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15 January 2020

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF DIABETES AGENTS: SGLT-2 INHIBITORS, GLP-1 AGONISTS AND DPP-4 INHIBITORS

PHARMAC invites proposals for the supply of diabetes agents: SGLT-2 inhibitors, GLP-1 agonists and DPP-4 inhibitors in New Zealand.

This request for proposals (**RFP**) letter incorporates the following schedules:

- Schedule 1 specifies the pharmaceuticals for which PHARMAC is requesting proposals and sets out the background to 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 sets out information about the estimated size of the subsidised market for the pharmaceutical; and
- Schedule 4 contains the RFP form in which you are to provide details of your proposal.

If you wish to submit a proposal, you must submit it to PHARMAC via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4.00 p.m. on Monday 16 March 2020**.

If you have any questions about this RFP, please post these on GETS. Responses to all questions will be published on GETS.

We look forward to receiving your proposal.

Yours sincerely

Andrew Davies
Acting Director of Operations

A1327714

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

1. Definitions

For the purposes of this RFP, the following definitions shall apply:

"**SGLT-2 inhibitor**" means sodium-glucose transport protein 2 inhibitors that inhibit sodium-glucose transport protein 2 (SGLT-2), used for the treatment of type 2 diabetes;

"**GLP-1 agonist**" means glucagon-like peptide-1 receptor agonists that are agonists of the glucagon-like peptide-1 (GLP-1) receptor, used for the treatment of type 2 diabetes; and

"**DPP-4 inhibitor**" means dipeptidyl peptidase 4 inhibitors that inhibit the enzyme dipeptidyl peptidase-4 (DPP-4), used for the treatment of type 2 diabetes.

"Proposal Set" means a proposal for a diabetes agent listed in this RFP which includes all of the relevant scenarios applicable to that agent, as set out in Table 1 below on page 5. For example, a Proposal Set for a single class of diabetes agent, a SGLT-2 inhibitor, would include scenarios 1,2,3,4 and 5, as set out in Table 1.

2. Pharmaceutical

PHARMAC is interested in considering proposals from suppliers of SGLT-2 inhibitors and/or GLP-1 agonists and/or DPP-4 inhibitors for the treatment of type 2 diabetes.

In the case of SGLT-2 inhibitors and GLP-1 agonists, PHARMAC is interested in proposals for medicines with established evidence of cardiovascular benefit. For the avoidance of doubt, evidence of a cardiovascular benefit for an agent that has not previously been considered by the Pharmacology and Therapeutics Advisory Committee (PTAC) should be submitted by suppliers at the time of the proposal submission. PHARMAC will seek clinical advice, at its sole discretion, on the cardiovascular benefit of any proposed SGLT-2 inhibitor or GLP-1 agonist.

3. Background to RFP

In New Zealand, it is estimated that the number of people living with a diagnosis of diabetes exceeds 240,000 people (predominantly type 2 diabetes). It is also estimated that there are about 100,000 people who have type 2 diabetes but have not yet had it diagnosed. Within the New Zealand population, the prevalence of diabetes in Māori and Pacific populations is estimated to be around three times higher than among other New Zealanders. Prevalence is also high among South Asian populations.

In February 2015, PHARMAC issued a Request for Information (RFI) to suppliers, clinicians and diabetes health care professionals about diabetes agents from the DPP-4 inhibitor, GLP-1 agonist and SGLT-2 inhibitor classes, including DPP-4 inhibitors in combination with metformin. As a result of the information received, and subsequent clinical advice, PHARMAC decided it was necessary to conduct additional analysis and notified that it would not progress to a Request for Proposals (RFP) or any other commercial process for these agents at that time.

Recent evidence has now shown that agents from the SGLT-2 inhibitor and GLP-1 agonist classes can provide benefits for people with type 2 diabetes beyond glycaemic control. For SGLT-2 inhibitors, agents have been shown to reduce rates of heart failure hospitalisation, all-cause death, progression to macroalbuminuria and initiation of renal replacement

therapy in comparison to standard care. For GLP-1 agonists, benefits have been shown in all-cause death and progression to macroalbuminuria.

Please refer to the "Clinical advice" section below for more information about the clinical advice PHARMAC has received in relation to the funding applications for SGLT-2 inhibitors and GLP-1 agonists.

Currently funded diabetes agents

PHARMAC funds a number of medicines and devices for the management of diabetes. Funded diabetes agents include alpha glucosidase inhibitors, oral hypoglycaemic agents (eg. metformin, sulfonylureas, pioglitazone and vildagliptin) and insulin. Insulins and diabetes management products (eg insulin needles and blood glucose meters and test strips) may, in general, be used for both type 1 and type 2 diabetes. Oral hypoglycaemic agents are generally used only in type 2 diabetes.

There are no SGLT-2 inhibitors or GLP-1 agonists currently funded in New Zealand. If medicines from these classes were to be funded, PHARMAC anticipates that they would be used in addition to current standard of care. The DPP-4 inhibitor vildagliptin, both as a single agent and in combination with metformin, has been funded in New Zealand with no restrictions since October 2018. The listing of vildagliptin and vildagliptin with metformin on the Pharmaceutical Schedule is subject to a confidential rebate.

Clinical advice

PHARMAC has sought advice from our clinical advisors on a number of occasions regarding the funding of the SGLT-2 and GLP-1 classes of diabetes agents. The evidence for these agents has evolved over time, as has the clinical advice received. Details of the advice PHARMAC has received regarding these medicines can be found on the PHARMAC website: funding applications for SGLT-2 inhibitors can be viewed on the Application Tracker here and funding applications for GLP-1 agonists can be viewed on the Application Tracker here. The most recent clinical advice we have received is summarised below.

In February 2019, PTAC considered that it was well-established that type 2 diabetes places a significant burden on the New Zealand Health system, and particularly Māori , Pacific peoples, and South Asian populations. In these groups type 2 diabetes is more prevalent, more severe, and generally has an earlier onset of disease. The Committee recommended that advice be sought from the Diabetes Subcommittee of PTAC regarding the appropriate place of SGLT-2 inhibitors and GLP-1 agonists in the New Zealand treatment paradigm, further consideration of class effect with these agents including the impact of trial population heterogeneity on reported outcomes, and appropriate access criteria including definition of high-risk cardiovascular populations.

In March 2019, the Diabetes Subcommittee of PTAC considered these agents and the request from PTAC regarding the appropriate place of SGLT-2 inhibitors and GLP-1 agonists in the New Zealand treatment paradigm. The Subcommittee suggested a set of Special Authority criteria that could be used if the treatments were too expensive for open listing. The Subcommittee considered that funding an agent from each of the SGLT-2 inhibitor and GLP-1 agonist classes would enable clinical decision making for the most appropriate therapy to address relative cardiovascular disease risk and health need of individual patients.

In November 2019, PHARMAC sought further feedback from the Diabetes, Cardiovascular and Nephrology Subcommittees of PTAC on proposed amendments to the suggested Special Authority criteria, based on additional feedback we had received from clinical stakeholders. In summary, the clinical advice received from these Subcommittees

indicated that while open access to SGLT-2 inhibitors and GLP-1 agonists would be preferred, the following Special Authority criteria would be clinically appropriate to ensure funded access for the patient groups most likely to benefit (if prescribing restrictions were necessary due to the expense of the treatments):

> Initial application from any relevant practitioner. Approvals valid without renewal for applications meeting the following criteria:
> All of the following:
> 1. Patient has type 2 diabetes; and
> 2. Patient has not achieved target HbA1c (of ≤53 mmol/mol) despite maximum tolerated doses of oral antidiabetic agents and/or insulin for at least 6 months; and
> 3. Treatment is to be used in conjunction with other measures to reduce cardiovascular risk in line with current standard of care; and
> 4. Treatment will not be used in combination with a funded [SGLT-2 inhibitor/GLP-1 agonist] *deleted as appropriate*; and
> 5. Treatment must be used as an adjunct to oral antidiabetic therapy and/or insulin; and
> 6. Either:
>   6.1. Patient has pre-existing cardiovascular disease or risk equivalent*; or
>   6.2. Patient has a 5-year absolute cardiovascular disease risk of 15% or greater according to a validated cardiovascular risk assessment calculator; or
>   6.3. Patient has diabetic kidney disease**
>
> Note: *Defined as; prior cardiovascular disease event (ie angina, myocardial infarction, percutaneous coronary intervention, coronary artery bypass grafting, transient ischaemic attack, ischaemic stroke, peripheral vascular disease), congestive heart failure or familial hypercholesterolaemia. ** Defined as: persistent albuminuria (albumin:creatinine ratio ≥ 3 mg/mmol, in at least two out of three samples over a 3-6 month period) and/or eGFR < 60 mL/min/1.73m^2 in the presence of diabetes, without alternative cause.

Special Authority criteria would be based on the clinical advice received from PHARMAC's network of clinical advisors. The criteria are intended to be indicative of the patient population and could be amended following consideration of responses to this RFP, feedback from public consultation, or further advice from PTAC and/or its Subcommittees. PHARMAC reserves the right to amend the restrictions as part of this RFP process through limited negotiations with a supplier, depending on the proposals received.

Reasons for running the RFP

PHARMAC considers that substantial health benefit could be gained through the funding of a SGLT-2 inhibitor and/or a GLP-1 agonist. PHARMAC is aware of multiple SGLT-2 inhibitors, GLP-1 agonists and DPP-4 inhibitors currently registered with Medsafe or available overseas. In light of this competition, the purpose of this RFP is:

(a) to determine whether funding of diabetes agent/s from the SGLT-2 inhibitor and/or GLP-1 agonist medicine classes is possible from the available budget *either* without any funding restrictions (open access) *or* with Special Authority criteria (as noted above) for people with type 2 diabetes and high cardiovascular risk; and

(b) to address an unmet health need by funding type 2 diabetes agent/s with proven cardiovascular benefit, with the aim of improving cardiovascular outcomes in a high-risk population in the most cost-effective way possible; and

(c) to offset expenditure on the new class/es by generating savings in the DPP-4 inhibitor market.

Possible outcomes from the RFP process

Depending on the responses received to this RFP, PHARMAC could decide:

- not to progress any proposals submitted in response to the RFP; or
- to progress proposals submitted in response to the RFP to fund a SGLT-2 inhibitor and/or a GLP-1 agonist and/or a DPP-4 inhibitor in any of the scenarios stated in Table 1 below.

Please note that pricing tables have been included in Schedule 4 for submitting proposals under the scenarios stated in Table 1 below.

Table 1: Summary of funding scenarios that PHARMAC anticipates could result from this RFP are as follows:

Scenario	**SGLT-2** **(open access*)** **Sole supply until 30 June 2023**	**SGLT-2** **(Special Authority criteria**)** **Sole supply until 30 June 2023**	**GLP-1** **(open access*)** **Sole supply until 30 June 2023**	**GLP-1** **(Special Authority criteria**)** **Sole supply until 30 June 2023**
1	✓		✓	
2	✓			✓
3	✓			
4		✓		✓
5		✓		
6			✓	
7				✓
All	In all scenarios a DPP-4 inhibitor would remain listed in the Schedule. This would be either as per the current arrangements (if no new supply agreement was awarded), or with a sole supply arrangement for all new patients†			

✓ Agents that would be funded under the given scenario.

* open access would be subject to the following endorsement note:

- SGLT-2 inhibitor: "[SGLT-2 inhibitor] will not be subsidised if patient is also receiving treatment with a funded GLP-1 agonist"
- GLP-1 agonist: "[GLP-1 agonist] will not be subsidised if patient is also receiving treatment with a funded SGLT-2 inhibitor"

** Note that Special Authority criteria would be based on the clinical advice received from PHARMAC's clinical advisors, as detailed in the clinical advice section of this RFP. However, the criteria are intended to be indicative of the patient population and could be amended following consideration of proposals to this RFP, feedback from public consultation, or further advice from PTAC and/or its Subcommittees. PHARMAC reserves the right to amend the restrictions as part of this RFP process through limited negotiations with a supplier, depending on the proposals received.

† In the case where sole supply is awarded for all new patients for a DPP-4 inhibitor other than vildagliptin, the following endorsements would be applied to vildagliptin and vildagliptin with metformin.

- In Section B of the Pharmaceutical Schedule: Subsidy by endorsement – Subsidised for patients who were taking vildagliptin or vildagliptin with metformin prior to [list date of new DPP-4 inhibitor] and the prescription is endorsed accordingly. Pharmacists may annotate the prescription as endorsed where there exists a record of prior dispensing of vildagliptin or vildagliptin with metformin.
- In Section H of the Pharmaceutical Schedule: Restricted – Initiation – for continuation use.

4. Types of proposals sought

PHARMAC is willing to consider the following types of proposals:

(a) Suppliers **MUST** submit at least one Proposal Set for sole subsidised supply in the community and hospital supply status in DHB Hospitals ("Sole Supply") for a single class of diabetes agent. Each Proposal Set for a single class of diabetes agent must contain only one of the following diabetes agents:

(i) of a SGLT-2 inhibitor (as a single agent); or

(ii) of a GLP-1 agonist (as a single agent); or

(iii) of a DPP-4 inhibitor (as a single agent and in a fixed dose combination with metformin, for new patients only).

(b) If submitting any Proposal Set for Sole Supply of a SGLT-2 inhibitor:

(i) Suppliers **MUST** submit a Proposal Set for a SGLT-2 inhibitor as a single agent according to each of the five (5) scenarios (1, 2, 3, 4 and 5) stated in Table 1 above.

(ii) Suppliers **MAY** also submit a Proposal Set for the listing of fixed dose combination products with metformin (ie a SGLT-2 inhibitor and metformin in a single tablet/capsule) alongside the single agent according to each of the five (5) scenarios (1, 2, 3, 4 and 5) stated in Table 1 above.

(iii) Suppliers **MAY** also submit bundled Proposal Sets for the listing of a GLP-1 agonist according to each of the three (3) scenarios (1, 2 and 4) stated in Table 1 above AND/OR a DPP-4 inhibitor (for new patients only) according to each of the five (5) scenarios (1, 2, 3, 4, and 5) stated in Table 1 above AND/OR a GLP-1 agonist and a DPP-4 inhibitor (for new patients only) according to each of the three (3) scenarios (1,2,4) stated in Table 1 above, in addition to the listing of the SGLT-2 inhibitor.

(c) If submitting any Proposal Set for Sole Supply of a GLP-1 agonist:

(i) suppliers **MUST** submit a Proposal Set according to each of the five (5) scenarios (1, 2, 4, 6 and 7) stated in Table 1 above.

(ii) Suppliers **MAY** also submit bundled Proposal Sets for the listing of a SGLT-2 inhibitor according to each of the three (3) scenarios (1, 2 and 4) stated in Table 1 above AND/OR a DPP-4 inhibitor (for new patients only) according to each of the five (5) scenarios (1, 2, 4, 6 and 7) stated in Table 1 above AND/OR a SGLT-2 inhibitor and DPP-4 inhibitor (for new patients only) according to each of the three (3) scenarios (1,2,4) stated in Table 1 above, in addition to the listing of the GLP-1 agonist.

(iii) If submitting a proposal for Sole Supply of an injectable agent, the supplier **MUST** specify in its proposal whether all necessary delivery devices are included within the proposal (eg needles).

(d) If submitting any Proposal Set for Sole Supply (for new patients only) of a DPP-4 inhibitor:

(i) Suppliers **MUST** submit a Proposal Set for the listing of a single agent and for a fixed dose combination with metformin (ie a DPP-4 inhibitor and metformin in a single tablet/capsule) according to each of the seven (7) scenarios (1, 2, 3, 4, 5, 6 and 7) stated in Table 1 above.

(ii) Suppliers **MAY** also submit bundled Proposal Sets for the listing of a SGLT-2 inhibitor AND/OR a GLP-1 agonist according to each of the relevant scenarios in Table 1 above AND/OR a SGLT-2 inhibitor and a GLP1 agonist according to each of the three (3) scenarios (1,2,4) stated in Table 1 above, in addition to the listing of the DPP-4 inhibitor.

(e) Proposals **MUST** include a period of Sole Supply for that class of agent (i.e. your brand of that class of agent would be the only product funded in the Pharmaceutical Schedule for that class of agents), provided that the Sole Supply period does not extend beyond 30 September 2023.

(f) If submitting a Proposal Set for the supply of a SGLT-2 inhibitor and/or a GLP-1 agonist, each SGLT-2 inhibitor and each GLP-1 agonist included in the Proposal Set **MUST** have evidence of cardiovascular benefit (as stated in section 2 of Schedule 1 of this RFP).

(g) Suppliers **MUST** submit proposals for supply for listing in Section B and Part II of Section H of the Pharmaceutical Schedule (ie for community and DHB hospital supply).

(h) Proposals **MAY** include any of the following arrangements (that may be confidential), provided that a supplier submits at least one proposal with a flat rebate structure of one price per unit regardless of expenditure:

(i) rebates or other risk-sharing arrangements;

(ii) a ‘hard’ cap, where a 100% rebate exists over a certain level of expenditure;

(iii) a ‘soft’ cap, where a rebate of less than 100% exists over a certain level of expenditure; and

(iv) a tiered pricing structure where the level of rebate is linked to certain levels of expenditure.

AND PROVIDED that any proposed rebate gives PHARMAC an option, with 6 months’ notice (not to be issued prior to the end of the Sole Supply period), in its sole discretion,

to amend the rebate structure to reflect the average net price per pack from the most recent preceding 6 month period.

(i) Proposals **MAY** include SGLT-2 inhibitors, GLP-1 agonists or DPP-4 inhibitors that have not yet gained all necessary Consents. Consents means all consents, permits, licences and authorisations, whether statutory or otherwise, required for the supply of the pharmaceutical in New Zealand (including Ministry of Health market approval).

- PHARMAC may require suppliers to demonstrate their ability to obtain the necessary Consents. Any proposals progressed to a provisional listing agreement would be subject to gaining all necessary Consents within a timeframe acceptable to PHARMAC. For example, you may be required to demonstrate that you have the dossier for your product/s ready to submit to Medsafe within one month of such a request being made by PHARMAC.

(j) PHARMAC is **NOT** willing to consider the following types of proposals:

(a) Proposals that involve an end date for rebates or other risk-sharing arrangements including expenditure caps or tiered pricing described above.

(b) Proposals that involve foreign currency exchange rate clauses or prices linked to any index.

(c) Two-part pricing arrangements, whereby PHARMAC may make an up-front payment (in addition to any ongoing subsidy) in return for the listing of a pharmaceutical on specific terms.

(d) Proposals for the concurrent listing (dual supply) of two agents of the same class of diabetes agent, except for DPP-4 inhibitors as indicated in Table 1 of this RFP.

(e) Proposals for the supply of medicines other than SGLT-2 inhibitors, GLP-1 agonists or DPP-4 inhibitors (unless part of a fixed dose combination with these agents as detailed in the types of proposals sought).

(f) Proposals for SGLT-2 inhibitors in fixed dose combinations with medicines other than metformin.

(g) Proposals for GLP-1 agonists in fixed dose combinations with other medicines.

(h) Proposals for Sole Supply of DPP-4 inhibitors for existing patients (eg proposals that would require patients currently taking vildagliptin and vildagliptin with metformin to switch to an alternative DPP-4 inhibitor).

Subject to the above, PHARMAC is open to considering any other types of proposals you may wish to put forward.

Samples

Suppliers **SHOULD** provide PHARMAC with artwork of labelling and images of the products with their proposal. Physical samples should be able to be provided upon request by PHARMAC only (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) within a reasonable timeframe of such a request. Physical samples should only be provided if requested.

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 Set. Each Proposal Set will be considered as a separate proposal.

   (b) Proposal Sets must be submitted no later than 4.00 p.m. (New Zealand time) on Monday 16 March 2020. Late Proposal Sets will only be considered at PHARMAC's discretion, considering the need for fairness to other suppliers and integrity of the RFP process.

   (c) You cannot withdraw your Proposal Sets, once submitted, while the RFP process is continuing.

   (d) If you have any enquiries about this RFP you should submit them on GETS. Responses to all enquiries will be published on GETS.

2. **Evaluation**

   (a) Following the deadline for submitting proposals, an Evaluation Committee comprising of PHARMAC staff will evaluate each Proposal Set to select its preferred proposal(s).

   (b) The Evaluation Committee will evaluate Proposal Sets in light of PHARMAC's statutory objective which is "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". In doing so the Evaluation Committee will be guided by the Factors for Consideration (**Factors**) that form part of PHARMAC's then current OPPs, as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. More information on the Factors can be found at www.pharmac.health.nz/factors-for-consideration.

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

   (d) The information to be taken into account in applying the Factors by the Evaluation Committee will be at its discretion, however it will include:

      (i) information provided by you in accordance with Schedule 4 of this RFP, including information provided under clause 3 below;

      (ii) any advice from PTAC, its relevant subcommittee, any relevant professional organisation or healthcare professionals. This may include specific clinical advice regarding relative risks and benefits of SGLT-2 inhibitors, GLP-1 agonists and DPP-4 inhibitors included in proposals following the closing of this RFP; and

(iii) any other information that the Evaluation Committee considers to be relevant having regard to probity principles.

(e) Each Proposal Set will be evaluated on the basis that the price offered, the expenditure entailed, and any other terms included in the Proposal Set, are the best that the supplier is able to offer. If you do not put forward your best terms you risk having your Proposal Set excluded at the evaluation stage.

(f) For the purpose of fiscal evaluation for this RFP, PHARMAC will assess any pricing offered as commencing from 1 September 2020. Suppliers may offer Proposal Sets that include a listing or price change prior to this date; however, any fiscal impact from this earlier listing/price change will not be included in PHARMAC's primary fiscal evaluation of Proposal Sets. If two or more Proposal Sets were determined by PHARMAC to be similar, having considered all the Factors, PHARMAC may undertake a secondary fiscal evaluation where we may consider the impact of earlier list date/price changes.

(g) PHARMAC is not bound to select the lowest priced Proposal Set or any proposal.

3. **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 Set(s), including (but not limited to):

(i) detailed information about your company structure, credit status and any other relevant company information; and

(ii) any other additional information about your pharmaceutical.

Please note that PHARMAC may seek advice from PTAC, its relevant Subcommittees, any relevant professional organisations or healthcare professionals with regard to your product including evaluation of any product samples.

(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.

4. **Negotiation**

(a) PHARMAC may negotiate with the submitter(s) of one or more preferred Proposal Sets, in the latter case whether or not the acceptance of either supplier's Proposal Set would exclude acceptance of the other Proposal Set.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals, which are available on request from PHARMAC, will apply.

(c) Given that PHARMAC expects your Proposal Set 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 Set, as a result of the impact that other negotiated terms may have on price.

(d) PHARMAC may negotiate and enter into a provisional agreement with a preferred supplier(s) on whatever special terms, in addition to PHARMAC's standard terms and conditions, PHARMAC considers appropriate.

(e) 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).

5. **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 decision-making framework as outlined in its OPPs with reference to the 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.

6. **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 Set or other proposal;

(iii) to seek clarification of any Proposal Set or other proposal;

(iv) to meet with any supplier in relation to its Proposal Set/s or other proposal;

(v) to enter into an agreement or arrangement that differs in material respects from that envisaged in this RFP letter;

(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 Set or other proposal in light of

consultation, or alternatively we may request that new Proposal Sets or other proposals be submitted;

(vii) to terminate this RFP process at any time, by notifying suppliers who submitted Proposal Sets or other proposals, and, following termination, to negotiate with any supplier(s) on whatever terms PHARMAC thinks fit;

(viii) to readvertise for Proposal Sets or other proposals.

(b) PHARMAC may consult or seek clinical advice from PTAC or its relevant sub-committee 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 submitting their Proposal Set(s) or other 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 operating unit Medsafe), the Minister of Health (or any Associate Ministers) or DHBs or advisors to PHARMAC with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your Proposal Set or other proposal.

(f) Proposal Sets or other 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 Set or other proposal will be taken as acceptance of the terms contained in this RFP letter. PHARMAC may exclude your Proposal Set or other proposal if you do not comply with any of the terms contained in this RFP letter.

(h) This is an RFP and not a tender. Your Proposal Set or other proposal is not an offer capable of being converted into a contract for the supply of SGLT-2 inhibitors, GLP-1 agonists and/or DPP-4 inhibitors or any other pharmaceuticals included in proposals 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 Set or other proposal and information exchanged between us in any negotiations relating to your Proposal Set or other 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 DHBs (**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 (or its delegate) 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.

7. Anticipated timetable

(a) Following receipt of Proposal Sets, PHARMAC anticipates:

(i) the Evaluation Committee evaluating Proposal Sets in March – May 2020;

(ii) seeking clinical advice (if necessary) in April – May 2020;

(iii) negotiating with submitter(s) of one or more preferred Proposal Sets in May 2020;

(iv) consulting on a provisional agreement in June 2020;

(v) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after July 2020;

provided that 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.

(b) Under this indicative timetable, PHARMAC expects the earliest that changes to the Pharmaceutical Schedule could be implemented is 1 September 2020.

8. Governing Law

This RFP is governed by New Zealand law, and the New Zealand courts have exclusive jurisdiction in all matters relating to this RFP.

Schedule 3: Current listing and market information

Current listing

There are no SGLT-2 inhibitors or GLP-1 agonists currently funded in New Zealand. The DPP-4 inhibitor vildagliptin, both as a single agent and in combination with metformin, has been funded in New Zealand with no restrictions since October 2018. The listing of vildagliptin and vildagliptin with metformin on the Pharmaceutical Schedule is subject to a confidential rebate.

Anticipated patient uptake

Although difficult to estimate, based on advice from our clinical experts, New Zealand data sources and a number of commercial assumptions, we consider that the number of patients who may access treatment under each scenario each year in New Zealand could be as shown in the table below. We have estimated a total of 120,000 people are using metformin and/or insulin regularly for type 2 diabetes in New Zealand, with 40,000 of these people estimated to be eligible (in total for either a SGLT-2 inhibitor or GLP-1 agonist) under the proposed Special Authority criteria. The estimated patient numbers for DPP-4 inhibitor treatment are based on forecast market dynamics. The patient numbers have then been estimated for each scenario based on variations in uptake and market share according to each of the scenarios. We have assumed that people would continue taking their currently funded medicines. These figures are subject to significant uncertainty and as such should be considered estimates only and are not a guarantee of market size or share.

Scenario	**SGLT-2 (open access*) Sole Supply until 30 June 2023**	**SGLT-2 (SA criteria) Sole Supply until 30 June 2023**	**GLP-1 (open access*) Sole Supply until 30 June 2023**	**GLP-1 (SA criteria) Sole Supply until 30 June 2023**
1	86,000	n/a	22,000	n/a
2	90,000	n/a	n/a	18,000
3	108,000	n/a	n/a	n/a
4	n/a	25,600	n/a	6,400
5	n/a	32,000	n/a	n/a
6	n/a	n/a	96,000	n/a
7	n/a	n/a	n/a	28,000
All	New patients to DPP-4 inhibitor treatment estimated as 30,000 per annum for all scenarios.			

* open access would be subject to the following endorsement note:

- SGLT-2 inhibitor: "[SGLT-2 inhibitor] will not be subsidised if patient is also receiving treatment with a funded GLP-1 receptor agonist"
- GLP-1 receptor agonist: "[GLP-1 agonist] will not be subsidised if patient is also receiving treatment with a funded SGLT-2 inhibitor"

See "Clinical Advice" section of this RFP for information on Special Authority criteria. Note that any changes to the Special Authority criteria may impact on patient numbers.

The information in this Schedule 3 is approximate and indicative only. PHARMAC makes no representation as to the accuracy of this information or as to the level of sales or likely sales of SGLT-2 inhibitors, GLP-1 agonists and/or DPP-4 inhibitors or any other pharmaceuticals and, while PHARMAC has taken all reasonable care in preparing the information included in this Schedule 3, it accepts no liability for any errors or omissions in the information. PHARMAC is not obliged to notify you in the event of any change to our estimates of market size.

Schedule 4: Proposal form

An electronic version of this form is available on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Katie Brownless

By electronic transfer using GETS **(www.gets.govt.nz)**

Dear Sir/Madam

Proposal for the supply of diabetes agents SGLT-2 inhibitors, GLP-1 agonists and/or DPP-4 inhibitors

In response to your request for proposals (**RFP**) dated 15 January 2020, we put forward the following proposal in respect of SGLT-2 inhibitors, GLP-1 agonists and/or DPP-4 inhibitors.

Set out below is further information in support of our proposal.

(a) Our contact details:

Name of supplier	
Contact person	
Address	
Phone	
Facsimile	
Email address	

(b) Details of pharmaceutical presentation:

Chemical name	
Strength(s) (e.g. 500 mg)	
Form(s) (e.g. injection)	
Brand name	
Pack size (e.g. 1 vial)	
Packaging type (e.g. prefilled syringe)	
Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C)	

If an injectable agent, state if needles are included	

(c) Details of pharmaceutical manufacture:

Name and address of manufacturer/s of the pharmaceutical (including API manufacturer, manufacturer of final dose form, packaging etc)	
Lead time (Time from notification of award to product being available to supply the New Zealand market)	
Details on pharmaceutical manufacturing sites and their registration with Medsafe or other international regulatory body (e.g. TGA, FDA, MHRA)	
Batch size/s	
Approximate manufacture time	
Approximate time for shipping	

(d) Key features of our proposal/s:

(e) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC and which scenarios the pricing applies to:

Proposal Sets:

Complete the relevant scenario tables for each class of agent included in your proposal.

Note: if pricing applies to all scenarios in a Proposal Set you may state this instead of completing the table for each scenario.

Proposal Sets for a single class of diabetes agent:

SGLT-2 inhibitors: (Pricing for each strength and pack size, as relevant to the agent, to be provided for each of the scenarios 1,2,3,4 and 5)

Scenario	SGLT-2 inhibitor pricing	SGLT-2 inhibitor + metformin fixed dose combination product pricing (if applicable)
1		
2		
3		
4		
5		

GLP-1 agonists: (Pricing for each strength and pack size, as relevant to the agent, to be provided for each of the scenarios 1,2,4,6 and 7.)

Scenario	GLP-1 agonist pricing
1	
2	
4	
6	
7	

DPP-4 inhibitors: (Pricing for each strength and pack size, as relevant to the agent, to be provided for each of the scenarios 1,2,3,4,5,6 and 7)

Scenario	DPP-4 inhibitor pricing	DPP-4 inhibitor + metformin fixed dose combination product pricing
1		
2		
3		
4		
5		
6		
7		

Bundled proposals (if applicable):

Pricing to be provided for each of the agents included in bundled proposals for the relevant scenarios as stated in Table 1, as below.

SGLT-2 inhibitor and GLP1 agonist:

Scenario	SGLT-2 inhibitor pricing	SGLT-2 inhibitor + metformin fixed dose combination product pricing (if applicable)	GLP-1 agonist pricing
1			
2			
4			

SGLT-2 inhibitor and DPP-4 inhibitor:

Scenario	SGLT-2 inhibitor pricing	SGLT-2 inhibitor + metformin fixed dose combination product pricing (if applicable)	DPP-4 inhibitor pricing	DPP-4 inhibitor + metformin fixed dose combination product pricing
1				
2				
3				
4				
5				

GLP-1 agonist and DPP-4 inhibitor:

Scenario	GLP-1 agonist pricing	DPP-4 inhibitor pricing	DPP-4 inhibitor + metformin fixed dose combination product pricing
1			
2			
4			
6			
7			

SGLT-2 inhibitor, GLP-1 agonist and DPP-4 inhibitor:

Scenario	SGLT-2 inhibitor pricing	SGLT-2 inhibitor + metformin fixed dose combination product pricing (if applicable)	GLP-1 agonist pricing	DPP-4 inhibitor pricing	DPP-4 inhibitor + metformin fixed dose combination product pricing
1					
2					
4					

(f) Clinical evidence of cardiovascular benefit for SGLT-2 inhibitors or GLP-1 agonists (if agent not previously considered by PTAC):

Clinical evidence can be provided as attachments as part of the RFP submission.

For examples of sources of clinical evidence that could be provided please see the Guidelines for Funding Applications to PHARMAC. For the avoidance of doubt a full funding application is not required.

(g) Evidence of market approval and any other required consents:

Date of market approval (please attach copy of Medsafe Gazette notice)	
OR Date of submission of dossier or changed-medicine notification submission (please attach confirmation from Medsafe that it has been submitted)	
OR Expected date of dossier or changed-medicine notification submission to Medsafe (please provide details)	

(h) Confirmation that there are no intellectual property barriers (including patent barriers) to our supply of this product for the proposed indications in New Zealand, with additional information if required:

(i) Information about our ability to ensure the continuity of supply of the pharmaceutical, including other countries where the product is provided:

(j) Information about our previous supply performance, existing supply commitments and relevant expertise:

(k) Proposals/suggestions (e.g. pricing, rebate arrangements, etc) regarding the pharmaceutical not expressly identified in this RFP that we would like PHARMAC to consider as part of our proposal:

(l) Reasons why PHARMAC should accept our proposal:

(m) Please include any additional information you consider relevant under PHARMAC's Factors for Consideration decision making framework: