PHARMAC
Pharmaceutical Management Agency

Level 9, 40 Mercer Street, Wellington 6011
PO Box 10-254, Wellington 6143, New Zealand
Phone 64-4-460-4990
Fax 64-4-460-4995
Information line **0800 66 00 50**
enquiry@pharmac.govt.nz
www.pharmac.govt.nz

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REQUEST FOR INFORMATION ON ANTI-DIABETIC AGENTS

PHARMAC is interested in receiving information from suppliers, clinicians and diabetes healthcare professionals in respect of the following classes of anti-diabetic agents:

a. dipeptidyl peptidase4 inhibitors (DPP4-inhibitors);

b. glucagon-like peptide-1 agonists (GLP-1s);

c. sodium glucose co-transporter 2 inhibitors (SGLT-2s); and

d. combination anti-diabetic agents (e.g. DPP4-inhibitors/metformin).

The purpose of this request for information (RFI) is to seek information to inform and assist PHARMAC in determining the most appropriate funding arrangement and process, which may include progressing to a request for proposals (RFP) or other competitive process at a later date.

If you wish to submit a response, you must submit it to PHARMAC by email no later than **5.00 pm on 5 March 2015.** Submissions and any questions you might have can be sent to Bronwyn Hale, Therapeutic Group Manager (bronwyn.hale@pharmac.govt.nz).

1. Background

1.2 Purpose

The purpose of this RFI is for PHARMAC to gauge the level of interest from suppliers of these particular classes of anti-diabetic agents, supplier's range of each agent and indicative pricing based upon the recommended access criteria.

PHARMAC also seeks input from clinicians and other diabetes healthcare professionals about these medicines, including on the clinical risks and benefits for people with diabetes to switch between anti-diabetic agents within a class and between anti-diabetic agents from difference classes.

Depending on the information that PHARMAC receives in response to this RFI, and depending on the available funding, PHARMAC may decide to commence negotiations with specific supplier(s) or issue an RFP or a conduct a different competitive process for the funded supply of these anti-diabetic agents in the community and in DHB hospitals.

PHARMAC may also seek further clinical advice before deciding upon its next steps depending on the responses received as a result of the RFI.

1.1 Current funding and PTAC advice

a. PHARMAC does not currently list the anti-diabetic agents from any of the classes identified below on the Pharmaceutical Schedule. PHARMAC has received a number of applications from suppliers for these different classes of anti-diabetic agents – see the list of bands & suppliers in the table below.

Class	**Anti-diabetic agent**	**Brands**
GLP-1s	Exenatide, liraglutide, lixisenatide	Byetta (Astra Zeneca), Victoza (Novo Nordisk), Lixisenatide (Lyxumia)
DPP4-inhibitors	Sitagliptin, vildagliptin, saxagliptin, linagliptin	Januvia (Merck Sharp and Dohme), Galvus (Novartis), Onglyza (Astra Zeneca), Trajenta (Boehringer Ingelheim)
SGLT-2s	dapaglifozin, canagliflozin	Forxiga (Astra Zeneca), Invokana (Janssen)
Combination anti-diabetic agents	sitagliptin and metformin	Janumet (Merck, Sharp and Dohme)

b. These applications have undergone review by PHARMAC's clinical advisory groups, including PTAC and the Diabetes Subcommittee of PTAC, and have been recommended for funding with a low priority subject to Special Authority criteria. Minutes relating to each of these applications can be found here: http://www.pharmac.govt.nz/ApplicationTracker

c. The most recent review of these applications was by the Diabetes Subcommittee of PTAC at its August 2014 meeting. The minutes from the Diabetes Subcommittee were ratified by PTAC at its November 2014 meeting. Full minutes of the August 2014 Diabetes Subcommittee meeting can be found at PHARMACs website: http://www.pharmac.health.nz/assets/ptac-diabetes-subcommittee-minutes-2014-08.pdf

d. The Diabetes Subcommittee advised:

> 2.10 The Subcommittee considered that depending on cost it may be appropriate for only one class of new agent to be funded out of the three classes for primary use. The Subcommittee considered that depending on the primary class of medication chosen there may be a clinical need for a second agent, particularly in patients with deteriorating renal function. The Subcommittee noted that a second agent may be required for patients intolerant to a single primary agent.

e. At its August 2014 meeting the Diabetes Subcommittee recommended the following Special Authority criteria could apply to all classes of the new anti-diabetic agents.

Initial application from any medical practitioner. Approvals valid for six months for applications meeting the following criteria:

1. Either:
   - 1.1. Patient is not achieving effective control of HbA1c despite treatment with maximum tolerated doses of metformin and sulphonylurea for at least 6 months; or
   - 1.2. Patient is not achieving target HbA1c despite treatment with maximum tolerated doses of sulphonylurea and metformin is contraindicated; or
   - 1.3. Patient is not achieving target HbA1c on maximum tolerated doses of metformin for the previous 6 months and is unable to use insulin or sulphonylureas as the risk of severe symptomatic hypoglycaemia is unacceptable in the opinion of the treating physician
2. Patient is not prescribed insulin
3. It is anticipated that a reduction in HbA1c of 5 mmol/mol would achieve the HbA1c target for that patient

Renewal from any medical practitioner. Approvals valid for two years for applications meeting the following criteria:

1. Patient has achieved an HbA1c reduction of at least 5 mmol/mol from baseline and;
2. Patient is not prescribed insulin

PHARMAC may also seek further clinical advice before deciding upon its next steps depending on the responses received as a result of the RFI.

2. Request for information

PHARMAC is asking relevant parties to provide further information in response to the questions posed. Our questions are grouped according to the following respondent types:

- Suppliers (see Appendix One)
- Clinicians and other Diabetes Healthcare Professionals (see Appendix Two)

3. Information requested under the Official Information Act

PHARMAC is not able to treat any part of your feedback as confidential unless you specifically request that it does. If you would like PHARMAC to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like withheld.

Feedback PHARMAC receives is subject to the Official Information Act 1982 (OIA) and any request to have information withheld will be considered in accordance with PHARMAC's obligations under the OIA.

4. Process/timeline

At this stage, PHARMAC expects to do the following:

a) Release of this request for information on 12 February 2015

b) Feedback due by 5 March 2015

c) Review of feedback in March 2015

d) Further discussion with submitter(s), if necessary, in March / April 2015

e) Evaluation of next steps in May to June 2015.

Under this timeline it is unlikely that PHARMAC would be commencing negotiations, or running a competitive process, for listing one or more of these anti-diabetic agents prior to July 2015.

Please note that the above timeframes are approximate only and may be extended.

We look forward to receiving your feedback.

Appendix One: Questions for Suppliers

1. Your contact details:
    a. Name of supplier;
    b. Contact person and title;
    c. Address;
    d. Phone; and
    e. Email.

2. Details about your Brand(s), including:
    a. generic (chemical) name,
    b. class of diabetes medicine (e.g. dipeptidyl peptidase4 inhibitor, glucagon-like peptide-1 agonist, sodium glucose co-transporter 2 inhibitor, combination anti-diabetic agent),
    c. presentation; form and strength (e.g. tablet, 25 mg);
    d. brand name;
    e. other countries where it is marketed and sold, and market share (if available);
    f. therapeutic product database report or similar (if available);
    g. disclosure of information on all known ongoing trials and patents.
    h. relevant consents held in New Zealand or overseas (e.g. registration under Section 20 of the 1981 Medicines Act, TGA approval, CE certification); and
    i. any other relevant information.

3. Indicative price per unit (excl. GST) for your brand of any pharmaceutical(s) in any class of these anti-diabetic agents ("Brand(s)"), based on:
    a. sole subsidised supply over a three year period, subject to the access criteria recommended by the Diabetes Subcommittee of PTAC; or
    b. dual or multiple subsidised supply over a three year period, subject to the access criteria recommended by the Diabetes Subcommittee of PTAC.

4. Indicative price per unit (excl. GST) for your Brand(s) based on your proposed access criteria and market share arrangements (e.g. sole supply, dual supply, multiple supply).

5. Your proposed (or current) distribution and supply arrangements in New Zealand.

6. Your proposed (or current) educational support and training to patients and clinicians.

7. If your Brand(s) is/are not currently being supplied to the New Zealand market, what would be the lead in time (in months) to get stock in to New Zealand?

8. Please provide evidence that illustrates whether patients with diabetes can (or cannot) switch between different anti-diabetic agents within the class or between different classes without compromising treatment efficacy and safety?

Appendix Two: Questions for Clinicians and Diabetes Healthcare Professionals

1. Do you have a preference for a particular class of these anti-diabetic agents? If so, are you able to identify some of the clinical benefits of this class?

2. Are you aware of any particular clinical risks associated with any of the classes of the anti-diabetic agents?

3. In your view, what are the key benefits of these anti-diabetic agents, including the key benefits over currently funded treatment options, for the treatment of diabetes mellitus type 2 (T2DM)?

4. Are you aware of any other emerging treatments for the treatment of T2DM?

5. What is your view of patients switching between anti-diabetic agents in any of the classes identified in this RFI? For example, switching within pharmaceuticals in the class of DPP4-inhibitors such as from sitagliptin to linagliptin or within pharmaceuticals in the class of SGLT2s such as from dapagliflozin to canagliflozin?

6. Are there any other matters that you consider should be taken in to account when PHARMAC is considering the funding for these classes of anti-diabetic agents?

7. What is your view of the Special Authority criteria for the anti-diabetic agents proposed by the Diabetes Subcommittee at its August 2014 meeting?

8. In your view is there a need for more than one class of the anti-diabetic agents to be funded and/or a need for more than one agent in any class? If so, are you able to provide supporting evidence for this view?