PHARMAC
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20 August 2025

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF PERMANENT CORONARY DRUG ELUTING STENTS (DES) TO HEALTH NEW ZEALAND HOSPITALS UNDER A MARKET SHARE ARRANGEMENT

Pharmac invites proposals for the supply of permanent coronary drug eluting stents to Health New Zealand 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, the type and range of products within scope of 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 specifies the response form and the information and evidence you need to include in your proposal;
- Attachment 1 is the form in which you can provide non-price information;
- Attachment 2 is the form in which you can provide price information; and
- Attachment 3 contains the proposed contract terms and conditions to list medical devices on the Pharmaceutical Schedule.

If you wish to submit a proposal, you must submit it to Pharmac via the Government Electronic Tenders Service (**GETS**) no later than 5.00 p.m. on 17 September 2025.

If you have any enquiries about this RFP, you should submit them via GETS, using the questions and answers function before 12pm, 4 September 2025. Responses to all enquires will be published on GETS. If you do need to get in touch via email, please contact procurement@pharmac.govt.nz

We look forward to receiving your proposal.

Yours sincerely

Catherine Epps
Director, Medical Devices

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

1. Developing and submitting your Proposal

(a) This is a competitive procurement process.

(b) Take time to read and understand the RFP.

(c) Take time to understand our Requirements.

(d) Take time to understand how your Proposal will be evaluated. See Schedule 2.

(e) For resources on tendering visit https://www.procurement.govt.nz/suppliers-2/

(f) If you have any enquiries about this RFP, you should submit them via GETS, using the questions and answers function before 12pm, 4 September 2025.

(g) Use the Response Form to submit your Proposal this is included in Schedule 3 and Attachment 2. This is a Microsoft Word document that you can download from GETS.

(h) You must use the form in Attachment 2 for your pricing information.

(i) Check you have provided all the necessary information in the correct format and order in Schedule 3 and Attachments 1 and 2.

(j) Complete and sign the declaration at the end of the Response Form included in Schedule 3 and Attachment 2.

(k) Submit your Proposal before the Deadline for Proposals stated in Schedule 2.

2. Products

Stents are small scaffold tubes that can be inserted into the narrowed coronary arteries of patients with atherosclerosis in a procedure called coronary angioplasty. The purpose of the stent is to help hold the artery open. Drug eluting stents are stents that have been coated with a pharmacologic agent that is known to suppress restenosis: the re-blocking or closing of an artery after angioplasty due to excess tissue growth inside or at the edge of the stent.

Permanent coronary drug eluting stents are classified based on the properties of the stent scaffold as permanent or bioresorbable. The scaffold of a permanent DES does not degrade over time and remains in the body permanently. The scaffold of a bioresorbable stent fully degrades over time. These two types of coronary DES are listed as separate subcategories in Part III of Section H of the Pharmaceutical Schedule. Permanent coronary DES are the predominant type of coronary DES used in Health New Zealand (“Health NZ”) hospitals.

3. Principal Supply Status

As part of this RFP opportunity, suppliers are invited to bid for “Principal Supply Status” (PSS) for the provision of permanent coronary drug-eluting stents (DES) in Health New

Zealand hospitals. The successful supplier will have their brand designated as the primary funded DES across Health NZ hospitals.

The principal supplier will be guaranteed a minimum share of the total funded market, within the Health NZ hospital setting, for a period of up to three years. Specifically, this opportunity includes a commitment to supply at least 65% of the total funded market, with the remaining 35% allocated as an "Alternative Brand Allowance" (ABA). The supply arrangements after the end of the Principal Supply Status are outlined in Attachment 3.

4. Background to RFP

Current Arrangements

As a result of the 2022 RFP process, Pharmac currently has a market share arrangement with Boston Scientific New Zealand Limited ("Boston Scientific") for the supply of DES in Health NZ hospitals. This arrangement meant that Boston Scientific has PSS with a minimum market share of 65% and covers the period from 1 March 2023 to 28 February 2026.

Expert advice sought in 2022 from the Interventional Cardiology Advisory Group (ICAG) reiterated the recommendation made at the August 2017 ICAG meeting, showing a strong preference for continuing with the 65% market share model, with a 35% alternative brand allowance. Additionally, PSS compliance data supports this approach. Therefore, Pharmac will approach the market with the same 65% market share model, in line with previous expert advice and supported by compliance data.

The current national annual expenditure for permanent coronary DES is approximately $6.1 million.

New Zealand public hospital market data for the period 1 July 2023 to 30 June 2024	
Total number of DES purchased	10,311 stents
Total spend ($NZ) on DES	~ $6.1 million

Why return to market

With the current PSS awarded to Boston Scientific set to expire on 28 February 2026, Pharmac is seeking proposals for the ongoing supply of DES in Health NZ hospitals.

5. Expected RFP Outcome

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

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

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

(iii) secure ongoing continuity of supply of DES for Health NZ hospitals.

(b) It is possible that Health NZ 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. Clinical experts from Health NZ will be advisors in the process to help inform these decisions.

(c) For the avoidance of doubt, Health NZ hospitals are required to comply with the Pharmaceutical Schedule as determined by Pharmac.

6. Requirements

Pharmac is seeking proposals from suppliers for the supply of permanent coronary DES to Health NZ hospitals under a PSS arrangement. Respondents must demonstrate their ability to provide clinically appropriate and reliable DES products supported by robust supply chain systems and strong education, transition and clinical support. Respondents must also demonstrate how they will contribute to broader outcomes such as sustainability and local economic support.

6.1 Product and Clinical Suitability

Respondents must demonstrate that their proposed DES products are clinically fit for purpose and appropriate for the needs of New Zealand patients and clinical settings.

(a) Product Scope

DES products must be permanent, drug-eluting, and suitable for use in Health NZ hospitals.

Products must be clinically appropriate and supported by published evidence relevant to the New Zealand context.

(b) Clinical Suitability

Respondents must submit detailed documentation and evidence demonstrating clinical appropriateness, including:

- Efficacy evidence from large clinical trials
- Safety data with long-term follow-up
- Product specifications, instructions for use, indications, contraindications, and post-market surveillance reports

In addition, Respondents are expected to submit any other relevant information about their product for example:

- Ease of use
- Change description

- Advantageous clinical features
- Visibility with imaging modalities

6.2 **Regulatory Compliance – Preconditions**

Respondents must demonstrate and provide evidence that their DES products meet relevant regulatory standards for medical devices.

- All DES must be registered on the Web-Assisted Notification of Devices (WAND) database at the time of submission.

All proposed DES must hold one or more of the following certifications:

- CE (Conformité Européenne)
- FDA (U.S. Food and Drug Administration)
- TGA (Therapeutic Goods Administration, Australia)

6.3 **Pricing Structure and Value for Money**

Respondents must demonstrate a pricing model that delivers value for money over the product's lifecycle and supports the proposed commitment model.

Respondents may propose tiered pricing linked to market share thresholds:

- Price applicable for when 65–79% of DES volume is supplied by the Respondent to an individual Health NZ hospital.
- Discounted price where 80% or more of volume is supplied to an individual Health NZ hospital.

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

(b) Suppliers may choose to submit an optional percentage volume-based tier pricing in accordance with the above tiered models. Optional tiered pricing proposals must:

(i) be based on the percentage range of individual Health NZ hospitals purchasing volume; and

(ii) match the percentage volume commitments set out above; and

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

(c) There may be a transition period to allow Health NZ 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.

Subject to the above, Pharmac is open to considering additional alternative pricing mechanisms that Respondents may wish to put forward, provided that they offer value to the New Zealand health system.t

6.4 Supply Chain and Stock Management

Respondents must demonstrate supply chain capabilities and stock management practices to ensure reliable, uninterrupted access for Health NZ Hospitals to DES products.

a) *Stock Holding and Inventory Management*

Respondents must maintain at least three months' supply of DES in New Zealand. In addition, Respondents are expected to have inventory management systems and local supply capabilities.

b) *Delivery and Logistics*

Respondents must provide delivery frequencies and logistics arrangements. This would include stating lead times under:

- Normal supply conditions
- Supply disruption
- Demand surge
- Implementation of market share model

c) *Recall Management*

Pharmac requires Respondents to have recall management processes and as such provide information relating to:

- Recall protocols
- Stakeholder communication
- Recovery procedures.

6.5 Consignment Stock

Respondents must demonstrate an understanding of consignment stock models and offer comprehensive support for management within hospital settings and confirm acceptance of no additional charges for consignment stock.

Respondents must provide information on:

- Storage conditions
- Roles and responsibilities (supplier vs hospital)
- Stock take and reconciliation processes
- Reporting frequency and format
- Stock replacement, transfer, and discrepancy investigation processes

6.6 Education, Training and Clinical Support

Respondents must demonstrate their ability to provide clinical education, training, and technical support at no additional cost to Health NZ Hospitals.

- Submit a written statement outlining your understanding of training and support expectations.

Provide an overview of planned training and education, including:

- Frequency and format (in-person, online)
- Location and delivery method
- Clinical content
- Target groups (hospital staff, clinicians, nurses, patients and any other relevant groups)
- Support hours (including after-hours/24-7 assistance if available)
- System for tracking attendance and effectiveness of training
- Detail prior experience supporting clinical transitions to new technologies.

6.7 Transition Support

Respondents must demonstrate a clear and structured transition plan for supporting the adoption of their DES products under a principal supply model.

Respondents must provide a transition plan including:

- Key milestones and timeframes
- Roles and responsibilities
- Support for training and change management
- Communication and issue escalation processes

6.8 Supply Continuity and Risk Management

Respondents must demonstrate proven ability to manage and mitigate supply risks and ensure continuity of supply across the national health system.

- Outline business continuity plans and supply risk mitigation strategies.
- Describe how shortfalls, delays, and demand surges would be managed.
- Provide a case study or example of past successful mitigation of a supply disruption.

6.9 Track Record and Experience

Respondents must demonstrate a track record in supplying DES or similar devices in New Zealand or comparable health systems.

- Describe previous experience supplying to public health systems.
- Include references or case studies where relevant.
- Detail customer service standards, issue resolution history, and any local presence or partnerships.

6.10 Complaints Management

Respondents must demonstrate an effective complaints management process that supports clinical safety, transparency, and continuous improvement.

- Outline roles and responsibilities for complaints handling.
- Describe escalation protocols and continuous quality improvement actions.

6.11 Implementation Capability

Respondents must demonstrate capacity to support a national-level implementation of DES products and ongoing support under a PSS arrangement.

- Provide an overview of resource planning and national coordination structures.
- Detail how implementation will be rolled out and supported across all regions.

6.12 **Broader Outcomes**

Respondents must demonstrate how they contribute to broader New Zealand Government outcomes, including environmental and economic sustainability.

6.13 **Supplier code of conduct**

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.

7. Out of Scope

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

- Proposals for any stents other than permanent coronary drug eluting stents (e.g. Bioresorbable, bare metal or non-coronary)
- Proposals that involve cross-bundling across any other stents (e.g. bare metal, covered, coronary graft system or reabsorbable), any other interventional cardiology device (e.g. guide wires and dilation balloons) or any other medical device.
- Proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- Proposals with tiered pricing structure that differ from Pharmac's structure stated in this RFP.
- Proposals that include rebates.
- Proposals for DES that are not WAND registered at the time of submission.
- Proposals for DES that do not hold CE, FDA or TDA certification at the time of submission.

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) Proposals must be submitted to Pharmac via the Government Electronic Tenders Service (GETS) no later than 5.00 p.m. (New Zealand time) on 17 September 2025. Late proposals will only be considered at Pharmac's discretion, taking into account 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, using the questions and answers function. Responses to all enquires will be published on GETS. If you do need to get in touch via email, please contact procurement@pharmac.govt.nz.

2. Evaluation Model

(a) The approach to this procurement is a single-stage RFP process with a two staged evaluation process. The first stage will involve a clinical suitability test/review conducted by ICAG members, who are a mix of interventional cardiologists, interventional cardiology specialist nurses, interventional cardiology service managers. Proposals that are deemed clinically suitable in this initial stage (pass/fail) will then be shortlisted for the second stage, which includes both non-price and price evaluations by internal Pharmac staff.

(b) The evaluation model that will be used is a weighted attribute method. Price is not a weighted criterion. All proposals that meet the pre-conditions, will be evaluated using the evaluation model as detailed below. Scores will assist in deciding which proposals are progressed, but ultimately the decision will be based on which proposal(s) we consider will provide the best overall public value in accordance with Pharmac's Factors for Consideration. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration. An initial review of proposals will be undertaken by Pharmac staff to ensure that the proposals are compliant and complete responses in accordance with the requirements of the RFP. Pharmac reserves the right, at its sole discretion, to not evaluate proposals further due to being non-compliant or materially incomplete.

(c) If a supplier scores 4 or less in any category or overall, the supplier may be put aside from further consideration, at the sole discretion of Pharmac.

(d) If at any point in time during the evaluation process a DES is deemed not clinically suitable in the New Zealand context, the proposal may be eliminated from being evaluated further.

(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.

3. Overarching Considerations

(a) The evaluation committee, consisting of Pharmac staff and clinical advisors, will evaluate proposals in light of Pharmac's statutory objective. In doing so, the evaluation committee will be guided by the Factors for Consideration. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

(b) The requirement for Pharmac to pursue its statutory objective means that emphasis will be given to those aspects of proposals that demonstrate "health outcomes", and those aspects of proposals that demonstrate the impact on the "funding provided" for devices. Those Factors that relate directly to these aspects will be given the greatest weight by the Evaluation Committee, but all Factors are important.

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.

(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. Evaluation Criteria and Weightings

Preconditions

(a) Each supplier must meet the following preconditions before their proposal will be considered for evaluation:

1.	Respondents proposed medical devices must be registered in the (WAND) database at the time of proposal submission.
2.	All proposed DES must hold one or more of the following certifications: • CE (Conformité Européenne) • FDA (U.S. Food and Drug Administration) • TGA (Therapeutic Goods Administration, Australia)

Having met all of the preconditions, qualifying proposals will be evaluated on their merits using the following evaluation criteria and weightings.

Criterion	Weighting
Company Information	Info Only
Clinical Suitability (ICAG)	Pass/Fail
Clinical Suitability and Quality	30%
Supply Chain, Stock Management and Track Record	30%
Education, Clinical Support and Complaints	20%
Transition and Implementation	15%
Broader Outcomes	5%
Price/Cost	Value Narrative
Contract tags or departures	Pass/Fail
Commitment to Supplier Code of Conduct	Pass/Fail
Total weightings	**100%**

6. Scoring

The following scoring scale will be used in evaluating proposals. Scores by individual evaluation members may be modified through a moderation process across the whole evaluation panel.

Rating	Definition	Score
EXCELLENT significantly exceeds the criterion	Exceeds the criterion. Exceptional demonstration by the Respondent of the relevant ability, understanding, experience, skills, resource and quality measures required to meet the criterion. Proposal identifies factors that will offer potential added value, with supporting evidence.	**9-10**

GOOD exceeds the criterion in some aspects	Satisfies the criterion with minor additional benefits. Above average demonstration by the Respondent of the relevant ability, understanding, experience, skills, resource and quality measures required to meet the criterion. Proposal identifies factors that will offer potential added value, with supporting evidence.	**7-8**
ACCEPTABLE meets the criterion in full, but at a minimal level	Satisfies the criterion. Demonstration by the Respondent of the relevant ability, understanding, experience, skills, resource, and quality measures required to meet the criterion, with supporting evidence.	**5-6**
MINOR RESERVATIONS marginally deficient	Satisfies the criterion with minor reservations. Some minor reservations of the Respondent's relevant ability, understanding, experience, skills, resource and quality measures required to meet the criterion, with little or no supporting evidence.	**3-4**
SERIOUS RESERVATIONS significant issues that need to be addressed	Satisfies the criterion with major reservations. Considerable reservations of the respondent's relevant ability, understanding, experience, skills, resource and quality measures required to meet the criterion, with little or no supporting evidence.	**1-2**
UNACCEPTABLE significant issues not capable of being resolved	Does not meet the criterion. Does not comply and/or insufficient information provided to demonstrate that the Respondent has the ability, understanding, experience, skills, resource and quality measures required to meet the criterion, with little or no supporting evidence.	**0**

7. Price

Pricing information will be required to be submitted in a prescribed format using the provided Microsoft Excel template in Attachment 2 to ensure consistency of key price information capture to allow comparable evaluation of requirements.

8. Value for Money

The value for money assessment will include consideration of the optimal combination of financial and non-financial factors through the lifecycle of the DES being procured in accordance with the requirements of the RFP. Any proposed contract amendments raised by a Respondent will also be assessed so we consider the extent to which a provider might be seeking to alter the contractual risk allocation proposed by Pharmac in the RFP.

The evaluation committee will consider the scores and overall value for money considering any additional information (e.g., answers to questions of clarification) to select the preferred Respondent.

If a Respondent offers a substantially lower price than other Proposals, we may make enquiries or require additional evidence to verify that the Respondent can meet all the requirements of the RFP.

Any information relating to the price must be clear, accurate and unambiguous. Prices must state whether they are exclusive or inclusive of Goods and Services Tax (GST).

(a) Respondents must use Attachment 2.

(b) Attachment 2 must show a breakdown of all costs, fees, expenses and charges.

(c) Respondents must show how they will manage risks and contingencies related to the delivery of the requirements of the RFP.

(d) Respondents must document all assumptions and dependencies that affect its pricing and/or the total cost.

(e) Respondents must tender prices in NZ$. Unless otherwise agreed, contractual payments will be in NZ$.

9. Evaluation Process and Due diligence

(a) For shortlisted Respondents, we may:

(i) reference check the Respondent and any named personnel

(ii) make other checks against the Respondent e.g. a search of the Companies Office or NZBN

(iii) inspect audited accounts for the last three financial years

(iv) undertake a credit check.

(v) request further evidence to demonstrate modern slavery is not used in the manufacture or supply of the proposed DES.

10. 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 the declaration in Schedule 3 and Attachment 1 of this RFP as part of your proposal by declaring that you have read and understood Pharmac's terms and conditions to list medical devices on the Pharmaceutical Schedule, 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).

11. 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 Pharmac's Factors for Consideration.

(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.

12. 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;

(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), Health NZ 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 Schedule 3 and Attachments 1, 2, and 3, 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, clinical advisors and other consultants, the Ministry of Health and Health NZ (**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.

13. Anticipated timetable

(a) Following receipt of proposals, Pharmac anticipates:

(i) the evaluation committee evaluating proposals from October 2025

(ii) negotiating with submitter(s) of one or more preferred proposals from October 2025;

(iii) consulting on any provisional agreement from November 2025; and

(iv) Pharmac's Board, or the Board's delegate, considering any provisional agreement for approval in or after January 2026.

(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 x.

(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.

14. 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.

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Schedule 3: Response Form

Instructions for Respondents

(a) Check that you have all the relevant documents, including:

(i) The Request for Proposals (RFP) which outlines the procurement process.
(ii) The Response Form (this one) to fill out your response.
(iii) The Pricing Response Form to provide the pricing details of your proposal.

(b) Please follow the layout of this Response Form:

(i) Don't change the section headings and sequence as this needs to be consistent across all Respondents.
(ii) Insert any extra images or graphs either as part of your answer or in a separate attachment (but make it clear in the Response Form that you have done so).
(iii) Do not insert links to long documents. They may not be viewed.

(c) Everything highlighted in **PURPLE** in this document is information for the Respondent (you). Delete these **PURPLE** parts before sending the Response Form.

(d) Write your response in the blue sections. Un-shade the blue once you have filled these out.

(e) Remember to make a note of the Deadline for Questions (12pm, 4 September 2025). The Q & A section is helpful for all Respondents so feel free to ask us if anything is unclear.

Checklist for Respondents

Have you:		
1.	Filled in all sections of the Response Form	☐
2.	File size: Your submission should be no greater than 50MB	☐
3.	Arranged for the declaration to be signed.	☐
4.	Prepared your Proposal (a) submit your response through GETS.	☐
5.	Deleted the PURPLE instructions from this Form.	
6.	Unshaded the blue highlighting where you have filled in your answer.	
7.	Arranged for the Proposal to be submitted electronically before the Deadline for Proposals (5pm, 17 September 2025).	☐
8.	(a) Included the following completed information in your submission: (i) Attachment 1: RFP Non-Price Response Form (ii) Attachment 2: RFP Pricing Response Form	☐

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Request for Proposal (RFP) Response Form

In response to the Request for Proposals

By: Pharmac
For: The supply of Drug Eluting Stents under a market share arrangement
Reference:

Date of this Proposal: [insert date]

Tēnā koe

Pharmac Director, Medical Devices
C/- Tom Gillard
Procurement Manager
Pharmac

Proposal for the supply of DES

In response to your request for proposals (**RFP**) dated **20 August 2025** we put forward the following proposal in respect of permanent coronary DES.

1. About the Respondent

RESPONDENT TIP

- This section gives basic information about your organisation and identifies your Point of Contact for the RFP process.
- If an item is not applicable, e.g. you do not have a registered office, complete the box by stating 'not applicable'.
- This information will be used for Proposals regarding drug eluting stents

(a) Our company details

Trading name:	[insert the name that you do business under]
Full legal name (if different):	[if applicable]
Physical address:	[if more than one office – put the address of your head office]

Postal address:	[e.g. P.O Box address]
Registered office:	[if you have a registered office insert the address here]
Business website:	[URL address]
Type of entity (legal status):	[sole trader / partnership / limited liability company / other please specify]
Registration number:	[if your organisation has a registration number insert it here e.g. NZBN number]

(b) Point of Contact for this RFP

Contact person:	[insert name]
Position:	[insert position]
Phone number:	[insert phone number]
Mobile number:	[insert mobile number]
Email address:	[insert email address]

(c) Liaison person(s) for Health NZ hospitals and Pharmac

Contact person:	[insert name]
Position:	[insert position]
Phone number:	[insert phone number]
Mobile number:	[insert mobile number]
Email address:	[insert email address]

(d) Customer support and general enquiries

Customer Service Hours (NZST)	[insert]
Phone number:	[insert phone number]
Email address:	[insert email address]

(e) Details of proposed contract manager

Contact person:	[insert name]
Position:	[insert position]
Phone number:	[insert phone number]
Mobile number:	[insert mobile number]
Email address:	[insert email address]

2. Response to the Requirements

RESPONDENT TIP

- Carefully read RFP. Then provide your response by demonstrating your organisation's ability to meet the criteria.
- Keep it simple. If an answer is in another document e.g. a marketing brochure, just cut and paste the relevant part into this form. Do not show the whole document unless necessary - we may not read it all.
- You may include extra information in your Proposal but only if it adds value and is relevant.

2.1 Pre-conditions

RESPONDENT TIP.

- You must be able to answer 'yes' to each of these pre-conditions. Make sure you can verify this.
- 'Yes' means you currently meet the pre-condition. If you cannot answer 'yes' to all, your Proposal will not be evaluated further.

	Pre-condition	Meets
1.	Respondents proposed medical devices must be registered in the Web-Assisted Notification of Devices (WAND) database at the time of proposal submission.	[Yes/No]
2.	All proposed DES must hold one or more of the following certifications: • CE (Conformité Européenne) • FDA (U.S. Food and Drug Administration) • TGA (Therapeutic Goods Administration, Australia)	[Yes/No]

3. Detailed Response to Requirements

3.1 Response to Evaluation Criteria

RESPONDENT TIP

- Your Proposal will be scored against your answers to these criteria. Aim to give answers that are relevant, concise and comprehensive.
- Consider the % weighting for each criterion. The higher the weighting the more important it is. Take the weightings into account in deciding how much detail to include.
- If you have made any assumption about the Requirements or delivery, clearly state the assumption.
- There may be several questions that relate to one criterion. If these questions are not individually weighted assume that they are of equal importance.

Company Information	**Info Only**
(a) Provide Information about company size, structure, New Zealand presence and annual turnover o Include sales/product support staff relevant to this RFP.	
[insert answer here]	
(b) Evidence of financial stability and ability to cover financial liabilities Include: o how you would cover your financial liabilities in the event of a major failure to supply (e.g. a recall)	

- information about your financial stability (e.g. guarantor companies)
- Attach supporting evidence (e.g. annual financial report, Companies Register financial statement, insurance certificate, bank letter).

[insert answer here]

(c) What are the qualifications and experience of your management and technical leadership?

[insert answer here]

(d) What business continuity and disaster recovery plans do you have in place?

[insert answer here]

Clinical Suitability (ICAG)	**Pass/Fail**

(a) Please provide the following:

- Efficacy evidence from clinical trials with large patient groups.
- Safety evidence from studies with long-term follow-up data.
- Product specifications, instructions for use, indications/contraindications, and surveillance data.
- Any other relevant information

[insert answer here]

Clinical Suitability and Quality	**Weighting 30%**

(a) Quality Management System(s) certification for your company

- If Yes, attach evidence

[insert answer here]

(b) Other relevant standards for the proposed products

List any other standards that are relevant to the proposed products including but not limited to:

- AS/NZ standards
- ISO standards
- IEC standards
- Describe the extent of compliance with the listed standard and the product range the standard applies to.

Attach evidence of compliance where available.

[insert answer here]

(c) Permit to supply the products to Health NZ hospitals

Include:

- a statement confirming that you have all the necessary rights and permits to supply the products and associated services to Health NZ hospitals, or
- information about process and expected timeframe for obtaining the necessary rights and permits to supply the products and associated services to Health NZ hospitals.P

[insert answer here]

(d) Please provide an overview of your DES product

Include:

- Ease of use
- Change description
- Advantageous clinical features
- Visibility with imaging modalities
- Any other relevant information

Supply Chain, Stock Management and Track Record	**Weighting 30%**

(a) Stock Holdings and Inventory Management

- Pharmac requires 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.
- What inventory management systems and practices are in place to ensure product availability?

[insert answer here]

(b) Recall Management

- Describe how a major recall of a proposed product(s) would be managed.

[insert answer here]

(c) Delivery Frequency and Logistics

- Outline your standard delivery frequency and logistics arrangements for supply to Health NZ hospitals.

- Indicate the typical dispatch and delivery timeframes from order confirmation

[insert answer here]

(d) Manufacture to delivery

For each product range, from start of manufacture to delivery to Health NZ hospitals or hospitals nominated locations, include:

- steps
- who is involved
- timeframes
- delivery frequency

[insert answer here]

(e) Lead times

State your standard lead times from order placement to delivery for 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

[insert answer here]

(f) Supply Continuity and Contingency Planning

Detail the processes and protocols you have in place to manage shortfalls in supply.

- Describe how you respond to unexpected spikes in demand
- Provide an example of a situation where you successfully mitigated a supply disruption.

[insert answer here]

(g) Consignment stock

- Provide a written statement of your understanding of consignment stock requirements within Health NZ hospitals.
- Provide information on required storage conditions (if any)
- Provide 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 Health NZ hospital
- Provide information on the reporting process (format and frequency)

[insert answer here]

(h) Track Record

- Please describe your past performance and experience in supplying similar products in New Zealand or comparable health systems

[insert answer here]

Education, Clinical Support and Complaints	**Weighting 20%**

(a) What are your standard support hours (NZ time) for customer support and orders

[insert answer here]

(b) Describe any 24/7 troubleshooting support relevant to the proposed products

[insert answer here]

(c) What experience do you have transitioning clinicians and support staff to new devices or systems?

[insert answer here]

(d) Provide a written statement outlining your understanding of educational and clinical support requirements.

[insert answer here]

(e) Include an overview of the training and education that would be regularly provided to Health NZ hospitals for the proposed products including:

- frequency
- location
- format
- content
- staff groups (e.g. hospital staff, clinicians, nurses, patients)
- tracking training and education service
- other relevant information

[insert answer here]

(f) Complaints Management

- Include overview of key roles and responsibilities for investigation and response, and escalation and continuous quality

improvement processes.

[insert answer here]

Transition and Implementation	**Weighting 15%**

(a) Transition

Please outline your proposed transition plan for supporting Health NZ hospitals in switching to their DES products if awarded Principal Supply Status

- This outline should include a detailed transition plan setting out the transition steps, roles and responsibilities, and timeframes specific to a market share model.

[insert answer here]

(b) Implementation

- Provide information on how you would organise and manage your resources to support a national implementation plan and provide ongoing national support.

[insert answer here]

Broader Outcomes	**Weighting 5%**

(a) What environmental sustainability initiatives or practices does your company have in place?

[insert answer here]

(b) How do you reduce environmental impact in your manufacturing, packaging, or distribution processes

[insert answer here]

(c) How does your company support New Zealand businesses and local supply chains?

[insert answer here]

Modern Slavery	**Pass/Fail**

(a) Briefly describe the steps your organisation takes to identify, assess and address modern slavery in your operations and supply chains relevant to this contract.

- Any relevant policies, procedures or frameworks.
- Your organisational capability and any partnerships that support your approach.

[insert answer here]

(b) Identify any known or potential modern slavery risks associated with the goods, services or works being provided. Describe:

- Actions taken or planned to mitigate these risks.
- Any challenges or barriers to taking action.

[insert answer here]

3.2 Price

RESPONDENT TIP

- Please do not submit any pricing information in this RFP Response Form. Instead, use the RFP Pricing Response form embedded below, or attached in the Attachments section on GETS.
- In your pricing information consider all risks, contingencies and other circumstances relating to the delivery of our Requirements

and include adequate provision for them.
- Document any assumptions that you have made in costing the Requirements.

Please submit your financial information and pricing using the Excel spreadsheet template accompanying the RFP in Attachment 2. Please provide as detailed a breakdown of the pricing as possible and describe any assumptions where relevant (i.e. the number of people being applied to a job and why, or if, that changes over time). Where possible, please provide information regarding subcontractor input as well as your input.

4. Proposed Contract

RESPONDENT TIP

- The proposed contracts for Drug Eluting Stents can be found in the Attachments section on GETS. Pharmac needs to know whether you are prepared to do business based on the Proposed Contract.
- If you have any suggestions or changes that you wish to alter in the Proposed Contract, please note below (and you may be asked why it is important).
- In deciding which Respondents to shortlist Pharmac will take into account each Respondent's willingness to meet the Contract terms and conditions.

Choose one and delete the other:

Having read and understood the Proposed Contract, I confirm that these terms and conditions are acceptable. If successful, I agree to sign a Contract based on the Proposed Contract.

OR

Having read and understood the Proposed Contract(Attachment 3), I have the following suggestions to make. If successful, I agree to sign a Contract based on the Proposed Contract subject to negotiating the following clauses:

Clause	Concern	Proposed solution
[insert number]	[briefly describe your concern about this clause]	[describe your suggested alternative wording for the clause or your solution]
[insert number]	[briefly describe your concern about this clause]	[describe your suggested alternative wording for the clause or your solution]

5. Declaration

RESPONDENT TIP

- Here you are asked to make a formal declaration. Select 'agree' or 'disagree' at the end of each row. If you don't, you will be deemed to have agreed.
- Have the declaration signed by someone who is authorised to sign and able to verify the declaration, e.g. chief executive or a senior manager.

Respondent's declaration		
Topic	Declaration	Respondent's declaration
RFP Terms:	I/we have read and fully understand this RFP, including the RFP Terms. I/we confirm that the Respondent agrees to be bound by them.	[agree / disagree]
Requirements:	I/we have read and fully understand the nature and extent of Pharmac's Requirements. I/we confirm that the Respondent has the necessary capacity and capability to fully meet or exceed the Requirements stated in this RFP.	[agree / disagree]
Supplier Code of Conduct	I/we have read and fully understand the New Zealand Government's Supplier Code of Conduct.	[agree / disagree]

Ethics:	By submitting this Proposal the Respondent warrants that it: • has not entered into any improper, illegal, collusive or anti-competitive arrangements with any Competitor • has not directly or indirectly approached any representative of Pharmac (other than the Point of Contact) to lobby or solicit information in relation to the RFP • has not attempted to influence, or provide any form of personal inducement, reward or benefit to any representative of Pharmac.	[agree / disagree]
Conflict of Interest declaration:	The Respondent warrants that it has no actual, potential or perceived Conflict of Interest in submitting this Proposal, or entering into a Contract to deliver the Requirements. Where a Conflict of Interest arises during the RFP process the Respondent will report it immediately to Pharmac's Point of Contact.	[agree / disagree]
Details of conflict of interest:	[if you think you may have a conflict of interest briefly describe the conflict and how you propose to manage it or write 'not applicable'].	

DECLARATION BY THE RESPONDENT

I/we declare that in submitting the Proposal and this declaration:

- the information provided is true, accurate and complete and not misleading in any material respect
- the Proposal does not contain any material that will infringe a third party's intellectual property rights

- I/we have secured all appropriate authorisations to submit this Proposal, to make the statements and to provide the information in the Proposal and I/we am/are not aware of any impediments to enter into a Contract to deliver the Requirements.

  I/we understand that the falsification of information, supplying misleading information or the suppression of material information in this declaration and the Proposal may result in the Proposal being eliminated from further participation in the RFP process and may be grounds for termination of any Contract awarded as a result of the RFP.