File Note

Subject	Supplier Briefing: Request for proposals for the supply of permanent coronary drug-eluting stents (DES) to District Health Boards under a market share procurement model
PHARMAC staff present	Matthew Wolfenden, Jacquie Pillay, Sarah Fitt
Suppliers present	Terumo, Surgical Supplies, Meril, Abbott Vascular, Intermed Medical, B. Braun New Zealand, Culpan Distributors, Boston Scientific, Medtronic, Bio-Excel, Biotronik
Date/Time event took place	15 November 2017, 1pm
Location	Novotel, Auckland Airport

Agenda

1. Introduction from Sarah Fitt
2. Presentation from Matthew Wolfenden
3. Question and answer session.

Themes of discussion from question and answer session

A. Discretionary variance (DV) limits and DV devices

- PHARMAC will monitor DES usage on a regular basis and assist District Health Boards (DHBs) in tracking their on-going compliance with any DV limits.
- National compliance with any DV limit will be measured by PHARMAC annually.
- If the annual national DV level is exceeded, individual DHB compliance will be measured by PHARMAC and the contracted supplier will be entitled to seek compensation from any individual DHB that has exceed the DV limit.
- DHBs will retain full choice over which DV devices they purchase.
- DV devices do not have to be listed on the Pharmaceutical Schedule.
- If a DV device is listed on the Pharmaceutical Schedule, the DHB must pay the national contract price for that device.
- PHARMAC will rely on DHBs to provide purchasing data for any DV devices they purchase that are not listed on the Pharmaceutical Schedule.
- Suppliers with contracts for Interventional Cardiology devices are required to provide PHARMAC with quarterly sales data reports for all contracted devices, including DV devices.

B. Tiered pricing

- Tier One pricing is mandatory for both Hospital Supply Status (HSS) and Dual Supply proposals.
- Tier Two pricing is optional for HSS proposals.
- Tier Two and Tier Three pricing is optional for Dual Supply proposals.
- Tiered pricing will be applied at the individual DHB level.
- A DHB can choose to change its volume commitment (tier commitment) with a supplier at any stage during the term of the contract.
- PHARMAC is not willing to consider proposals with tier structures that differ from those set out in the RFP.
- It is the responsibility of the supplier to work with DHBs to implement and monitor compliance with volume commitments related to optional tier pricing.

- Any contracted tiered pricing models would be shared with all DHBs.
- PHARMAC intends to publish Tier One pricing on the Pharmaceutical Schedule. If a supplier has concerns about the Tier One price being published, this should be stated in the RFP response along with justification for requesting confidentiality.
- Confidentiality of optional Tier Two and Tier Three pricing will be open to negotiation with the successful supplier(s).

C. Foreign currency exchange rate clauses

- PHARMAC is not willing to consider proposals that involve foreign currency exchange rate clauses or prices linked to any index.
- It is expected that suppliers consider the exchange rate fluctuations over an indicative 36-month exclusivity period when submitting proposals.

D. Term of contract

- PHARMAC anticipates that the duration of any hospital supply status/ dual supply status would be up to 36 months (excluding any transition period).
- If at any stage prior, PHARMAC determines that the duration of any hospital supply status/ dual supply status will be significantly less than 36 months, this will be discussed and negotiated.

E. Pricing

- PHARMAC expects your proposal to be the best you can offer, PHARMAC does not intend to initiate negotiations with you on price.
- 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.
- Suppliers are required to provide full details of any conditions or proposed terms related to the pricing submitted.

F. Bundling

- PHARMAC is not willing to consider proposals that involve cross-bundling across different interventional cardiology subcategories (e.g. bare metal stents, dilatation balloon catheters, guidewires) or any other hospital medical devices.
- The impact of dissolving existing bundle models associated with DES will be considered by PHARMAC.
- Any supplier of DES with existing bundle models must include in their submission information on how they would plan to manage the financial impact to DHBs of dissolving bundle models that will need to occur if PHARMAC implements market share agreements for DES.

G. Holding stock in New Zealand

- The preferred stock holding option is for suppliers to hold a minimum of 3 months stock of DES in New Zealand.
- 3-month stock includes consignment stock held in DHB hospitals.
- If a supplier cannot hold 3 months stock in New Zealand, their submission must include information on how they would ensure continuity of supply to DHB hospitals.

H. Market size

- The estimated hospital market size for DES as stated in the RFP has been sourced from supplier datasets provided to PHARMAC as part of reporting requirements under national contracting agreements.
- HSS would offer a single supplier a minimum share of 65% of the DHB hospital market.

- Dual Supply status would offer two suppliers collectively, a minimum of 90% of the DHB hospital market, with no guarantee of share to either supplier.
- PHARMAC makes no representation as to the level of sales or likely sales of permanent coronary DES into DHBs, under either a HSS or Dual Supply market share model.
- DHB clinicians will retain full choice over which type of coronary stent they use for individual patients e.g. permanent DES vs bioresorbable DES vs bare metal stent.

I. International Regulatory Certification

- PHARMAC is willing to consider DES that hold, or are in the process of obtaining, Therapeutic Goods Administration (TGA) or Food and Drug Administration (FDA) or Conformité Européenne (CE) approval at the time of submission for this RFP.
- PHARMAC is aware that some DES may only hold certification from other international regulatory bodies (e.g. Pharmaceutical and Medical Devices Agency in Japan).
- The RFP requirement for DES to hold TGA or FDA or CE approval is based on a recommendation made by the Interventional Cardiology Advisory Group (ICAG).

J. Clinical trial vs patient registry

- DES used to treat patients enrolled in clinical trials are excluded from any DV limits.
- DES used to treat patients enrolled in patient registries are included in any DV limits.

K. Submission of supporting documents

- Suppliers must submit all supporting documents as described in the RFP, even if the DES submitted are currently being purchased by DHBs.
- If a supplier has evidence in development, that is not available to submit at the time the RFP closes, they should include in their submission a description of this evidence, and indicate when they expect it would be available for submission to PHARMAC.
- Acceptance of any evidence submitted after the RFP closure date will be at PHARMAC's discretion.

L. Pharmaceutical Schedule

- PHARMAC works within the NZ Government rules for sourcing when establishing contracts for medical devices.
- All medical devices covered by PHARMAC national contracts are listed in Part III of Section H of the Pharmaceutical Schedule.
- PHARMAC is not planning to run any procurement processes in the near future for national contracting of DES devices not currently listed on the Pharmaceutical Schedule.
- DES not currently listed on the Pharmaceutical Schedule may still be purchased by DHBs as DV devices.

M. Pricing related to alternate supply/stock-holding models

- Suppliers must submit pricing that applies to preferred supply and stock-holding models described in the RFP (e.g. consignment stock held by DHBs and 3 months stock held by the supplier in New Zealand).
- Suppliers may choose to submit additional pricing for alternate supply and stock-holding models for consideration by PHARMAC.

N. Suppliers that market multiple brands of DES

- Suppliers are welcome to submit multiple brands of DES in a single submission, for consideration for either HSS or Dual Supply models.