) presence of a flange
(vii) colour of:
  I. barrel;
  II. plunger.
(viii) if enteral syringe is packaged with a tip cap.
(ix) non-sterile or sterile
(x) if TGA registered for oral and tube use

e Enteral Accessories shall include but not limited to the following:
(i) tip Caps;
(ii) adaptor caps for medication bottles;
(iii) mixing cannula/drawing up straws;
(iv) enteral feeding tube adaptors;
(v) cleaning brushes;
(vi) extension sets
(vii) extension tubing with and without Y-port/bifurcation

f For each accessory offered, Respondents shall provide the following information in the Product Description on the Tender Response Worksheet:

(i) brand name;
(ii) sizes;
(iii) clear or type of colours;
(iv) Non-sterile and sterile

Appendix 1 - Product List

Category		Subcategory	
1	Enteral Formula Products	1.01	< 1 Kcal/mL (<4.2 kJ/mL) Peptide or Amino acid based
		1.02	< 1 Kcal/mL (<4.2 kJ/mL) Other
		1.03	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Standard protein without added fibre
		1.04	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Standard protein with added fibre
		1.05	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) High protein without added fibre
		1.06	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) High protein with added fibre
		1.07	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Pediatric without added fibre
		1.08	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Pediatric with added fibre
		1.09	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Low sodium
		1.10	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Low carbohydrate, high protein
		1.11	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Peptide or Amino acid based
		1.12	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Other
		1.13	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) Standard protein without added fibre
		1.14	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) Standard protein with added fibre
		1.15	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) High protein without added fibre
		1.16	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) High protein with added fibre
		1.17	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) Pediatric without added fibre
		1.18	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) Pediatric with added fibre
		1.19	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) low carbohydrate, high protein
		1.20	1.5 - 1.9Kcal/mL (6.3 - 8.0 kJ/mL) other
		1.21	≥ 2.0 Kcal/mL (≥8.4 kJ/mL) Standard protein without added fibre
		1.22	≥ 2.0 Kcal/mL (≥8.4 kJ/mL) Standard protein with added fibre
		1.23	≥ 2.0 Kcal/mL (≥8.4 kJ/mL) High protein without added fibre
		1.24	≥ 2.0 Kcal/mL (≥8.4 kJ/mL) High protein with added fibre

Category		Subcategory	
		1.25	≥ 2.0 Kcal/mL (≥8.4 kJ/mL) Modified electrolyte
		1.26	Whole food ingredients
2	Oral Nutrition Support Products	2.01	< 1 Kcal/mL (<4.2 kJ/mL) Milky-type varieties without added fibre
		2.02	< 1 Kcal/mL (<4.2 kJ/mL) Milky-type varieties with added fibre
		2.03	< 1 Kcal/mL (<4.2 kJ/mL) Non-Milk varieties without added fibre
		2.04	< 1 Kcal/mL (<4.2 kJ/mL) Other
		2.05	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Milky-type varieties without added fibre
		2.06	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Milky-type varieties with added fibre
		2.07	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Non-Milk varieties without added fibre
		2.08	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Peptide or Amino acid based
		2.09	1 - 1.4 Kcal/mL (4.2 - 5.88 kJ/mL) Other
		2.10	1.5 - 2 Kcal/mL (6.3 - 8.0 kJ/mL) Milky-type varieties without added fibre
		2.11	1.5 - 2 Kcal/mL (6.3 - 8.0 kJ/mL) Milky-type varieties with added fibre
		2.12	1.5 - 2 Kcal/mL (6.3 - 8.0 kJ/mL) Non-Milk varieties without added fibre
		2.13	1.5 - 2 Kcal/mL (6.3 - 8.0 kJ/mL) Other
		2.14	> 2.0 Kcal/mL (> 8.4 kJ/mL) Milky-type varieties without added fibre
		2.15	> 2.0 Kcal/mL (> 8.4 kJ/mL) Milky-type varieties with added fibre
		2.16	Whole food ingredients
3	Thickened Beverages	3.01	Mildly thick fluid – IDDSI Level 2 Fruit Drink/Cordial Base
		3.02	Mildly thick fluid – IDDSI Level 2 Fruit Juice Base
		3.03	Mildly thick fluid – IDDSI Level 2 Milk-type Base
		3.04	Mildly thick fluid – IDDSI Level 2 Tea/Coffee Base
		3.05	Mildly thick fluid – IDDSI Level 2 Water
		3.06	Moderately thick fluid – IDDSI Level 3 Fruit Drink/Cordial Base
		3.07	Moderately thick fluid – IDDSI Level 3 Fruit Juice Base

Category		Subcategory	
		3.08	Moderately thick fluid – IDDSI Level 3 Milk-type Base
		3.09	Moderately thick fluid - IDDSI Level 3 Tea/Coffee Base
		3.10	Moderately thick fluid – IDDSI Level 3 Water
		3.11	Extremely thick fluid – IDDSI Level 4 Fruit Drink/Cordial Base
		3.12	Extremely thick fluid – IDDSI Level 4 Fruit Juice Base
		3.13	Extremely thick fluid – IDDSI Level 4 Milk-type Base
		3.14	Extremely thick fluid – IDDSI Level 4 Tea/Coffee Base
		3.15	Extremely thick fluid – IDDSI Level 4 Water
4	Thickening Agents	4.01	Thickening Agents
5	Modular Products	5.01	Glucose Polymers
		5.02	Protein Powder
		5.03	Fibre Powder
		5.04	Fat Emulsions
		5.05	Combination Products
6	Enteral Feed Administration Sets, Feeding Bags and Accessories	6.01	Pump-driven administration sets – with or without ENFit
		6.02	Gravity administration sets – with or without ENFit
		6.03	Feeding bags with integral administration sets – with or without ENFit
		6.04	Feeding bags without integral administration sets
		6.05	Accessories to facilitate the provision of enteral feed administration
7	Enteral Feeding Pumps	7.01	Volumetric Enteral Feeding Pumps
		7.02	Enteral Syringe Driver Feeding Pumps
8	Nutritional Meal Replacement Products	8.01	Nutritional Bars
		8.02	Nutritional Desserts
		8.03	Nutritional Shakes
		8.04	Nutritional Soups

Category		Subcategory	
		8.05	Nutritional Products - Others
9	Enteral Syringes and accessories	9.01	Enteral Syringes, non sterile - oral
		9.02	Enteral Syringes, sterile - oral
		9.03	Enteral Accessories - oral
		9.04	Enteral Syringes, non sterile - ENFit
		9.05	Enteral Syringes, sterile - ENFit
		9.06	Enteral Accessories - ENFit

Appendix 2 - Compliance Requirements

Australian Standards, Orders, Legislation and Regulations

a. It is the responsibility of the Respondent to ensure that all products offered comply with the Compliance Requirements listed below. This is not an exhaustive list, Respondents must ensure they comply with any other Compliance Requirements that are not listed below, this includes primary and subordinate instruments of the State and Commonwealth, and any relevant amendments, revisions or consolidations.

The relevant legislation for Enteral Feeding and Oral Nutrition Support products may include, but is not limited to:

(i) *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019)

STANDARD NUMBER	STANDARD NUMBER
Standard 3– Preventing and Controlling Healthcare Associated Infections	National Safety and Quality Health Service Standards NSQHSS) by Australian Commission on Safety and Quality in Health Care (ACSQHC).
ISO 80369-3	Small-bore connectors for liquid and gases in healthcare applications- Part 3: Connectors for enteral applications.
ISO 594-1	Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 1: General requirements.
ISO 594-2	Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment -- Part 2: Lock fittings.
ISO 7886-1	Sterile hypodermic syringes for single use -- Part 1: Syringes for manual use.
ISO 7886-2	Sterile hypodermic syringes for single use -- Part 2: Syringes for use with power-driven syringe pumps.
ISO 7886-4	Sterile hypodermic syringes for single use -- Part 4: Syringes with re-use prevention feature.
ISO 11135	Sterilisation of health care products – Ethylene oxide.
AS/NZS 4187	Cleaning, disinfecting and sterilizing reusable medical and surgical instruments and equipment, and maintenance of associated environments in health care facilities.
AS1079.4	Packaging of items (sterile) for patient care Part 4: Flexible Packaging Systems – for single use in hospitals.
EN11137	Sterilisation of health care product – Radiation.
AS/NZS 3200.1.0:1998 and IEC60601 is an equivalent	Medical Electrical Equipment – General requirements of safety – Parent Standard
AS/NZS 3200.2.24:1999 and IEC60601 is an equivalent	Medical electrical equipment - Particular requirements for safety - Infusion pumps and controllers

STANDARD NUMBER	STANDARD NUMBER
AS/NZS 3200.1.2.2005 and IEC60601 is an equivalent	Medical electrical equipment - General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests
Standard 3– Preventing and Controlling Healthcare Associated Infections	National Safety and Quality Health Service Standards NSQHSS) by Australian Commission on Safety and Quality in Health Care (ACSQHC).

Legislation

b. The references to the below legislation include any amendments, revisions or consolidations to those references.

(i) Therapeutic Goods Administration (1991), Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods

(ii) Therapeutic Goods Administration (2011), *Australian Regulatory Guidelines for Medical Devices.*

Guidelines and Other References

c. The references to the below guidelines include any amendments, revisions or consolidations to those guidelines.

(i) "Nutrient Reference Values for Australia and New Zealand" endorsed by the National Health and Medical Research Council on 9 September 2005;

(ii) IDDSI info: https://iddsi.org/Resources guidelines

(iii) NHMRC (2019), *Australian Guidelines for the Prevention and Control of Infection in Healthcare, Commonwealth of Australia*;

(iv) Therapeutic Goods Administration (1991), Therapeutic Goods Order No. 37: General Requirements for Labels for Therapeutic Goods;

(v) *Uniform Recall Procedure for Therapeutic Goods* (URPTG) (V2.1, February 2019). Therapeutic Goods Administration (2011), *Australian Regulatory Guidelines for Medical Devices;*

(vi) Therapeutic Goods Administration (2011), Australian Regulatory Guidelines for Medical Devices;

(vii) ISO 13485 – Medical Devices Quality Management System. References Table of Subcategory Definitions; and

(viii) Australian New Zealand Food Standards Code 1.2.9: Legibility Requirements.

Uniform Recall Procedure for Therapeutic Goods (URPTG) (V2.1, February 2019). Therapeutic Goods Administration (2011), *Australian Regulatory Guidelines for Medical Devices*

Appendix 3 - Reference Table of Subcategory Definitions

Nutrient	% Energy	Reference Range
Energy Level: <1.0 Kcal/100ml (<4.2kJ/100ml)		
Standard Protein, amino acids and peptides	13 – 16 %	
With Added Fibre		≥ 8 g/L
Energy Level: 1.0 – 1.4 Kcal/100ml (4.2 – 5.9 kJ/100ml)		
Standard Protein, amino acids and peptides	13 – 16 %	
Standard Protein, amino acids and peptides (Paediatric)	10 – 13 %	
High Protein	> 16 %	
Low Carbohydrate	< 40 %	
Low Sodium		< 20 mg/L
With Added Fibre		≥ 8 g/L
Energy Level: 1.5 – 1.9 Kcal/100ml (6.3-8.0kJ/100ml)		
Standard Protein, amino acids and peptides	14 – 18 %	
Standard Protein, amino acids and peptides (Paediatric)	10 – 13 %	
High Protein	> 18 %	
Low Carbohydrate	< 40 %	
With Added Fibre		≥ 8 g/L
Energy Level: 2 Kcal/100ml or greater (≥8.4 kJ/100ml)		
Standard Protein, amino acids and peptides	14 – 18 %	
High Protein	> 18 %	
Low Protein	< 10 %	
Modified Electrolyte		Na < 45 mg/L K < 40 mg/L P < 750 mg/L
With Added Fibre		≥ 8 g/L