PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
Information line **0800 66 00 50**
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

9 November 2018

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF SINGLE-USE STERILE SURGICAL DRAPES, GOWNS AND PROCEDURE PACKS

PHARMAC invites proposals for the supply of single-use Sterile Surgical Drapes, Gowns and Procedure Packs ("Surgical Drapes, Gowns and Procedure Packs") to New Zealand District Health Board (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 **4.00pm 19 December 2018**.

If you have any questions about this RFP, please post these on GETS, no later than 10 December 2018.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

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

1. Products

PHARMAC is interested in considering proposals from suppliers of Surgical Drapes, Gowns and Procedure Packs.

The focus of the RFP is Surgical Drapes, Gowns and Procedure Packs that are purchased for use by DHBs and does not include reusable, non-surgical or non-sterile products.

The full scope of 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. The Surgical Drapes, Gowns and Procedure Packs category is the latest category 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 Surgical Drapes, Gowns and Procedure Packs used by DHB Hospitals. It is expected that Surgical Drapes, Gowns and Procedure Packs subject to a National Contract will be listed in Part III of Section H of the Pharmaceutical Schedule. The National Contracts would not be exclusive of other suppliers, and it is likely that multiple suppliers of equivalent Surgical Drapes, Gowns and Procedure Packs will be listed, where appropriate.

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

3. Expected outcome of the RFP

(a) PHARMAC intends to establish National Contracts with suppliers to:

(i) list a range of Surgical Drapes, Gowns and Procedure Packs available for use by DHB Hospitals in Part III of Section H of the Pharmaceutical Schedule;

(ii) secure future supply of Surgical Drapes, Gowns and Procedure Packs for DHB Hospitals at competitive prices;

(iii) ensure access to an appropriate level of clinical support, and education, training and associated materials about Surgical Drapes, Gowns and Procedure Packs, for relevant DHB Hospital health professionals;

(iv) engage and establish relationships with suppliers of Surgical Drapes, Gowns and Procedure Packs; and

(v) move commercial arrangements for Surgical Drapes, Gowns and Procedure Packs 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 Surgical Drapes, Gowns and Procedure Packs are contracted for and listed in the Pharmaceutical Schedule. In the event a National Contract is entered into with a supplier as an outcome of this RFP process, and the Surgical Drapes, Gowns and Procedure Packs 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 Surgical Drapes, Gowns and Procedure Packs;

(ii) it will be discretionary for DHB Hospitals to purchase the Surgical Drapes, Gowns and Procedure Packs from the supplier, however where they do, DHB Hospitals will be expected to purchase the Surgical Drapes, Gowns and Procedure Packs under the PHARMAC National Contract;

(iii) it is anticipated that multiple suppliers of Surgical Drapes, Gowns and Procedure Packs will be listed, where appropriate; and

(iv) 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:

(i) proposals for Surgical Drapes, Gowns and Procedure Packs as stated in Schedule 1 clause 5(a) of this RFP;

(ii) a single pricing option per Surgical Drape, Gown and Procedure Pack product; and

(iii) additional pricing options you would like PHARMAC to consider.

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

(b) Suppliers wishing to submit proposals MUST submit proposals for the supply of Surgical Drapes, Gowns and Procedure Packs to DHB Hospitals with pricing to be published on the Pharmaceutical Schedule (without volume/spend commitment).

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

(d) All proposals will need to demonstrate clinical and/or financial benefits for DHB Hospitals in accordance with the evaluation criteria stated in Schedule 2, clause 2. In evaluating this information supplier's current arrangements with DHB Hospitals for the supply of Surgical Drapes, Gowns and Procedure Packs will also be considered.

(e) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Surgical Drapes, Gowns and Procedure Packs during the life of the National Contract, and that if agreed between the parties, the

changed or upgraded product would be made available to DHB Hospitals within a reasonable timeframe.

(f) PHARMAC is not willing to consider proposals for cross-category bundles of products (eg. bundling Surgical Drapes, Gowns and Procedure Packs with Personal Protective Equipment where pricing and/or terms in one category is dependent on usage in the other).

(g) Where a proposal includes the supply of custom Procedure Packs suppliers MUST include details of the proposed model/methodology that would be used to calculate the price of new custom Procedure Pack configurations requested by DHB Hospitals under the national contracting framework.

(h) 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 the Surgical Drapes, Gowns and Procedure Packs category

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

PHARMAC is willing to consider proposals for Surgical Drapes, Gowns and Procedure Packs for listing in Part III of Section H of the Pharmaceutical Schedule for use by DHB Hospitals. The following products are considered **'in scope'** of this RFP:

(i) Single-use sterile surgical drapes as follows:

- Single drapes
- Multiple drape packs
- Drapes for all surgical sub-specialities including but not limited to:
  - Anaesthetics
  - Angiography/Cath lab/Pacemaker
  - Arthroscopy
  - Caesarean
  - Cardiothoracic
  - Central Venous Line
  - Dental
  - ENT
  - Extremity
  - Oral/Maxillofacial
  - Neurosurgery
  - Spine
  - General Endoscopy
  - Laparoscopy
  - Laparotomy
  - Lithotomy
  - Obstetrics/Gynae
  - Orthopaedics/Major Extremity
  - Paediatric
  - Plastic Surgery
  - Universal/Multiprocedural
  - Urology
  - Ophthalmic

- Minor Procedure
- Split sheets/ U-drapes
- Incise drapes – impregnated and non-impregnated

- Accessory/Equipment drapes including but not limited to:
  - Back Table Covers/Trolley Drapes
  - Mayo covers
  - Ring Stand Covers
  - Chair covers
  - Operating table covers
  - Stockinettes
  - Equipment covers – C-arms, light handles, microscopes, cameras, ultrasound probes etc
  - Utility drapes
  - Instrument pouches
  - Isolation bags
  - Fluid pouches
  - Magnetic drapes
  - Operating Room towels
  - Other

(ii) Single-use sterile surgical gowns as follows:
- Single gowns
- Multiple gown packs

(iii) Single-use sterile surgical procedure packs/trays:
- Standard packs/trays
- Custom packs/trays
- Surgical procedure packs/trays for all surgical sub-specialities including but not limited to:
  - Anaesthetics
  - Angiography/Cath lab/Pacemaker
  - Arthroscopy
  - Caesarean
  - Cardiothoracic
  - Central Venous Line
  - Dental
  - ENT
  - Extremity
  - Oral/Maxillofacial
  - Neurosurgery
  - Spine
  - General Endoscopy
  - Laparoscopy
  - Laparotomy
  - Lithotomy
  - Obstetrics/Gynae
  - Orthopaedics/Major Extremity
  - Paediatric
  - Plastic Surgery
  - Universal/Multiprocedural
  - Urology
  - Ophthalmic
  - Other

(b) <u>Out of scope</u>

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

(i) Minor Procedure Packs/Trays (e.g. suture removal or IV kits)

(ii) Non-sterile surgical gowns

(iii) Non-sterile surgical drapes

(iv) Multiple-use surgical gowns

(v) Multiple-use surgical drapes

(vi) Non-surgical grade gowns (e.g. isolation gowns, cytotoxic gowns)

(vii) Non-surgical grade drapes

(viii) Non-sterile surgical packs

(ix) Multiple-use sterile surgical packs

(x) Other surgical apparel (e.g. booties, hair covers, scrubs)

(c) Miscellaneous Surgical Drapes, Gowns and Procedure Packs which are not identified in this RFP as either:

(i) 'in scope' as stated in clause 5(a) of this Schedule; or

(ii) 'out of scope' as stated in clause 5(b) of this Schedule,

will be considered through this process at PHARMAC's discretion.

Schedule 2: RFP process

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

1. Submission

(a) You may submit more than one proposal. Each proposal will be considered as a separate proposal.

(b) All proposals must be submitted by a single submitter. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single submission.

(c) All proposals must be submitted to PHARMAC via GETS no later than **4.00pm (New Zealand time) on 19 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 by 10 December 2018 (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 (**OPPs**), 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 and Attachments 1, 3, 4, and 5 of this RFP;

(ii) your ability to legally supply the proposed products to New Zealand DHB Hospitals;

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

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

(B) training and education in equipment cleaning and maintenance (where applicable);

(C) technical support (where applicable);

(D) equipment tracking, maintenance and repair (where applicable); and

(E) transition support;

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

(A) stock management;

(B) supply chain;

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

(v) your ability to demonstrate clinical and/or financial value benefits for DHB Hospitals;

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

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

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

(ix) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

(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. Category specific terms, including terms for equipment, would be negotiated with successful submitter(s) and would be included within Parts 8 and 9 of the National Contract.

(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 the terms and conditions you would seek to amend during any negotiation.

(d) Given that PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiation with you on price. However, PHARMAC does not exclude the possibility that the final price agreed will be different from the price put forward in your proposal, as a result of the impact that other negotiated terms may have on price.

(e) PHARMAC may negotiate and enter into a provisional National Contract with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.

(f) If PHARMAC and the supplier(s) are unable to reach a provisional National Contract within what PHARMAC considers to be a reasonable time, PHARMAC may terminate those negotiations and negotiate with a different supplier(s).

5. Consultation and approval

(a) Any provisional National Contract will be conditional on consultation with suppliers and other interested parties, to the extent PHARMAC considers consultation to be necessary or appropriate, and on-Board approval (or approval by the Board's delegate acting under delegated authority).

(b) PHARMAC will not consider any counter-offers received during consultation.

(c) The provisional National Contract and responses to consultation will be considered by PHARMAC's Board (or by the Board's delegate acting under delegated authority) in accordance with the FFC in PHARMAC's then current Operating Policies and Procedures.

(d) If the Board or its delegate does not approve the provisional National Contract, then PHARMAC may initiate negotiations for a provisional National Contract with any other supplier(s).

(e) The RFP process will be complete once PHARMAC has notified suppliers of either:

(i) the Board's or its delegate's decision to accept a negotiated National Contract; or

(ii) the termination of the RFP process.

6. Miscellaneous

(a) PHARMAC reserves the right, having regard to probity principles:

(i) to make such adjustments to the above RFP process as it considers appropriate, at any time during the process, provided that it notifies suppliers affected by those changes;

(ii) not to accept any proposal;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(vi) to suspend this RFP process. For example, if during the RFP process (and before a provisional National Contract is entered into) it becomes apparent to PHARMAC that further consultation is appropriate or required we may suspend the RFP process in order to consult. In this situation we may ask you to adapt and resubmit your proposal in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit; and

(viii) to re-advertise for proposals.

(b) You must not initiate or engage in any communication with other suppliers in relation to the RFP, whether before or after submitting their proposal(s), until such time as a provisional National Contract is accepted by PHARMAC's Board or the Board's delegate.

(c) You must not at any time initiate any communication with PHARMAC, the Ministry of Health (including its operation unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs, or advisors to PHARMAC, with a view to influencing the outcome of this RFP process.

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

(e) You must limit the information provided to that which is requested in 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.

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

(g) Your submission of a proposal will be taken as acceptance of the terms contained in this RFP. PHARMAC may exclude your proposal if you do not comply with any of the terms contained in this RFP document.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of Single-use Sterile Surgical Drapes, Gowns and Procedure Packs by PHARMAC's apparent acceptance, and instead a separate agreement needs to be negotiated.

(i) PHARMAC is not liable in any way whatsoever for any direct or indirect loss (including loss of profit), damage or cost of any kind incurred by you or any other person in relation to this RFP.

(j) It is possible that more than one supplier may be awarded a National Contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Surgical Drapes or restricts the terms that may be agreed with any other supplier.

(k) PHARMAC will consider your proposal and information exchanged between the parties in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal advisors and other consultants, the Ministry of Health and DHBs ("**Confidential Information"**). However, you acknowledge that it may be necessary or appropriate for PHARMAC to release Confidential Information:

(i) pursuant to the Official Information Act 1982; or

(ii) in the course of consultation on a provisional National Contract entered into with a supplier; or

(iii) in publicly notifying any approval by the PHARMAC Board of that National Contract; or

(iv) otherwise pursuant to PHARMAC's public law or any other legal obligations.

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

7. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the PHARMAC internal Evaluation Committee evaluating proposals from February 2019;

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

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

(iv) PHARMAC's Board, or the Board's delegate, considering any provisional National Contracts from 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. PHARMAC expects to evaluate proposals in tranches which may result in some National Contracts being implemented before all proposals have been evaluated.

(b) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is June 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: Surgical Drapes, Gowns and Procedure Packs spreadsheet	You **must** complete all fields in **Attachment 1** for each proposed product. If you consider a field not applicable you must state "N/A".
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. You **must** provide WAND registration numbers for your proposed products in the relevant column in **Attachment 1.** Where WAND registration is not applicable to a proposed product you **must** state the reason why it is not applicable in the relevant column in **Attachment 1.**
International compliance	You **must** provide evidence of international compliance certification including TGA, FDA CE or other compliance certification held for all proposed products by completing the relevant columns in **Attachment 1** for each proposed product. You **must** attach a copy of all relevant certificates and include the certificate number in the file name of the attached document so that it can be easily identified. You **must** include the file name(s) of the attached document(s) in the relevant table in **Attachment 4.**
EN 13795	You **must** provide evidence that all of the surgical drapes and gowns included in your proposal, including those in any proposed procedure packs, meet EN 13795 by completing the relevant columns in **Attachment 1**. If any of the surgical drapes and gowns included in your proposal, including those in any proposed procedure packs, have not been tested against EN 13795 you **must** provide evidence of alternate equivalent standards that they meet by completing the relevant columns in **Attachment 1**. You **must** attach a copy of all relevant certificates. You **must** include the file name(s) of the attached document(s) in the relevant table in **Attachment 4.**
ANSI/AAMI PB70:2012	For all surgical drapes and gowns included in your proposal, including those in any proposed procedure packs, you **must** provide evidence of the AAMMI Level that the product meets by completing the relevant columns in **Attachment 1**. If any of the surgical drapes and gowns included in your proposal, including those in any proposed procedure packs have not been tested against ANSI/AAMI PB70:2012 you **must** provide details of the alternative equivalent liquid barrier level standard that they meet by completing the relevant columns in **Attachment 1**. You **must** attach a copy of all relevant certificates.

Document	Evidence / Information
	You **must** include the file name(s) of the attached document(s) in the relevant table in **Attachment 4.**
Flammability rating	You **must** provide evidence of the flammability rating (e.g. Class 1 CFR1610 or Class I1-21 ISO 11810-1) of all of the surgical drapes and gowns included in your proposal, including those in any proposed procedure packs, by completing the relevant columns in **Attachment 1**. You **must** provide evidence of the flammability rating of any products in surgical procedure packs included in your proposal, where flammability of the product is a known risk in a surgical environment, by completing the relevant columns in **Attachment 1**. You **must** attach a copy of all relevant certificates. You **must** include the file name(s) of the attached document(s) in the relevant table in **Attachment 4.**
GS1 (GTIN) and UNSPSC	It is desirable that you provide GTIN and UNSPSC codes for each proposed Surgical Drape, Gown and Procedure Pack 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. Please provide any GTIN and UNSPC codes in the relevant columns in **Attachment 1**. GTIN provided **must** be 14 digits and **must** be a unique number for each product and product presentation.
DHB usage data	For each line item submitted you **must** provide national (all DHBs combined) volume and cost information for all DHB Hospitals for the period **1 October 2017 to 30 September 2018** by completing the relevant columns in **Attachment 1**. The above data **must** include any sales to DHB Hospitals via logistics providers.
Stock status	For each line item submitted you **must** provide details of the stock levels held in NZ by completing the relevant columns in **Attachment 1**.
Lead times	For each line item submitted you **must** provide details of the delivery lead time for: • DHBs currently purchasing the product; • A new DHB wanting to transition to the product; • Any product that is not currently held in stock in NZ and not ordered on a regular basis by DHBs (i.e. indent stock) by completing the relevant columns in **Attachment 1.**
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**.

Document	Evidence / Information
	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**.
Attachment 4: Document and information checklist	You **must** complete the document and information checklist set out in **Attachment 4**. You **must** note the file names of all documents attached to support your proposal in the relevant tables provided in **Attachment 4.**
Attachment 5: Financial analysis of your Surgical Drapes, Gowns and Procedure Packs	If any of your proposed products were supplied to any DHB Hospital(s) (contracted and non-contracted) for the period **1 October 2017 to 30 September 2018** you **must** provide a detailed financial impact analysis of your proposal for each product and each DHB based on recent usage by completing **Attachment 5**. Any sales via Onelink or other 3PL provider **must** be allocated to the relevant DHB in the financial impact analysis. If you have submitted any alternative pricing options for consideration, you **must** provide a detailed financial impact analysis for each alternative pricing option proposed. You **must** provide a detailed description of any special conditions that the DHB had to meet to qualify for the price paid for any proposed product during the period **1 October 2017 to 30 September 2018** by completing the relevant column in **Attachment 5.**
Schedule 4: Proposal form	You **must** complete all sections of Schedule 4. If you consider a section to be not applicable, you **must** state "N/A". The response you provide in each section **must** be comprehensive and relevant to the information that has been requested, and you **must** include all requested attachments. You **must** include the file name(s) of the attached document(s) in the relevant table in **Attachment 4.**

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/- Josh Wiles
Procurement Manager

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

Dear Sir/Madam

Proposal for the supply of Single-use Sterile Surgical Drapes, Gowns and Procedure Packs

In response to your request for proposals (**RFP**) dated 9 November 2018 we put forward the following proposal in respect of Surgical Drapes, Gowns and Procedure Packs.

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, 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	
New Zealand Business Number	
Address	
Phone	
Email	
Facsimile	
(b) Contact person (s) for this RFP	
Name	
Position	
Phone	
Mobile	
Email	
(c) Liaison person(s) for DHB Hospitals and PHARMAC	
Name	
Position	
Phone	
Facsimile	

Email	
Detail training and experience	
(d) Customer Support and General Enquiries	
Customer Service Hours (NZST)	
Phone	
Facsimile	
Email	
(e) Details of proposed Contract Manager	
Name	
Position	
Phone	
Email	

(f) Executive summary	
Proposal summary Include: • overview of products and services including whether the proposal is for surgical drapes and/or surgical gowns and/or surgical procedure packs • benefits to DHB Hospitals of this proposal • why PHARMAC should accept this proposal	**Maximum 500 words**

(g) Information about our company, contracts and markets	
Company information	
Type of entity (legal status) E.g., 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. **Attach** Organisational Chart, note the file name of the attachment in the response column and in the relevant table in Attachment 4	
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). For suppliers not currently based in New Zealand include information on whether you intend to establish local representation in New Zealand and how you would manage the needs of DHB Hospitals from your current location.	
Company ownership	

State ownership (e.g. 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 (as detailed in Part 6, clause 28 of PHARMAC's Terms of Listing of Medical Devices on the Pharmaceutical Schedule -Attachment 2) Include: • how you would cover your financial liabilities in the event of a major failure to supply (e.g. a recall) • information about your financial stability (e.g. annual turnover, guarantor companies) **Attach** supporting evidence (e.g. annual financial report, Companies Register financial statement, insurance certificate, bank letter), note the file name of the attachment in the response column and in the relevant table in Attachment 4.	
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 (e.g. now standing agreement after contract expiry) Can be provided as an attachment, note the file name of the attachment in the response column and in the relevant table in Attachment 4.	
Products or procurement options not included Include any Surgical Drapes, Gowns and Procedure Packs and any procurement options currently supplied to DHB Hospitals (contracted or not	

contracted) that are not included in this proposal and the reason for this.	
Information on other major markets for proposed product ranges. For each product range include: • type of market (e.g. private hospital, public hospital) • any contracts held • annual revenue • any other relevant information	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.*
Products not currently purchased by DHBs For any products included in your proposal that are not currently purchased by DHB Hospitals provide: • whether the products are actively marketed in New Zealand • how the proposal demonstrates clinical and/or financial value benefit for DHBs	
Other relevant company and market information	

(h) 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 implementation support, clinical support, 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 (e.g. surgeons, theatre nurses,) • other relevant information	
Training and education materials Include training and education materials that would be provided to DHB Hospitals purchasing the proposed products, including but not limited to theatre clinical staff. Include details of any other educational/developmental sponsorship your company provides (if any) for DHB Hospital staff associated with Drapes, Gowns and Procedure Packs (eg. conference packages, conference fees, travel and accommodation expenses). Include whether it is paid in full or partially subsidised by your company.	
Transition support Include an outline of the support that would be provided to DHB Hospitals transitioning to the proposed products. **Attach** a detailed transition plan setting out the transition steps, roles and responsibilities and timeframes. Note the file name of the attachment in the response column and in the relevant table in Attachment 4. If you are a current supplier, outline how your proposal would support DHBs currently purchasing your single-use Sterile Surgical Drapes, Gowns and Procedure Packs to transition to a PHARMAC agreement should this eventuate.	
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 your ability to support the proposed products.	

(i) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals		
Stock Management		
Stock holding within New Zealand As detailed in Part 6 clause 26.1 of PHARMAC's Terms of Listing of Medical Devices on the Pharmaceutical Schedule (Attachment 2), PHARMAC's preferred option for stock levels is three months' supply in New Zealand for all products included in your proposal that have forecast purchases by DHB Hospitals. 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.		
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, 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	

(j) Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, attach evidence.** Note the file name of the attachment in the response column and in the relevant table in Attachment 4. 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.** Note the file name of the attachment in the response column and in the relevant table in Attachment 4. Include: • manufacturer's name • relevant section(s) of standard where certification is not for full standard	ISO 9001	ISO 13485	Other
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	Standard	Compliance	Evidence

Describe the extent of compliance with the listed standard and the product range the standard applies to. Please include detail of any other standards your proposed products comply with in this table. **Attach** evidence of compliance where available. Note the file name of the attachment in the response column and in the relevant table in Attachment 4. Information related to CE/FDA/TGA certification, EN13795, ANSI/AAMI PB70:2012 and flammability rating is captured in Attachment 1. Please do not include this information in your response to this question.			
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.			
WAND exempt medical devices Provide justification for any medical devices that are exempt from notification on WAND. Products that are WAND exempt should be identified in Attachment 1.			
International compliance exemption Provide justification for any medical devices that are exempt from international compliance certification			

(k) Pricing and financial analysis of our proposal

Financial impact Include: • overview of how proposed pricing compares to that currently offered to DHB Hospitals • justification for any price increases for DHB Hospitals as a result of the proposal Your response must discuss and support the detailed financial impact analysis submitted in Attachment 5.	***NB.*** *Only required if any of the proposed products are currently supplied to DHB Hospitals*
Alternative pricing models Include: • details of any alternative pricing models and associated qualification requirements • details of any DHB Hospitals currently accessing the alternative pricing models • details of how you would implement and monitor qualification requirements for DHB Hospitals. Any alternative pricing models must have a financial analysis submitted in Attachment 5 if any of the proposed products are currently supplied to DHB Hospitals.	
Proposed model/methodology that would be used to calculate the price of new custom Procedure Pack configurations requested by DHB Hospitals under the national contracting framework. Include: • any tools that are used by you and/or provided to a DHB Hospital to assist in the design and development of Procedure Packs • details of how this compares to the model/methodology used to price custom Procedure Packs currently in use in DHB Hospitals • details of strategies you employ to assist DHBs in reducing the cost of new custom Procedure Pack configurations. • details of any customer Procedure Packs currently in development for	

DHB Hospitals that are not listed in Attachment 1. Can be provided as an attachment, note the file name of the attachment in the response column and in the relevant table in Attachment 4.	
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) 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.	