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15 November 2019

Dear Suppliers

**ADJUSTMENTS TO THE DENTAL AND ORAL HEALTH PRODUCTS REQUEST FOR PROPOSALS PROCESS**

We refer to the Request for Proposals for Supply of Dental and Oral Health Products issued by PHARMAC on 19 September 2019.

PHARMAC has decided to make adjustments to the RFP process, in consideration of supplier feedback following the release of the RFP. In summary PHARMAC has decided to:

- extend the period for the submission of RFP proposals to 4pm on 19 March 2020;
- allow suppliers to submit product specific information in two stages; and
- allow suppliers to submit product pricing in two stages.

PHARMAC advises that suppliers read this letter and the associated documents stated below, which sets out the details of the adjustments.

All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) (www.gets.govt.nz) no later than 4pm, 19 March 2020.

Unless the context otherwise requires, all terms defined in this letter and attached documents shall have the same meaning as those terms defined in the RFP.

If you have any questions about this RFP, please post these via GETS. We encourage suppliers to register with GETS and subscribe to this RFP to ensure they are kept up to date with this process.

We look forward to receiving your proposal.

Yours sincerely

Lisa Williams
Director of Operations

# RFP Adjustment

## 1. Background

On 19 September 2019 PHARMAC released a request for proposals for supply of Dental and Oral Health Products to New Zealand DHB hospitals and their associated community settings ("the RFP").

Suppliers wishing to submit a proposal in response to the RFP were asked to complete and submit five key documents with associated information and evidence.

These key documents were:

- Schedule 4: Proposal form;
- Attachment 1. Dental and Oral Health Proposed Product List (excel);
- Attachment 2. Financial Impact Oral & Dental Health Products (excel);
- Attachment 4. Acceptance of PHARMAC's standard terms and conditions (word); and
- Attachment 5. Document and information checklist for Dental and Oral Health Products RFP (word).

*Supplier Feedback*

Following the release of the RFP PHARMAC received feedback from a number of suppliers. On 23 October 2019 representatives from PHARMAC attended a meeting organised by the Medical Technology Association of New Zealand (MTANZ) with suppliers in its Dental Industry Group. A file note of this meeting is provided as Appendix 1 below. Feedback received to date has highlighted the following points:

- The dental and oral health product market in New Zealand is largely private. Many of the suppliers in this market specialise in the supply of dental and oral health products and do not supply other medical devices or associated products. Because of these factors there may be less supplier experience with, and available resources for, government procurement of dental and oral health products;
- The volume of products within the scope of the RFP is vast and getting all the requested information will require significant resource without any certainty on the outcome;
- The timing of the RFP coincides with wider sector changes, including the European regulatory changes which would impact products sourced through Europe;
- Many dental and oral health products used in New Zealand will have increased regulatory requirements to meet in Europe as a result of classification changes, which may impact supply in New Zealand;
- In the context of the wider sector changes, portions of the requested information are likely to change over the coming months, which would require re-work for both suppliers and PHARMAC;
- Considering the sector changes, associated unknowns for suppliers and anticipated timeframe for the RFP process, the process may not attract the best offers if pricing needs to be confirmed with initial submissions.

As a consequence of the supplier feedback, PHARMAC has decided to make adjustments to the RFP process as stated in this document.

## 2. Extension of period for the submission of RFP proposals

All proposals for the RFP must be submitted to PHARMAC via GETS no later than **4pm New Zealand time on 19 March 2020**. Late proposals will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

Please note: the questions and answers function on the GETS RFP page will allow RFP questions until 4pm on 16 December 2019.

## 3. Submission of product specific information in two stages

PHARMAC has adjusted the RFP process to allow suppliers to submit product specific information in two stages as follows:

Suppliers may either:

(a) submit its proposal in accordance with the information requested in the RFP issued on 19 September 2019 which would follow a one-stage process; or

(b) submit its proposal in accordance with the information requested in the revised Schedule 4 and Attachment 1 documents which would follow a two-stage process.

For clarification purposes the key changes to Schedule 4, Attachment 1 and the evaluation process are highlighted in paragraph 5 of this document.

## 4. Submission of product pricing information in two stages

(a) All suppliers MUST either submit:

i) current (current at March 2020) or proposed pricing, for existing DHB Hospital suppliers; or

ii) proposed pricing, for new DHB Hospital suppliers,

in its proposal by 4pm on 19 March 2020 ("**Submission Pricing**").

(b) Submission Pricing would be considered as part of PHARMAC's first stage evaluation of a supplier's proposal.

(c) All suppliers whose proposals have been notified as being progressed by PHARMAC would then have an option to:

i) elect for its proposals Submission Pricing to be considered its final proposed DHB hospital pricing (Final Pricing); or

ii) elect to change its Submission Pricing, with the new pricing to be considered its Final Pricing

(d) Suppliers who have submitted information as per 3(a) above and have elected to maintain Submission Pricing as the Final Pricing as per 4(c)(i) above would be eligible to be progressed via a one stage process.

(e) All suppliers electing to change Submission Pricing as per 4(c)(ii) above would have its Final Pricing considered by PHARMAC prior to progression of its proposal. A substantive difference between Submission Pricing and Final Pricing may require PHARMAC to further evaluate progression of relevant proposals.

## 5. Key changes to Schedule 4, Attachment 1 and the evaluation process

*Schedule 4 and Attachment 1*

To provide clarity on information to be considered by PHARMAC in either the first stage or stage two, PHARMAC has revised Schedule 4 and Attachment 1 of the RFP to identify stage one and stage two information, as summarised in the below table:

| **Key changes** | **Schedule 4: Proposal form** | **Attachment 1. Dental and Oral Health Proposed Product List** |
|---|---|---|
| REVISED document name change | Revised document is named: **REVISED Schedule 4 for Dental and Oral Health Products RFP (word)** | Revised document is named: **REVISED Attachment 1. Dental and Oral Health Proposed Product List (excel)** |
| Identification of first stage product specific information and second stage product specific information. | The response columns of the Proposal Form tables are:<br>• Un-coloured if information requested must be submitted by **4pm** on **19 March 2020** (first stage product specific information); or<br>• Shaded in blue if information is considered to be second stage product specific information. | • In each of the applicable product information tabs ('Dental Equipment', 'Dental Devices', 'Dental Materials', 'Dental Anaesthetics', 'Miscellaneous') any information requested in a column that has not been greyed out needs to be submitted by **4pm** on **19 March 2020** consistent with the instructions provided in the instructions tab of the revised Attachment 1 document;<br>• In each of the applicable product information tabs ('Dental Equipment', 'Dental Devices', 'Dental Materials', 'Dental Anaesthetics', 'Miscellaneous') any information requested in a column that has been greyed is considered second stage product specific information. |
| Identification and amendment to price and financial information. | Price and financial information is identified in yellow and needs to be submitted by **4pm** on **19 March 2020**.<br>Financial impact information only needs to be submitted by current suppliers wishing to follow a one-stage process and have put forward proposed pricing. | • Suppliers must submit Submission Pricing by **4pm** on **19 March 2020**; and<br>• suppliers must clearly identify whether the Submission Pricing is current pricing or proposed pricing by selecting pricing type in the cell above the pricing column. |
| These documents are available to download on the PHARMAC website here and GETS | | |

Please note:

- PHARMAC recognises that a number of suppliers may have already invested a significant amount of resource in filling out the original documents. The revised documents more clearly identify the stage two information from stage one information requirements but have not substantively changed.

- Either the original Schedule 4 and Attachment 1 documents or revised Schedule 4 and Attachment 1 documents would be considered by PHARMAC.

- Stage two information would still be required of suppliers whose proposals are being progressed following the first stage evaluation. Suppliers can choose to submit this completed information by 19 March 2020 as per 3(c) above.

*See 'Figure 1' below for diagrammatic representation of process.*

*Changes in Evaluation Process*

(a) In summary, the RFP process set out in Schedule 2 of the RFP will not be substantively changed as a result of the option for a supplier to submit its proposal information in two stages. The points specified below, provide a summary as to how the process will be applied for either a stage one or stage two process.

(b) A supplier who elects to submit its proposal as a one-stage-process proposal, shall be evaluated in accordance with the information provided by the supplier to PHARMAC on or before 19 March 2020. Following this evaluation PHARMAC may request further information and may:

i) negotiate with a supplier a provisional National Contract; or

*if a substantive change (such as a proposed Final Price being an increase from Submission Pricing) is identified from the evaluated proposal*

ii) re-evaluate the proposal in light of the change in information.

(c) A supplier who elects to submit its proposal as a two-stage-process proposal, shall be provisionally evaluated in accordance with the information provided by the supplier to PHARMAC on or before 19 March 2020. Following this first stage evaluation, PHARMAC shall notify the supplier whether its proposal is to be provisionally progressed and the time period in which the supplier needs to submit its stage two information to PHARMAC. Following the submission of the stage two information, PHARMAC may request further information and may:

i) negotiate with a supplier a provisional National Contract; or

*if a substantive change (such as a proposed Final Price being an increase from Submission Pricing)*

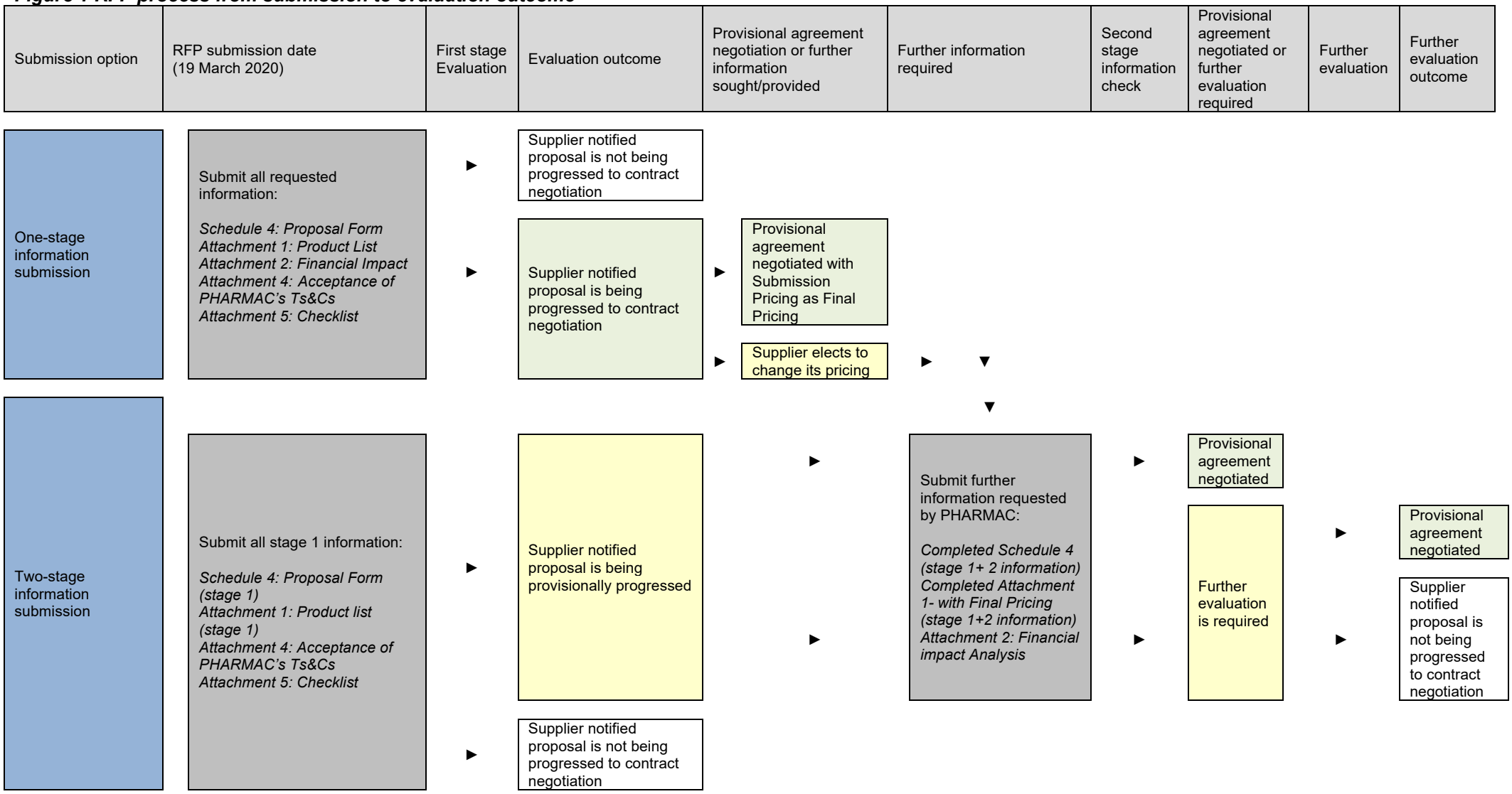
ii) re-evaluate the proposal in light of the change in information.

(d) PHARMAC makes no representation that any proposal which has been provisionally progressed will be progressed to negotiation of a provisional National Contract.

(e) A supplier who elects to submit its proposal as a two-stage-process proposal, must complete all the required information as required in the RFP. Please note that suppliers must include a proposed price if only current pricing was submitted to PHARMAC by the supplier on or before 19 March 2020

(f) PHARMAC has provided 'Figure 1' below, which sets out how the RFP evaluation process will work.

***Figure 1 RFP process from submission to evaluation outcome***



## Appendix 1 – File note of 23 October 2019 Meeting.

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# File Note

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| **Subject**: | Dental and Oral Health Products Request for Proposals (RFP) | | |
| **Event Type**: | Meeting | | |
| **Author**: | PHARMAC | | |
| **Attendees**: | **PHARMAC** | **Medical Technology Association of New Zealand (MTANZ)** | **MTANZ New Zealand Dental Industry Group (DIG) members** |
| | Director of Operations<br>Manager, Device Funding<br>Device Category Manager | Three representatives from MTANZ | Representative from Crown Dental<br>Representative from Healthcare Essentials<br>Representative from HenrySchein<br>Representative from 3M<br>**via Phone:**<br>Representative from Ivoclarvivadent<br>Representatives from Oraltec NZ Ltd |
| **Location**: | MTANZ Office<br>Level 1<br>303 Manukau Road<br>Epsom | | |
| **Date event took place**: | 23 October 2019<br>10:30am- 12:00pm | | |

### Agenda Items:

1. **General:**
   1.1. Conduct of the meeting
2. **PHARMAC Presentation:**
   2.1. Background on PHARMAC's work in Devices
   2.2. PHARMAC's management approach
   2.3. PHARMAC's National Contracting Objectives
   2.4. Dental & Oral Health Products RFP
   2.5. Challenges and possible solutions to participation in the RFP
3. **Open Discussion**

# 1. General

## 1.1. Conduct of the Meeting

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| MTANZ | Compliance of Competition Law Statement was read out for all attending industry members to acknowledge and agree to before the commencement of the meeting. The statement required members to acknowledge that they are required to make independent commercial decisions based on their own knowledge, skill and independent advice or assessment. |
| PHARMAC | PHARMAC outlined that it is a Crown Entity that follows the Government Procurement Rules, and noted that there is a current open RFP process that is the topic of discussion today.<br><br>**Action:** In order to respect the interests of all suppliers interested in participating in the RFP process, attendees were notified that a record of the discussion at, and any questions and answers during, the meeting would be made available to all parties via publication on the PHARMAC Dental & Oral Health Product RFP page (**RFx ID: 21609822**) on the New Zealand Government Electronic Tenders Service (GETS). |

# 2. PHARMAC Presentation

*PHARMAC presented some slides (attached to the end of this document) to provide background and to aid discussion. Discussion points raised during the presentation have been identified via blue highlighting in the summary tables below and, to provide further context, web links have also been provided in the summary tables.*

*The below summary tables reflect the substantive discussion at the meeting, however, PHARMAC accepts no liability for any errors or omissions. PHARMAC notes that the summary tables also records interpretations and/or opinions expressed by attendees which are not PHARMAC's view or position.*

## 2.1. Background on PHARMAC's work in Devices

**PHARMAC**

**What are the benefits of PHARMAC's work in devices?**

These are the benefits of fairer access that Cabinet expected from PHARMAC's involvement when it asked PHARMAC to move into this area.

- More consistent access to medical devices for consumers
- Helping DHBs manage spending in a sustainable way – we all recognise that resources are limited so we want to get the greatest gains from the resources we have.
- Freeing up funding for new technology or other health initiatives
- High level of transparency around funding decisions

**Consultation**

- PHARMAC recognise that devices are different to pharmaceuticals and PHARMAC needs to understand and take these differences into account.
- Our most recent consultation has just closed and the next steps will be informed by responses to consultation. There's a lot to think about.
- PHARMAC released the summary of submissions in September. PHARMAC will be engaging and consulting further to develop and finalise operational details.

**What the sector sees as important**

- During PHARMAC's initial consultation in 2014 we found there were recurring themes and considerations raised, which gave us a good sense of what people thought was most important in determining how we would apply the model to medical devices.

*Web reference for reader: Consulting on our approach*

- These things came up again in our most recent consultation. Some examples include:

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| ○ Innovation | ○ National consistency | ○ Clinical input |
| ○ Competitive market | ○ High quality devices | ○ Interconnectivity |
| ○ Patient safety | ○ Lower evidence base | ○ Range and diversity |
| ○ Total lifetime costs | ○ Local flexibility | ○ IT and consumables |
| ○ Whole pathway costs | ○ Assessment criteria | |

- Just as one size does not fit all, no one thing is most important to everyone.
- We know we need to take a multidisciplinary approach that includes clinicians, allied health professionals, consumers and the medical device industry. The process will allow clinical choice where appropriate, support multiple suppliers, take a long-term view and consider the total cost of products and the total care pathway.

**What we have learnt**

- We know that a 'one size fits all' approach won't work for hospital medical devices.
- We recognise that devices are different to pharmaceuticals
- We need to understand and take these differences into account.
- We've received a wealth of information from the sector and are building on that from our experience.

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| **MTANZ** | A significant aspect to Medical Devices which does not appear to be highlighted that is key to patient safety and successful health outcomes is the services Medical Devices suppliers provide that support Medical Device use such as clinical training, education. This value add is not necessarily apparent when comparing Medical Devices |
| **PHARMAC** | Supporting services provided as part of supply of Medical Devices would be considered within the broader context of total costs + total care pathway of Medical Devices. Many of the national contracts that we've already entered into record agreements around support services provided by the supplier. |

## 2.2. PHARMAC's management approach

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| **PHARMAC** | **Update on our current work**<br>• Where are we currently:<br>  ○ Entering contracts with suppliers since 2014, with nearly half of all categories under contract, which is around 108,000 products under PHARMAC contract<br>  ○ Contracting category by category (What's happening in each category)<br>  ○ Our focus is now on getting all suppliers under national contracts, working through the current RFPs, estimate 6-10 more RFPs to do to complete the list, aiming to complete national contracting in 12-18 months of the last RFP release. We expect to provide clearer guidance on timeframes in the first half of 2020.<br>• National contracts<br>  ○ This is about building the schedule of devices that are used in DHBs.<br>  ○ Where DHBs are using PHARMAC contracted products, they must observe PHARMAC's contract terms<br>• Taking a long-term approach<br>  ○ We need to develop an approach that is building a sustainable business model, while we will be looking to create competition, this needs to be done in a way that ensures a viable commercial devices market |
| **MTANZ** | Is PHARMAC going to meet the 2020 deadline or the revised 2021 deadline? |
| **PHARMAC** | The 2020 timeframe was discussed in the recent consultation as an earliest date for starting the next phase of our work in devices. A number of stakeholders provided feedback that the 2020 date was not possible, and this was addressed in our communications to the sector when we released the summary of submissions. No new timeframe was determined. We are considering the detailed feedback, and aim to give a clearer indication on timing in the first half of 2020. |

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| **PHARMAC** | **Next steps for medical devices**<br>• There is still a lot of work to do to operationalise our longer-term approach. We will need to work particularly closely with those parties who will have a significant operational role to refine these details.<br>• When the new approach will commence will depend on the feedback we receive and the work we need to do to design the operational detail. We will also need to complete the list we're building of the medical devices that DHBs are currently using before the new approach could be implemented.<br>• We know that when changes of this magnitude are put into practice, it's likely that modifications will be required post-implementation and are committed to making any adjustments necessary on an ongoing basis. |
| **MTANZ** | Will there be more resource for PHARMAC to achieve its goals? |
| **PHARMAC** | We have recently formed a Device Strategy & Development Team which is expanded resourcing. This Team is helping with planning and developing our approach further, and part of its work will involve consideration of the PHARMAC resource requirements necessary to operationalise our approach. |

## 2.3. PHARMAC's National Contracting Objectives

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| **PHARMAC** | **PHARMAC's National Contracting Objectives**<br>• We are currently building the list, primarily through contracting following RFPs for specific categories of Medical Devices for national Pharmaceutical Schedule listing agreements.<br>• Our objectives for national contracting are to:<br>  ○ Build relationships with device companies and DHB stakeholders;<br>  ○ Compile a list of devices that largely reflects what DHB hospitals are purchasing/using;<br>  ○ Develop our understanding of the products;<br>  ○ Secure supply and price, on national terms for all DHBs;<br>  ○ Ensure appropriate levels of clinical and technical training, education and support if provided.<br>• We want to be able to do this for the Dental and Oral Health Products area<br>**PHARMAC's Management Approach Benefits and Misconceptions…**<br>**Benefits:**<br>• Fairer access to Medical Devices: PHARMAC's approach, which is still under development, is working towards a funding model that would better enable fairer access to Medical Devices across New Zealand i.e. no matter where you are in New Zealand, your DHB would have the same access to devices for the services it delivers<br>• Single agency for commercial relations: Contract Management and Supply<br>• Improved administrative efficiencies: contractual, Medical Device list, and pricing updates can more easily be administered through more standard agreement structure. |

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| **MTANZ** | Presumably this is aligned with the Finance Procurement and Information Management System (FPIM)? |
| | *Web reference for reader:*<br>*Ministry of Health News release: Ministry of Health and NZ Health Partnerships (NZHP) simplify DHB procurement*<br>*NZHP Web link: Health Finance Procurement and Information Management System* |
| **PHARMAC** | Yes, the goal is for PHARMAC process and systems to align with the FPIM. PHARMAC representatives are working with NZHP, MoH, and DHBs to support implementation of the FPIM programme. |
| **PHARMAC** | **PHARMAC's Management Approach Benefits and Misconceptions continued….**<br>• Larger potential market: Although a supplier may be currently supplying just a few DHBs, having a national agreement with PHARMAC would make it easier for additional DHBs to start using those Medical Devices.<br>**Misconceptions:**<br>• *PHARMAC expects price reductions across the board:*<br>While PHARMAC does expect pricing to be competitive, we expect suppliers to bid sustainably. Price is one of many factors PHARMAC takes into consideration, when making decisions in pursuit of its statutory objective. To help PHARMAC meet its statutory objectives, PHARMAC is guided by its Factors for Consideration<br>• *PHARMAC will reduce the value of this market through its competitive processes:*<br>While improving value for money is one of the things that the PHARMAC Management Approach would aim to achieve, this isn't just about driving prices down - we also look at how money 'saved' can be re-invested into new Medical Devices not currently available in DHBs. |
| | • *The PHARMAC model favours the bigger players:*<br>If we can draw comparisons to PHARMAC management of medicines, we have found that the model has provided new opportunity for suppliers. For example one of the areas where new/smaller players' barrier to market entry has been reduced is via our annual Pharmaceutical Tender process – over the years we have actually seen the number of suppliers participating in this process increase |
| **MTANZ** | The annual Tender would be inappropriate for Medical Devices. There is no way a tendering process used for medicines could be applied to Medical Devices with their increased level of complexity. |
| **PHARMAC** | This is just an example of how centralised procurement with a standardised process can reduced barriers to market entry, in no way are we implying that it would be appropriate to be used for all Medical Devices; it's not even a commercial approach that can be used for all medicines.<br>PHARMAC has made it clear it intends to build up its knowledge base, and external expert advice framework in order for it to consider appropriate commercial approaches, which may well be different for different Medical Devices. |
| **PHARMAC** | **PHARMAC's Management Approach Benefits and Misconceptions continued….** |

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| | • *You must accept PHARMAC's Standard Terms and Conditions in order to get an agreement*:<br>PHARMAC is open to adapting supply agreements where the standard terms do not adequately reflect a supplier's supply model or the needs of a particular Medical Device / Medical Device Category, taking account of the impact these changes may have on DHBs. |
| **MTANZ** | A number of the standard terms and conditions are not acceptable to industry. |
| **PHARMAC** | PHARMAC has shown through supply agreements already established that it and suppliers can reach mutually acceptable terms, and we are looking forward to hearing the industry group representatives comments. PHARMAC respects that MTANZ and the suppliers it represents would wish to pursue terms which reflect their best interests. Equally PHARMAC, acting on behalf of DHBs, will seek terms that best reflect the interests of DHBs. This is the nature of commercial negotiations. Both parties take on risks in contractual relations and the degree of risk a party is prepared to take on is likely to reflect its ability to control or mitigate the risk and manage the outcomes if the risk eventuates. |
| | **PHARMAC's Management Approach Benefits and Misconceptions continued….**<br>• *PHARMAC is unlikely to take on industry advice:*<br>o To date engagement with the medical devices industry has been good, and we appreciate this, as it helps us better understand the market.<br>o A key part of PHARMAC's approach is inviting the conversation with all stakeholders to ensure the new management approach will be effective, practical and successful.<br>o PHARMAC regularly seeks feedback from stakeholders including industry to help make sure we are appropriately recognizing the different considerations Medical Devices raise<br>o We recognize the dental and oral health market in NZ is relatively unique with a significant private market, and more limited public market portion.<br>o We consult regularly, this enables PHARMAC to consider all views when making its decisions, PHARMAC does consider feedback and makes changes to its proposed approaches based on that feedback. |

## 2.4. Dental & Oral Health Product RFP

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| **PHARMAC** | **What does it mean when PHARMAC enters into a National Contract with a supplier(s)?**<br>• Listings are non-exclusive and will include pricing and details of the Medical Devices included.<br>• It will be up to DHBs to determine what Medical Devices they purchase. However, where they do, DHBs are expected to purchase under the terms of the PHARMAC Agreement.<br>• For now, DHBs may purchase Medical Devices not contracted by PHARMAC at their discretion.<br>• The National Contract would have an effective date for when DHBs will be able to purchase under the National Contract. DHBs will not be required to individually approve the National Contract before it comes into effect.<br>• Multiple Agreements are likely to eventuate from a PHARMAC National Contracting RFP process. They won't happen all at once but over time as negotiations are progressed with various suppliers that have had a proposal recommended for progression. |

## 2.5. Challenges and possible solutions to participation in the RFP

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| **PHARMAC** | **Working with Dental & Oral Health Product Suppliers: Challenges and Solutions**<br>• Challenges industry has raised previously:<br>  ○ Small value market (<$10 million per annum) – which is split amongst multiple incumbent suppliers, limited value;<br>  ○ Longer-term contractual obligations could impact on long term commercial viability;<br>  ○ Detail requested in RFP and timeframe given in the context of 1,000s of SKUs is a significant challenge, particularly in light of regulatory changes happening internationally.<br>• Possible solutions – Questions for industry<br>  ○ What aspects of the RFP are considered too resource heavy?<br>  ○ What are your concerns about PHARMAC's management of Medical Devices?<br>  ○ What are the possible solutions to this? |

## 3. Open Discussion

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| **MTANZ** | The Dental Industry is an area where PHARMAC can tap into already established Groups like the DIG. And its an area where there is an immediate need to consider as the business is very different from other Device Categories. |
| **PHARMAC** | Noted that this is why PHARMAC is here today, to understand the immediate concerns of the industry in the context of the current open Dental & Oral Health Products RFP. |
| **DIG member** | **Timing of Dental and Oral Health Products RFP in the context of wider industry resource constraints:**<br>• New Therapeutics Products Legislation<br>• International Changes impacting suppliers – implementation of the new European Medical Devices Regulation |

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| | • Supplier capability in the Dental and Oral Health area |
| | **The proposed New Zealand Therapeutics Products legislation**<br>• The new proposed legislation is going to have significant impacts on Dental & Oral Health suppliers.<br>• Many Dental & Oral Health products are provided by parallel importers who are unlikely to be equipped to comply with the new proposed legislation.<br>• Sponsorship, and implications of being a sponsor under the new legislation, is likely to impact supply.<br>• As a result likely to see market exits from these suppliers and/or rationalisation of products. |
| | *Web reference for reader: Therapeutic Products Regulatory Scheme consultation* |
| | **European Medical Devices Regulation (MDR)**<br>• Internationally there is expected to be a significant impact on suppliers, and supply chains due to EU regulatory changes effective from May 2020.<br>• The Dental & Oral Health Industry is anticipated to be impacted more significantly because of more stringent regulatory requirements being applied to this area following an up-classification of these Medical Devices in the new European regulatory regime.<br>• Products supplied in NZ that are manufactured in Europe will be impacted by these changes. Some companies may have warehousing exemptions which reduced impact, but does not limit it*<br>** CE-Marked legacy devices have a up to (5) more years to transition, this assumes the Medical Device has been manufactured, packaged, labelled and released into a finished goods warehouse before the transition end date of May 2020.*<br>• A significant impact is large amounts of product information will be required to change<br>• Therefore, a large amount of the product information requested in PHARMAC's RFP will become obsolete and require updating following the EU changes, eg GTINS & labelling changes |
| | *Web reference for reader:* European Medicines Agency Medical Devices webpage |
| **PHARMAC** | • Noted that GTINS although a preference are not mandatory |
| **DIG member** | • Noted that, in the submission form attached to the RFP, PHARMAC has outlined that if the requested information is not known suppliers do not need to submit it. |
| **PHARMAC** | • Clarified that the RFP acknowledges that the product specific requested information may not be available in time for close of the RFP - suppliers are able to submit information as 'TBC' and an expected date for the information requested to be received by. All information is required for a Medical Device to be listed on the Pharmaceutical Schedule via a listing agreement*<br>*this is outlined on the Instructions tab of Attachment 01 of the RFP |

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| **DIG member** | • Significant administrative burden is associated with the changes that will be enforced by the European MDR. The degree of impact will be dependent on whether a products information requires minor updates or much more significant (as is expected from a change to classification). Dental and Oral Health products are likely to be the later.<br>• At May 2020 Class 1 Classified Medical Devices (approx. 50% of medical device market) will not meet new MDR requirements because manufacturers self-declare conformity and current certificates will expire 26 May 2020<br>• There will be increased clinical evaluation requirements in the EU which will substantially impact supply chain.<br>• Some suppliers are expected to leave the market or undertake significant product SKU rationalisation.<br>• The cost of change is substantial |
| **MTANZ** | • Noted members expected these changes and reclassifications to cost the global Medical Device Industry over $500 million.<br>• To add to the supplier burden, the European regime has departed from using the GMDN Code nomenclature in favour of the Italian CND nomenclature. This is a substantial departure for international nomenclature use. |
| **DIG member** | • There are currently only 5 current notified bodies approved to undertake Medical Device assessment and regulation under the new MDR.<br>• There is already a substantial bottle neck and a building backlog of applications.<br>• Suppliers late to submit will be impacted severely.<br>• Suppliers that have products exempt for the regulatory requirement at May 2020 (by being stored in a finished product warehouse) still have significant additional data change requirements |
| **PHARMAC** | • CE-marking is just one of the international regulatory certifications that can be used as evidence of quality and product suitability in the RFP. For example, if products are supplied in Australia suppliers could choose to use ARTG number preferentially in their submission. |
| **DIG members** | • If a product is manufactured or in some other way comes under the remit of the European regulatory requirements it will be impacted.<br>• Not all products are supplied into the Australian market by every supplier. Most suppliers do choose to harmonise supply across Australia and New Zealand to improve the commercial viability of the New Zealand market.<br>• For Medical Device distributors without distribution right in Australia this information could be more difficult to obtain, as they are often in competition with their Australian counterparts.<br>• Due to the reclassification of many Dental & Oral Health products there are more changes than other devices which may only require as little as a label change. All products still need to undergo conformity assessment by a newly designated Notified Body (except Class 1) |
| **PHARMAC** | • In relation to the RFP, what will change in the product information supplied by suppliers? |
| **DIG members** | • GTINS |

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| | • Finished Product Codes (which may also be used as a supplier's Ordering Code)<br>• International Compliance Certificates + Certificate numbers<br>• Range of products available for supply (up to 25% of products expected to be rationalised) |
| **MTANZ** | • Smaller market, such that in New Zealand many suppliers in the Dental and Oral health area have limited or no experience in government procurement.<br>• Some suppliers have questioned what benefit is there to participating in this RFP for them. The Dental & Oral Health market in New Zealand is dominantly private with only about 10% public. |
| **DIG members** | • Willingness to participate is in the context of the number of SKUS (tens of thousands) and number of requested information fields per product ie the magnitude of resource vs commercial benefit (<$10 million per annum). |
| **PHARMAC** | • There are a number of reasons why engaging with the process would be beneficial, we have talked about a few of these eg the efficiency gains for all parties, transparency of process. The information sought is more extensive due to needing to build a list and develop the agreements to enable the longer-term benefits discussed. |
| **DIG members** | • The New Zealand public market is important to us. It is recognised by Dental & Oral Health suppliers that the public Dental & Oral health services DHBs provide are largely meeting the unmet needs of those in lower socioeconomic groups, and we want to continue to supply to this market in a sustainable way.<br>• Timing and information requirements of the RFP in the context of wider sector change is a challenge.<br>• With this particular RFP not really offering anything, some suppliers may choose to wait until there is a market exclusivity opportunity. |
| **PHARMAC** | • There will be no easier time for a Medical Device product to be considered for listing on the PHARMAC Pharmaceutical Schedule than now. |
| **MTANZ** | • What about product changing classification? Medsafe is now requiring silver fluoride varnish to be assessed as medicine, this is a product that provides a substantial benefit in particular to lower socioeconomic groups that benefit from the DHB service.<br>• The data to support a medicines application is not there for many supplier's products.<br>• Internationally it is considered a Medical Device |
| | Note: silver fluoride varnish is considered in-scope of the open Dental and Oral Health Products RFP – as identified on the 'Scope' tab of Attachment 1 of the RFP under the Dental hygiene and preventative care devices and materials subcategory. |
| **DIG member** | • Medsafe is just enforcing the NZ legislation which has specific requirements for fluoride containing products.<br>• Unfortunately for Medsafe a pragmatic approach is not allowable within the confines of the current legislation. |
| **PHARMAC** | • At what point is it likely there would be some supplier portfolio stability? |

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| | • Are there solutions that the industry sees in the context of both the changing New Zealand environment and International environment, that align with PHARMAC's objectives under this process? |
| **DIG members** | **Information Submission**<br>• It seems that the RFP serves multiple purposes for PHARMAC and not all information is necessarily required right from the beginning.<br>• Most of the information requested appears to be a data gathering exercise to inform PHARMAC, or build the contract not necessarily assess the supplier's capabilities to supply under a PHARMAC agreement.<br>• PHARMAC has outlined it wants a list that largely reflects what DHBs currently use. It would make sense the information gathering happens in two stages.<br>**DIG Proposed solution for PHARMAC consideration - Make RFP submission a two-stage process:**<br>• **Stage 1:** Submission of vital information required to assess progression of RFP proposal to contract negotiation<br>• **Stage 2:** Following successful progression past Stage 1, Submission of information required for a product to be listed on the Pharmaceutical Schedule and develop a supply agreement. |
| **DIG members** | **Price submission**<br>• The anticipated PHARMAC RFP process would be long (expected listing date of February 2021 is a long time away from submission of pricing).<br>• Some suppliers are able to hold pricing with their manufacturers for approximately 2 years, however with that proposed timeframe half of that price holding will be taken up by the process to get to a listing agreement.<br>• While some larger suppliers have the resources to put in place means to protect them from foreign exchange risks, it's incredibly expensive so not all suppliers will have that nor will the suppliers that do have it for all products.<br>• Because of the risks, suppliers are unlikely to be able to put their best foot forward and offer the best pricing as they would need to protect themselves.<br>• Manufacturers recognise the good in supply public services and often allow for reduced pricing as a result, but this is unlikely to be realised if price needs to account for risk.<br>• It seems that the primary objectives of this exercise are for PHARMAC to gain knowledge, build its list and develop relationships and secondary to all of this is the actual Price of products<br>**DIG proposed solution for PHARMAC consideration - Make RFP submission for the current price and allow the national agreement price to be negotiated:**<br>• Suppliers should provide current pricing at time of submission.<br>• Once PHARMAC has decided to progress a supplier to contract negotiations, and a listing date is likely to occur within a 6 month timeframe for example a supplier can provide final proposed price to include in the agreement. |
| **PHARMAC** | • What about the RFP submission timeframe? Is this suitable? |

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| **MTANZ** | • Similar issue with the IVD tender (Laboratory products), large portfolio of products.<br>• Yes, an extension would be helpful.<br>• With deadline already close to Christmas, would need to extend to at least late February/March 2020 |
| **PHARMAC** | • Out of having a two-stage approach as discussed previously and longer time to submit, what would be preferred? |
| **DIG members** | • Two-stage information submission process would make the RFP more palatable for suppliers and would lower barriers to response. |

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| **PHARMAC, MTANZ and DIG members** | **Closing comments**<br>• All attendees agreed that the meeting was a good opportunity to understand the Dental & Oral Health Product market from an industry perspective and PHARMAC's intentions in the market.<br>• Industry attendees have proposed some possible solutions to the problems suppliers face with responding to the RFP.<br>• **Action**: PHARMAC to consider possible proposed solutions with respect to the open Dental & Oral Health RFP. Any decisions PHARMAC makes will be communicated via GETS<br>• Ongoing open communication, such as the engagement today, is in everyone's best interest. |

# PHARMAC and Dental and Oral Health Products

*Lisa Williams - Director of Operations*

*Andrew Davies - Manger, Device Funding*

*Chloe Dimock - Device Category Manager*

# Topics

- Background on PHARMAC’s work in Devices
- PHARMAC’s ‘National Contracting’ Objectives
- PHARMAC’s management approach
- Dental & Oral Health Product RFP
- Challenges and possible solutions

# What are the benefits of PHARMAC's work in devices?

- More consistent access to medical devices
- Helping DHBs manage spending in a sustainable way
- Freeing up funding for new technology or other health initiatives
- High level of transparency around funding decisions


# Consultation

Our **decisions are informed by consultation feedback and input from experts**. We know that a '**one size fits all' approach won't work** for hospital medical devices. We've received a wealth of information from the sector and are building on that from our experience.

# We know what the sector sees as important

- Patient safety
- High quality devices
- Clinical input
- Total lifetime costs
- Lower evidence base
- Interconnectivity
- Innovation
- Whole pathway costs
- Local flexibility
- Range and diversity
- Competitive market
- National consistency
- Assessment criteria
- IT and consumables

# What we have learned

- Devices is a huge and complex area
- Not all categories will require the same approach
- We can’t take a ‘one size fits all’ approach
- Devices are not the same as medicines

# Update on our current work

- National contracts - $255 million

  spend pa under agreement
- Working category by category – 28 category RFPs complete or in progress
- Ground work for long term approach
- Consultation review

| PHARMAC CONTRACTS* | CATEGORIES WE'RE WORKING ON IN 2018/2019 | OTHER CATEGORIES COMING UP (2019/2020) |
|---|---|---|
| Anaesthesia small equipment | Audiology | Diagnostic imaging |
| Disposable laparoscopic devices | Cardiothoracic surgery | Gastroenterology equipment |
| Endomechanical and electrosurgical | Dental equipment | Invasive ventilation equipment |
| Haemodialysis | Drapes, gowns and procedure packs | Personal protective equipment |
| Hand hygiene | Enteral nutrition | Rhythm devices and electrophysiology |
| Interventional cardiology | Infusion devices | Surgical instruments |
| Interventional radiology | Laboratory products | Theatre equipment |
| Needles and syringes | Non-invasive ventilation equipment | Ward equipment |
| Negative pressure wound therapy | Obstetric and gynaecology | |
| Orthopaedic implants | Ophthalmology | |
| Patient warming and cooling products | Patient monitoring (excluding ECG and critical care) | |
| Respiratory care | Rehabilitation equipment | |
| Single use instruments | Surgical implants | |
| Sterilisation packaging products | Surgical suction and wound drainage | |
| Surgical gloves | | |
| Surgical sutures | | |
| Thermometers | | |
| VTE prevention | | |
| Urology, ostomy and continence | | |
| Wound care products | | |

# Next steps for medical devices

- Now focused on developing the operational details
- Will continue to get input to help shape our approach
- How and when this will take place is still to be decided

# PHARMAC's National Contracting Objectives

- Through National Contracting Request for Proposals (RFPs) we want to:
  - Build important **relationships** with device stakeholders;
  - Compile a **list of devices** that largely reflects what DHBs are using;
  - Develop our **understanding** of these products;
  - Secure **supply and price**, on **national terms** for all DHBs;
  - Ensure appropriate levels of clinical and technical **training, education and support** if provided.

# PHARMAC's management approach
# Benefits and Misconceptions

Ultimately, PHARMAC expects to make choices about which new medical devices will be introduced for use in DHB Hospitals, that will get the best health outcomes from within a set amount of funding

| Benefits | Misconceptions |
|---|---|
| • Fairer access to Medical Devices;<br>• Single agency for commercial relations;<br>• Improved administrative efficiency;<br>• One agreement for all DHBs | • PHARMAC expects price reductions across the board;<br>• PHARMAC will reduce the value of this market through its competitive processes;<br>• The PHARMAC model favours bigger players;<br>• There is no room for negotiation with PHARMAC's Standard Terms and Conditions<br>• PHARMAC is unlikely to take on industry advice |

# Dental & Oral Health Products RFP

- What does it mean when PHARMAC enters into a National Contract with a supplier(s) through this RFP?
  - Listings are non-exclusive
  - It will be up to DHBs to determine what Medical Devices they purchase. Including evaluating their clinical suitability.
  - Where a Medical Device is included in a PHARMAC National Contract DHBs must purchase under the terms of that contract.
  - The National Contract would have an effective date.
  - National Contracts with multiple suppliers are likely to be agreed to over a period of time.

# Working with Dental & Oral Health Product Suppliers
## **Challenges and Solutions**

## Challenges industry has raised:

- Small value market (<$10 million per annum) – which is split amongst multiple incumbent suppliers, limited value;
- Longer-term contractual obligations could impact on long term commercial viability;
- Detail requested in RFP and timeframe given in the context of 1,000s of SKUs is a significant challenge.

## Possible solutions – Questions for industry

- What aspects of the RFP are considered too resource heavy?
- What are your concerns about PHARMAC’s management of Medical Devices?
- What are the possible solutions to this?

# Contact

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