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Pharmaceutical Management Agency

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25 October 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF NON-SURGICAL ANTIMICROBIAL HAND HYGIENE PRODUCTS

PHARMAC invites proposals for the supply of non-surgical antimicrobial hand hygiene **(Hand Hygiene**) products to District Health Board (**DHB**) hospitals in New Zealand.

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

- Schedule 1 sets out the background to the RFP, the range of products PHARMAC is seeking proposals for and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedules 3 to 5 and Attachment 1 specify the format, company and product information and specifications that you must include as part of your proposal; and
- Attachment 2 contains PHARMAC Standard Terms and Conditions for Medical Devices.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **5.00 pm Friday 1 December 2017.**

If you have any questions about this RFP, please submit these via GETS.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

Schedule 1: Medical Devices, 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 DHBs. In August 2012, Cabinet approved an accelerated plan for transitioning this work to PHARMAC.

(b) *Reasons for running the RFP*

PHARMAC is taking a phased approach to its activity in medical devices. The objective of this activity is to help achieve national consistency in managing medical devices, improve transparency of decision-making and improve the cost-effectiveness of public spending to generate savings for re-investment into health.

(c) *Impact of RFP*

PHARMAC intends to establish national listing agreements (**National Contracts**) with suppliers to secure supply of Hand Hygiene products used in DHB hospitals. It is expected that Hand Hygiene products subject to a listing agreement will be listed in Part III of Section H of the Pharmaceutical Schedule. Listing agreements would not be exclusive of other suppliers, and it is possible that multiple suppliers of equivalent Hand Hygiene products will be listed, where appropriate.

(d) *Previous PHARMAC procurement activity in this category*

In June 2016 PHARMAC published an invitation for expressions of interest (**EOI**) for the supply of Hand Hygiene products to DHB hospitals.

During this activity, PHARMAC received advice from Medsafe that all antimicrobial skin products (e.g. hand rubs, soaps, wipes) used as part of the provision of health services (as defined in section 2 of the Health and Disability Commissioner Act) are considered to be medicines. This regulation was inserted as regulation 58A during an amendment of the Medicines Regulations (1984) in 2011.

Information obtained from responses to the EOI for Hand Hygiene products indicated that the majority of Hand Hygiene suppliers were unaware of the regulatory requirements for antimicrobial skin products used in the provision of health services and their products had not been approved as medicines.

PHARMAC terminated the EOI for Hand Hygiene products and postponed progressing the procurement of this category until late 2017 to allow suppliers time to complete the approval process for their products.

The scope of this category of Medical Devices has changed since the EOI published in June 2016. PHARMAC's Hand Hygiene product category no longer includes:

- non-antimicrobial liquid hand soaps products - these are covered by All-of-Government contracts managed by the Ministry of Business, Innovation and Employment; or
- moisturisers – these are currently listed in Part II of Section H of the Pharmaceutical Schedule.

2. Expected outcome of the RFP

(a) As a result of this RFP, PHARMAC expects to:

(i) list a range of Hand Hygiene products available for use in DHB hospitals in Part III of Section H of the Pharmaceutical Schedule;

(ii) secure future supply of Hand Hygiene products for DHB hospitals at competitive prices;

(iii) ensure access to an appropriate level of clinical support, education and training for relevant health professionals;

(iv) engage and establish relationships with new and current suppliers of Hand Hygiene products; and

(v) move commercial arrangements for Hand Hygiene products into a national framework administered by PHARMAC to create better health outcomes for patients within the funding available in DHB hospitals.

(b) PHARMAC recognises that the use of medical devices touches a wide group of health professionals. Therefore, in the event an agreement is entered into with a supplier as an outcome of this RFP process and the Hand Hygiene 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 Hand Hygiene products;

(ii) it will be discretionary for DHBs to purchase the Hand Hygiene products from the supplier, however where they do, DHB Hospitals will be expected to purchase these Hand Hygiene products under the PHARMAC listing agreement;

(iii) it is anticipated that multiple suppliers of Hand Hygiene products will be listed, where appropriate; and

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

(c) 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 comply with the Pharmaceutical Schedule as determined by PHARMAC.

3. Types of proposals sought

(a) PHARMAC is willing to consider the proposals for Hand Hygiene products that hold, or are significantly through the process of obtaining, Medsafe consent to be distributed as a medicine in New Zealand for listing in Part III of Section H of the Pharmaceutical Schedule for use in DHB hospitals.

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

(c) Proposals must meet all the mandatory requirements as set out in the responses column of Schedule 5.

(d) Proposals may be submitted on the basis that there may be incremental changes or upgrades for the proposed Hand Hygiene products during the life of the PHARMAC listing agreement, and that if agreed between PHARMAC and the successful supplier, the changed or upgraded product would be made available to DHBs within a reasonable timeframe.

(e) Suppliers must complete Schedules 3 to 5 and Attachment 1 and provide all requested supporting documents. Proposals that do not include the completed Schedules, Attachment 1 or requested supporting documents, or do not conform to all instructions provided in the RFP, may be excluded from consideration.

4 Scope of Hand Hygiene products category

(a) In-Scope

For the purposes of this RFP, PHARMAC is willing to consider proposals for non-surgical antimicrobial hand hygiene products that hold, or are significantly through the process of obtaining, Medsafe consent to be distributed as a medicine in New Zealand.

The following non-surgical antimicrobial hand hygiene products are considered 'in scope' of this RFP:

(i) liquid alcohol based hand rubs;

(ii) foam alcohol based hand rubs;

(iii) gel alcohol based hand rubs;

(iv) alcohol based hand rubs with second active ingredient;

(v) liquid non-alcohol based hand rubs;

(vi) foam non-alcohol based hand rubs;

(vii) gel non-alcohol based hand rubs;

(viii) antimicrobial liquid hand soaps; and

(ix) dispensers and/or accessories (e.g. lanyards, wall brackets) associated with the above products.

(b) Out-of-scope

PHARMAC is not willing to consider proposals for Hand Hygiene products that do not hold, or are not significantly through the process of obtaining, Medsafe consent to be distributed as a medicine in New Zealand.

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

(i) non-antimicrobial liquid hand soaps;

(ii) moisturisers;

(iii) alcohol wipes;

(iv) detergent / disinfection wipes;

(v) towelettes;

(vi) hand towels and dispensers;

(vii) tablet soap;

(viii) surface sanitisers;

(ix) surgical scrub brushes;

(x) surgical hand scrub;

(xi) surgical skin preparations;

(xii) adhesive removers;

(xiii) pre and post-operative body washes;

(xiv) barrier breams;

(xv) surface sanitizers; and

(xvi) environmental sanitizers.

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 Supplier. Submitters may have joint commercial arrangements with other suppliers and these can be combined into a single proposal.

(c) All proposals must be submitted to PHARMAC via GETS no later than 5.00 pm (New Zealand time) on **Friday 1 December 2017**. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and maintaining the 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.

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" ("pharmaceutical" is defined to include medical devices). In doing so the Evaluation Committee will be guided by the Factors for Consideration (**Factors**) that form part of PHARMAC's then current Operating Policies and Procedures (**OPP**s), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable.

(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 Factors which relate directly to these aspects will be given the greatest weight by the Evaluation Committee but all Factors 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 Schedules 3 to 5 and Attachment 1 of this RFP;

(ii) evidence provided by you in accordance with the requirements set out in Schedule 3 of this RFP;

(iii) information on your ability to meet PHARMAC's Standard Terms and Conditions (as set out in Schedule 4 and Attachment 2);

(iv) information on your 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 products;

(B) information for patients (where applicable); and

(C) supply chain to support sustainable provision of products;

(v) DHB usage data and, where applicable, reference sites;

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

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

(viii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(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 suppliers 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 Schedule 4 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 negotiations 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 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 Factors in PHARMAC's then 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(s); 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 agreement 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 you and/or they submit a proposal(s), until such time as a provisional agreement 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 operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC with a view to influencing the outcome of this RFP process.

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

(e) You must limit the information provided to that which is requested in Schedules 3 to 5 and Attachment 1 and provide it succinctly and clearly.

(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 it does not comply with any of the terms contained in this RFP.

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of Hand Hygiene products 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 contract as a result of this RFP. Nothing in this RFP prevents PHARMAC from entering into agreements with other suppliers in respect of Hand Hygiene products or restricts the terms that may be agreed with any other supplier.

(k) PHARMAC will consider your proposal and information exchanged between us 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.

(l) 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

Following receipt of proposals, PHARMAC anticipates:

(a) The Evaluation Committee evaluating proposals in January – February 2018;

(b) negotiating with submitter(s) of one or more preferred proposals in March 2018;

(c) consulting on provisional agreement(s) in April 2018;

(d) PHARMAC's Board, or the Board's delegate, considering provisional agreement(s) for approval in or after May 2018; and

(e) Hand Hygiene products agreement(s) being approved, and agreement(s) finalised for 1 July 2018 listing,

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

8. Governing Law

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

Schedule 3: Proposal form

Note: An electronic version of this form is available on GETS or on PHARMAC's website. You should expand the boxes as necessary. Parts (a) to (q) are mandatory and must be completed, Parts (r) to (t) are optional.

[*Supplier to insert date*]

Director of Operations
C/- Jacquie Pillay
Senior Device Category Manager
PHARMAC

By electronic transfer using GETS.

Dear Madam

Proposal for the supply of Hand Hygiene products to DHB Hospitals

In response to your request for proposals (**RFP**) dated 25 October 2017, we put forward the following proposal in respect of Hand Hygiene products.

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

Signed for and behalf of < insert name of submitter>

Signature:

<Insert name>

<Insert designation>

(a) Our contact details:

Full legal trading name of supplier in New Zealand	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Key features of our proposal:

(c) Information about our company structure - in New Zealand and globally (if applicable):

(d) Information about our financial resources:
Your response must include information about your ability to manage liability in the event of a major product recall or failure to supply event as described in Part 6 of PHARMAC's standard terms and conditions for the supply of medical devices – refer to Attachment 2.

(e) Information about our Business Continuity Plan:

(f) Information about management, technical skills, qualifications and experience of our company's staff:
Your response must include information that relates specifically to staff involved in the supply and support of Hand Hygiene products.

(g) Information about our current supply arrangements, supply volumes and relevant supply terms in other major markets including recent tenders awarded (in New Zealand and/or other countries):
Your response must include information that relates specifically to the supply of Hand Hygiene products.

(h) Information about our previous supply performance and relevant expertise in providing Hand Hygiene products, in New Zealand and in other countries:

(i) Information about our relevant business, supply chain and manufacturing quality assurance processes:
If you are not the manufacturer of the products, your response must also include information that relates to the manufacturer's quality assurance processes. Please indicate in your response what international standards (e.g. ISO, GMP) these processes meet, if any, and if they are externally audited.

(j) Information on our proposed distribution and supply arrangements for Hand Hygiene products and our ability to ensure continuity of supply to DHB hospitals:
Your response must include information on:
- *whether you are a manufacturer or distributor of the proposed products;*
- *terms of any distribution agreements if you are not the manufacturer (e.g. duration and exclusivity of the distribution agreement);*
- *the supply chain used to bring stock to New Zealand;*
- *your ability to hold a minimum of 3 months stock of these products in New Zealand (preferred stock holding option) or your ability to ensure continuity of supply if 3 months stock cannot be held in New Zealand;*
- *minimum order size;*
- *delivery frequency;*
- *freight charges- if any (free into store is the preferred model);*

- *lead times for a stable demand situation;*
- *your processes and lead times in the event of supply disruptions;*
- *your processes and lead times when there is an unexpected surge in demand for your products; and*
- *any specific measures you will take to secure stock for New Zealand from international production*.

(k) Information on current or proposed resources and activities we would make available or implement to support DHB hospitals purchasing our product (e.g. training, clinical support and education resources/materials):
Your response must include:
- *a statement of your understanding of DHB hospital educational, training and clinical support requirements;*
- *information on the scope, format, quantity and frequency of education, training and clinical support activities;*
- *information on the scope, format and quantity of education resources/materials (including those directed at patients);*
- *information on any additional costs associated with education and clinical support – if any (the preferred model is for education and clinical support activities and resources to be provided free of charge);*
- *information on the skills and experience of your education, training and clinical support staff;*
- *information on how you would track education, training and clinical support services provided to a DHB hospital and report this information to the DHB; and*
- *your proposed transition plan for DHBs wanting to change to your brand.*

(l) Information on current or proposed complaints management processes, including ability to recall stock, refund or credit for damaged or faulty goods:

(m) Evidence that the proposed Hand Hygiene products hold, or are significantly through the process of obtaining, Medsafe consent to be distributed as a medicine in New Zealand:
Insert additional rows to the tables, as required. Copies of all listed Gazette notices must be attached to your submission. If you are in the process of obtaining market approval please attach evidence of the current evaluation status of the new medicine application with Medsafe. Please label these documents as Gazette Notice <insert date>, Medsafe Status <insert date of submission>.

Hand Hygiene products that hold market approval	
Hand Hygiene product	**Date of market approval**

Hand Hygiene products that are in the process of obtaining market approval		
Hand Hygiene product	**Date of Dossier Submission**	**Evaluation Status*** A = Initial evaluation B =Request for information #1 C = Evaluation of additional information #1 D = Request for information #2 E = Evaluation of additional information #2 F = completed

(n) Contact details (name, job title, hospital name and full address, phone number and email) for 2 supply chain referees and 2 clinical referees, who can be contacted if required, regarding our company's performance in supplying and supporting their hospitals use of your Hand Hygiene products:
These can be overseas referees if you are not currently selling product in New Zealand.

(o) Information relating to any existing alternative price models, currently accessed by DHBs, that involve the proposed Hand Hygiene products (e.g. volume commitment pricing, bundles, rebates):
If none, please write not applicable.
Your response must include:

- *a detailed description of the model(s) including pricing and qualification requirements to access alternative pricing model(s);*
- *a list of DHBs currently accessing the model(s) and the level/type of alternative pricing/rebates accessed by each DHB; and*
- *$ value of the alternative pricing/rebate model(s) for each DHB for the period 1 October 2016 – 30 September 2017.*

Note: Additional documents (e.g. spreadsheets) may be attached to your submission to assist in providing this information. Please label these documents as Alternative Price Model- Attachment 1, Alternative Price Model- Attachment 2 etc.

(p) Information relating to pricing ($NZ, GST exclusive) submitted in our proposal, including any related conditions or proposed terms affecting cost for PHARMAC:
If none, please write not applicable.

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

(r) Proposals/suggestions regarding Hand Hygiene products, not expressly identified in this RFP, that we would like PHARMAC to consider as part of our proposal:

(s) Reasons why PHARMAC should accept our proposal:

(t) Additional information that PHARMAC should consider when evaluating our proposal:
Consider any relevant information under PHARMAC's Factors for Consideration *decision making framework.*

Schedule 4: Acceptance of PHARMAC Standard Terms and Conditions for Medical Devices Part 1-7

An electronic version of this form is available on GETS or on PHARMAC's website.

Note: Parts 1-7 are standard terms and conditions. Parts 8 and 9 and all Schedules contain terms and conditions specific to the individual supplier and its contracted devices and have not been attached. Where reference is made in Parts 1-7, to Part 8, Part 9 and the Schedules, the required detail will be negotiated with the successful supplier.

Proposal for the supply of Hand Hygiene products

[Company name] declares the following:

I have read and understood the proposed PHARMAC Standard Terms and Conditions for Medical Devices Parts 1-7 (Attachment 2) and **agree/disagree** with the terms and conditions of contract.

I have provided detailed comment about all terms and conditions we do not agree with in the table below:

Signature(s):

Name:

Position:

Date:

Additional rows can be added to the table as required

Clause Number	Comments

Schedule 5: Checklist of documents to be submitted with your proposal

An electronic version of this form is available on GETS or on PHARMAC's website.

Refer to main RFP document for full details regarding required documents.

Please ensure all of the following documents are submitted with your proposal. Proposals that do not include mandatory responses will only be considered at PHARMAC's discretion, taking into account fairness to other suppliers and maintaining the integrity of the RFP process.

Schedule / Attachments/Appendices	**Response**	**Attached to submission (Yes/No)**
Schedule 3 – Proposal form	Mandatory • *Parts (a) to (q) are mandatory and must be completed* • *Parts (r) to (t) are optional*	
Schedule 4 - Acceptance of PHARMAC Standard Terms and Conditions for Medical Devices Part 1-7	Mandatory	
Schedule 5 - Checklist of documents to be submitted with your proposal	Mandatory	
Attachment 1: • Products and pricing spreadsheet • Financial impact analysis by DHB	Mandatory • *Provision of GS1(GTIN) and UNSPSC numbers is desirable (not mandatory).* • *The financial impact analysis is only applicable where a proposed Hand Hygiene product is currently supplied to one or more DHB hospitals.* • *Please ensure that all instructions as written at the top of the spreadsheet and in the column headings have been followed and that all mandatory information is provided.*	
Gazette notices and/ or evidence that you are in the process of obtaining market approval – refer Schedule 3(m)	Mandatory • *Gazette notices for products with Medsafe market approval must be submitted.* • *If you are in the process of obtaining Medsafe market approval you must provide of the current evaluation status of the new medicine application with Medsafe. Please label these documents as Gazette Notice <insert date>, Medsafe Status <insert date of submission>.*	
Alternative price model attachments – refer Schedule 3(o)	Optional • *Please label these documents as Alternative Price Model- Attachment 1, Alternative Price Model- Attachment 2 etc*	