PHARMAC
Pharmaceutical Management Agency

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22 February 2016

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF INSULIN GLARGINE

PHARMAC invites proposals for the supply of insulin glargine in New Zealand.

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

- Schedule 1 specifies the pharmaceutical 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 market size for insulin glargine in the community and DHB hospitals; 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 Services (GETS) no later than **5.00 p.m**. on **21 March 2016**.

If you have any questions about this RFP, please contact Bronwyn Hale (Therapeutic Group Manager) through GETS (www.gets.govt.nz) or by email bronwyn.hale@pharmac.govt.nz at PHARMAC.

We look forward to receiving your proposal.

Yours sincerely

Sarah Fitt

Sarah Fitt
Director of Operations

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

1. Pharmaceutical

PHARMAC is interested in considering any proposals from suppliers of **the long-acting insulin preparation, insulin glargine (including biosimilar insulin glargine), including associated delivery devices** for the treatment of Type 1 and Type 2 diabetes mellitus.

2. Background to RFP

The background to this RFP is as follows:

2.1 *Current listing arrangement*

(a) Insulin glargine is currently the only long-acting insulin preparation fully subsidised by PHARMAC without any restrictions. Three different presentations of insulin glargine are currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule as follows:

Chemical	Presentation	Pack size and packaging	Pack price ($NZ, excl. GST)	Brand name (Supplier)
Insulin glargine	Inj 100 u per ml, 3 ml	5 cartridges	$94.50*	Lantus (Sanofi-Aventis)
	Inj 100 u per ml, 3 ml	5 disposable pens	$94.50*	Lantus SoloStar (Sanofi-Aventis)
	Inj 100 u per ml, 10 ml	1 vial	$63.00*	Lantus (Sanofi-Aventis)

**Prices are subject to confidential rebates*

(b) Insulin glargine is currently supplied in three different delivery presentations (cartridges, disposable pens and vials). The vial requires a syringe for administration whereas the cartridge requires a compatible reusable delivery device (currently supplied free of charge). The disposable pen is prefilled and ready to use.

(c) Further market information is provided in *Schedule 3: Current listing and market information* below.

2.2 *Reasons for running the RFP*

(a) PHARMAC previously issued an RFP for long-acting insulin on 21 December 2009. This process resulted in an agreement with Sanofi-Aventis New Zealand Limited (Sanofi-Aventis) in May 2010, for the listing and supply of insulin glargine (Lantus), insulin glulisine (Apidra), hydrocortisone with cinchocaine (Proctosedyl) and povidone iodine (Betadine).

(b) Restrictions on delisting and subsidy reduction for Lantus and Lantus SoloStar ended on 1 August 2015.

(c) PHARMAC is aware of biosimilar presentations of insulin glargine which are currently seeking regulatory approval or being launched in other countries meaning that competition in this market is now imminent.

2.3 *Expected outcome of the RFP*

(a) As a result of this RFP, we expect to:

(i) secure future supply of insulin glargine in the community and DHB hospitals at competitive prices;

(ii) ensure access to clinically appropriate delivery devices for insulin glargine; and

(iii) ensure access to appropriate level of customer support, education and training for patients and relevant health professionals.

2.4 *Relevant PTAC advice:*

(a) PHARMAC sought clinical advice from the Diabetes Subcommittee of PTAC regarding biosimilar insulin glargine in April 2015. In summary it advised:

(i) A switch to a biosimilar insulin glargine would not necessarily be problematic for patients with diabetes as there is precedent for switching between brands of insulin and these are essentially biosimilars.

(ii) Any difficulties with a switch experienced by patients in the insulin glargine market may relate more to a different administering device for the insulin, so this would need to be managed carefully should it occur.

3. Types of proposals sought

3.1 *PHARMAC is willing to consider the following types of proposals:*

(a) proposals that involve sole subsidised supply of the Pharmaceutical (as defined in clause 1 above) in the community and hospital supply status in DHB hospitals for a period of up to 3 years, provided that sole subsidised supply and hospital supply status does not extend beyond 30 June 2020;

(b) proposals that involve subsidy and delisting protection for a period of up to 3 years, provided that subsidy and delisting protection does not extend beyond 30 June 2020;

(c) proposals that include current and/or any new packaging, form and strength of insulin glargine;

(d) proposals that include expenditure caps, rebates (including volume-based rebates) or other expenditure risk-sharing mechanisms; and

(e) proposals that outline patient and relevant health professional education, training and support services.

3.2 *PHARMAC is not willing to consider the following types of proposals:*

(a) proposals that involve an end date for any proposed expenditure caps, rebates (including volume-based rebates) or other expenditure risk-sharing mechanisms;

(b) cross-deal or bundling arrangements in respect of more than one chemical entity, therapeutic group or sub-group;

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

3.3 *Proposals for different presentations, forms and strengths of insulin glargine*

(a) PHARMAC reserves the right to add, amend and/ or delist different presentations, forms and strengths of insulin glargine currently listed in Section B and Part II of Section H of the Pharmaceutical Schedule as a result of this RFP process.

3.4 *DV Limit for insulin glargine in DHB hospitals*

(a) Please note that a DV Limit of up to 20% may apply in the event a supplier is awarded Hospital Supply Status.

(b) DHB hospital usage of insulin glargine currently accounts for less than 1% of the total (community and DHB hospital) insulin glargine market by unit volume.

4. Other considerations

(a) Biosimilar competition for insulin glargine presents PHARMAC with an opportunity to reduce the costs of insulin glargine and improve health outcomes for New Zealanders.

(b) PHARMAC notes that a brand switch is not a certain outcome of this RFP; however, it is one potential outcome. Without limiting the circumstances in which PHARMAC may consider it appropriate to consult in the course of this RFP process, PHARMAC would undertake consultation if a brand switch were to be considered.

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. Each proposal will be considered as a separate proposal.

(b) All proposals must be submitted to PHARMAC via the Government Electronic Tenders Service (GETS) no later than 5pm (New Zealand time) on **21 March 2016**. Late proposals will only be considered at PHARMAC's discretion, taking into account the need for fairness to other suppliers and integrity of the RFP process.

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

(d) If you have any enquiries about this RFP you should contact Bronwyn Hale, (bronwyn.hale@pharmac.govt.nz) or submit questions through GETS (www.gets.govt.nz).

2. **Evaluation**

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

(b) The Evaluation Committee will evaluate proposals 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 decision mechanism set out in PHARMAC's then current Operating Policies and Procedures (OPPs), as published on PHARMAC's website (www.pharmac.govt.nz), to the extent applicable. The information to be taken into account in applying the decision mechanism by the Evaluation Committee will be at its discretion, however it will include:

(i) the information included in your proposal (Schedule 4: Proposal form);

(ii) any advice from PTAC, its relevant sub-committee (eg Diabetes Subcommittee of PTAC);

(iii) any advice from any other relevant organisations and/or health professionals;

(iv) any advice or feedback that PHARMAC receives regarding the clinical acceptability and usability of any delivery device(s) required to administer your brand of insulin glargine;

(v) any other matters that the Evaluation Committee considers to be relevant (provided that PHARMAC will notify such matters and allow an opportunity for submitters of proposals to address them).

(c) Please note that from 1 July 2016 PHARMAC is changing the way in which it makes decisions, instead of the current Decision Criteria it will be using the Factors

for Consideration (FFC). Please be aware of the FFC. More information on the FFC can be found at www.pharmac.health.nz/factors-for-consideration.

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

(d) PHARMAC is not bound to select the lowest priced proposal or any proposal.

(e) Suppliers must provide PHARMAC with samples of the various presentations, forms and strengths of insulin glargine included in the proposal (and, if supply is intended to be in a different presentation, form and strength from the provided samples, information about differences must be supplied) no later than 10 business days after **21 March 2016**.

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, including (but not limited to):

(i) additional product samples, in which case you must supply the requested sample within 15 business days of PHARMAC's request;

(ii) additional information on any customer support, training and educational resources that may be available to health professionals during switchover to your brand of insulin glargine and throughout the term of any contract (if applicable); and

(iii) detailed information about your company structure, credit status and any other relevant company information.

(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 proposals, in the latter case whether or not the acceptance of either supplier's proposal would exclude acceptance of the other proposal.

(b) Negotiations will proceed on the basis that PHARMAC's standard terms and conditions for supply of pharmaceuticals (see Attachment One), will apply.

(c) Given that PHARMAC expects your proposal 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, 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 the decision mechanism in PHARMAC's then current OPPs.

(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:

(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;

(iii) to seek clarification of any proposal;

(iv) to meet with any supplier in relation to its proposal;

(v) 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 in light of consultation, or alternatively we may request that new proposals be submitted;

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

(vii) to re-advertise for 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(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's directors or officers, the Ministry of Health (including its operating unit Medsafe), the Minister of Health (or any Associate Ministers) or District Health Boards or advisors to PHARMAC, patient groups or professional organisations with a view to influencing the outcome of this RFP process.

(e) You must pay your own costs for preparing and submitting your proposal.

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

(h) This is an RFP and not a tender. Your proposal is not an offer capable of being converted into a contract for the supply of insulin glargine 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 and information exchanged between us in any negotiations relating to your proposal, excluding information already in the public domain, to be confidential to us and our employees, legal 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 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 proposals, PHARMAC anticipates:

(i) the Evaluation Committee evaluating proposals in March 2016;

(ii) negotiating with submitter(s) of one or more preferred proposals in April 2016;

(iii) consulting on a provisional agreement in April – May 2016; and

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after May - June 2016,

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, the earliest that changes to the Pharmaceutical Schedule could be implemented is July – August 2016.

(c) Please note that if a proposal for sole supply is accepted, the date of implementation for that may be later to allow for an orderly transition to any sole supply arrangement.

Schedule 3: Current listing and market information

The following information, illustrated in the tables below, relates to the estimated:

- subsidised market size of insulin glargine in the community (Table 1);
- number of units of insulin glargine purchased by DHB hospitals (Table 2); and
- number of patients dispensed insulin glargine in the community (Table 3).

The information 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 insulin glargine and, while PHARMAC has taken all reasonable care in preparing the information set out below, 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 the figures below.

Table 1: Subsidised units of insulin glargine in the community for each relevant period

Strength and form	Year Ending 30 June 2013	Year Ending 30 June 2014	Year Ending 30 June 2015
Inj 100 u per ml, 3 ml (cartridge)	250,000	290,000	310,000
Inj 100 u per ml, 3 ml (disposable pen)	390,000	540,000	680,000
Inj 100 u per ml, 10 ml (vial)	5,500	5,000	4,900

*Figures rounded to two significant figures.

Table 2: Purchased units of insulin glargine in DHB hospitals for each relevant period

Strength and form	Year Ending 30 June 2013	Year Ending 30 June 2014	Year Ending 30 June 2015
Inj 100 u per ml, 3 ml (cartridge)	3,200	3,900	4,300
Inj 100 u per ml, 3 ml (disposable pen)	700	910	1,100
Inj 100 u per ml, 10 ml (vial)	1,100	1,300	1,300

*Figures rounded to two significant figures.

Table 3: Number of patients dispensed insulin glargine in the community for each relevant period

Strength and form	Year Ending 30 June 2013	Year Ending 30 June 2014	Year Ending 30 June 2015
Inj 100 u per ml, 3 ml (cartridge)	8,600	9,200	9,400
Inj 100 u per ml, 3 ml (disposable pen)	13,000	17,000	20,000
Inj 100 u per ml, 10 ml (vial)	530	510	500

*Figures rounded to two significant figures.

Schedule 4: Proposal form

An electronic version of this form is available on PHARMAC's website at www.pharmac.govt.nz and on GETS (www.gets.govt.nz). You should expand the boxes as necessary.

[*Supplier to insert date*]

Director of Operations
PHARMAC
C/- Bronwyn Hale
Therapeutic Group Manager

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

Dear Sir/Madam

Proposal for the supply of insulin glargine

In response to your request for proposals (**RFP**) dated **22 February 2016**, we put forward the following proposal in respect of insulin glargine:

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 (e.g. 100 u per ml, 3 ml)	
Form (e.g. injection)	
Brand name	
Pack size (e.g. 5 x 3 ml)	
Packaging type (e.g. pre-filled cartridge)	

(c) Key features of our proposal:

(d) Information relating to pricing ($NZ, GST exclusive), including any related conditions or proposed terms affecting cost for PHARMAC (e.g. price in return for sole supply, reference price protection, risk sharing mechanisms, etc.):

(e) 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 (please attach confirmation from Medsafe that dossier has been submitted)	
OR Expected date of dossier submission to Medsafe	

(f) Information about our ability to ensure the continuity of supply of the pharmaceutical:

(g) Information about our previous supply performance and relevant expertise:

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

(i) Information on our proposed customer support, training and education provided to patients and health professionals, including any proposed implementation plan for the national roll out of our brand of insulin glargine (if applicable):

(j) Information regarding any delivery device(s) required to administer our brand of insulin glargine, including any associated costs to patients, DHB hospitals or PHARMAC (if any):

(k) Reasons why PHARMAC should accept our proposal:

(l) Additional information that PHARMAC should consider when evaluating our proposal: