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

6 November 2017

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PERMANENT CORONARY DRUG-ELUTING STENTS TO DISTRICT HEALTH BOARDS UNDER A MARKET SHARE PROCUREMENT MODEL

PHARMAC invites proposals for the supply of permanent coronary drug-eluting stents to New Zealand District Health Board (**DHB**) Hospitals under a market share procurement model.

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

- Schedule 1 specifies the range of devices for which PHARMAC is requesting proposals and sets out the background to the RFP and the types of proposals sought;
- Schedule 2 describes the process that PHARMAC expects to follow in relation to the RFP;
- Schedule 3 sets out information about the estimated size of the current market for the devices;
- Schedules 4 to 7 and Attachment 1 specify the information and evidence you need to include in your proposal and provide the RFP forms in which you are to provide details of your proposal.

If you wish to submit a proposal, please submit it to PHARMAC via the Government Electronic Tenders Service (**GETS**) no later than **4.00 p.m**. on **Friday 15 December 2017**.

If you have any inquiries about this RFP you should submit them via GETS. Answers to questions will be provided through GETS. PHARMAC will also post any addenda through GETS. We encourage interested suppliers to register with GETS and subscribe to this RFP to be kept up to date.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

A1073657

Schedule 1: Background to RFP and types of proposals sought

1. Medical Device

PHARMAC is interested in considering any market share proposals from suppliers of permanent coronary drug-eluting stents (**DES**) in the form of:

(a) a proposal to be the primary supplier for these products, with a minimum share of 65% of the DHB hospital market; and/or

(b) a proposal to be one of two suppliers, which collectively share a minimum of 90% of the DHB hospital market.

2. Background to RFP

The background to this RFP is as follows:

(a) In April 2014 PHARMAC issued a registration of interest (**ROI**) for the supply of interventional cardiology devices to DHB Hospitals. This process resulted in the establishment of non-exclusive national listing agreements with thirteen suppliers covering the majority of interventional cardiology devices currently purchased by DHB Hospitals. Details of the Interventional Cardiology devices listed in Part III of Section H of the Pharmaceutical Schedule can be found on our website.

(b) In April 2015 PHARMAC issued a discussion document on PHARMAC's proposed approach to market share procurement (**MSP**) for hospital medical devices. A summary of the submissions received and PHARMACs responses to the key themes can be found on our website.

(c) In 2016, PHARMAC sought nominations from the New Zealand Branch of the Cardiac Society of Australia and New Zealand (**CSANZ**) for the formation of an Interventional Cardiology Advisory Group (**ICAG**) to provide objective clinical advice to assist PHARMAC in determining strategies going forward in regard to managing future assessment, standardisation, prioritisation and procurement of interventional cardiology devices.

(d) In 2017, PHARMAC sought clinical advice from the ICAG to assist with the development of this market share RFP – the minutes of ICAG meetings can be found on our website. We expect to continue to seek clinical advice from the ICAG and other relevant stakeholders throughout the RFP process.

(e) PHARMAC is now seeking proposals for the supply of DES to New Zealand DHB Hospitals under a market share procurement model.

(f) This RFP is open to all suppliers of DES. Suppliers do not need to have current contracts with PHARMAC or be currently supplying to DHB hospitals in New Zealand.

(g) By undertaking this RFP process, we expect to:

i. generate a greater level of competition so that further savings can be realised for DHB Hospitals, while still providing access to clinically appropriate ranges of DES; and

ii. provide national consistency and equitable access to clinically appropriate DES across all DHBs with cardiac catheterisation laboratories.

(h) The impact to DHBs for any RFP decision will depend on the nature of the decision, the current product mix at individual DHBs and existing contractual arrangements in place at individual DHBs (e.g. bundle arrangements). Costs associated with the implementation of a market share model will be assessed and considered by PHARMAC throughout the process.

(i) It is possible that some DHBs may be required to make changes to product mix or suppliers depending on the outcome. Where appropriate, PHARMAC expect to provide support to DHBs to allow a smooth transition into any new arrangements.

(j) 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. Scope of RFP

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

For the purpose of this RFP, PHARMAC is willing to consider proposals for DES that meet the following mandatory criteria:

i. are permanent coronary DES;

ii. are WAND registered at the time of submission for this RFP;

iii. hold, or are in the process of obtaining, CE certification or FDA certification or TGA approval at the time of submission for this RFP. PHARMAC will consider proposals where your product/s are yet to obtain CE or FDA or TGA certification. In those circumstances, you will be required to demonstrate your ability to obtain the relevant certification within a timeframe acceptable to PHARMAC; and

iv. are fit for purpose and clinically appropriate for the majority of patients in New Zealand as evidenced through clinical trial data/registry data/surveillance data.

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

For the purpose of this RFP, PHARMAC is not willing to consider proposals for any other devices, including but not limited to:

i. any stents other than permanent coronary drug eluting stents (e.g. bioresorbable stents, bare metal stents, non-coronary stents);

ii. other interventional cardiology devices (e.g. dilatation balloon catheters, guidewires);

iii. other medical devices.

4. Market Share Models and Discretionary Variance Limits

(a) For the purpose of this RFP, PHARMAC is seeking proposals for up to two suppliers for DES. The possible outcomes of the RFP process are as follows:

Scenario 1: Hospital supply status with 35% discretionary variance (DV) limit	DHBs must purchase from a single supplier, selected brands of DES, for at least 65% of DES purchased, with the discretion to purchase outside this range for up to 35% of DES purchased.
Scenario 2: Dual supply with 10% discretionary variance (DV) limit	DHBs must purchase from a choice of two suppliers', selected brands of DES, for at least 90% of DES purchased, with the discretion to purchase outside this range for up to 10% of DES purchased.

(b) PHARMAC anticipates that the terms and conditions relating to DV limits will operate on the following basis:

i. a DV limit applies only to DES;

ii. a DV device is any DES that is not listed as having hospital supply status or dual supply status in Part III Section H of the Pharmaceutical Schedule;

iii. DV devices are not required to be listed in Part III Section H of the Pharmaceutical Schedule;

iv. DV limit usage for DHB Hospitals will be reviewed to monitor compliance at least once every 12 months, with additional reviews at PHARMAC's discretion; and

v. Compliance with any DV limit will be measured at a national level. If the national DV level is exceeded, individual DHB compliance will be measured and any DHB that has exceeded the DV limit will be required to compensate the supplier.

5. **Types of proposals sought**

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

i. <u>Hospital Supply Status</u>

Hospital supply status of DES with 35% DV limit	
Tier One (Mandatory) *≤79% volume commitment*	The hospital supply status model requires a minimum of 65% of DES to be purchased from the contracted supplier over the hospital supply status period. This price is the maximum price to be paid by any individual DHB purchasing up to 79% of its DES from you.
Tier Two (Optional) *80+% volume commitment*	Price accessible to any individual DHB that commits to purchasing 80% or more of its DES from you. *An individual DHB can choose to change its commitment level at any time during the term of the PHARMAC agreement provided it meets the 65% minimum requirement.*

ii. Dual supply

Dual suppliers of DES with 10% DV limit	
Tier One (Mandatory) No volume commitment	Price accessible to any individual DHB with no commitment to volume.
Tier Two (Optional) *60% -79% volume commitment*	Price accessible to any individual DHB that commits to purchasing a percentage of its total DES usage from you, that falls within a stated tier. *An individual DHB can choose to change its commitment level at any time during the term of the PHARMAC agreement.*
Tier Three (Optional) *80+% volume commitment*	

(b) Proposals must only include devices that are in scope in section 3(a) above.

(c) Suppliers may choose to submit hospital supply status and/or dual supplier market share proposals. If a supplier chooses to submit only one type of proposal (e.g. hospital supply status), that proposal will not be able to be accepted if PHARMAC decides to progress an alternate model (e.g. dual supplier).

(d) All suppliers must submit a Tier One price for publication on the Pharmaceutical Schedule.

(e) Suppliers may choose to submit optional percentage volume based tier pricing in accordance with section 5(a)i. and ii. above. Optional tiered pricing proposals must:

i. be based on the percentage range of individual DHB Hospital purchasing volume;

ii. match the percentage volume commitments set out in section 5(a)i. and ii. above; and

iii. be supplied as a price per unit purchased.

(f) PHARMAC is not willing to consider the following types of proposals:

i. proposals for devices that are out of scope and/or do not meet the mandatory requirements set out in section 3(a) above at the time of submission for this RFP;

ii. proposals that involve cross-bundling across different interventional cardiology subcategories (e.g. bare metal stents, dilatation balloon catheters, guidewires) or any other hospital medical devices;

iii. proposals that involve foreign currency exchange rate clauses or prices linked to any index; or

iv. proposals with tier structures that differ from those set out in section 5(a)i. and ii. above.

(g) PHARMAC expects there would be a transition period of at least three months to allow DHBs to coordinate change to any new market share arrangements. The exact length and term of the transition period would be determined following consultation with DHBs and other stakeholders on any provisional agreements arising from this RFP, but would be no shorter than three months.

(h) PHARMAC anticipates that the duration of any hospital supply status/ dual supply status would be up to 36 months. This excludes any transition period as described in section 5(g) above.

(i) At the end of the hospital supply status or dual supply status period, the successful supplier(s) of DES would cease to have any exclusive supply status in DHB hospitals, but would remain listed in Part III of Section H of the Pharmaceutical Schedule subject to the terms and conditions as agreed between the successful supplier(s) and PHARMAC.

(j) Proposals should be submitted on the basis that there may be incremental changes or upgrades for the in-scope devices during the life of the contract, 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.

(k) Suppliers must complete Schedules 4 to 7 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.

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward. For the avoidance of doubt, PHARMAC may vary aspects of the supply arrangements set out above and may consider, at its sole discretion, any other alternative supply arrangements.

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) Proposals must be submitted to PHARMAC **via the Government Electronic Tender Service** (**GETS**) no later than **4.00 p.m**. (New Zealand time) on **Friday 15 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. **RFP Supplier Meetings**

   (a) As the market share procurement model for medical devices may be new for some suppliers, we will provide an opportunity for PHARMAC staff to answer any questions you might have regarding this RFP process. We expect to hold one supplier briefing meeting in Auckland as follows:

   Date: Wednesday, 15 November 2017
   Time: 1pm
   Location: Takaparawhau Board Room
   BNZ Partners Business Centre
   Level 8 - Deloitte Tower
   80 Queen Street,
   Auckland 1010

   (b) The time and location of the supplier briefing meeting may be subject to change. Suppliers are requested to register their interest in attending this meeting by completing the registration form on the PHARMAC interventional cardiology webpage. All registered individuals will be notified of any changes to the supplier briefing meeting by email.

   (c) Following the supplier briefing meeting, a summary of the key discussion points and questions will be published on the PHARMAC website for those suppliers who were unable to attend.

3. **Evaluation**

   (a) Following the deadline for submitting proposals an Evaluation Committee comprising PHARMAC staff will evaluate each proposal to select its preferred proposal(s) (if any).

(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 (**OPPs**), as published on PHARMAC's website, 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 Schedule 4 to 7 and Attachment 1 of this RFP;

(ii) any advice from ICAG, PTAC or its relevant sub-committee;

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

(iv) any advice from ICAG, relevant clinicians and/or DHB staff as a result of any product evaluations (if applicable); and

(v) 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 and/or do not provide all mandatory information in the requested format, you risk having your proposal excluded at the evaluation stage.

(f) PHARMAC is not bound to select the lowest priced proposal or any proposal.

4. **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):

(i) product samples, in which case you must supply the requested sample within 15 business working days of PHARMAC's request;

(ii) additional information on any customer support, training and educational resources and clinical support that may be available to DHBs during any major switchover to your DES and throughout the life of the contract;

(iii) detailed information about you 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.

5. **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 6 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).

6. **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.

7. **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 document;

(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) PHARMAC may consult or seek clinical advice from PTAC, its relevant sub-committee or the ICAG 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 you and/or they submit a proposal(s), until such time as a provisional agreement(s) 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 (including the ICAG), 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 Schedules 4 to 7 and Attachment 1 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.

(g) Proposals are submitted in reliance 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 document. 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 DES by PHARMAC's apparent acceptance and 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 DES or restricts the terms that may be agreed with any other supplier.

(l) 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.

(m) 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.

8. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in January – March 2018;

(ii) negotiating with submitter(s) of one or more preferred proposals in April – May 2018;

(iii) consulting on a provisional agreement(s) in May-June 2018;

(iv) PHARMAC's Board, or the Board's delegate, considering provisional agreement(s) for approval in or after June 2018;

(b) For the avoidance of doubt, the timeframes set out in (a) above are only approximate and may be extended, without notice being required from PHARMAC, if any stages of the RFP process take longer than anticipated.

(c) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is August 2018.

(d) Please note that if a proposal is accepted, the date of implementation may be later to allow for an orderly transition to any new supply arrangement.

Schedule 3: Estimated DHB hospital market size for DES

The following information relates to the estimated market size of DES in DHB Hospitals over the period 1 July 2016 to 30 June 2017. The information has been sourced from supplier datasets provided to PHARMAC as part of reporting requirements under national contracting agreements. This information is approximate and indicative only.

PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of DES and, while PHARMAC has taken all reasonable care in preparing the information set out below, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to the figures below.

DHB hospital market data for the period 1 July 2016 to 30 June 2017	
Total number of DES purchased	10,174 stents
Total spend ($NZ) on DES	~ $8.5 million

Schedule 4: 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 (s) are mandatory and must be completed, Parts (t) to (v) are optional.

[*Supplier to insert date*]

Director of Operations
C/- Matthew Wolfenden
Senior Procurement Manager
PHARMAC

By electronic transfer using GETS.

Dear Sir

Proposal for the supply of permanent coronary drug-eluting stents (DES)

In response to your request for proposals (**RFP**) dated 6 November 2017, we put forward the following proposal in respect of DES.

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 DES.

(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 DES.

(h) Information about our previous supply performance and relevant expertise in providing DES, 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 device, 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 DES and our ability to ensure continuity of supply of DES to DHB hospitals:
Your response must include information on:

- *whether you are a manufacturer or distributor of the proposed DES;*
- *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 DES stock to New Zealand*
- *your ability to hold a minimum of 3 months stock of these devices 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 devices; and*
- *any specific measures you will take to secure stock for New Zealand from international production*.

(k) Information regarding the installation and management of consignment stock within DHB hospitals:
Your response must include:
- *a statement of your understanding of DHB consignment stock requirements:*
- *information on required storage conditions (if any);*
- *information on the shelf life of the DES;*
- *information on the processes for stock-takes, stock replacement, stock transfers and investigating and resolving stock discrepancies and delineation of which tasks your staff and DHB staff are responsible for;*
- *information on reporting processes (format and frequency) to DHBs and PHARMAC; and*
- *details of any additional costs associated with consignment stock – if any (the preferred model is for no additional charges to be associated with consignment stock).*

(l) Information on current or proposed resources and activities we would make available or implement to support DHBs, clinicians and patients during and following a brand switch to 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;*
- *your proposed transition plan for DHBs requiring a brand switch; and*
- *information on how you would organise and manage your resources to support a national implementation plan and provide on-going national support.*

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

(n) Evidence of WAND registration and CE or TGA or FDA certification:
Insert additional rows to the table as required. Copies of all listed WAND registrations and CE or TGA or FDA certificates must be attached to your submission. If you are in the process of obtaining CE or TGA or FDA certification for a DES please write "In progress" and provide evidence of the certification process being underway.

Brand name of proposed DES	**WAND registration number(s)**	**CE or TGA or FDA certificate number(s)**

(o) 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 DES.

(p) Information relating to any existing alternative price models, currently accessed by DHBs, that involve the proposed DES (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;*
- *$ value of the alternative pricing/rebate model(s) for each DHB for the period 1 October 2016 – 30 September 2017; and*
- *how you would plan to manage the financial impact to DHBs of dissolving bundle models (if applicable) that will need to occur if PHARMAC implements market share agreements for DES.*

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.

(q) Additional information about our company's capabilities/capacity that demonstrates our ability to support exclusive supply of DES to DHB hospitals, in either a hospital supply status or dual supplier model:

If none, please write not applicable.

(r) 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.

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

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

(u) Reasons why PHARMAC should accept our proposal:

(v) Additional information that PHARMAC should consider when evaluating our proposal: *Consider any relevant information under PHARMAC's Factors for Consideration decision making framework.*

Schedule 5: Supporting documents

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

(a) Suppliers must submit the following documents for the proposed DES:

i. Product specifications; and

ii. Instructions for use (**IFU**) / Directions for use (**DFU**);

(b) Suppliers must submit evidence of the effectiveness and safety of the proposed DES in accordance with Section 5.8 PHARMAC Guidelines for Funding Applications, including but not limited to:

i. all identified Randomised Control Trials (**RCTs**) published as full articles in peer-reviewed journals in the English language that report (or give sufficient data to calculate) outcomes by intention-to-treat (**ITT**);

ii. one complete electronic copy of the clinical study report summaries from the pivotal RCTs;

iii. a register of all ongoing trials on the pharmaceutical for the relevant indication(s) known to the supplier, including trials not directly funded by the supplier (this can be in the form of a print-out from clinicaltrials.gov);

iv. copies of all published errata (or corrections), retractions, editorials, and journal correspondence directly relating to the published trials submitted as part of a supplier's proposal;

v. if including data from unpublished trials, specify why each trial has not been published and expected dates of publication (if applicable);

vi. a declaration that all unpublished clinical trials known to the supplier have been disclosed, including those known to the supplier to have been undertaken by other companies that may distribute, market or license the pharmaceutical in New Zealand; and

vii. information on the incidence and descriptions of adverse reactions including data collected from observational longitudinal clinical studies, RCTs, case reports on adverse drug reactions and expected/unexpected side effects and post-marketing surveillance data.

Note: The New Zealand Health and Disability Act 2000 defines a pharmaceutical as a "medicine, therapeutic medical device, or related product or related thing".

(c) Supporting documents must be submitted electronically and preferably in a searchable (non-scanned) format.

(d) The file name of all supporting documents must include an Appendix Reference Number and refer to content of the document (e.g. Appendix 1 - Product Specifications, Appendix 2 - Instructions for Use).

(e) Suppliers must record a list of all supporting documents attached to its submission in the table below. Additional rows can be inserted as required.

File names of supporting document attached to our submission

Schedule 6: Acceptance of PHARMAC's 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 provision of permanent coronary DES under a market share agreement

On behalf of **[Company name]** I declare 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 7: 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 4 – Proposal form	Mandatory • *Parts (a) to (s) are mandatory and must be completed* • *Parts (t) to (v) are optional*	
Schedule 5 – Supporting documents	Mandatory	
Schedule 6 - Acceptance of PHARMAC Standard Terms and Conditions for Medical Devices Part 1-7	Mandatory	
Schedule 7 - Checklist of documents to be submitted with your proposal	Mandatory	
Attachment 1 – DES products and pricing spreadsheet *Please ensure that all instructions as written at the top of the spreadsheet and in column headings have been followed and that all mandatory information is provided.*	Mandatory • *Tier One pricing is mandatory for both hospital supply status and dual supply models. Any proposals that do not include a Tier One price will not be considered by PHARMAC (unless noted as provided at no cost to the DHB).* • *Hospital supply status model: Tier Two price is optional (refer Schedule 1).* • *Dual supplier model: Tier Two and Tier Three price is optional (refer Schedule 1).* • *Provision of GS1(GTIN) and UNSPSC numbers is desirable (not mandatory).*	
WAND printouts for all proposed DES	Mandatory	
CE or FDA or TGA certificates for all proposed DES	Mandatory • *CE or FDA or TGA certificates must be submitted* • *If you are in the process of obtaining CE or TGA or FDA certification you must provide evidence of the certification process being underway.*	
Supporting documents i.e. all of the appendices as listed in the table in Schedule 5	Mandatory	

Schedule / Attachments/Appendices	Response	Attached to submission (Yes/No)
Alternative price model attachments – refer Schedule 4 (p)	Optional	