PHARMAC
TE PĀTAKA WHAIORANGA

Level 9, 40 Mercer Street, Wellington
PO Box 10254, Wellington 6143, New Zealand
P: +64 4 460 4990 | F: +64 4 460 4995
www.pharmac.govt.nz

29 March 2022

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PERMANENT CORONARY DRUG-ELUTING STENTS TO NEW ZEALAND PUBLIC HOSPITALS UNDER A MARKET SHARE PROCUREMENT MODEL

Pharmac invites proposals for the supply of permanent coronary drug-eluting stents to New Zealand public hospitals under a market share procurement model.

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

- Schedule 1 sets out the background to the RFP and the range of devices included and 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;
- Schedule 4 specifies the information and evidence you need to include in your proposal;
- Schedule 5 and Attachments 1, 2, 4 and 5 contain the forms in which you are to provide the details of your proposal; and
- Attachment 3 contains the Pharmac 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**) no later than **5.00pm Tuesday 26 April 2022**.

If you have any questions about this RFP, please post these on GETS. A supplier briefing meeting will be held at 3.00pm on Tuesday 5 April 2022.

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 permanent coronary drug-eluting stents (**DES**) for awarding Principal Supply Status with a minimum share of 65% of the New Zealand public hospital market.

2. **RFP background and impact**

(a) 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.

(b) In 2017, Pharmac sought clinical advice from the ICAG to assist with the development of a market share RFP – the minutes of ICAG meetings can be found on our website.

(c) In November 2017, Pharmac issued an RFP for the supply of DES to DHB hospitals under a market share procurement model. The RFP included the following two options:

(i) a proposal to be the primary supplier of DES with a minimum share of 65% of the DHB hospital market; and/or

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

(d) In March 2019, Pharmac notified the market of a decision to award market share for DES to Abbott Laboratories NZ Limited as the primary supplier of DES with a minimum share of 65% of the DHB hospital market. This minimum commitment expires later this year.

(e) In 2022, Pharmac sought further advice from ICAG regarding the level of market share and is now seeking proposals for the supply of DES to New Zealand public hospitals under the same 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 New Zealand public hospitals.

(g) To date the medical device agreements that Pharmac has entered into have been for supply to DHB hospitals. Pharmac acknowledges the Pae Ora (Healthy Futures) Bill (**Bill**) is currently in the legislative process that would establish a new structure and new accountability arrangements for the publicly funded health system. Based on the timeframes for progression of the Bill it is anticipated that any resulting agreement from this process would be for supply of DES to Health New Zealand hospitals rather than DHB hospitals. In this respect any reference to DHB hospitals in this RFP, shall also be interpreted to be references to Health New Zealand hospitals, subject to the Pae Ora (Healthy Futures) Act 2021 coming into force.

3. **Expected outcome of the RFP**

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

(i) generate a greater level of competition so that further savings can be realised for New Zealand public hospitals, while still providing access to clinically appropriate ranges of DES;

(ii) provide national consistency and equitable access to clinically appropriate DES across all New Zealand public hospitals with cardiac catheterisation laboratories; and

(iii) secure ongoing continuity of supply of DES for New Zealand public hospitals.

(b) It is possible that New Zealand public hospitals may be required to make changes to product mix or suppliers depending on the outcome. Where appropriate, Pharmac expects to provide support to hospitals to allow a smooth transition into any new arrangements.

(c) For the avoidance of doubt, DHB hospitals and Health New Zealand hospitals (as applicable) are required to comply with the Pharmaceutical Schedule as determined by Pharmac.

4. **Types of proposals sought**

(a) Pharmac is willing to consider proposals for Principal Supply Status of DES with an Alternative Brand Allowance of 35%. The pricing options are as follows:

(i) Tier 1 (mandatory) ≤79% volume commitment – the Principal Supply Status model requires a minimum of 65% of DES to be purchased from the contracted supplier over the Principal Supply Status period. This price is the maximum price to be paid by an individual DHB hospital purchasing up to 79% of its DES from you.

(ii) Tier 2 (optional) 80%+ volume commitment – price accessible to any individual DHB hospital that commits to purchasing 80% or more of its DES from you. An individual DHB hospital can choose to change its commitment level at any time during the term of the Pharmac agreement provided it meets the 65% minimum requirement.

(b) Proposals must only include devices that are in scope in section 5(a) below.

(c) All suppliers must submit a Tier 1 price for publication on the Pharmaceutical Schedule.

(d) Suppliers may choose to submit an optional percentage volume based tier pricing in accordance with section 4(a)(ii) above. Optional tiered pricing proposals must:

(i) be based on the percentage range of individual New Zealand public hospitals purchasing volume; and

(ii) match the percentage volume commitments set out in section 4(a)(ii) above; and

(iii) be supplied as a price per unit purchased.

(e) There may be a transition period to allow New Zealand public hospitals to coordinate change to any new market share arrangements. The exact length and term of the transition period would be determined following ICAG advice and consultation with stakeholders on any provisional agreement arising from this RFP, but would be no shorter than three months.

(f) Pharmac anticipates that the duration of any Principal Supply Status would be up to 36 months. This excludes any transition period as described in section 4(e) above.

(g) At the end of the Principal Supply Status period, the successful supplier of DES would cease to have any exclusive supply status in New Zealand public hospitals but would remain listed in the Pharmaceutical Schedule for hospital supply, subject to the terms and conditions as agreed between the successful supplier and Pharmac.

(h) 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 device would be made available to New Zealand public hospitals within a reasonable timeframe.

(i) Suppliers must complete Schedule 5 and Attachments 1, 2, 4 and 5 and provide all requested supporting documents. Proposals that do not include the completed information or supporting documents, or do not conform to all instructions provided in the RFP, may be excluded from consideration.

(j) The New Zealand Government is committed to sustainable and inclusive government procurement and the Supplier Code of Conduct outlines the Government's expectations of suppliers in this respect. Pharmac expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct.

(k) Pharmac is not willing to consider the following types of proposals:

(i) for devices that are out of scope as set out in section 5(b) below and/or do not meet the mandatory requirements;

(ii) proposals that involve bundling across different interventional cardiology sub-categories (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 that are linked to any index;

(iv) proposals which do not meet Pharmac's pricing requirements, for example the tier volume commitments differ from those set out in section 4(a) above;

(v) proposals that include rebates;

(vi) proposals that include DES that are not notified on WAND at the time of submission of your proposal; or

(vii) proposals that include DES that do not hold CE, FDA or TGA certification at the time of submission of your proposal and are unable to obtain such certification in a timeframe that is acceptable to Pharmac.

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, whilst considering the need for fairness to suppliers and integrity of the RFP process.

5. Scope of RFP

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

For the purposes 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 of a proposal 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 of a proposal 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 purposes 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); or

(iii) other medical devices.

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 **5.00pm** (New Zealand time) on **Tuesday 26 April 2022**. 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.

2. **RFP supplier meeting**

   (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 via Zoom at 3.00pm on Tuesday 5 April 2022.

   (b) The date and time 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 website. 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 GETS and 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 (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 (**FFC**) that form part of Pharmac's current Operating Policies and Procedures (**OPPs**), as published on Pharmac's website, to the extent applicable.

(c) 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 Schedule 5 and Attachments 1, 2, 4 and 5 of this RFP;

(ii) any advice from ICAG, PTAC or its relevant advisory committees;

(iii) any advice from relevant clinicians and/or New Zealand public hospital staff; and

(iv) 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).

(d) 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.

(e) 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) additional information on any customer support, training and education resources and clinical support that may be available to New Zealand public hospitals during any major switchover to your DES and throughout the life of the contract; and

(ii) 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.

5. **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 terms and conditions to list medical devices on the Pharmaceutical Schedule, which are available as a download (Attachment 3) from GETS, will apply.

(c) You **must** complete and submit Attachment 4 of this RFP as part of your proposal by declaring that you have read and understood Pharmac's terms and conditions for the supply of medical devices, and where you disagree with any of the 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 agreement with a preferred supplier(s) on whatever special terms, in addition to Pharmac's 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 FFC 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; 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 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) Pharmac may consult or seek expert advice from PTAC, its relevant advisory committees 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 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), New Zealand public hospitals or their representatives, 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.

(b) You must limit the information provided to that which is requested in Schedules 4 and 5 and Attachments 1, 2, 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 document. 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 DES 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) 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 New Zealand public hospitals (**Confidential Information**). However, you acknowledge that it may be necessary or appropriate for Pharmac to release Confidential Information:

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

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

(iii) in publicly notifying any approval by the Pharmac Board of that agreement; or

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

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

8. Anticipated timetable

(a) Following receipt of proposals, Pharmac anticipates:

(i) the Evaluation Committee evaluating proposals from April 2022;

(ii) negotiating with submitter(s) of one or more preferred proposals from June 2022;

(iii) consulting on any provisional agreement from June 2022; and

(iv) Pharmac's Board, or the Board's delegate, considering any provisional agreement for approval in or after July 2022.

(b) For the avoidance of doubt, 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.

(c) Under this indicative timetable, the earliest that changes to the Pharmaceutical Schedule could be implemented is August 2022.

(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.

9. 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: Estimated New Zealand public hospital market size for DES

The following information relates to the estimated market size of DES in New Zealand public hospitals over the period 1 July 2020 to 30 June 2021. 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.

National compliance with the current market share arrangement has been met for the first two years and is on track to be met for the current year.

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.

New Zealand public hospital market data for the period 1 July 2020 to 30 June 2021	
Total number of DES purchased	10,185 stents
Total spend ($NZ) on DES	~ $6.5 million

Schedule 4: 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: **DES spreadsheet**	You **must** complete all fields in Attachment 1 for each proposed DES. If you consider a field not applicable you must state "NA".
Pricing	You **must** include Tier 1 pricing for all your proposed DES. Tier 2 pricing is optional (refer Schedule 1, section 4(a)).
WAND	You **must** be able to legally supply your proposed DES to New Zealand public hospitals as evidenced by WAND registration number. Please **do not** provide WAND documents. Where WAND is not applicable to a proposed product you **must** state the reason why it is not applicable.
International compliance	You **must** provide evidence of international compliance certification. The name of the certifying body and certificate number must be included in Attachment 1 for each proposed product and you **must** attach a copy of all relevant certificates.
GS1 (GTIN)	It is desirable that you provide GTIN codes for each proposed DES at the time of submitting your proposal. Please note that Pharmac's terms and conditions require provision of GTIN codes, if requested by Pharmac or a DHB, within six months of the request.
Non-DHB reference sites	If you **are not** currently supplying a proposed DES to any New Zealand public hospital, you **must** provide three clinical reference sites for that DES.
Attachment 2: **Supporting documentation**	You **must** provide the following documents for the proposed DES: • Product specifications • Instructions for use / directions for use • Evidence of the effectiveness and safety of the proposed DES in accordance with Section 5.8 of the Guidelines for Funding Applications to Pharmac, including but not limited to: o 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

Document	Evidence / Information
	(ITT) o one complete electronic copy of the clinical study report summaries from the pivotal RCTs o 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) o 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 o if including data from unpublished trials, specify why each trial has not been published and expected dates of publication (if applicable) o 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 o 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". You **must** list all supporting documents included in your proposal as set out in Attachment 2. You **must** submit all supporting documents electronically in a searchable (non-scanned) format and the file name **must** include an Appendix reference number and refer to the content of the document (eg. Appendix 1 - Product Specifications, Appendix 2 - Instructions for Use).
Attachment 4: **Acceptance of Pharmac's standard terms and conditions**	You **must** complete, sign and date the declaration set out in Attachment 4. You **must** indicate whether you agree or disagree with Pharmac's terms and conditions for medical devices for your proposed DES. If you do not agree with any of Pharmac's terms and conditions for medical devices for your proposed DES you **must** provide detailed comment, including any proposed alternative clauses and justification, in Table 1 of Attachment 4. 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 4.

Document	Evidence / Information
Attachment 5: **Document and information checklist**	You **must** complete the document and information checklist set out in Attachment 4. You **must** note any additional attachments not specifically listed in the box provided in Attachment 4.
Schedule 5: **Proposal form**	You **must** complete all sections of Schedule 5. If you consider a section to be not applicable, you **must** state "NA". The response you provide in each section **must** be comprehensive and relevant to the information that has been requested, and you **must** include relevant attachments.

Schedule 5: Proposal form

An electronic version of this form is available on Pharmac's website and on GETS. You should expand the boxes as necessary.

[Supplier to insert date]

Director of Operations
Pharmac
c/- Alyssa Currie
Senior Device Category Manager

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

Dear Sir/Madam

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

In response to your request for proposals (**RFP**) dated 29 March 2022 we put forward the following proposal in respect of the supply of DES.

Please refer to Schedule 4 for information and evidence to be included in your proposal. You must also include information as outlined Attachments 1,2, 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 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) Any conflicts of interest	

(a) Executive summary	
Proposal summary Include: • overview of products and services • benefits to New Zealand public hospitals of this proposal • why Pharmac should accept this proposal	**Maximum 500 words**

(b) Information about our company, contracts and markets	
Company information	
Type of entity (legal status) Eg, a New Zealand registered limited liability company	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
City and country of residence of our company	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
Information about company size, structure and annual turnover Include sales/product support staff relevant to this RFP. **Attach** Organisational Chart.	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
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)	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
Established locations within New Zealand Include function of each location (eg. head office, warehouse).	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
Company ownership State ownership (eg. public ownership) Include:	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*

• any parent companies and relationships • names and percentage shareholdings of the major shareholders and directors	
Does your organisation identify as being a Māori business? Pharmac is committed to the Government's progressive procurement approach to increase the diversity of government suppliers and achieve broader economic and social outcomes, with a specific focus on Māori businesses. As part of this approach, Pharmac is committed to gaining a better understanding of how our agency can support the economic and social outcomes for Māori through our procurement. Pharmac is therefore gathering information from organisations as to whether they identify as a Māori business. A Māori business for Government procurement purposes is: • One that has at least 50% Māori ownership, or • A Māori Authority as defined by Inland Revenue. Within these definitions, does your organisation identify as a Māori business? This information will inform Pharmac's supplier's database and will be reported to NZGPP, subject to any concerns you identify (see box below).	*[Yes / No]* *In line with this policy, Pharmac is committed to understand and support what roles Māori businesses play in our supply chain. You can add any further comment on how your company supports economic and social outcomes for Māori in question (h) below.*
For some of its procurement Pharmac is required to report to NZGPP on whether an organisation identifies as a Māori business as part of new progressive procurement reporting requirements. Please indicate either 'Yes' or 'No' as to whether you agree to Pharmac reporting on your organisation's status as a Māori business. If you indicate 'No', please provide reasons for our consideration.	*[Yes / No]*
New Zealand Government Broader Outcomes Provide detail on how your Organisation supports social, economic, cultural and environmental outcomes beyond supply of Pharmaceuticals (see New Zealand Government Procurement Broader Outcomes). Provide detail on how your organisation: • supports New Zealand businesses, including Māori, Pasifika and regional businesses, as well as social enterprises if relevant • supports improving conditions for New Zealand workers and support workforce diversity.	
Evidence of financial stability and ability to cover financial liabilities	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*

Include: • how you would cover your financial liabilities in the event of a major failure to supply (eg. a recall) • information about your financial stability (eg. annual turnover, guarantor companies) **Attach** supporting evidence (eg. annual financial report, Companies Register financial statement, insurance certificate, bank letter).	
Contracts and markets	
Current contracts and standing agreements in place with New Zealand public hospitals or organisations acting on their behalf Include all New Zealand public hospital contracts, not just those relevant to this RFP. For each provide: • parties to the agreement • contract reference number • type of agreement (national/regional/hospital specific) • range of products covered • expiry date • other relevant information (eg. now standing agreement after contract expiry) Can be provided as an attachment, note name of attachment in response column.	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
Products not included Include any DES currently supplied to New Zealand public hospitals (contracted or not contracted) that are not included in this proposal and the reason for this.	
Healthcare customers in New Zealand Include New Zealand public hospital and private healthcare organisations.	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*
Information on other major markets for proposed product ranges. For each product range include: • type of market (eg. private hospital, public hospital) • any contracts held	***NB.*** *Only required for product ranges that New Zealand DHB Hospitals are <u>not</u> currently purchasing.*

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

(c) 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	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES unless the support hours differ from what is in your agreement.*	
Product support staff Include information about technical skills, experience and qualifications of the staff that would be involved in supporting the proposed products (including those providing training and education).		
Training and education Include an overview of the training and education that would be regularly provided to New Zealand public hospitals for the proposed products including: • frequency • location • format • content • staff groups (eg. hospital, community) • tracking training and education service • other relevant information		
Training and education materials	For DHB Hospital staff	For patients

Include training and education materials that would be provided to New Zealand public hospitals purchasing the proposed products.		
Transition support Include an outline of the support that would be provided to New Zealand public hospitals transitioning to the proposed products under a market share model. **Attach** a detailed transition plan setting out the transition steps, roles and responsibilities, and timeframes specific to a market share model. Note name of attachment in response column.		
Implementation support Include information on how you would organise and manage your resources to support a national implementation plan and provide ongoing national support.		
Complaints management processes Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality improvement processes.	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*	
Other relevant information about ability to support the proposed products Include any additional information about your company's capabilities and capacity that demonstrates an ability to support exclusive supply of DES to New Zealand public hospitals.		

(d) Information about our compliance with regulations and standards			
Quality Management System(s) certification for your company **If Yes, attach evidence** Include relevant section(s) of standard where certification is not for full standard.	ISO 9001 [Yes/No]	ISO 13485 [Yes/No]	Other [specify]
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	Standard	Compliance	Evidence

• ISO standards • IEC standards Describe the extent of compliance with the listed standard and the product range the standard applies to. **Attach** evidence of compliance where available.			
Permit to supply the products to New Zealand public hospitals Include: • a statement confirming that you have all the necessary rights and permits to supply the products and associated services to New Zealand public 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 public hospitals.			

(e) Information about our proposed distribution and supply arrangements and ability to ensure continuity of supply to DHB Hospitals	
Stock Management	
Consignment stock Include: • a statement about your understanding of New Zealand public hospitals consignment stock requirements • information on required storage conditions (if any) • information on the processes for stock takes, stock replacement, stock transfers, investigating and resolving stock discrepancies, and delineation of responsibilities sit with you and the New Zealand public hospital • information on the reporting process (format and frequency)	
Stock holding within New Zealand Pharmac's terms and conditions require three months stock to be held in New Zealand. Include detail about how you would set and manage your stock levels in New Zealand for the proposed DES.	
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.	***NB.*** *Not required if you currently have a Pharmac agreement for Interventional Cardiology that includes DES.*	
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 New Zealand public hospitals or hospitals nominated locations, include: • steps • who is involved • timeframes • delivery frequency		
Lead times Include detail on the lead time for supplying DES: • in a stable demand situation • in the event of a supply disruption • in the event of an unexpected surge in demand • to implement a market share model		
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 New Zealand public 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 New Zealand public hospitals • communication with Pharmac • how stock is prioritised • other relevant information		

Previous supply performance Include detail on your supply performance in relation to supplying DES to New Zealand public hospitals.	

(f) Pricing information	
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. Note that Pharmac's preferred pricing model is free into store.	

(g) Environmental Sustainability	
Does your Organisation have an environmental/sustainability policy? If yes, attach or provide link.	Yes/No
Does your Organisation have a sustainability report? If yes, attach or provide link.	Yes/No
How does your Organisation contribute to environmental sustainability? Please describe the measures you take to contribute to environmental sustainability – in general and specifically in relation to this RFP.	
Has your Organisation received any environmental/sustainability award(s)?	Yes/No

If yes, provide details.	
Has your Organisation received any environmental fine/prosecution(s)? If yes, provide details.	Yes/No
Has your Organisation received any environmental audit(s) or does it comply with a recognised standard? If yes, provide details.	Yes/No

(h) Other relevant information	
Working with key stakeholders Include information about how you envisage working with Pharmac and other key stakeholders.	
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.	
Other information Include any other information that you would like Pharmac to consider when evaluating this proposal. Please consider: • Any relevant information under Pharmac's Factors for Consideration decision making framework. • Any relevant information that demonstrates how you would meet the government expectations outlined in the Supplier Code of Conduct.	