PHARMAC
Pharmaceutical Management Agency

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26 February 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF HAEMODIALYSIS EQUIPMENT AND PRODUCTS

PHARMAC invites proposals for the supply of Haemodialysis equipment and products to New Zealand DHB hospitals and their associated community settings.

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; and
- Schedule 4 and Attachments 1, 3 and 4 contain the forms in which you are to provide the details of your proposal.
- 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 5.00 p.m. on **30 April 2018**.

If you have any questions about this RFP, please post these on GETS. All questions must be received no later than **5.00pm 20 April 2018**.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

Schedule 1: Background to RFP and types of proposals sought

1. **Background to RFP**

(a) *PHARMAC's role in Medical Devices*

In 2010, Cabinet decided that PHARMAC would assume responsibility for managing the assessment, standardisation, prioritisation and procurement of medical devices for the District Health Boards (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' Operation Policy Framework, DHBs are required to comply with the Pharmaceutical Schedule as determined by PHARMAC.

(b) *Reasons for running the RFP*

PHARMAC is taking a phased approach to its activity in medical devices. More categories of medical devices will gradually be listed in the Pharmaceutical Schedule. Haemodialysis Equipment and Products were indicated as being part of the second tranche of categories that would be listed.

(c) *Impact of RFP*

PHARMAC intends to establish national listing agreements **(National Contracts)** with suppliers to secure the supply of Haemodialysis Equipment and Products used by DHBs in hospital and community settings, including treatment provided in patients' homes. It is expected that Haemodialysis Equipment and Products subject to a National Contract will be listed in Section H, Part III of the Pharmaceutical Schedule. National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent Haemodialysis Equipment and Products will be listed.

There may be some products associated with, but not exclusive to, Haemodialysis Equipment and Products that are already listed in Part III of Section H of the Pharmaceutical Schedule as the result of previous contracting activity. Suppliers who currently have products associated with Haemodialysis listed in Part III of Section H of the Pharmaceutical Schedule may choose to submit for consideration additional proposals via this RFP, to amend their current agreement for these products, or to extend their product ranges.

(d) *Current market status*

PHARMAC recognises that Haemodialysis services are complex. Not all DHBs provide a service, some only support a limited hospital-based service for non-complex dialysis, while the larger DHBs provide layered services that include home dialysis, satellite clinics and intensive care level treatments. Each DHB has a different service agreement, although generally based on a price-per-treatment (PPT) model. Each PPT contains a number of variables. These may include one or more of the following:

(i) Equipment that could include Haemodialysis machines, water treatment machines, home dialysis machines, continuous dialysis machines;

(ii) Various loan payment arrangements for equipment including lease and rent-to-buy;

(iii) Set list of consumable items per treatment;

(iv) Customised packs;

(v) Training for clinical staff and clinical engineers;

(vi) Maintenance and repairs support and/or provision of technical services

(vii) Home dialysis patient support – stock management, education, 24/7 support line;

(viii) Unit equipment such as therapeutic chairs, IV poles or trollies.

PHARMAC recognises that for Haemodialysis services to continue under a national contract there will need to be enough flexibility and options within a standard contractual framework to enable DHBs to transition to the national contract without being disadvantaged or causing unnecessary disruptions to the service, and to have access to the level of support they are currently receiving should they wish to continue with it.

Expected outcome of the RFP

(e) PHARMAC intends to establish National Contracts with suppliers in the category of Haemodialysis Equipment and Products to:

(i) List a range of Haemodialysis Equipment and Products available for use by DHB Hospitals in Section H, Part III of the Pharmaceutical Schedule;

(ii) Secure future supply of Haemodialysis Equipment and Products for DHB Hospitals at competitive prices;

(iii) Ensure access to appropriate clinical engineering support as required by a DHB hospital;

(iv) Secure a range of options for DHBs to access Haemodialysis Equipment and Products, including outright purchase, lease, rent-to-buy and supplier provided equipment options[1];

[1] In the context of this RFP, supplier provided equipment means when the DHB Hospital purchases an agreed number of consumables, the supplier provides the associated piece of equipment at no charge to the DHB Hospital.

(v) Ensure access to an appropriate level of clinical support, education and training for relevant DHB health professionals (and where appropriate, for home Haemodialysis patients and their families);

(vi) Ensure access to an appropriate level of technical support and training for other relevant DHB personnel, including but not limited to, clinical engineers;

(vii) Engage and establish relationships with new and current suppliers of Haemodialysis Equipment and Products; and

(viii) Move commercial arrangements for Haemodialysis Equipment and Products into a national framework administered by PHARMAC so that long term opportunities can be created to provide better health outcomes for patients within the funding available to DHBs.

(f) This RFP is the only process PHARMAC expects to run prior to negotiation with suppliers, to determine whether the Haemodialysis Equipment and Products are contracted for and listed in the Pharmaceutical Schedule. Therefore, in the event a National Contract is agreed with a supplier as an outcome of this RFP process, and the Haemodialysis Equipment and Products are listed in Part III of Section H of the Pharmaceutical Schedule:

(i) the listing shall be non-exclusive and will include pricing and details of the Haemodialysis Equipment and Products;

(ii) it will be discretionary for DHBs to procure the Haemodialysis Equipment and Products from the supplier, however where they do, DHB Hospitals will be required to procure these Haemodialysis Equipment and Products under the PHARMAC agreement;

(iii) it is anticipated that multiple suppliers of Haemodialysis Equipment and Products will be listed;

(iv) any resultant National Contract will be between the supplier and PHARMAC. DHBs will be able to procure under the National Contract, effective from the listing date, and will not be required to individually approve the agreement for it to come into effect;

(v) there may be alternative options for procuring Haemodialysis Equipment and Products, such as various loan options, that are included in the National Contract that are not already listed in Part III of Section H of the Pharmaceutical Schedule; and

(vi) it will be at the DHB's discretion as to which procurement options they wish to use within the National Contract and will be decided by them in discussion with the supplier.

(g) For the avoidance of doubt, under the New Zealand Public Health and Disability Act 2000, as well as under DHBs' Operational Policy Framework, DHBs are required to act in accordance with the Pharmaceutical Schedule.

2. **Scope of Haemodialysis Equipment and Products category**

(a) PHARMAC is willing to consider proposals that involve Haemodialysis Equipment and Products 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) Haemodialysis filters;

(ii) Haemodialysis blood lines and sets;

(iii) Haemodialysis fistula needles;

(iv) Haemodialysis customised packs;

(v) Haemodialysis accessories (E.g. effluent bags, transducer protectors, other equipment);

(vi) Haemodialysis solutions;

(vii) Haemodialysis water treatment products including reverse osmosis machines;

(viii) Haemodialysis machines including full purchase, loan or rent-to-buy agreements (including CVVHD and CAVHD); and

(ix) Support packages associated with the provision of haemodialysis equipment and consumables (including training, maintenance, replacement parts and customer support).

(b) 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:

(i) Haemodialysis Equipment and Products already specifically listed in Part III of Section H of the Schedule (*unless* it is an additional proposal, an amendment to a current agreement for these products or an extension of the product range);

(ii) Unit equipment including but not limited to therapeutic chairs, free standing IV poles or trolleys; and

(iii) Any products that are not part of a Haemodialysis system.

3. **Types of proposals sought**

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

(i) Proposals for the supply of Haemodialysis consumable products only to DHB Hospitals;

(ii) Proposals (including price-per-treatment arrangements) for the supply of Haemodialysis equipment with outright purchase and various loan options, including lease, rent-to-buy and supplier provided equipment options, with or without consumable products;

(iii) Proposals that include options for the supply of maintenance and repair services or appropriate training of and support for DHB hospital clinical engineers;

(iv) Proposals for the supply of Haemodialysis Equipment and Products to DHB hospitals, satellite centres and patient's homes;

(v) Proposals with a single price per supply option;

(vi) Alternative pricing options; and

(vii) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Haemodialysis Equipment and Products during the life of the National Contract, and that if agreed between the parties, the changed or upgraded product would be made available to DHBs within a reasonable timeframe.

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

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

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

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 on the documentation provided. Do not alter the forms in any way.

(c) All RFPs must be submitted by a single Submitter. Submitters may have joint commercial arrangements with other suppliers which can be combined into a single submission.

(d) All proposals must be submitted to PHARMAC via GETS no later than 5.00 p.m. (New Zealand time) on **30 April 2018**. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and the integrity of the RFP process.

(e) You cannot withdraw your proposal once submitted, while the RFP process is continuing.

(f) If you have any enquiries about this RFP, you should submit them via GETS (www.gets.govt.nz). All questions must be received no later than **5.00pm 20 April 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 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 provided by you in accordance with Schedule 3 and 4 of this RFP and attachments 1, 3 and 4.

(ii) information and evidence requirements as set out in Schedule 3 of this RFP;

(iii) ability to provide the appropriate level of product support, including but not limited to:

(A) clinical training and education in the use and handling of all equipment and products;

(B) general training and education in equipment care and maintenance;

(C) technical training and support for clinical engineers;

(D) information for patients including training and support for home Haemodialysis;

(E) supply chain to support sustainable provision of products (including home dialysis patients); and

(F) equipment tracking, maintenance and repair.

(iv) provision of DHB usage data where applicable,

(v) potential impacts on current DHB arrangements for the repayment of equipment purchases;

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

(vii) any information received from reference sites and referees (where applicable); and

(viii) 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 for supply of medical devices, which are available as a download (Attachment 2) from GETS, will apply.

(c) 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 which 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, due to the impact that other negotiated terms may have on price.

(e) PHARMAC may negotiate and enter into a provisional agreement 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 agreement 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 agreement 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 agreement 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 current OPPs.

(d) If the Board or its delegate does not approve the provisional agreement, then PHARMAC may initiate negotiations for a provisional agreement 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 agreement; 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 any provisional agreement) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process to consult. In this situation we may ask you to adapt and resubmit your proposal because of the 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) PHARMAC may consult or seek clinical advice from PTAC, relevant sub-committee or advisory committee at any stage of the RFP process. PHARMAC will notify you if the clinical advice results in any changes to the terms of the RFP.

(c) 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 a provisional agreement is accepted by PHARMAC's Board or the Board's delegate.

(d) 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.

(e) You must pay your own costs for preparing and submitting your proposal.

(f) You must limit the information provided to that which is requested in Schedule 3 and 4 and Attachments 1, 3 and 4 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.

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

(h) 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.

(i) 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 Haemodialysis Equipment and Products by PHARMAC's apparent acceptance; instead a separate agreement needs to be negotiated.

(j) 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.

(k) It is possible that more than one supplier may be awarded a contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Haemodialysis Equipment and Products or restricts the terms that may be agreed with any other supplier.

(l) 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 agreement entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that agreement; 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 May 2018;

(ii) negotiating with submitter(s) of one or more preferred proposals from July to November 2018

(iii) consulting on any provisional agreements from November 2018;

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional agreements in or after December 2018; and

(v) Haemodialysis Equipment and Products being listed as agreements are approved, and that all agreements would be finalised for listing in January 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 January 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 responses will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

Requirement	**Evidence / Information**	**Response**
Pricing, types and sizes, and procurement options	Detailed information about all proposed Haemodialysis Equipment and Products and any related conditions or proposed terms as set out in **Attachment 1** (and **Schedule 4** as needed).	Mandatory
Spare parts and accessories pricing and details	Details of proposed spare parts or specialised accessories/maintenance equipment required throughout the useful life of any proposed Haemodialysis equipment as set out in **Attachment 1** (and **Schedule 4** as needed) Applicable where your proposal includes Haemodialysis equipment offered for outright purchase, or lease to buy	Mandatory (where applicable)
WAND registration	All proposed Haemodialysis Equipment and Products must be WAND registered. WAND registration number must be provided for all Haemodialysis Equipment and Products set out in **Attachment 1**. Please **do not** provide WAND documents.	Mandatory (where applicable)
International compliance	Evidence of international compliance certificates must be provided (e.g. ARTG, CE Mark, FDA) for all Haemodialysis Equipment and Products set out in **Attachment 1.** Please **attach** copies of certificates.	Mandatory
GS1 (GTIN) and UNSPCS	Provide codes for each proposed Haemodialysis Product as set out in **Attachment 1.**	Desirable
Biocompatibility	Indicate if any Haemodialysis Equipment and Products as set out in **Attachment 1** contain latex.	Mandatory (where applicable)
DHB current usage data	Provide volume and pricing information by DHB for the period **1 January 2017 to 31 December 2017** for all line	Mandatory

Requirement	Evidence / Information	Response
	items, submitted in **Financial Impact Analysis sheet, Attachment 1**. Applicable where you are currently supplying a proposed Haemodialysis Product to DHB Hospitals, including rent-to-buy and lease options.	(where applicable)
Equipment outright purchase	Provide detailed information about outright purchase options in your proposal as set out in **Attachment 1** and **Schedule 4.** Applicable if your proposal includes Haemodialysis equipment offered for outright purchase.	Mandatory (where applicable)
Equipment loan options, including but not limited to lease and rent to buy.	Provide detailed information about each loan option in your proposal as set out in **Attachment 1** and **Schedule 4.** This should include details regarding responsibilities for maintenance, calibration and servicing during and after loan period. Applicable where your proposal includes rent or lease to buy options. Include details of how changes to any payment plans will be managed as part of price per treatment proposals	Mandatory (where applicable)
Current DHB Hospital contracts	Provide details of DHB Hospital current contracts including expiry as set out in **Schedule 4**, and any additional cost and volume information not already included in **Attachment 1**. Applicable where you currently have an agreement with DHB Hospital(s) to provide Haemodialysis Equipment and Products, including outright purchase and loan options, including but not limited to lease and rent-to-buy arrangements.	Mandatory (where applicable)
	Provide details of any Haemodialysis Equipment and Products, supply options or professional development support currently provided to DHB Hospitals that you have **not** included in this proposal, and rationale for this, as set out in **Schedule 4**. Applicable where your proposal does not include all Haemodialysis Equipment and Products and supply options that you currently provide to DHB Hospitals (contracted or non-contracted)	Mandatory (where applicable)
	For all DHBs that have a current contract with you, provide a detailed transition plan from current arrangements to a national PHARMAC contract in particular how any possible penalties or ongoing payment plans will be managed.	Mandatory

Requirement	Evidence / Information	Response
Financial analysis of your proposal	Provide an overview of how your proposed pricing compares to the contracted/non-contracted pricing **currently** offered to DHBs in **Schedule 4.** Provide **(in Excel format as part of Attachment 1)** a detailed **Financial Impact Analysis** of your proposal for each DHB for each Haemodialysis Product included in your proposal. This will include: 1) The product description and code for line items included in any PPT proposal; 2) Your current (as at December 2017) and proposed prices for all line items (including equipment) and the following calculations: a) Current price x annual DHB volume (1 January 2017 – 31 December 2017) b) Proposed price x annual DHB volume (1 January 2017 – 31 December 2017) 3) The difference between a) and b). 4) The impact of any current or proposed rebates 5) All service, maintenance and support, freight and any other charges to be included in the PPT For proposed **Price-per-Treatment (PPT**) options, provide **(in Excel format on spreadsheets provided as part of Attachment 1)** a detailed **PPT proposal analysis and breakdown** of your proposed pricing options. If your proposed option cannot be submitted in the requested format a separate spreadsheet may be used.	Mandatory
Associated services	Provide information on any associated services (E.g. servicing, maintenance, patient support etc.) included in any Price-Per-Treatment proposal including a breakdown of all costs relative to the total PPT price.	Mandatory
Transition planning	Provide information detailing how you would assist DHBs to transition to your equipment and/or products from another supplier. This must include:	Mandatory

Requirement	Evidence / Information	Response
	a) Staggered equipment changes across all DHB service delivery sites in a DHB b) Transition training program for all staff (Please **attach** an example of a detailed transition plan.) c) Support for home dialysis services d) Any other transition support offered	
Distribution and supply arrangements	Provide information relating to your ability to ensure continuity of supply of products to DHB Hospitals, satellite centres and patients' homes; as set out in **Schedule 4**.	Mandatory
Other major markets	Provide information about your Haemodialysis Equipment and Product supply in other major markets as set out in **Schedule 4**. Applicable where your Haemodialysis Equipment and Product supply experience is for countries other than New Zealand DHBs.	Mandatory (where applicable)
Organisational information	Provide information about your organisation as set out in **Schedule 4**.	Mandatory
Safety, performance and standards and security	Provide information about the standards that are applicable to the products being proposed and your role in managing them in **Schedule 4.** Whether a standard is applicable or not will depend on the type of Haemodialysis Equipment or Product you have included in your proposal, and your role (if any) in ongoing maintenance or management of the Haemodialysis Equipment or Product. This includes but is not limited to: a) equipment manufacture and supply, including any applicable regulatory standards b) maintenance and repairs, c) equipment fleet management,	Mandatory (where applicable)

Requirement	Evidence / Information	Response
	d) any other quality control requirements. Provide information on any device that has the ability to retain patient information or data, and how this data is managed securely. It is mandatory that you complete this section in **Schedule 4.**	
Quality management systems	Provide information about your current or proposed complaints management processes, including: a) ability to recall stock, b) refund or credit for damaged or faulty goods, as set out in **Schedule 4.**	Mandatory
	Describe the degree to which your organisation and relevant parties in your supply chain conform to ISO 9000-Quality management or ISO 1345:2016 Medical devices quality management systems as set out in **Schedule 4**.	Mandatory
DHB Hospital education and training requirements	Provide a statement of your understanding of DHB Hospital educational requirements and your experience in providing training and product support for the proposed Haemodialysis Equipment and Products, as set out in **Schedule 4**.	Mandatory
	Provide information about the operating manuals and other instructions and guides that would be provided to DHB Hospitals that procure your proposed Haemodialysis Equipment and Products, as set out in **Schedule 4.** Please **do not** provide full operating manuals for any proposed Haemodialysis equipment.	Mandatory
	Provide details about any professional development funding support to be provided for renal staff as set out in **Schedule 4**	Mandatory (as applicable)
Patient information	Provide information about patient instructions and/or educational resources that would be provided to DHB Hospitals to support the proposed Haemodialysis Equipment and Products, as set out in **Schedule 4**. Please **do not** provide copies of all available patient information resources. Applicable where your proposal includes Haemodialysis Equipment and Products intended for use in home settings.	Mandatory

Requirement	Evidence / Information	Response
Consignment stock arrangements	Provide information related to your ability to support consignment products as set out in **Attachment 1** and **Schedule 4**. Applicable where a proposed Haemodialysis Product is available on consignment.	Mandatory (where applicable)
Servicing, warranties and cleaning	Provide details for service agreements, warranties, cleaning and reprocessing instructions for Haemodialysis Equipment and Products included in your proposal, as set out in **Schedule 4**. Applicable where your proposal includes reusable equipment or products for outright purchase and/or products or equipment that require cleaning during use, and/or where your proposal requires DHB Hospital management of reusable lease equipment.	Mandatory (where applicable)
Waste reduction and recycling	Provide information about manufacturing waste reduction policies and New Zealand recycling processes relevant to your proposed Haemodialysis Equipment and Products, as set out in **Schedule 4**.	Desirable
Custom kit supply	Describe your ability to source and supply custom Haemodialysis kits (e.g. 'on-pack', 'off-pack') for individual DHB Hospitals as set out in **Schedule 4**. Include information about the pricing model you would use to ensure comparable pricing between DHBs. All components of any proposed kit should be set out in **Attachment 1.**	Desirable
Working with PHARMAC and other stakeholders	Provide information about how you envisage working with PHARMAC and other key stakeholders, as set out in **Schedule 4**.	Mandatory

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/- Sarah Penno
Device Category Manager

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

Dear Sir/Madam

Proposal for the supply of Haemodialysis Equipment and Products

In response to your request for proposals (**RFP**) dated 26 February 2018 we put forward the following proposal in respect of Haemodialysis Equipment and Products.

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

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

(a) Our contact details:

Full legal trading name in NZ	
Key Contact person	
Address	
Phone	
Mobile phone	
Facsimile	
Email address	

(b) Key features of our proposal and associated available services:

(c) Information relating to pricing ($NZ, GST exclusive) inserted in Attachment 1, including any related conditions or proposed terms:

[Include general details,(e.g. conditions on pricing) of any outright purchase, lease or rent-to-buy arrangements for Equipment items included in Attachment 1] *[Any other details related to pricing listed in Attachment 1]*

(d) Information relating to outright purchase of Haemodialysis Equipment included in proposal, in addition to that set out in **Attachment 1**:

[Respective supplier and DHB responsibilities for maintenance and repairs including provision of spare parts] *[Replacement policies]* *[Electrical and non-electrical safety features]* *[Compatibility with New Zealand power supply and power points for mains operated equipment]* *[Delivery lead in time]* *[Product support, training and education]* *[Other relevant information]*

(e) Additional information relating to Haemodialysis Equipment loan options, including but not limited to lease, and rent-to-buy arrangements including price-per-treatment proposals, detailed in **Attachment 1**:

[Itemise all charges contained within any price-per-treatment proposal (E.g. delivery, maintenance, stock management, training etc.) relative to the total price]

[Delivery timeframe(s)]

[Respective supplier and DHB responsibilities for maintenance and repairs]

[Risk and liability during key exchange and activity points]

[Product support, training and education]

[Identify any differences between hospital, in-centre and home haemodialysis e.g. PPT costs, conditions, extra charges etc.]

[information regarding any proposed penalty clauses including volume commitment expectations]

[Termination terms and conditions]

[Highlight any differences between current arrangements with DHB Hospitals and the proposals]

[Other relevant information about the arrangement(s) being proposed]

[Include items such as consumable products, servicing, other items]

[provide details of any restrictions on listed items]

(f) Information regarding items not included in a Price-per-treatment proposal as listed in addition to what provided in **Attachment 1**:

(g) Information about current contracts we have in place with DHB Hospitals, in addition to that included in **Attachment 1**:

[Expiry dates]

[Additional cost and volume data/information]

[Other relevant information about current contracts in place with DHB Hospitals]

[Describe how current arrangements will be transitioned to a PHARMAC national contract – in particular, how changes to any payment plans will be managed.]

[Provide a detailed transition plan for each currently held DHB contract]

(h) Information about items **NOT** included in this proposal:

*[Haemodialysis Equipment and Products, procurement options, services or professional development support currently provided to DHB Hospitals that are **not** included in proposal, and reasons for this]*

(i) Financial analysis of our proposal:

[Overview of how pricing compares to that currently offered to DHB Hospitals]

*[Details should be included in **Attachment 1**]*

(j) Information about our proposed distribution and supply arrangements including our ability to ensure continuity of supply to all DHB Hospitals, satellite centres and home dialysis patients:

[Whether you are a manufacturer or distributor of the proposed Haemodialysis Equipment and Products]

[Terms of any distribution agreements, if you are not the manufacturer, for example the duration and exclusivity of the distribution agreement]

[Details of distribution and stock-holding in New Zealand]

[Details of system to manage home haemodialysis patients' treatment 'prescriptions' and supplies]

[Delivery frequency and lead in times, including under stable demand situations, in the event of supply disruptions, and when there is an unexpected surge in demand]

[Specific measures to secure stock for New Zealand from international production, including information about agreements in place with other parties in supply chain and notice periods required for any changes]

[Any freight and delivery costs to DHB Hospitals, satellite centres and/or home dialysis patients]

[Other relevant supply chain arrangements]

(k) Information about our other major markets and previous supply performance (if not currently supplying to New Zealand DHB Hospitals):

[Private New Zealand market(s)]

[International markets]

[Recent tenders awarded]

[Reference sites where proposed Equipment is used in similar ways and settings to DHBs],

(l) Information about our organisation:

[Organisational structure] *[Management, technical skills, experience and qualifications of staff in relation to the proposed Haemodialysis Equipment and Products]* *[Customer support hours for repairs, troubleshooting and advice]* *[Other relevant information about organisation]*

(m) Information about our compliance with safety and performance standards in relation to our role in the supply, management and support of the Haemodialysis equipment and products proposed (e.g. AS/NZS IEC Medical Electrical Equipment standards):

Standard **(E.g. IEC, AS/NZS standards)**	**Information about the extent to which we conform with the standard**	**Conformance evidence attached?**
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*
[List relevant standard]	*[include reference to relevant Haemodialysis Product(s)]*	*[Yes/No/NA]*

(n) Information on our device that has the ability to retain patient information or data, and how this data is managed securely.

[Information as to which device, what patient data is entered, how data is retained and how patient privacy is ensured]

(o) Information about our Quality Management Systems

[Information about conformance to ISO 9000 Quality management or ISO 1345:2016 Medical devices quality management systems. ***Attach*** *evidence where available]*

[Information about our current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods]

[Information on any recent product issues and/or complaints (give example) from staff and the process used to respond to this]

(p) Our understanding of DHB educational requirements and our experience in providing training and product support for the devices submitted:

[include clinical and non-clinical staff]

[technical skills, experience and qualifications of staff involved in training]

(q) Information about our ability to support a DHB to transition to our products:

[Overview of transition support including expected lead times with detailed transition plan ***attached****]*

[information should include but not limited to details on training, technical support, management of home dialysis patients]

(r) Information about operating manuals, instructions and guides that would be provided for the safe and appropriate use, and maintenance, of our Haemodialysis Equipment and Products

[Overview of content of operating manuals, instructions and guides for the range of Haemodialysis Equipment and Products proposed for clinical and technical personnel. Please ***do not*** *include copies of full equipment operating or service manuals]*

(s) Our understanding of patient educational requirements and our experience in providing training and product support for home Haemodialysis patients:

[Overview of patient information resources and training for Haemodialysis equipment and products intended for use in home settings]

[information on support, after-hours help and trouble-shooting for home dialysis patients]

[information on stock management in the home]

(t) Information about our current (and/or proposed) consignment stock management system:

[Risk and liability arrangements]

[Responsibility for stock management including stock management for home Haemodialysis patients]

[Auditing arrangements]

[Other relevant consignment stock management information]

(u) Details of our warranties and services for maintenance, servicing and calibration for all equipment:

*[Warranty information in addition to that included in **Attachment 1**, including warranties for repairs and spare parts]*

[Frequency of calibration and maintenance]

[Replacement and repair policies]

[Duration of availability of spare parts after date of delivery]

*[Duration of availability of maintenance and calibration services after date of equipment delivery **including for equipment used by home haemodialysis patients**]*

[Cost of respective services included within the warranty period and following expiry of the warranty period]

[include any associated costs e.g. freight charges for servicing or replacement of loan machines]

[Include details related to preventive servicing and corrective maintenance and repairs including whether performed by supplier, DHB clinical engineers on-site, or at off-site service centre]

[Training of DHB technical staff (e.g. clinical engineers)]

[Other relevant information about maintenance, servicing and calibration services]

(v) Information about manufacturing waste reduction policies and within New Zealand recycling processes:

(w) Information about any proposals to support dialysis staff professional development programmes:

[include details of any grants, conferences or other proposed support being offered and any conditions imposed on their use]

(x) Information about how we envisage working with PHARMAC and other key stakeholders:

(y) Proposal/suggestions (e.g. pricing,) regarding a medical device **not** expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(z) Reasons why PHARMAC should accept our proposal:

(aa) Additional information that PHARMAC should consider when evaluating our proposal: