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24 October 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF FEEDING DEVICES AND/OR SPECIAL FOODS DELIVERED ENTERALLY OR ORALLY

PHARMAC invites proposals for the supply of Feeding Devices and/or Special Foods products to New Zealand DHB hospitals and DHB funded associated services.

Please note that the procurement process set out in this document is also stage one of a potential two-stage procurement process for the supply of Special Foods in the community. In this respect, in the event that a supplier's Special Food product is listed in Part II of Section H of the Pharmaceutical Schedule, through a PHARMAC national listing agreement (as a result of stage one or otherwise), at the time that stage two is commenced, a supplier shall be eligible to submit a proposal in response to any procurement process issued by PHARMAC as part of stage two.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 sets out the background to the RFP and the range of products included and types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 specifies the information and evidence you need to include in your proposal;
- Schedule 4 and 5, and Attachments 01, 02, 03, 05 and 06 contain the forms in which you are to provide the details of your proposal;
- Attachment 04 contains the PHARMAC standard terms and conditions to list the Feeding Devices and/or Special Foods on the Pharmaceutical Schedule; and
- Attachment 07 contains the pdf version of the Special Foods Part II of Section H listings as of October 2018.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4pm (NZST), Friday 14 December 2018**.

If you have any questions about this RFP, please post these on GETS.

We look forward to receiving your proposal.

Yours sincerely

A handwritten signature in black ink, appearing to be 'LW', with a long horizontal flourish extending to the right.

Lisa Williams
Director of Operations

Schedule 1: Products, background to RFP and types of proposals sought

1. Products

PHARMAC is interested in considering proposals from suppliers of Feeding Devices and/or Special Foods for use in New Zealand District Health Board Hospitals and their funded associated services (**DHB Hospitals**).

Suppliers should also note the procurement process set out in this document is stage one of a potential two-stage procurement process for the supply of Special Foods in the community.

In this RFP, the following definitions shall apply:

“Feeding Devices” means medical devices used to deliver or support the delivery of Special Foods into the body via an oral or enteral route, which fall under two groups:

- **Non-Dedicated Feeding Devices:** includes Feeding Devices not dedicated to feeding equipment; and
- **Feeding Equipment and Associated Devices:** includes feeding equipment, associated spare parts, accessories and dedicated consumable medical devices.

The Feeding Devices that are in scope of this RFP are stated in Schedule 1, clause 5.1(a) below.

“Special Foods” means those products that aid in the dietary management of people with certain diseases, disorders or medical conditions, which fall under two groups:

- **Enteral Special Foods** intended to be consumed via the enteral feeding route only; and
- **Oral Special Foods** intended to be consumed orally but may also be consumed via the enteral feeding route.

The Special Foods that are in scope of this RFP are stated Schedule 1, clause 5.2(a) below.

“Comparable Special Food Product” means a Special Food that is determined, at the sole discretion of PHARMAC, to meet the same clinical need/intended use as another currently funded Special Food, but where the exact presentation of the Comparable Special Food Product is not currently listed in Part II of Section H of the Pharmaceutical Schedule.

“National Contracts” means national Pharmaceutical Schedule listing agreements between PHARMAC and suppliers for either Feeding Devices or Special Foods.

2. RFP background

2.1 PHARMAC’s role in Feeding Devices and Special Foods

PHARMAC’s role in Feeding Devices

The Feeding Devices in the scope of this RFP are classified as medical devices. In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the DHBs. In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC.

Under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to act consistently with the Pharmaceutical Schedule.

PHARMAC is working towards applying the full PHARMAC model to medical devices in a carefully planned way. PHARMAC started by contracting for products that DHB hospitals already buy and listing these in Part III of Section H of the Pharmaceutical Schedule. To date, contracting has primarily been done through open RFPs for National Contracts.

Ultimately, PHARMAC will make choices about which new medical devices will be introduced for use in DHB Hospitals, that will get the best health outcomes from within a set amount of funding. This is similar to the work we already do in deciding which medicines may be given in DHB Hospitals. As part of the transition from national contracting to a more mature management phase, there will be a point in the future where DHB Hospitals can only purchase medical devices that are listed on the PHARMAC Pharmaceutical Schedule. When that occurs, any supplier wishing to have their medical devices listed on the Pharmaceutical Schedule may have to wait for a PHARMAC process (such as a relevant procurement process) before they can sell to DHB Hospitals.

PHARMAC's role in Special Foods

PHARMAC has been managing supply of, investment in, and government expenditure on, Special Foods subsidised for use in the community setting for more than twenty years; as reflected in the listings in Section D of the Pharmaceutical Schedule.

Since July 2013, PHARMAC has been managing the supply of, and investment in, new Special Foods for DHB Hospitals, as reflected in the listings in Part II of [Section H of the Pharmaceutical Schedule](#). From 1 July 2018, PHARMAC was given responsibility for managing all public expenditure on medicines and Special Foods, whether they are used in the community or in a DHB Hospital. This means that DHBs' expenditure on medicines and Special Foods, which was once split between the Combined Pharmaceutical Budget (CPB) managed by PHARMAC and DHB Hospitals' own budgets for medicines and Special Foods, is now all part of PHARMAC's CPB.

2.2 Reasons for running this RFP

Feeding Devices

The Feeding Devices category is the latest category of medical devices that PHARMAC has commenced procurement activity in and intends to establish National Contracts with suppliers to secure the supply of and nationally consistent pricing for Feeding Devices used by DHB Hospitals.

Special Foods

To ensure appropriate longer-term funding mechanisms (through the CPB) are in place for Special Foods used in DHB Hospitals, PHARMAC is working to ensure that Special Foods used by DHB Hospitals are subject to National Contracts.

Due to the relationship between some Feeding Devices and Special Foods, PHARMAC considers that it is appropriate to align procurement processes for securing National Contracts for Feeding Devices and Special Foods.

2.3 Impacts of RFP

Feeding Devices

PHARMAC intends to establish National Contracts with suppliers to secure the supply of Feeding Devices used by DHB Hospitals. It is expected that Feeding Devices subject to a National Contract will be listed in [Part III of Section H of the Pharmaceutical Schedule](#). The National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent Feeding Devices would be listed, where appropriate.

Special Foods

Stage One of Procurement Process for Special Foods

PHARMAC intends to establish revised and/or additional National Contracts with suppliers to secure the supply of Special Foods used by DHB Hospitals. It is expected that Special Foods subject to a National Contract will be listed in Part II of Section H of the Pharmaceutical Schedule. The National Contracts would not be exclusive, and it is likely that multiple suppliers of Special Foods would be listed, where appropriate. PHARMAC is interested in proposals for supply of Special Food types:

- currently funded as listed in Part II of Section H of the Pharmaceutical Schedule (see Attachment 07); and
- Comparable Special Food Products.

A supplier(s) that currently has a National Contract in place with PHARMAC for supply of its Special Food product(s) in DHB Hospitals can submit a proposal(s) to form a revised National Contract for those and/or additional Special Food product(s) to be considered through this RFP process.

Special Food presentations that are currently listed in Part II of Section H without a PHARMAC National Contract in place would either be:

- (a) listed subject to National Contracts formed as a result of this RFP; or
- (b) their continued listing may be reviewed and the product(s) may be delisted if no National Contract is entered into.

Only Special Foods listed in Part II of Section H of the Pharmaceutical Schedule would be funded (through the CPB) for use in DHB Hospitals.

Stage Two of Procurement Process for Special Foods

Following the outcome of Stage One (described above), PHARMAC may, at its discretion, determine whether to implement a second procurement stage for community supply of Special Foods.

Following Stage One, suppliers whose Special Food product is listed in Part II of Section H of the Pharmaceutical Schedule, subject to a National Contract, will be eligible to

submit a proposal in response any procurement process issued by PHARMAC as part of stage two.

For the avoidance of doubt:

- Stage Two would be a separate process to this RFP and, if Stage Two proceeds, eligible suppliers will be notified accordingly; and
- Participation in Stage One is not mandatory to be eligible to participate in Stage Two; provided that a supplier's Special Food(s) is listed in Part II of Section H of the Pharmaceutical Schedule through a National Contract at the time that Stage Two is commenced.

3. Expected outcome of the RFP

- (a) PHARMAC intends to establish National Contracts with suppliers in the Feeding Devices and Special Foods categories to:
- (i) list a range of Feeding Devices available for use by DHB Hospitals in Part III of Section H of the Pharmaceutical Schedule, subject to National Contracts;
 - (ii) ensure that a range of Special Foods for use by DHB Hospitals is listed in Part II of Section H of the Pharmaceutical Schedule subject to National Contracts.
 - (iii) secure future supply of Feeding Devices and Special Foods for DHB Hospitals at nationally consistent competitive prices;
 - (iv) ensure access to an appropriate level of clinical support, and education, training and associated materials, for relevant DHB Hospital health professionals;
 - (v) ensure access to an appropriate level of technical support for relevant DHB Hospital personnel;
 - (vi) engage and establish relationships with new and current suppliers of Feeding Devices and Special Foods; and
 - (vii) move commercial arrangements for Feeding Devices and Special Foods used in DHB Hospitals into a national framework administered by PHARMAC, to create better health outcomes for patients within the funding available.
- (b) This RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the Feeding Devices and Special Foods are contracted for and (as applicable) listed in Section H of the Pharmaceutical Schedule. PHARMAC recognises that the use of Feeding Devices and Special Foods touches a wide group of patients and health professionals. Therefore, in the event that a National Contract(s) is entered into with a supplier(s) as an outcome of this RFP process, and the Feeding Devices and Special Foods are, or continue to be, listed in Section H of the Pharmaceutical Schedule:
- (i) the listing shall be non-exclusive and will include pricing and details of the Feeding Devices and Special Foods;

- (ii) multiple suppliers of Feeding Devices and Special Foods may be listed, where appropriate;
- (iii) the resultant National Contract will be between the supplier and PHARMAC. DHBs will be able to purchase under the terms of the National Contract, effective from the listing date, and will not be required to individually approve the National Contract for it to come into effect;

Feeding Devices

- (iv) purchase of Feeding Devices will be at the discretion of each DHB Hospital; however, where they choose to purchase Feeding Devices listed in the Pharmaceutical Schedule, DHB Hospitals must purchase the Feeding Devices under the terms and conditions of the PHARMAC National Contract(s);

Special Foods

- (v) DHB Hospitals would continue to be required to provide access to Special Foods listed in Part II of Section H of the Pharmaceutical Schedule, subject to the relevant current access criteria as set out in the Pharmaceutical Schedule. DHB Hospitals would be required to purchase Special Foods under the terms and conditions either of the PHARMAC National Contract(s) formed as a result of this RFP or otherwise.

4. Types of proposals sought

4.1 Proposals sought

- (a) Suppliers may submit separate proposals for Feeding Devices and/or Special Foods and it is not a requirement that a supplier submits proposals for both Feeding Devices and Special Foods. However, suppliers should note the additional types of proposals allowed, as described in clause 4.2 below, in respect of product bundling.
- (b) Suppliers **MUST** submit proposals for National Contracts for Feeding Devices and/or Special Foods with pricing to be published on the Pharmaceutical Schedule and no volume/spend commitments.
- (c) Suppliers wishing to submit a proposal **MUST** only submit products once either as:
 - (i) a Non-Dedicated Feeding Devices product;
 - (ii) a Feeding Equipment and Associated Devices product;
 - (iii) an Enteral Special Foods product; or
 - (iv) an Oral Special Foods product.
- (d) Proposals must meet all the mandatory information and evidence requirements as set out in:

Schedule 4 and Attachments 01, 02, 05, 06 (Feeding Devices proposals)

Schedule 5 and Attachments 03, 05, 06. (Special Food proposals)

- (e) Proposals for Feeding Devices may be submitted on the basis that there may be incremental changes or upgrades for the proposed Feeding Devices during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHB Hospitals within a reasonable timeframe.
- (f) PHARMAC is not willing to consider 'out of scope' products as stated in Schedule 1, clause 5.1(b) and 5.2(b).

4.2 Additional types of proposals PHARMAC would be willing to consider:

- (a) Proposals for Feeding Devices with additional pricing model options.
- (b) Proposals with alternative options to access Feeding Equipment and Associated Devices, including outright purchase, lease, rent, rent to buy and supplier provided equipment options¹;
- (c) Proposals for Special Foods that include rebates (including volume-based rebates) or other expenditure risk-sharing mechanisms.
- (d) Proposals for Special Foods that include future price reductions, such as for Special Food markets where uptake may be unknown.
- (e) Proposals for Special Foods that includes a period of protection from Pharmaceutical Schedule delisting.
- (f) Proposals for Comparable Special Food Products:

PHARMAC would also be willing to consider proposals for Special Foods not currently listed in Part II of Section H of the Pharmaceutical Schedule. However, to be progressed through this RFP they would need to be considered by PHARMAC to be Comparable Special Food Products. PHARMAC is likely to seek clinical advice prior to determining whether a product is considered a Comparable Special Food Product

- (g) Proposals for alternative pricing options that involve product bundling, provided that the bundling **MUST** be within the defined groups below:
 - (i) **Group 1:** Non-Dedicated Feeding Devices
 - (ii) **Group 2:** Feeding Equipment and Associated Devices:
 - (iii) **Group 3:** Enteral Special Foods.
 - (iv) **Group 4:** Oral Special Foods.

¹ In the context of this RFP, supplier provided equipment means when the DHB Hospital purchases an agreed number of consumables or pays a different agreed price for consumables, in return for the supplier providing the associated piece of equipment at no charge to the DHB Hospital (this includes 'free on loan' models).

Suppliers that submit bundling alternative pricing options for Group 2 and Group 3 would also be eligible to submit a proposal for bundled alternative pricing for:

- (v) **Group 5:** Group 2 + Group 3.

For the avoidance of doubt, PHARMAC, at its sole discretion, may determine whether to select any or none of the alternative pricing options stated above.

Please note that complex additional pricing models that would pose a significant administrative burden to PHARMAC or DHB Hospitals are unlikely to be progressed.

4.3 Types of proposals PHARMAC would not be willing to consider:

- (a) Proposals for Special Foods that involve fluctuating pricing, such as tier pricing proposals.
- (b) Proposals for (or that include) unfunded non-Comparable Special Food Products.

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

5. Scope

5.1 Feeding Devices

- (a) **In scope**

PHARMAC is willing to consider proposals for Feeding Devices for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals and the following products are considered ‘**in scope**’ of this RFP:

(i) Feeding Equipment and Associated Devices:		
Equipment + Spare Parts	Dedicated Accessories	Dedicated Consumables
Including but not limited to: <ul style="list-style-type: none"> • Enteral feeding infusion pumps (including syringe pumps only intended to be used for enteral feed delivery) and associated spare parts. • Other Feeding Equipment and associated spare parts. 	Including but not limited to: <ul style="list-style-type: none"> • pump stands/poles; • pump chargers; • pump clamps; • ambulatory-pump backpacks/transport devices. 	Including but not limited to: <ul style="list-style-type: none"> • adaptors; • giving sets; • drainage bags; • irrigation devices; • enteral-nutrition bags or containers; • connectors or extensions; • tube securing devices; • cleaning/un-clogging devices; • feeding set valves; tubing sets.

(ii) Non-Dedicated Feeding Devices	
Individual Feeding Devices	Feeding Device Kits or Sets
<p>Including but not limited to:</p> <ul style="list-style-type: none"> • Adaptors: <ul style="list-style-type: none"> ○ Feeding set adaptors ○ Funnel adaptors ○ Transitional adaptors ○ Y-port adaptors • Bags or containers for hanging decanted liquid or powdered feeds; • Drainage bags, and tubes; • Enteral tube cleaning / unblocking devices • Feeding administration devices: <ul style="list-style-type: none"> ○ extension tubing; ○ accessories such as clamps connectors, and bag spikes; • Feeding tubes (for short and long-term use): <ul style="list-style-type: none"> ○ Nasogastric feeding tubes; ○ duodenostomy (tubes); ○ gastrostomy tubes (including button fit devices); ○ jejunostomy tubes (including button fit devices) • Feeding tube accessories: <ul style="list-style-type: none"> ○ feeding tube fixation devices • Feeding stoma devices: <ul style="list-style-type: none"> ○ Dilators; ○ measuring devices; ○ seals/ stoppers • Oral and/or enteral syringes: <ul style="list-style-type: none"> ○ single use; ○ reusable • Oral and/or enteral syringes accessories: <ul style="list-style-type: none"> ○ Adaptors; ○ Caps; ○ Filters; ○ feeding straws 	<p>Including but not limited to:</p> <ul style="list-style-type: none"> • Dilator kits; • Extension-tube sets; • Gastrointestinal anchor kits; • Giving sets; • Irrigation sets • Naso-jejunal feeding tube placement kits: <ul style="list-style-type: none"> ○ Radiologically placed with: <ul style="list-style-type: none"> ▪ Tip-weighted devices ▪ Directionable devices ○ Endoscopically placed: <ul style="list-style-type: none"> ▪ through-the-scope; ▪ those requiring direct placement ○ Guided using magnetic devices • Percutaneous endoscopically placed tubes kits: <ul style="list-style-type: none"> ○ Percutaneous Endoscopic Gastrostomy (PEG) Kits; ○ Percutaneous Endoscopic Gastro-jejunostomy (PEG-J) Kits; • Percutaneous radiologically placed tubes kits: <ul style="list-style-type: none"> ○ Radiologically Introduced Gastrostomy (RIG); ○ Radiologically Introduced Jejunostomy (RIJ) • Surgically placed jejunostomy tube kits. • Surfactant kits

(b) **Out of scope**

PHARMAC is not willing to consider proposals for any other Feeding Device products for this RFP, including but not limited to the following products as identified as **'out of scope'** for this RFP:

- (i) Infusion pumps which have multiple infusion route capabilities including enteral feeding (for example also can provide intravenous, and subcutaneous infusions).
- (ii) Infant Feeding Devices such as:
 - Baby bottles;
 - Breast pumps;
 - Breast shells or shields;
 - Breast pump kits;
 - Breast feeding pillows;
 - Breast pump accessories or accessory kits;
 - Breast milk warmers; and
 - Nursing bottle nipples

5.2 Special Foods

(a) In scope

PHARMAC is willing to consider proposals for Special Foods for listing in Section H of the Pharmaceutical Schedule for use by DHB Hospitals and the following products are considered **'in scope'** of this RFP:

- (i) Special Foods currently subject to a National Contract and listed in Section H of the Pharmaceutical Schedule as stated in Attachment 07;
- (ii) Special Foods currently not subject to a National Contract, but listed in Section H of the Pharmaceutical Schedule as 'example brands' as stated in Attachment 07; and
- (iii) Comparable Special Food Products, that are comparable to listed Special Foods as stated in Attachment 07.

(b) Out of scope

PHARMAC is not willing to consider proposals for any other Special Foods, including, but not limited to, the following products as identified as **'out of scope'** for this RFP:

- (i) intravenous nutrition products;
- (ii) micronutrient (vitamin and mineral) supplements;
- (iii) gluten free foods such as gluten-free baking powder and gluten-free pasta.

Schedule 2: RFP process

PHARMAC expects to follow the process set out below in the sequence indicated.

1. Submission

- (a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.
- (b) All proposals must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single submission.
- (c) All proposals must be submitted to PHARMAC via GETS no later than **4 pm** (New Zealand standard time) on **Friday 14 December 2018**. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.
- (d) You cannot withdraw your proposal, once submitted, while the RFP process is continuing.
- (e) If you have any enquiries about this RFP, you should submit them via GETS (www.gets.govt.nz). The close date for questions is **4 pm, Wednesday 21 November 2018**.

2. Evaluation

- (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s).
- (b) The Evaluation Committee will evaluate proposals in light of PHARMAC's statutory objective, which is "to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment and from within the amount of funding provided". In doing so, the Evaluation Committee will be guided by the Factors for Consideration (**FFC**) that form part of PHARMAC's current Operating Policies and Procedures, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.
- (c) The information considered during the evaluation process will be at the discretion of the Evaluation Committee however it will include:
 - (i) information and evidence provided by you in accordance with Schedules 3, 4 and 5 of this RFP;
 - (ii) your ability to legally supply the proposed products to New Zealand DHB Hospitals;
 - (iii) your ability to provide the appropriate level of product management and support, including but not limited to:

- (A) clinical training and education in the use and handling of products;
 - (B) training and support in equipment cleaning and maintenance (where applicable);
 - (C) technical support, where applicable;
 - (D) information for patients, where applicable;
 - (E) supply chain to support sustainable provision of products;
 - (F) equipment tracking, maintenance and repair (where applicable); and
 - (G) transition support;
- (iv) your ability to ensure continuity of supply to DHB Hospitals including but not limited to:
- (A) stock management;
 - (B) supply chain;
 - (C) identification and management of key risks to continuity of supply;
- (v) DHB Hospital usage and financial impact, where applicable;
- (vi) other major markets for the proposed products, where applicable;
- (vii) provision of reference sites, where applicable;
- (viii) any advice received from relevant clinicians and/or DHB Hospital staff; and
- (ix) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).
- (d) Each proposal will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the proposal, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your proposal excluded at the evaluation stage.
- (e) PHARMAC is not bound to select the lowest priced proposal or any proposal.

3. **PHARMAC may request further information**

- (a) PHARMAC may request such further information as it considers necessary from or about you for the purposes of clarifying or evaluating your proposal, including (but not limited to) detailed information about your company structure, credit status and any other relevant company information.
- (b) If PHARMAC requests further information from or about you, it is not obliged to request the same or any other information from or about any other party provided that, in PHARMAC's judgment, this would not be unfair to any other party.

4. **Negotiation**

- (a) PHARMAC may negotiate with the submitter(s) of one or more preferred proposals; in the latter case, whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.
- (b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions to list medical devices on the Pharmaceutical Schedule, which are available as a download (Attachment 04) from GETS, will apply. Please note that that PHARMAC's standard terms and conditions may be modified in the context of Special Foods.
- (c) You **must** complete and submit Attachment 05 of this RFP as part of your proposal by declaring that you have read and understood PHARMAC's standard terms and conditions for the supply of medical devices, and where you disagree with any of the standard terms and conditions, include comments about the terms and conditions you would seek to amend during any negotiation.
- (d) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiation with you on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.
- (e) PHARMAC may negotiate and enter into a provisional National Contract with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.
- (f) If PHARMAC and the supplier(s) are unable to reach a provisional National Contract within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. **Consultation and approval**

- (a) Any provisional National Contract will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on Board approval (or approval by the Board's delegate acting under delegated authority).
- (b) PHARMAC will not consider any counter-offers received during consultation.
- (c) The provisional National Contract and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with the FFC in PHARMAC's then current Operating Policies and Procedures.
- (d) If the Board or its delegate does not approve the provisional National Contract, then PHARMAC may initiate negotiations for a provisional National Contract with any other supplier(s).
- (e) The RFP process will be complete once PHARMAC has notified suppliers of either:

- (i) the Board's or its delegate's decision to accept a negotiated National Contract; or
- (ii) the termination of the RFP process.

6. Miscellaneous

- (a) PHARMAC reserves the right, having regard to probity principles:
 - (i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;
 - (ii) not to accept any proposal;
 - (iii) to seek clarification of any proposal;
 - (iv) to meet with any supplier in relation to its proposal;
 - (v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;
 - (vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional National Contract is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;
 - (vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit; and
 - (viii) to re-advertise for proposals.
- (b) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional National Contract is accepted by PHARMAC's Board or the Board's delegate.
- (c) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC, with a view to influencing the outcome of this RFP process.
- (d) You must pay your own costs for preparing and submitting your proposal.
- (e) You must limit the information provided to that which is requested in Schedules 3, 4 and 5 and Attachments 01, 02, 03, 05 and 06, and provide it succinctly and clearly. Please do not provide brochures or additional information (e.g. PEHNZ forms and presentations) unless specifically requested to do so.

- (f) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.
- (g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP.
- (h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of Feeding Devices and/or Special Foods by PHARMAC's apparent acceptance, and instead a separate agreement needs to be negotiated.
- (i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.
- (j) It is possible that more than one supplier may be awarded a National Contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Feeding Devices and Special Foods or restricts the terms that may be agreed with any other supplier.
- (k) PHARMAC will consider your proposal and information exchanged between the parties in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs ("**Confidential Information**"). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:
 - (i) pursuant to the Official Information Act 1982; or
 - (ii) in the course of consultation on a provisional National Contract entered into with a supplier; or
 - (iii) in publicly notifying any approval by the PHARMAC Board of that National Contract; or
 - (iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

PHARMAC may consult with you before deciding whether to disclose Confidential Information for the purposes described in sub-clauses (i) to (iv) above. You acknowledge, however, that it is for PHARMAC to decide, in its absolute discretion, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

7. **Anticipated timetable**

- (a) Following receipt of proposals, PHARMAC anticipates:
 - (i) the PHARMAC internal Evaluation Committee evaluating proposals **from February/March 2019;**

- (ii) negotiating with submitter(s) of one or more preferred proposals **from April/May 2019**;
- (iii) consulting on any provisional National Contracts **from June 2019**; and
- (iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts **from August 2019**.

provided that the above time frames are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

- (b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is **1 October 2019**.

8. **Governing Law**

The RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Information and evidence to be included in your proposal

Please include the following information and evidence in your proposal. Proposals that do not include mandatory information and evidence will only be considered at PHARMAC’s discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

Document	Evidence / Information
Attachment 01: Feeding Devices Product List	You must complete all fields in Attachment 01 for each proposed product. If you consider a field not applicable you must state “NA”.
WAND	You must be able to legally supply your proposed products to New Zealand DHB Hospitals as evidenced by WAND registration number. Please do not provide WAND documents. Where WAND is not applicable to a proposed product you must state the reason why it is not applicable.
International compliance	You must provide evidence of international compliance certification. The name of the certifying body and certificate number must be included in Attachment 01 for each proposed product and you must attach a copy of all relevant certificates.
GS1 (GTIN) and UNSPSC	It is desirable that you provide GTIN and UNSPSC codes for each proposed Feeding Device at the time of submitting your proposal.
DHB usage data	If you are currently supplying a proposed Feeding Device to any DHB Hospital, you must provide combined volume and cost information for all DHB Hospitals for the period [1 October 17 - 30 September 18 or all line items submitted in Attachment 01 You must also include any sales to DHB Hospitals via logistics providers.
Non-DHB reference sites	If you are not currently supplying a proposed Feeding Device to any DHB Hospital, you must provide three clinical reference sites for that product range. It is desirable that the clinical reference sites you provide use the proposed Feeding Device products in similar clinical settings as DHB Hospitals would use them.
Attachment 02: Feeding Devices Financial analysis of your proposal	If any of your proposed products are currently supplied to DHB Hospitals (contracted and non-contracted) you must provide a detailed financial impact analysis of your proposal for each DHB based on recent usage; to be attached as an Excel spreadsheet. A preferred format is included in Attachment 02. You may provide your financial analysis in an alternative format

Document	Evidence / Information
	<p>provided it includes the following for each DHB and each proposed product:</p> <ul style="list-style-type: none"> (a) the product description, code and brand; (b) your current (as at October 2018] price offered to each DHB; (c) your proposed price (as included in Attachment 01); (d) DHB Hospital sales volume (including via logistics providers) for 1 October 17 - 30 September 18 projected annual cost to each DHB at current price <i>current price (b) x DHB sales volume (d)</i> (e) projected annual cost to each DHB at proposed price <i>proposed price (c) x DHB sales volume (d)</i> (f) projected financial impact for each DHB of your proposal <i>projected annual cost at proposed price (f) – projected annual cost at current price (e)</i>
Attachment 03: Special Foods Products spreadsheet	You must complete all fields in Attachment 03 for each proposed product. If you consider a field not applicable you must state “NA”.
GS1 (GTIN)	It is desirable that you provide GTIN codes for each proposed Special Foods at the time of submitting your proposal.
DHB usage data	If you are currently supplying a proposed Special Foods to any DHB Hospital, you must provide combined volume and cost information for all DHB Hospitals for the period 1 October 17 - 30 September 18 or all line items submitted in Attachment 03 . You must also include any sales to DHB Hospitals via logistics providers.
Nutritional Information	Full nutritional product datasheet or equivalent.
Attachment 05: Acceptance of PHARMAC’s standard terms and conditions	You must complete, sign and date the declaration set out in Attachment 05. You must indicate whether you agree or disagree with PHARMAC’s standard terms and conditions for medical devices for your proposed products. If you do not agree with any of PHARMAC’s standard terms and conditions for medical devices for your proposed

Document	Evidence / Information
	<p>products you must provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 05.</p> <p>If you would like PHARMAC to consider any other terms and conditions that are not included in PHARMAC's standard terms and conditions, you must provide details and justification in Table 2 of Attachment 05.</p>
<p>Attachment 06: Document and information checklist</p>	<p>You must complete the document and information checklist set out in Attachment 06.</p> <p>You must note any additional attachments not specifically listed in the box provided in Attachment 06.</p>
<p>Schedule 4: Proposal form for Feeding Device suppliers</p>	<p>You must complete all sections of Schedule 4. If you consider a section to be not applicable, you must state "NA".</p> <p>The response you provide in each section must be comprehensive and relevant to the information that has been requested, and you must include relevant attachments.</p>
<p>Schedule 5: Proposal form for Special Food suppliers</p>	<p>You must complete all sections of Schedule 5. If you consider a section to be not applicable, you must state "NA".</p> <p>The response you provide in each section must be comprehensive and relevant to the information that has been requested, and you must include relevant attachments.</p>

Schedule 4: Proposal Form for Feeding Device Suppliers

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[Supplier to insert date]

Director of Operations
PHARMAC
c/- Chloë Dimock
Device Category Manager

By electronic transfer using GETS (www.gets.govt.nz)

Dear Sir/Madam

Proposal for the supply of Feeding Devices

In response to your request for proposals (RFP) dated **24 October 2018** we put forward the following proposal in respect of the supply of Feeding Devices.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 01, 02, 05 and 06 as part of your proposal.

Set out below is further information in support of our proposal.

1. Company details	
Full legal trading name in New Zealand	
Address	
Phone	
Email	
Facsimile	
2. Contact person (s) for this RFP	
Name, Position	
Phone	
Mobile	
Email	

3. Executive summary	
Proposal summary Include: <ul style="list-style-type: none"> • overview of products and services • benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal 	Maximum 500 words

4. Information about our company, contracts and markets	
NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.	
Company information	
(a) Type of entity (legal status) Eg, a New Zealand registered limited liability company	
(b) City and country of residence of our company e.g. Sydney, Australia	
(c) Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. <u>Attach</u> Organisational Chart.	
(d) Total number of New Zealand based staff Include FTE for each section (eg.5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration)	
(e) Established locations within New Zealand	

<p>Include function of each location (eg. head office, warehouse).</p>	
<p>(f) If you are currently not based in New Zealand:</p> <p>Do you intend to establish a company location(s) here?</p> <p>How would you manage the needs of your New Zealand DHB Hospital customers from where you are located?</p> <p>N/A if New Zealand based</p>	
<p>(g) Company ownership</p> <p>State ownership (eg. public ownership)</p> <p>Include:</p> <ul style="list-style-type: none"> • If your organisation is controlled by an overseas entity; • if your organisation is part of a group of entities owned by a 'parent' company-please outline your relationship with these companies • names and percentage shareholdings of the major shareholders and directors 	
<p>(h) Evidence of financial stability and ability to cover financial liabilities</p> <p>Attach supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter).</p>	
Contracts and markets	
<p>(i) Current contracts and standing agreements in place with DHB Hospitals or organisations acting on their behalf</p>	

<p>Include all DHB contracts, not just those relevant to this RFP.</p> <p>For each provide:</p> <ul style="list-style-type: none"> parties to the agreement contract reference number type of agreement (national/regional/DHB specific) range of products covered expiry date other relevant information (eg. now standing agreement after contract expiry) <p>Can be provided as an attachment, note name of attachment in response column.</p>	
<p>(j) Products not included</p> <p>Include any Feeding Devices currently supplied to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this. Please identify:</p> <ul style="list-style-type: none"> If this is due to manufacture discontinuation and when the expected discontinuation date is; If superseding products have been proposed in your proposals instead; <p>If you are currently providing transitional adaptors (for DHB Hospital adoption of ISO standard 80369-3:2016 for small bore connectors for enteral applications) to New Zealand DHB Hospitals and have not proposed these products in your proposal:</p> <ul style="list-style-type: none"> Are these products being discontinued by the manufacturer? How long will these adaptors remain available for DHBs still undergoing the transition to adopting ISO standard 80369-3:2016 enteral feeding. 	
<p>(k) Healthcare customers in New Zealand</p> <p>Include DHB Hospital and private healthcare organisations for the proposed Feeding Devices and other Medical Devices (please give a short summary for these, including type of Medical Devices supplied)</p>	
<p>(l) Information on other major markets for proposed product ranges.</p>	<p><i>NB. Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.</i></p>

For each product range include: <ul style="list-style-type: none"> • type of market (eg. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information 	
(m) Information about clinical reference sites Provide information about each reference site included in Attachment 01 or 02 including the location and relevant clinical settings in which the product is used (eg. inpatient care, outpatient clinics, home use).	<i>NB. Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.</i>
(n) Other relevant company and market information	

5. Information about our ability to manage and support our proposed Feeding Devices		
NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.		
Training and Education		
(a) Training and education Include an overview of the training and education that would be regularly provided to DHB Hospitals for the proposed products including: <ul style="list-style-type: none"> • frequency • location • format • content • staff groups (eg. hospital, community) • other relevant information 		
(b) Training and education materials Include training and education materials that would be provided to DHB Hospitals purchasing the proposed products.	For DHB Hospital staff	For patients
(c) Product support staff information about the staff that would be involved in supporting the proposed		

<p>products (including those staff providing clinical training and support). Include:</p> <ul style="list-style-type: none"> • technical skills; • experience; • qualifications; and • other role responsibilities (eg if they are responsible for supporting other major Device Categories etc) 	
DHB Transition	
<p>(d) Experience transitioning DHB Hospitals or other similar facility to your Feeding Devices</p> <p>Please outline:</p> <ul style="list-style-type: none"> • extent of transition (eg switching multiple product ranges within a category for majority of DHB use, or one product range for portion of DHBs hospital use); • when transition occurred; • extra resources utilised (eg whether international product/transition specialist were called on for a period); 	
<p>(e) Transition support</p> <p>Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products.</p> <p>NB: this includes transitions to other products supplied by your company (for example transition to ISO 80369-3:2016 compliant connection).</p> <p>Attach a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.</p>	
<p>(f) Transition to National Contracts</p> <ul style="list-style-type: none"> • Please outline if you foresee any challenges for your company to move to a National Contract. Are there solutions to these challenges which you would like PHARMAC to consider? 	
Customer Support	
<p>(g) Customer support hours</p> <p>Include:</p> <ul style="list-style-type: none"> • standard support hours (NZ time) for customer support and orders any 24/7 troubleshooting support relevant to the proposed products 	

<ul style="list-style-type: none"> customer support for community patients if different to the DHB support hours. 	
<p>(h) Complaints management processes</p> <p>Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.</p>	
<p>(i) Please identify whether your company provides support for DHB Hospital funded community use of proposed Feeding Devices and what this support entails.</p> <p>Please consider: training and support of community based healthcare professionals, patients and carers. Troubleshooting support in the community</p>	
<p>(j) Other relevant information about ability to support the proposed products.</p>	

6. Information about our compliance with regulations and standards			
NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.			
<p>(a) Quality Management System(s) certification for your company</p> <p>If Yes, <u>attach</u> evidence</p> <p>Include relevant section(s) of standard where certification is not for full standard.</p>	ISO 9001	ISO 13485	Other
	[Yes/No]	[Yes/No]	[specify]
<p>(b) Quality Management Systems(s) certification for manufacturer(s)</p> <p>If Yes, <u>attach</u> evidence</p> <p>Include:</p>	ISO 9001	ISO 13485	Other

<ul style="list-style-type: none"> • manufacturer's name • relevant section(s) of standard where certification is not for full standard 			
<p>(c) Other relevant standards for the proposed products</p> <p>List any other standards that are relevant to the proposed products including but not limited to:</p> <ul style="list-style-type: none"> • AS/NZ standards (eg AS/NZS3551) • ISO standards • IEC standards <p>Describe the extent of compliance with the listed standard and the product range the standard applies to.</p> <p>Attach evidence of compliance where available.</p>	Standard	Compliance	Evidence
<p>(d) Right to supply to New Zealand DHB hospitals</p> <p>Include:</p> <ul style="list-style-type: none"> • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. • information about process and expected timeframe for obtaining the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. • the relevant permits and rights may vary between products. Permits and rights include, but are not limited to, distribution rights and New Zealand legislative requirements for specific types of products. 			

7. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals

NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.

Stock Management

<p>(a) Stock holding within New Zealand</p> <p>Include any relevant information about how you would set and manage</p>	
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your stock levels in New Zealand for the proposed products.		
(b) Warehouse location(s) within New Zealand Include if warehouse owned by company or owned by a logistics provider.		
(c) Consignment stock Outline if your company is offering any consignment stock; and how it intends to manage this: risk and liability, responsibility for management, auditing arrangements etc		
(d) Outline how your company manages its Feeding Devices Inventory and Forecasting		
(e) Please outline how your company would manage a recall of its Feeding Devices. Include how a major recall of a proposed product(s) would be managed. Please identify any differences in how you would manage: <ul style="list-style-type: none"> • Feeding Device Equipment and dedicated accessories or consumables; • Feeding Devices used in the community setting 		
Supply Chain		
(f) Company role in supply chain	Manufacturer	Distributor
	[Yes/No]	[Yes/No]
(g) Distribution agreement(s) overview Include exclusivity, expiry date, termination notice period.	NB. Not required if you are the manufacturer and distributor of all proposed products.	
(h) Manufacture to delivery For each product range, from start of manufacture to delivery to DHB Hospitals or DHB Hospital nominated locations (eg. home delivery), include: <ul style="list-style-type: none"> • steps 		

<ul style="list-style-type: none"> • who is involved • timeframes for each step 	
Potential supply issues and response to unexpected increase in demand	
<p>(i) Key supply continuity risks and mitigations</p> <p>For each product range include the key risks to continuity of supply to DHB Hospitals and the steps that will be taken to mitigate these risks.</p>	
<p>(j) Response to unexpected increase in demand</p> <p>Include:</p> <ul style="list-style-type: none"> • any access to alternative international supply and timeframes • communication with DHB Hospitals • communication with PHARMAC • how stock is prioritised • other relevant information 	
<p>(k) Please provide any further details you would like PHARMAC to know about your company's experience and capabilities in relation to continuity of supply of the proposed Feeding Devices.</p> <p>Please provide a succinct summary [preferably <500 words]</p>	

8. Financial analysis of our proposal	
NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.	
<p>(a) Financial impact</p> <p>Include overview of how proposed pricing compares to that currently offered to DHB Hospitals.</p> <p>Attach detail in Excel format.</p> <p>(preferred format is included in Attachment 02; alternative formats may be submitted provided the detail set out in Schedule 3 is included).</p>	<p>NB. Only required if the proposed products are currently supplied to DHB Hospitals</p>

9. Other relevant information

NB: for suppliers of Enteral Feeding Pumps please provide pump specific information in the relevant section of the 'Feeding Pump' Tab of Attachment 01.

(a) Pricing information

Include any information related to pricing provided in Attachment 01, including any related conditions or proposed terms.

(b) Alternative pricing models

Include:

- details of any alternative pricing models and associated qualification requirements
- details of any DHB Hospitals currently accessing the alternative pricing models

Any alternative pricing models must have financial analysis **attached** in Excel format.

Please note that complex additional pricing models that would pose a significant administrative burden to PHARMAC or DHB Hospitals are unlikely to be progressed.

(c) Additional charges

Include any charges not included in pricing provided in Attachment 01 or 02 and associated conditions.

(d) Additional options

Include any additional proposals or suggestions not expressly identified in this RFP that you would like PHARMAC to consider as part of this proposal.

(e) Continuity of care

Include information about willingness and ability to provide a congruent range of products to healthcare providers funded by non-DHB entities, to enable continuity of patient care.

Eg. ACC, palliative care providers.

(f) Working with key stakeholders

Include information about how you envisage working with PHARMAC and other key stakeholders.

(g) Other information

Please state any other information you would like PHARMAC to consider when evaluating this proposal.

Please consider any relevant information under PHARMAC's [Factors for Consideration](#) decision making framework.

Schedule 5: Proposal Form for Special Foods Suppliers

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[Supplier to insert date]

Director of Operations
PHARMAC
c/- Matthew Tyson
Therapeutic Group Manager

By electronic transfer using GETS (www.gets.govt.nz)

Dear Sir/Madam

Proposal for the supply of Special Foods

In response to your request for proposals (RFP) dated **24 October 2018** we put forward the following proposal in respect of the supply of Special Foods.

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 03, 05 and 06 as part of your proposal.

Set out below is further information in support of our proposal.

1. Company details	
Full legal trading name in New Zealand	
Address	
Phone	
Email	
Facsimile	
2. Contact person (s) for this RFP	
Name, Position	
Phone	
Mobile	
Email	

3. Executive summary – Special Foods proposal	
Proposal summary Include: <ul style="list-style-type: none"> overview of products and services benefits to DHB Hospitals of this proposal why PHARMAC should accept this proposal 	<u>Maximum 500 words</u>

4. Information about our company, contracts and markets	
Company information	
(a) Type of entity (legal status) Eg, a New Zealand registered limited liability company	
(b) City and country of residence of our company e.g. Sydney, Australia	
(c) Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. <u>Attach</u> Organisational Chart.	
(d) Total number of New Zealand based staff Include FTE for each section (eg. 5 FTE sale/product support, 4 FTE logistics, 3 FTE corporate and administration)	
(e) Established locations within New Zealand Include function of each location (eg. head office, warehouse).	
(f) If you are currently not based in New Zealand: Do you intend to establish a company location(s) here?	

<p>How would you manage the needs of your New Zealand DHB Hospital customers from where you are located?</p> <p>N/A if New Zealand based</p>	
<p>(g) Company ownership</p> <p>State ownership (eg. public ownership)</p> <p>Include:</p> <ul style="list-style-type: none"> • If your organisation is controlled by an overseas entity; • if your organisation is part of a group of entities owned by a 'parent' company-please outline your relationship with these companies • names and percentage shareholdings of the major shareholders and directors 	
<p>(h) Evidence of financial stability and ability to cover financial liabilities</p> <p>Include:</p> <ul style="list-style-type: none"> • how you would cover your financial liabilities in the event of a major failure to supply (eg. a recall) • information about your financial stability (eg. annual turnover, guarantor companies) <p>Attach supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter).</p>	
Contracts and markets	
<p>(i) Current contracts and standing agreements in place with DHB Hospitals or organisations acting on their behalf</p> <p>Include all DHB contracts, not just those relevant to this RFP.</p> <p>For each provide:</p> <ul style="list-style-type: none"> • parties to the agreement • contract reference number • type of agreement (national/regional/DHB specific) 	

<ul style="list-style-type: none"> • range of products covered • expiry date • other relevant information (eg. now standing agreement after contract expiry) <p>Can be provided as an attachment, note name of attachment in response column.</p>	
<p>(j) Special Foods used by DHB Hospitals not included in the proposal</p> <p>Include any Special Foods currently supplied to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this. This includes flavours not supplied to DHB Hospitals. Please identify:</p> <ul style="list-style-type: none"> • If this is due to manufacture discontinuation and when the expected discontinuation date is 	
<p>(k) Special Foods that are not funded or considered to be Comparable Special Foods products</p> <p>Please list Special Food products: that your company has in its portfolio that have not been proposed for supply; and would be interested in supplying into the [funded] New Zealand market.</p>	
<p>(l) Information on other major markets for proposed Special Foods.</p> <p>For each product range include:</p> <ul style="list-style-type: none"> • type of market (eg. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information 	<p><i>NB. Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.</i></p>
<p>(m) Other relevant company and market information</p>	

5. Information about our ability to manage and support our proposed Special Foods	
Training and Education	
(a) Training and education Include an overview of the training and education that would be regularly provided to DHB Hospitals for the proposed products including: <ul style="list-style-type: none"> • frequency • location • format • content • staff groups (eg. hospital, community) • other relevant information 	
DHB Transition	
(b) Experience transitioning DHB Hospitals or similar facilities to your Special Foods Please outline: <ul style="list-style-type: none"> • extent of transition (eg switching multiple product ranges within a category for majority of DHB use, or one product range for portion of DHBs hospital use); • when transition occurred; • extra resources utilised (eg whether international product/transition specialist were called on for a period); 	
(c) Transition support Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products. NB: this includes transitions to other products supplied by your company. <u>Attach</u> a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.	
(d) Transition to National Contracts Please outline if you foresee any challenges for your company to move to a National Contract. Are there solutions to these challenges which you would like PHARMAC to consider?	

Customer Support	
(e) Customer support hours Include: <ul style="list-style-type: none"> • standard support hours (NZ time) for customer support and orders any 24/7 troubleshooting support relevant to the proposed products • customer support for community patients if different to the DHB support hours 	
(f) Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.	
(g) Other relevant information about ability to support the proposed Special Foods.	

6. Information about our compliance with regulations and standards			
(a) Quality Management System(s) certification for your company and manufacturer If Yes, <u>attach</u> evidence Include relevant section(s) of standard where certification is not for full standard.	ISO 9001	Other	
	[Yes/No]	[specify]	
(b) Other relevant standards for the proposed Special Foods List any other standards that are relevant to the proposed products including but not limited to: <ul style="list-style-type: none"> • AS/NZ standards • ISO standards • FSANZ regulations • CODEX Alimentarius Describe the extent of compliance with the listed standard and the product range the standard applies to. <u>Attach</u> evidence of compliance where available.	Standard	Compliance	Evidence

<p>(c) Right to supply to New Zealand DHB Hospitals</p> <p>Include:</p> <ul style="list-style-type: none"> • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. • information about process and expected timeframe for obtaining the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals. • The relevant permits and rights may vary between products. Permits and rights include, but are not limited to, distribution rights and New Zealand legislative requirements for specific types of products. 	
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7. Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals	
Stock Management	
<p>(a) Stock holding within New Zealand</p> <p>Include any relevant information about how you would set and manage your stock levels in New Zealand for the proposed Special Foods.</p> <p>Are there challenges your company would have in maintaining three (3) or more months stock in New Zealand for any or all products? Do you have any solutions to overcome those challenges that you would like PHARMAC to consider?</p>	
<p>(b) Warehouse location(s) within New Zealand</p> <p>Include if warehouse owned by company or owned by a logistics provider.</p>	
<p>(c) If your primary warehouse is off-shore, what provisions does your company have in place for the timely delivery of its products to New Zealand DHB Hospitals?</p> <p>Please specifically address in your response how you would manage urgent clinical situations where a patient requires the Special Food in less than 24</p>	

hours		
<p>(d) Is your company capable of doing next day delivery of Special Foods for all DHB Hospitals?</p> <p>If No, please outline</p> <ul style="list-style-type: none"> • Why • Whether you can do next day delivery for some New Zealand DHB Hospitals but not all, and list which DHB Hospitals you would be able to do next-day delivery for. 		
<p>(e) Outline how your company manages its Special Foods Inventory and Forecasting</p>		
Supply Chain		
<p>(f) Company role in supply chain</p>	<p>Manufacturer</p>	<p>Distributor</p>
	<p>[Yes/No]</p>	<p>[Yes/No]</p>
<p>(g) Distribution agreement(s) overview</p> <p>Include exclusivity, expiry date, termination notice period.</p>	<p><i>NB. Not required if you are the manufacturer and distributor of all proposed products.</i></p>	
<p>(h) Manufacture to delivery</p> <p>For each product range, from start of manufacture to delivery to DHB Hospitals or DHB Hospital nominated locations (eg. home delivery), include:</p> <ul style="list-style-type: none"> • steps • who is involved • timeframes for each step 		
Potential supply issues and response to unexpected increase in demand		
<p>(i) Key supply continuity risks and mitigations</p> <p>For each product range include the key risks to continuity of supply to DHB Hospitals and the steps that will be taken to mitigate these risks.</p>		
<p>(j) Response to unexpected increase in demand</p> <p>Include:</p>		

<ul style="list-style-type: none"> • any access to alternative international supply and timeframes • communication with DHB Hospitals • communication with PHARMAC • how stock is prioritised • other relevant information 	
Low Volume Special Foods products	
<p>(k) For low volume items / items your company does not sell into New Zealand currently (including similar products eg different flavours)- what are possible solutions you see to enable DHB Hospitals access to these products through a National Contract?</p>	
<p>(l) how would your company propose to provide low volume products on an urgent basis?</p> <p>Some products need to be urgently available upon patient admission to the hospital (within 8 hours of ordering). In your answer please consider all DHB hospital locations, some are more remote than others.</p>	
Direct to Patient Distribution of Special Foods	
<p>(m) Does your company provide or support direct distribution of Special Foods to patients in the community in any New Zealand DHB currently?</p> <p>Please list: DHBs with:</p> <ul style="list-style-type: none"> • an overview of your involvement/support in direct to patient distribution of Special Foods for each applicable DHB; • an overview of any applicable contracts you have in place with the DHB for providing this service; • how this works from the supplier-side in each applicable DHB (eg supply chain from order/prescription to patients, any third-party logistic providers you utilise for this service and associated costs involved). 	
Other supply chain information	
<p>(n) Please provide any further details you would like PHARMAC to know about your company's experience and capabilities in relation to of supply of the</p>	

proposed Special Foods.	
Please provide a succinct summary [preferably <500 words]	

8. Financial analysis of our proposal	
(a) Financial impact	<i>NB. Only required if the proposed products are currently supplied to DHB Hospitals</i>
<p>Include overview of how proposed pricing compares to that currently offered to DHB Hospitals.</p> <p>Attach detail in Excel format.</p> <p>(preferred format is included in Attachment 03; alternative formats may be submitted provided the detail set out in Schedule 3 is included).</p>	

9. Other relevant information	
(a) Pricing information	
<p>Include any information related to pricing provided in Attachment 03, including any related conditions or proposed terms.</p>	
(b) Alternative pricing models	
<p>Include:</p> <ul style="list-style-type: none"> • details of any alternative pricing models and associated qualification requirements • details of any DHB Hospitals currently accessing the alternative pricing models <p>Any alternative pricing models must have financial analysis attached in Excel format.</p> <p>Please note that complex additional pricing models that would pose a significant administrative burden to PHARMAC or DHB Hospitals are unlikely to be progressed.</p>	

<p>(c) Additional charges</p> <p>Include any charges <u>not</u> included in pricing provided in Attachment 03 and associated conditions.</p>	
<p>(d) Additional options</p> <p>Include any additional proposals or suggestions not expressly identified in this RFP that you would like PHARMAC to consider as part of this proposal.</p>	
<p>(e) Working with key stakeholders</p> <p>Include information about how you envisage working with PHARMAC and other key stakeholders.</p>	
<p>(f) Other information</p> <p>Please state any other information you would like PHARMAC to consider when evaluating this proposal.</p> <p>Please consider any relevant information under PHARMAC's Factors for Consideration decision making framework</p>	