PHARMAC
Pharmaceutical Management Agency

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15 October 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF MULTI-CATEGORY PATIENT ASSESSMENT, MONITORING AND TREATMENT EQUIPMENT AND CONSUMABLES

PHARMAC invites proposals for the supply of multi-category patient assessment, monitoring and treatment equipment and consumables ("**Patient Assessment, Monitoring and Treatment Devices''**) to New Zealand DHB Hospitals.

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 Attachments 1, 3, 4 and 5, contain the forms in which you are to provide the details of your proposal; and
- Attachment 2 contains the PHARMAC standard terms and conditions to list medical devices on the Pharmaceutical Schedule.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4pm (New Zealand time) on 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

Greg Williams
Acting Director of Operations

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

1. **Products**

PHARMAC is interested in considering proposals from suppliers for Patient Assessment, Monitoring and Treatment Devices used in a range of DHB Hospital clinical areas including:

- Audiology
- Ear, Nose and Throat (ENT)
- Ophthalmology
- Neurosciences and Psychology
- Urology
- Gastroenterology
- Dermatology
- Somnology
- Vascular Medicine
- Wards and Outpatient Clinics

The products which are in scope of the RFP are stated in Schedule 1, clause 5(a) below.

2. **RFP background and impact**

PHARMAC is taking a phased approach to its activity in medical devices. This Patient Assessment, Monitoring and Treatment Devices RFP includes the latest categories of medical devices that PHARMAC has commenced procurement activity in.

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

There may be some products associated with Patient Assessment, Monitoring and Treatment Devices that are already listed in Section H, Part III of the Pharmaceutical Schedule as the result of previous contracting activity. Suppliers who currently have products associated with Patient Assessment, Monitoring and Treatment Devices listed in Section H, Part III of the Pharmaceutical Schedule under other categories may submit additional proposals via this RFP that could result in an amendment to their current agreement.

3. **Expected outcome of the RFP**

(a) PHARMAC intends to establish National Contracts with suppliers of Patient Assessment, Monitoring and Treatment Devices to:

- list a range of Patient Assessment, Monitoring and Treatment Devices available for use by DHB Hospitals in Section H, Part III of the Pharmaceutical Schedule;

- secure future supply of Patient Assessment, Monitoring and Treatment Devices for DHB Hospitals at competitive prices;

- ensure access to an appropriate level of clinical support, and education, training and associated materials, for relevant DHB Hospital health professionals;

- ensure access to an appropriate level of technical support for other relevant DHB Hospital personnel;

- engage and establish relationships with new and current suppliers of Patient Assessment, Monitoring and Treatment Devices; and

- move commercial arrangements for Patient Assessment, Monitoring and Treatment Devices into a national framework administered by PHARMAC, to create better health outcomes for patients within the funding available to DHB Hospitals.

(b) This RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the Patient Assessment, Monitoring and Treatment Devices are contracted for and listed in the Pharmaceutical Schedule. PHARMAC recognises that the use of Patient Assessment, Monitoring and Treatment Devices touches a wide range of clinical areas, health professionals and patients. In the event a National Contract is entered into with a supplier as an outcome of this RFP process, and the Patient Assessment, Monitoring and Treatment Devices are listed in Section H, Part III of the Pharmaceutical Schedule:

- the listing shall be non-exclusive and will include pricing and details of the Patient Assessment, Monitoring and Treatment Devices;

- it will be discretionary for DHB Hospitals to purchase the Patient Assessment, Monitoring and Treatment Devices from the supplier, however where they do, DHB Hospitals will be expected to purchase the Patient Assessment, Monitoring and Treatment Devices under the PHARMAC National Contract;

- it is anticipated that multiple suppliers of Patient Assessment, Monitoring and Treatment Devices will be listed, where appropriate; and

- any resultant National Contract will be between the supplier and PHARMAC. DHBs will be able to purchase under 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.

4. **Types of proposals sought**

(a) PHARMAC is willing to consider the following types of proposals:

- proposals for the supply of Patient Assessment, Monitoring and Treatment Devices as stated in Schedule 1 clause 5(a) of this RFP;

- proposals for Patient Assessment, Monitoring and Treatment Devices with a range of equipment supply options including outright purchase and various loan options such as lease, rent, rent-to-buy and supplier provided equipment;

- proposals with a single price per Patient Assessment, Monitoring and Treatment Device (and per supply option, as applicable); and

- alternative pricing options

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

(b) Proposals must meet all the mandatory information and evidence requirements as set out in Schedule 3.

(c) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Patient Assessment, Monitoring and Treatment 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.

(d) PHARMAC is not willing to consider proposals for cross-category bundles of products.

(e) PHARMAC is not willing to consider out of scope products as stated in Schedule 1, clause 5(b) of this RFP.

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

5. **Scope of Patient Assessment, Monitoring and Treatment Devices RFP**

(a) <u>In scope</u>

PHARMAC is willing to consider proposals for Patient Assessment, Monitoring and Treatment Devices for listing in Section H, Part III of the Pharmaceutical Schedule for use by DHB Hospitals; and the following products are considered **'in scope'** of this RFP:

(i) Audiology equipment and consumables

- Audiometers
- Tympanometers
- Other hearing and middle ear assessment devices
- Hearing aid fitting, testing and repair devices and materials
- Accessories and parts

(ii) ENT equipment and consumables

- Otoscopes
- Otoscope/Ophthalmoscope kits
- Nasolaryngoscopes
- Stroboscopes
- Light sources
- Throat illuminators
- Accessories and parts
- Nasal splints
- Epistaxis devices
- ENT dressings and minor procedure packs
- ENT irrigation devices
- Ear tips
- ENT suction devices
- Single use tongue depressors

(iii) Ophthalmology equipment and consumables

- Ophthalmoscopes
- Otoscope/Ophthalmoscope kits
- Biometry devices
- Slit lamps
- Phoropters
- Eye cameras (eg. retinal camera)
- Projection devices
- Retinoscopes
- Keratoscopes
- Eye ultrasounds
- Tonometers
- Synoptophores
- Ophthalmometers
- Visual field testing devices
- Eye lasers
- Phacoemulsification machines
- Light sources
- Accessories and parts
- Ocular injection devices
- Eye dressings and minor procedure packs
- Eye irrigation devices (eg. eye baths)
- Cataract management devices (eg. dark glasses)
- Eye prostheses
- Vision testing and correction products (eg. eye charts, contact lenses, occluders, lensmeters)

(iv) Neurosciences equipment and consumables

- Electromyographs
- Electroencephalographs
- Neurostimulators
- Electrotherapy devices
- Nerve conduction study devices
- Accessories and parts
- Sensory testing devices
- Electroconvulsive therapy devices
- Psycho-diagnostic test kits

(v) Urology equipment and consumables

- Urodynamic machines
- Urodynamic catheters and bags
- Bladder scanners
- Accessories and parts

(vi) Doppler and Ankle Brachial Index (ABI) equipment and consumables

- Foetal dopplers
- Vascular dopplers
- Systolic BP dopplers
- ABI devices
- Accessories and parts

(vii) Medical measurement and scales equipment and consumables

- Height rulers
- Goniometers
- Medical measurement kits
- Tape measures
- Radio-opaque tapes and rulers
- Skin fold callipers
- Baby measuring boards/rods
- Scales (sling/chair/bed/standing/ wheelchair/baby)
- Accessories and parts

(viii) Monitoring equipment and consumables

- Non-invasive BP monitors
- Pulse oximeters
- Ambulatory (worn) BP monitors
- Multiparameter monitors (eg. BP, pulse oximeter, HR)
- Accessories and parts

(ix) Rectal and gastrointestinal equipment and consumables

- Rigid endoscopes (proctoscopes, sigmoidoscopies, anoscopes)
- GI manometry devices
- Nasogastric/duodenal drainage tubes
- Enema devices
- Rectal tubes
- Anal dilators
- Accessories and parts

(x) Examination microscopes and magnification equipment and consumables

- Head mounted microscopes
- Skin surface microscopes
- Fixed/portable microscopes
- Magnification devices
- Accessories and parts

(xi) Examination and treatment chairs and tables

- Treatment chairs
- Examination and treatment tables
- Clinician stools
- Accessories and parts

(xii) Stethoscopes

- Acoustic stethoscopes
- Electronic stethoscopes
- Stethoscope kits
- Specialised stethoscopes
- Accessories and parts

(xiii) Sleep assessment and apnoea monitoring equipment and consumables

- Polysomnography systems
- Apnoea monitors (all ages)
- Accessories and parts

(xiv) Cryotherapy equipment and consumables

- Cryotherapy guns
- Cryotherapy pens
- Accessories and parts

(xv) Hand-held lighting

- Examination penlights
- Examination torches
- Vein finders
- Accessories and parts

(xvi) Other Patient Assessment Monitoring and Treatment Devices that are not specifically noted as out of scope in 5(b) below.

(b) Out of scope

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

- hearing aids, cochlear implants and aural ventilation tubes;
- devices used under the New Zealand Ministry of Health's Universal Newborn Hearing Screening Programme;
- laryngoscopes, bronchoscopes, gastroscopes, colonoscopes, flexible sigmoidoscopies, cystoscopes, hysteroscopes;
- medical instruments (eg. nasal specula, tuning forks, reflex hammers, cerumen hooks, curettes);
- surgical instruments (eg. micro ear instruments, micro eye instruments);
- microsurgery microscopes;
- cautery and diathermy devices;
- sleep apnoea treatment devices;
- ECG machines and cardiac monitoring devices;
- critical care assessment and monitoring devices, including neonatal unit devices (eg. intra-cranial pressure, intra-abdominal pressure, intra-compartmental pressure, phototherapy devices);
- point of care testing devices (eg. urinalysis dipsticks, glucometers, blood gas analysers, anticoagulation monitoring devices);
- diagnostic imaging devices;
- non-urodynamic urinary catheters and drainage bags;
- obstetrics and gynaecology devices;
- eye irrigation fluids, diagnostic eye dyes and intra-ocular silicone oils;
- ward beds, theatre tables and dental chairs; and
- examination room lighting.

Please note that where a device is specifically noted as in scope in 5(a) above, it is able to be submitted, even if it could also be interpreted to be within a range of devices noted as out of scope in 5(b). For example, a foetal doppler used in the obstetrics area is in scope.

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 RFPs 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 **4pm (New Zealand time) on 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).

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 requirement for PHARMAC to pursue its statutory objective means that particular emphasis will be given to those aspects of proposals which demonstrate "health outcomes", and those aspects of proposals which demonstrate the impact on the "funding provided" for pharmaceuticals. Those FFC which relate directly to these aspects will be given greatest weight by the Evaluation Committee but all FFC are important.

   (d) 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 and 4 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) technical support, where applicable;

(C) information for patients, where applicable;

(D) transition support;

(iv) your ability to ensure continuity of supply to DHB Hospitals including but not limited to:

(A) stock management;

(B) robustness of supply chain;

(C) identification and management of key risks to continuity of supply;

(v) your ability to comply with quality management system and other applicable standards;

(vi) DHB Hospital usage and financial impact, where applicable;

(vii) other major markets for the proposed products, where applicable;

(viii) provision of reference sites, where applicable;

(ix) any advice received from relevant clinicians and/or DHB Hospital staff; and

(x) 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).

(e) 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.

(f) 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 2) from GETS, will apply.

(c) Subject to paragraph (e) below, you **must** complete and submit Attachment 3 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. In this respect PHARMAC acknowledges that PHARMAC's standard terms and conditions for the supply of medical devices may require amendment, as a consequence of those special terms, including but not limited to terms relating to alternative equipment procurement options such as rent, rent-to-buy, lease and supplier provided equipment.

(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 PHARMAC 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.

(b) You must limit the information provided to that which is requested in Schedule 3 and 4 and Attachments 1, 3, 4 and 5, 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 in this RFP document.

(e) Proposals are submitted in reliance on your own knowledge, skill, and independent advice, and not in reliance on any representations made by PHARMAC.

(f) 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 document.

(g) 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 Patient Assessment, Monitoring and Treatment Devices by PHARMAC's apparent acceptance, and instead a separate agreement needs to be negotiated.

(h) 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.

(i) 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 Patient Assessment, Monitoring and Treatment Devices or restricts the terms that may be agreed with any other supplier.

(j) 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 January 2019

(ii) negotiating with submitter(s) of one or more preferred proposals from March 2019;

(iii) consulting on any provisional National Contracts from May 2019; and

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts from June 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 July 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 1: Product detail	You **must** complete all fields in Attachment 1 for each proposed product. If you consider a field not applicable you must state "N/A". You **must** include a price for each proposed product in Attachment 1. If your proposal includes free of charge products, you **must** state "$0" in the price column in Attachment 1, **do not** leave the cell blank.
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 1 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 product at the time of submitting your proposal. Please note that PHARMAC's standard terms and conditions require provision of GTIN numbers, if requested by PHARMAC or a DHB, within six months of the request.
DHB usage data for proposed products	If you are currently supplying a proposed product to any DHB Hospital, you **must** provide the combined volume and revenue information across all DHB Hospital for each line items submitted in **Attachment 1**: • For each line in the Equipment and Spare Parts spreadsheets, combined volume and revenue information for all DHB Hospitals for the **five-year** period from 1 July 2013 to 30 June 2018 • For each line in the Accessories and Consumables spreadsheet, combined volume and revenue information for all DHB Hospitals for the **one-year** period from 1 July 2017 to 30 June 2018.

Document	Evidence / Information
	If you have no sales for a line you must state "0" in both the volume and revenue columns of Attachment 1. Your sales volumes **must** be reported in the same Unit of Measure as the proposed Supplier Unit of Measure. You **must** also include any sales to DHB Hospitals via their contracted logistics providers in the above volume and revenue information and these sales **must** be attributed to the correct DHB and, where applicable, converted to the proposed Supplier Unit of Measure. If any of your proposed equipment or spare parts supersede a product that is no longer available but that has been purchased from a DHB Hospital from you in the last five years you **must** note "Yes" in the relevant cell in Attachment 1 for each line this applies to and you **must** provide the sales data for all superseded equipment or spare parts, as set out further below.
Non-DHB reference sites	If you **are not** currently supplying a proposed product to any DHB Hospital, you **must** provide three clinical reference sites for that product in **Attachment 1** and provide information about the reference sites in **Schedule 4**. It is desirable that the clinical reference sites you provide use the proposed products in similar clinical settings as DHB Hospitals would use them.
Attachment 3: **Acceptance of PHARMAC's standard terms and conditions**	You **must** complete, sign and date the declaration set out in Attachment 3. 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 products you **must** provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 3. 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 3. This includes any terms and conditions related to alternative equipment procurement options such as rent, rent-to-buy, lease and supplier provided equipment.
Attachment 4: **Document and information checklist**	You **must** complete the document and information checklist set out in Attachment 4. You **must** note any additional attachments not specifically listed in the box provided in Attachment 4.

Document	Evidence / Information
Attachment 5: **Financial analysis and superseded products data**	You **must** complete the relevant spreadsheets in Attachment 5 if: • any of your proposed equipment or spare parts have been supplied to any DHB Hospital (contracted or non-contracted, purchased or non-purchased option) in the five-year period from 1 July 2013 to 30 June 2018; • any of your proposed accessories or consumables have been supplied to any DHB Hospital (contracted or non-contracted) in the one-year period from 1 July 2017 to 30 June 2018; or • any of your proposed equipment or spare parts supersede a product that is no longer available but that has been supplied to any DHB Hospital from you in the five-year period from 1 July 2013 to 30 June 2018. Your supply volumes **must** be reported in the same Unit of Measure as the proposed Supplier Unit of Measure. You **must** also include any supply volumes to DHB Hospitals via their contracted logistics providers in the above financial analysis and these volumes **must** be attributed to the correct DHB and, where applicable, converted to the proposed Supplier Unit of Measure. You **must not** overwrite the calculations in Attachment 5 for the financial analysis of any of your proposed products. If your proposal includes alternative pricing for products supplied to DHB Hospitals in the time period(s) set out above, you **must** include the financial analysis in the "Alternative pricing analysis" spreadsheet of Attachment 5. Your calculations and assumptions **must** be included. If your proposal includes non-purchase options (eg. loan, lease, rent, rent-to-buy) for equipment supplied to DHB Hospitals in the time period(s) set out above, you **must** include the financial analysis in the "Non-purchase option analysis" spreadsheet of Attachment 5. Your calculations and assumptions **must** be included.
Schedule 4: **Proposal form**	You **must** complete all sections of Schedule 4. If you consider a section to be not applicable, you **must** state "NA". 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.

Schedule 4: Proposal form

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/- Denise Mundy
Senior Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of multi-category patient assessment, monitoring and treatment equipment and consumables

In response to your request for proposals (**RFP**) dated 15 October 2018 we put forward the following proposal in respect of multi-category patient assessment, monitoring and treatment equipment and consumables ("**Patient Assessment, Monitoring and Treatment Devices**").

Please refer to Schedule 3 for information and evidence to be included in your proposal. You must also include information as outlined in Attachments 1,3, 4 and 5 as part of your proposal.

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

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

(c) Executive summary	
Proposal summary Include: • overview of products and services • benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal	**Maximum 500 words**

(d) Information about our company, contracts and markets	
Company information	
Type of entity (legal status) Eg. a New Zealand registered limited liability company	
City and country of residence of our company	
Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. Include all other portfolios held by sales/product support staff. **Attach** Organisational Chart.	
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)	
Established locations within New Zealand Include function of each location (eg. head office, warehouse).	
Company ownership State ownership (eg. public ownership) Include: • any parent companies and relationships	

• names and percentage shareholdings of the major shareholders and directors	
Evidence of financial stability and ability to cover financial liabilities Include: • 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) **Attach** supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter).	
Contracts and markets	
Current contracts and standing agreements in place with DHB Hospitals or organisations acting on their behalf Include all DHB contracts, not just those relevant to this RFP. For each provide: • 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) Can be provided as an attachment, note name of attachment in response column and in Attachment 4.	
Products or procurement options not included Include any products or procurement options currently provided to DHB Hospitals (contracted or not contracted) that are not included in this proposal and the reason for this.	
Healthcare customers in New Zealand Include DHB Hospital and private healthcare organisations.	
Information on other major markets for proposed product	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are not currently*

ranges. For each product range include: • type of market (eg. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information	*purchasing.*
Information about clinical reference sites Provide information about each reference site included in Attachment 1 including the location and relevant clinical settings in which the product is used (eg. inpatient care, outpatient clinics, home use).	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.*
Other relevant company and market information	

(e) Information about our ability to manage and support our proposed products	
Customer support hours Include: • standard support hours (NZ time) for customer support and orders • any 24/7 troubleshooting support relevant to the proposed products	
Product support staff Include information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education).	
Training and education Include an overview of the training and education that would be regularly provided to DHB Hospitals for the proposed products including: • frequency • location • format	

• content • staff groups (eg. hospital, community) • other relevant information		
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 (where applicable)
Transition support Include an outline of the support that would be provided to a DHB Hospital transitioning to the proposed products. **Attach** a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note name of attachment in response column.		
Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.		
Other relevant information about ability to support the proposed products.		

(f) Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, attach evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
Quality Management Systems(s) certification for manufacturer(s) **If Yes, attach evidence** Include: • manufacturer's name	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]

• relevant section(s) of standard where certification is not for full standard			
Other relevant standards for the proposed products List any other standards that are relevant to the proposed products including but not limited to: • AS/NZ standards • ISO standards • IEC standards Describe the extent of compliance with the listed standard and the product range the standard applies to. Product specific information can be included in Attachment 1. **Attach** evidence of compliance where available.	Standard	Compliance	Evidence
Permit to supply the products to New Zealand DHB Hospitals Include: • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand DHB Hospitals, or • 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.			

(g) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals	
Stock Management	
Minimum shelf life on delivery Include for each product range the minimum shelf life on delivery to a DHB Hospital.	

Stock holding within New Zealand Include any relevant information about how you would set and manage your stock levels in New Zealand for the proposed products.		
Warehouse location(s) within New Zealand Include if warehouse owned by company or owned by a logistics provider.		
Recall management Include how a major recall of a proposed product(s) would be managed. If your proposal includes equipment and consumables, ensure that information provided is relevant to the different types of products.		
Supply Chain		
Company role in supply chain	Manufacturer	Distributor
	[Yes/No]	[Yes/No]
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.*	
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: • steps • who is involved • timeframes		
Potential supply issues and response to unexpected increase in demand		
Key supply continuity risks and mitigations 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.		
Response to unexpected increase in demand Include: • any access to alternative international supply and timeframes • communication with DHB Hospitals • communication with PHARMAC		

• how stock is prioritised • other relevant information	

(h) Pricing and financial analysis of our proposal	
Financial impact Include overview of how proposed pricing compares to that currently offered to DHB Hospitals. Include any non-purchase options (eg. rent or equipment financing arrangements) currently in place with DHB Hospitals. **Attach** detail in **Attachment 5**. If any proposed equipment supersedes a previous model supplied to a DHB Hospital in the last 5 years, please note this in Attachment 1 and provide the cost, volume and matching detail for the previous model in the 'Superseded equipment data (5yr)' spreadsheet in Attachment 5, in addition to the financial impact analysis for your proposed equipment.	***NB.*** *Only required if the proposed consumable product has been supplied to a DHB Hospital in the last year* ***or*** *if proposed equipment (or a previous model of the proposed equipment) has been supplied to DHB Hospitals in the last 5 years.*
Alternative pricing models Include: • details of any proposed alternative pricing models and associated qualification requirements • details of any existing alternative pricing models offered to DHBs and which DHB Hospitals are accessing the alternative pricing • details of how you would implement and monitor qualification requirements for DHB Hospitals Any alternative pricing models must have financial analysis included in **Attachment 5,** along with your calculations and assumptions.	
Pricing information Include any information related to pricing provided in Attachment 1, including any related conditions or proposed terms.	

Additional charges Include any charges not included in pricing provided in Attachment 1 and associated conditions.	

(i) Information about equipment	
Equipment details Provide overview information relating to proposed terms for supplying equipment supplied to DHBs in addition to details provided in Attachment 1, including the range of procurement options being proposed (eg. outright purchase, rent, loan, lease, rent-to-buy). In a separate **attachment**, include, for each procurement option: • the applicable equipment product codes • delivery, receipt, installation and acceptance procedures • details of risk and liability during key exchange activity points • details of any consignment arrangements • details of any termination terms and conditions • any differences between current arrangements with DHB Hospitals and proposed arrangements • product support, training and education • charge for any non-purchase options, if any (eg. monthly rental charge, free of charge loan) • fleet management responsibilities for any non-purchase options Please note the name of the attachment in the adjacent box under your overview as well as in the checklist in Attachment 4. Where you have non-purchase equipment options currently in place with any DHB Hospital please include the financial analysis, by DHB Hospital, of any proposed non-purchase options in **Attachment 5**. Pricing for outright purchase options is to be included in **Attachment 1.**	***NB.*** *Only required if the proposed products include equipment*

Warranties, servicing and calibration Provide information relating to proposed warranty, servicing and calibration terms for equipment in addition to details provide in Attachment 1. Include: • details of replacement and repairs policy • overview of warranty coverage, including warranty terms for repairs and spare parts • cost for all maintenance and calibration services within the warranty period and following expiry of warranty period (eg. hourly labour rate for repairs outside of warranty, maintenance servicing costs per device per year, any freight charges or travel and accommodation costs) • training of DHB staff (eg. clinical engineers), and any associated costs • any differences between current arrangements with DHB Hospitals and proposed arrangements If the detail varies according to the type of equipment or procurement option, please note this here and include the relevant information with the attachment in the Equipment details section above.	
Operating and maintenance manuals Include an overview of the content of operating manuals, instructions and guides for use by clinical and technical personnel. **Do not** include copies of full equipment operating or maintenance manuals.	

(j) Other relevant information	
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. Also refer to Attachment 3.	

Working with key stakeholders Include information about how you envisage working with PHARMAC and other key stakeholders.	
Other information Include any other information that you would like PHARMAC to consider when evaluating this proposal.	