**Interventional Cardiology Advisory Group**
**Meeting held 23 August 2017**

**(minutes for web publishing)**

In consideration of the upcoming request for proposals for permanent coronary drug eluting stents (DES) PHARMAC is publishing the relevant portions of the minutes of the Interventional Cardiology Advisory Group meetings that relate to DES and to the development of a market share procurement process for these devices.

The role of the Interventional Cardiology Advisory Group is to:

- provide objective advice to PHARMAC on the possible approaches for standardisation and rationalisation of interventional cardiology devices nationally,
- assist with defining requirements and specifications that require consideration in relation to each interventional cardiology subcategory,
- review clinical evidence and appropriateness of new interventional cardiology devices and/or new technology offered by interventional cardiology suppliers,
- help ensure that products are fit for purpose, clinically appropriate and meet the needs of patients at a sustainable cost, and
- consider, make recommendations or report to PHARMAC and/ or PTAC on matters that may be referred to it by PHARMAC.

# Record of the Interventional Cardiology Advisory Group meeting held at PHARMAC on 23 August 2017

*Present from the Interventional Cardiology Advisory Group:*

Scott Harding (Chair)
Seif El-Jack
Sandi Graham
Barry Kneale
Madhav Menon
Rajesh Nair
Marius Rademaker
Mark Weatherall
Mark Webster

## Summary of Recommendations

The Group made the following recommendations:

5.4 The Group **recommended** that the most appropriate description to be used to define the scope of a market share RFP for DES was permanent drug-eluting coronary stent.

5.8 The Group **recommended** that a DES market share RFP should include a mandatory requirement for suppliers to provide a comprehensive report of all post-marketing surveillance data relevant to the DES submitted.

5.9 The Group **recommended** that to reduce publication and selection bias in evidence provided by the manufacturer, a DES market share RFP should include a mandatory requirement for suppliers to provide a detailed literature search relevant to the DES submitted, in accordance with the PHARMAC guidelines for Funding Applications.

5.13 The Group **recommended t**hat certification by either the Therapeutic Goods Administration (TGA) or Food and Drug Administration (FDA) or Conformité Européenne (CE) should be a mandatory requirement in a DES market share RFP.

5.18 The Group **recommended** that that it be mandatory for suppliers to hold DES sufficient stock in New Zealand, not Australia, to reduce the risk of out-of-stock events related to unforeseen shipping delays.

5.19 The Group **recommended** it be mandatory, for a market share DES contract, that suppliers hold a minimum of three-months stock in New Zealand.

5.21 The Group **recommended** that 6 ICAG members, including 5 Interventional Cardiologists, would be an appropriate quorum for the technical assessment of proposals and making final recommendations to PHARMAC.

5.24 The Group **recommended** that the following professional groups should be specifically targeted by PHARMAC for consultation and notification of market share procurement activity for DES:

i. CSANZ New Zealand

ii. New Zealand Cardiac Network (Ministry of Health)

iii. Interventional Working Group

iv. National Heart Foundation

5.25 The Group **recommended** that when consulting on provisional agreement(s) PHARMAC should publish detail regarding the evaluation process to provide assurance to the public, clinicians and companies that significant clinical input was sought when evaluating submissions.

5.27 The Group **recommended** that PHARMAC attend the Interventional Working Group meeting in Queenstown on 29-30 September 2017 to provide attendees with an update on national contracting for Interventional Cardiology devices and information on the proposed market share process for DES.

## 1 Market share process for drug eluting stents (DES)

1.1 The Group noted a paper by PHARMAC staff, titled Market Share Process for Drug Eluting Stents, seeking advice from the Group (ICAG) regarding:

- Scope and mandatory requirements for a DES market share RFP
- Discretionary variance values that should be applied to single and dual supplier market share models for DES
- Evaluation of proposals received in response to a DES market share RFP
- Consultation regarding a move to market share model for DES
- Implementation of a market share model for DES

*RFP Document*

1.2 The Group noted that there was a large range of DES brands on the market globally, including many which are not currently in use in New Zealand. A PHARMAC DES market share RFP would be open to any company wanting to submit DES for consideration, however to be successful a supplier would have to meet appropriate quality standards for both products and support.

1.3 The Group considered that the proposed scope description, durable platform drug-eluting coronary stents, was potentially misleading as durable is a term that is generally used to describe the polymer coating on a DES, and not the scaffold of the stent.

1.4 The Group **recommended** that the most appropriate description to be used to define the scope of a market share RFP for DES was permanent drug-eluting coronary stent.

1.5 The Group noted that a DES market share RFP would require suppliers to provide a dossier of information for all DES submitted for consideration, including:

i. Technical data – stent and delivery system

ii. Instructions for Use

iii. Indications/Contraindications

iv. Warnings/Precautions

v. Safety data

vi. Efficacy data

1.6 The Group noted that there are registries of post marketing surveillance data that track complaints, faults and recalls for medical devices. The Group noted that the United States Manufacturer and User Facility Device Experience (MAUDE) is one example of a post marketing surveillance registry.

1.7 The Group considered that all suppliers will also hold their own registries of post marketing surveillance data.

1.8 The Group **recommended** that a DES market share RFP should include a mandatory requirement for suppliers to provide a comprehensive report of all post-marketing surveillance data relevant to the DES submitted, similar to the periodic update reports (PSUR) of medicines.

1.9 The Group **recommended** that to reduce publication and selection bias in evidence provided by the manufacturer, a DES market share RFP should include a mandatory requirement for suppliers to provide a detailed literature search relevant to the DES submitted, in accordance with the PHARMAC guidelines for Funding Applications.

1.10 The Group noted that PHARMAC currently asks that literature searches to be completed for drug funding applications and recommended that wording from PHARMAC Guidelines for Funding Applications, relevant to literature searches, be included in a RFP document.

1.11 The Group considered that although the development of innovative DES is slowing, product modifications are being made to current DES to enhance function, safety and deliverability. The Group considered that these modifications can, and do, add value to clinical practice. The Group considered that market share contracts should contain wording to manage product modifications.

1.12 The Group noted that notification on the WAND database was the only regulatory requirement for a DES to be legally supplied in New Zealand and that proof of WAND notification would be a mandatory requirement in a DES market share RFP.

1.13 The Group **recommended** that certification by either Therapeutic Goods Administration (TGA) or Food and Drug Administration (FDA) or Conformité Européenne (CE) should be a mandatory requirement in a DES market share RFP.

1.14 The Group considered that a Dual Supplier market share model that required DHBs to purchase from a choice of two suppliers' selected brands of DES, in 90% of cases, with the discretion to purchase outside this range in 10% of cases, to be clinically acceptable.

1.15 The Group considered that a Single Supplier market share model that required DHBs to purchase from a single supplier's brand of DES, in 65% of cases, with the discretion to purchase outside this range in 35% of cases, to be clinically acceptable.

1.16 The Group noted the mandatory information that would be requested in the RFP so that PHARMAC could assess the business, supply chain and quality management capabilities and experience of companies that submit proposal.

1.17 The Group considered that suppliers should also be required to submit information specifically related to stock-holding capability in New Zealand.

1.18 The Group **recommended** that that it be mandatory for suppliers to hold sufficient DES stock in New Zealand, not Australia, to reduce the risk of out-of-stock events related to unforeseen shipping delays.

1.19 The Group **recommended** it be mandatory, for a market share DES contract, that suppliers hold a minimum of three-months stock in New Zealand.

1.20 The Group considered that the current members of the Interventional Cardiology Advisory Group were an appropriate group of individuals to assist in evaluating technical, safety and efficacy data submitted in RFP proposals.

1.21 The Group **recommended** that 6 ICAG members, including 5 Interventional Cardiologists, would be an appropriate quorum for the technical assessment of proposals and making final recommendations to PHARMAC.

1.22 The Group considered that it would be appropriate for the initial technical assessment of DES proposals to be performed without knowledge of the pricing offered by each supplier.

1.23 The Group considered that there were not any situations where in vitro and/or in vivo testing would be required to assess DES submitted for consideration for a market share RFP.

1.24 The Group **recommended** that the following professional groups should be specifically targeted by PHARMAC for consultation and notification of market share procurement activity for DES:

i. CSANZ New Zealand
ii. New Zealand Cardiac Network (Ministry of Health)
iii. Interventional Working Group
iv. National Heart Foundation

1.25 The Group **recommended** that when consulting on provisional agreement(s) PHARMAC should publish detail regarding the evaluation process to provide assurance to the public, clinicians and companies that significant clinical input was sought when evaluating submissions.

1.26 The Group considered that clinician acceptance of the outcome of a DES market share process could be facilitated by providing transparency of the evaluation process undertaken.

1.27 The Group **recommended** that PHARMAC attend the Interventional Working Group meeting in Queenstown on 29-30 September 2017 to provide attendees with an update on national contracting for Interventional Cardiology devices and information on the proposed market share process for DES.

1.28 The Group considered that a transition period of 3 months was appropriate following a market share RFP, for DHBs required to change brands of DES.

1.29 The Group considered that transition to a new DES requires minimal (or no) training and documentation changes for clinical staff and would not impact significantly on existing clinical resources.

1.30 The Group considered that the biggest impact of a transition to a new DES would be for DHB procurement staff managing the upload of new codes into computer systems and the swap-out of consignment stock.

1.31 The Group considered that non-coronary use of DES was infrequent and that this could be managed in the discretionary component of the RFP.

1.32 The Group considered that it would be appropriate for DES market share contracts to include clauses that exempt registered clinical trials, including first in man studies, from the market share contract requirements.

1.33 The Group considered that a 3-year market-share contract term for DES to be reasonable.

1.34 The Group noted that the New Zealand branch of the Cardiac Society of Australia & New Zealand (CSANZ) relies heavily on sponsorship from industry for national and regional conferences[1].

1.35 The Group noted that DHB funding for registrar, nurse and technician education is extremely limited, and these staff rely heavily on industry funded training programmes and industry sponsorship to attend conferences.

1.36 The Group considered that a market share model for DES may result in companies reducing/removing industry sponsorship and industry funded training opportunities which could impact negatively on clinical development opportunities for registrars, nurses and technicians.

1.37 The Group considered that a market share model for DES could impact negatively on a DHBs ability to access/upgrade technologies such as Fractional Flow Reserve, Optical Coherence Tomography, Rotational Atherectomy Systems and Intravascular Ultrasound, The Group noted that suppliers have previously provided these technologies, free of charge or at significantly reduced prices and provide service contracts free of charge to DHBs purchasing large volumes of DES.

1.38 The Group noted that some DHBs are currently accessing contracted “bundle deals” from Interventional Cardiology companies where products such as balloon catheters and guidewires are offered at significantly reduced prices when the DHB commits to purchasing the majority of their DES from the same company. The Group noted that a market share model for DES would potentially result in the disestablishment of the existing bundle deals, and result in a price increase for the bundled products for these DHBs.

[1]PHARMAC comment: It is not clear market share agreements would significantly impact on industry sponsorship. Financial impacts, including those related to training and professional development would be considered during PHARMAC’s decision making processes and would be monitored if market share agreements were established.