PHARMAC
Pharmaceutical Management Agency

Supplier briefing:
Permanent Coronary Drug-Eluting Stents Market Share RFP
Auckland – 15 November 2017

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Agenda

- This presentation will cover:
  - Introduction
  - Background
  - Scope of RFP
  - Market share proposals
  - Discretionary variance (DV) limits
  - Types of proposals being sought
  - Implementation, exclusivity & upgrades
  - Evaluation
  - Submitting proposals
  - Anticipated timeframes

- Opportunity to ask questions at the end of presentation

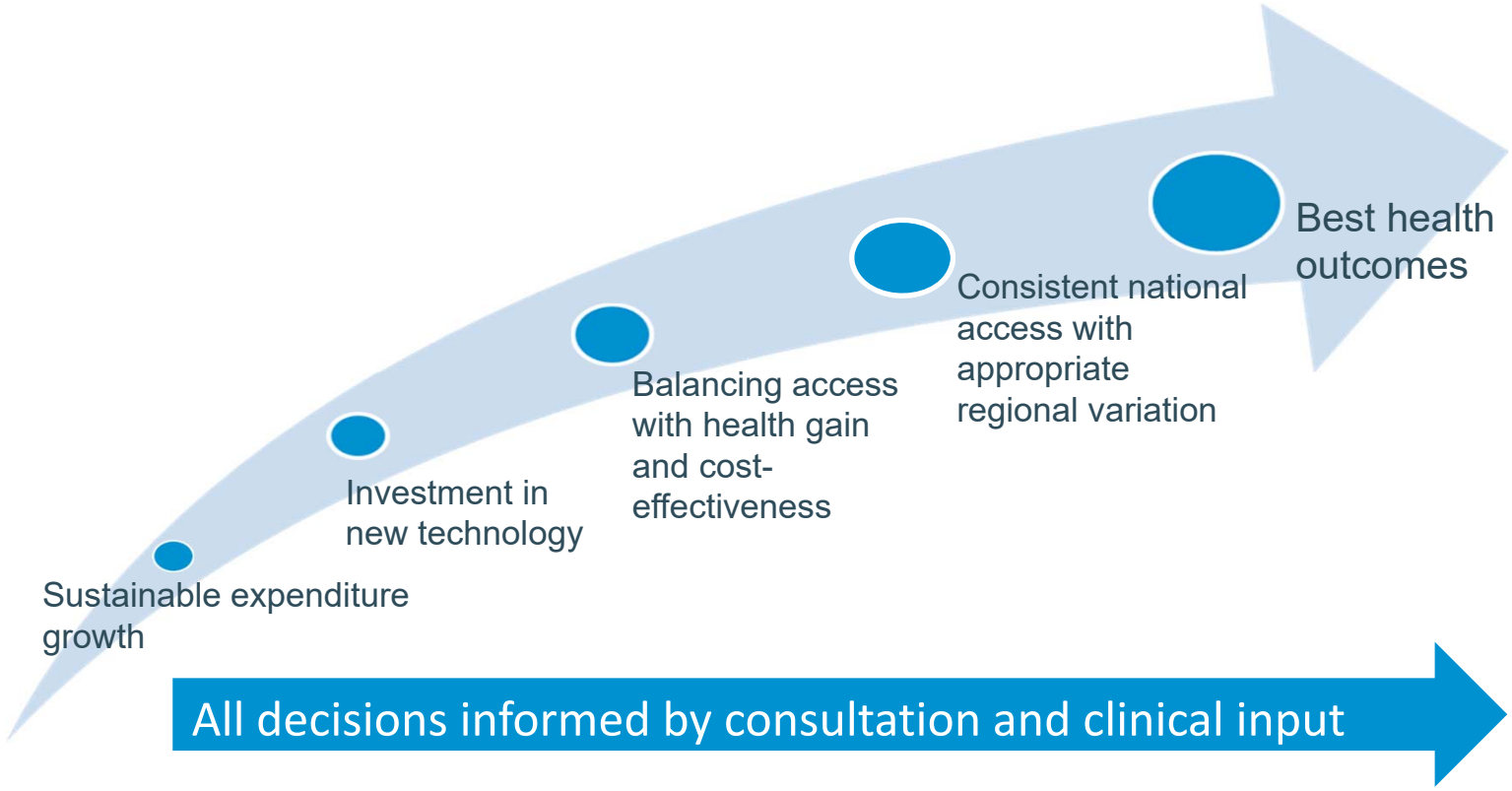
Our objective

"…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."

- ***New Zealand Public Health and Disability Act 2000***

PHARMAC's role

What's driving us?



Medical devices – the story so far

Where we're at

Framework & timeline

Background


Drug-Eluting Stent
MSP RFP
Nov 2017
ICAG Clinical Advice
Feb 2017
13 National Contracts
7 DES Suppliers
DES ~40% of
Category Expenditure
Medical Devices
MSP Approach
Discussion Document
April 2015
Interventional
Cardiology Advisory
Group (ICAG)
Established 2016
Interventional
Cardiology
ROI
April 2014

In Scope

- Mandatory criteria at the time of submission:
  - Must propose permanent coronary DES
  - Must be WAND registered
  - Must hold, or be in the process of obtaining, CE or FDA or TGA approval
  - Must be fit for purpose and clinically appropriate for the majority of patients in New Zealand as evidenced through:
    - clinical trial data;
    - registry data;
    - surveillance data.

Out of Scope

- PHARMAC will not be considering proposals for any other devices, including but not limited to:
  - Any stents other than permanent coronary drug eluting stents
    - e.g. bioresorbable stents, bare metal stents, non-coronary stents
  - Other interventional cardiology devices
    - e.g. dilatation balloon catheters, guidewires
  - Other medical devices.

Market Share Procurement Proposals

- A proposal to be the primary supplier for these products.
  - Hospital Supply Status (HSS).
  - Guaranteed minimum share of 65% of DHB hospital market.
  - DHB hospitals would be subject to a 35% Discretionary Variance (DV) limit

- A proposal to be one of two suppliers for these products.
  - Dual Supply Status (DSS).
  - Combined minimum of 90% of the DHB hospital market.
  - DHB hospitals would be able to purchase up to10% from other suppliers.

- Suppliers may choose to submit hospital supply status **and/or** dual supplier market share proposals.

What is a DV limit?

- Discretionary Variance (DV) limit
- Allows DHB hospitals to purchase *DV products* outside of the PHARMAC selected supplier products.
  - A *DV product* is any DES that is not listed as having hospital supply status or dual supply status in Part III Section H of the Pharmaceutical Schedule.
  - DV devices are not required to be listed in Part III Section H of the Pharmaceutical Schedule.

Monitoring DVs

- DV limit usage for DHB Hospitals would be reviewed to monitor compliance at least once every 12 months.
- Compliance with any DV limit will be measured at a national level.
- If the national DV level is exceeded:
  - Individual DHB compliance will be measured.
  - Any DHB that has exceeded the DV limit will be required to compensate the supplier.

Types of Proposal Sought – *Hospital Sole Supply*

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

- Tiered pricing would be made available to all DHBs.

Types of Proposal Sought – *Dual Supply*

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

- Tiered pricing would be made available to all DHBs.

Types of Proposal Sought – General

- Proposals must only include devices that are in scope.
- All suppliers must submit a Tier One price for publication on the Pharmaceutical Schedule.
- Suppliers may choose to submit optional percentage volume based tier pricing.
- Optional tiered pricing proposals must:
  - be based on the percentage range of individual DHB Hospital purchasing volume;
  - match the specified percentage volume commitments; and
  - be supplied as a price per unit purchased.

What Don’t We Want?

- Proposals for out of scope devices.
- Proposals that do not meet the mandatory requirements.
- Proposals that involve cross-bundling.
- Proposals that link to exchange rate or other indices.
- Proposals with tier structures that differ from those described.

Implementation, Exclusivity & Upgrades

- Transition Period
  - Suppliers should allow for a transition period of at least three months.
  - The exact length of the transition period would be determined following consultation.
- Exclusivity Period
  - The duration of any exclusivity period would be up to 36 months, excludes transition.
- Arrangements After Exclusivity Period
  - Successful supplier(s) would cease to have any exclusive supply status.
  - Products would remain listed subject to the terms agreed during negotiation.
- Technology Lifecycle
  - 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.

Evaluation

- Starting point will be PHARMAC's statutory objective:

  "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."

- We will be guided by the *Factors for Consideration.*
  - All factors are important, **Health outcomes** and **impact on funding** in particular.

Factors for Consideration

Information to be Evaluated

- Information to be reviewed by the Evaluation Committee:
  - Information provided by you.
  - Clinical advice from:
    - ICAG, PTAC or relevant sub-committee advice;
    - Relevant clinicians and/or DHB staff.
  - Any other relevant information.

Submitting Your Proposals

- Closing date is **4.00 pm (NZ), Friday 15 December 2017**.
- All proposals must be submitted through GETS (www.gets.govt.nz).
  - GETS RFx ID #19186447
- Schedule 7 sets out all of the documents that you should include in your proposal.
- You may also include any other additional information that you think PHARMAC should consider when evaluating your proposals.
  - Please do not provide brochures, PEHNZ forms or presentations.

What To Include..

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

Anticipated Timeframes

Period	Activity
January – March 2018	Evaluation
April – May 2018	Negotiations
May – June 2018	Consultation
June 2018	Board decisions
August 2018	Earliest possible changes to the Schedule

Questions

- All questions and answers from this meeting will be posted on GETS.
- Please submit any further questions via GETS.
- All questions and answers will be posted on GETS.
- Questions feature will close on 24 November 2018.

- **We encourage interested suppliers to register with GETS and subscribe to this RFP to be kept up to date.**