26 August 2011

Dear Supplier

REQUEST FOR PROPOSALS – SUPPLY OF DIABETES MANAGEMENT PRODUCTS

PHARMAC invites proposals for the supply of diabetes management products 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 size of the current 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 no later than 4.00 p.m. on 20 October 2011,

If you have any questions about this RFP, please contact Natalie Davis at PHARMAC by telephone on (04) 916 7562 or by email natalie.davis@pharmac.govt.nz.

We look forward to receiving your proposal.

Yours sincerely

Matthew Brougham
Chief Executive
Schedule 1: Pharmaceutical, background to RFP and types of proposals sought

1. Pharmaceuticals

PHARMAC is interested in considering any proposal from suppliers of the following products (referred to collectively within this RFP as ‘diabetes management products’):

- blood glucose test strips and blood glucose diagnostic test meters; and/or
- blood ketone test strips and blood ketone diagnostic test meters; and/or
- lancets; and/or
- insulin pumps and insulin pump consumables; and/or
- rapid acting insulin.

2. Background to RFP

PHARMAC ran an RFP in 2008 for diabetes management products which included blood glucose test strips and meters, blood and urine ketone test strips, and lancets. The current listings and subsidies are a result of that process. Lancets were not funded as a result of the RFP. Subsidy and listing protection for all blood glucose test strips and meters, blood and urine ketone test strips ended on the 30 June 2011.

Blood glucose test strips and blood glucose diagnostic test meters

- Blood glucose test strips and diagnostic test meters are currently listed fully subsidised in Section B of the Pharmaceutical Schedule.

- There are six brands of blood glucose test strips (with or without lancets) currently listed in the Pharmaceutical Schedule.

<table>
<thead>
<tr>
<th>Brand</th>
<th>Quantity and presentation</th>
<th>List price and subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accu-Chek Performa</td>
<td>50 test strips</td>
<td>$21.65*</td>
</tr>
<tr>
<td>FreeStyle Lite</td>
<td>50 test strips</td>
<td>$21.65</td>
</tr>
<tr>
<td>Optium 5</td>
<td>50 test strips</td>
<td>$21.65</td>
</tr>
<tr>
<td>On Call Advanced</td>
<td>50 test strips and 5 lancets</td>
<td>$19.10</td>
</tr>
<tr>
<td>CareSens</td>
<td>50 test strips and 5 lancets</td>
<td>$19.60</td>
</tr>
<tr>
<td>SensoCard</td>
<td>50 test strips</td>
<td>$26.20</td>
</tr>
</tbody>
</table>

* a confidential rebate exists in relation to this product

- The following restriction applies to the prescribing and dispensing of blood glucose test strips in the community:

  The number of test strips available on a prescription is restricted to 50 unless:

  1. Prescribed with insulin or a sulphonylurea but are on a different prescription and the prescription is endorsed accordingly; or
2. Prescribed on the same prescription as insulin or a sulphonylurea in which case the prescription is deemed to be endorsed; or

3. Prescribed for a pregnant woman with diabetes and endorsed accordingly.

- There are 6 brands of blood glucose diagnostic test meters currently listed in the Pharmaceutical Schedule.

<table>
<thead>
<tr>
<th>Brand</th>
<th>List price and subsidy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accu-Chek Performa</td>
<td>$19.00*</td>
</tr>
<tr>
<td>FreeStyle Lite</td>
<td>$9.00</td>
</tr>
<tr>
<td>Optium Xceed</td>
<td>$9.00</td>
</tr>
<tr>
<td>CareSens POP</td>
<td>$6.00</td>
</tr>
<tr>
<td>CareSens II</td>
<td>$9.00</td>
</tr>
<tr>
<td>On Call Advanced</td>
<td>$9.00</td>
</tr>
</tbody>
</table>

* a confidential rebate exists in relation to this product

- The following restriction applies to the prescribing and dispensing of blood glucose diagnostic test meters in the community:

A diagnostic blood glucose test meter is subsidised for patients who begin insulin or sulphonylurea therapy after 1 March 2005 or is prescribed for a pregnant woman with diabetes. Only one meter per patient. No further prescriptions will be subsidised. The prescription must be endorsed accordingly.

- Sensocard meters are provided via the Foundation for the Blind.

**Blood and Urine ketone test strips and blood ketone diagnostic test meters**

- Blood ketone test strips (Optium Blood Ketone Test Strips) are listed with full subsidy on the Pharmaceutical Schedule. The subsidy is currently $7.07 for a 10 strip pack.

- Urine ketone test strips (Ketostix) are listed with full subsidy on the Pharmaceutical Schedule in a 20 strip pack and subsidy of $14.14.

- The following restriction applies to the prescribing and dispensing of blood ketone test strips and urine ketone test strips:

  Maximum of 20 strips per prescription; not on a BSO.

- The Optium Xceed blood glucose meter (listed above) has dual functionality (tests blood glucose and blood ketones) and is the only funded blood ketone diagnostic test meter currently available on the Pharmaceutical Schedule.

**Lancets and lancet devices**

- Individual lancet devices and lancet device consumables are not currently listed or funded on the Pharmaceutical Schedule.

- In 2007 PHARMAC conducted a Request For Information (RFI) to investigate the feasibility of funding lancet devices. PHARMAC considers that funding lancet devices
is not necessary given that these are already supplied free of charge with blood diagnostic test meters.

- PHARMAC considers that the most appropriate way to provide lancets to patients is by inclusion with blood glucose test strips. The high cost of distribution when compared with the cost of lancets makes the funding of individual boxes of lancets unfeasible. Two brands of funded blood glucose test strips include 5 lancets in each box (CareSens and On Call Advanced).

**Rapid Acting Insulin**

- There are currently three types of insulin listed in Section B of the Pharmaceutical Schedule under the sub-heading of ‘Insulin - Rapid Acting Preparations’. All brands are fully subsidised.

<table>
<thead>
<tr>
<th>Insulin</th>
<th>Subsidy, (Price), Pack Size and Presentation</th>
<th>Brand</th>
</tr>
</thead>
<tbody>
<tr>
<td>Insulin aspart inj 100 u/ml</td>
<td>$51.19 per 5 x 3 ml cartridges</td>
<td>NovoRapid Penfill</td>
</tr>
<tr>
<td></td>
<td>$30.03 per 10 ml vial</td>
<td>NovoRapid</td>
</tr>
<tr>
<td>Insulin glulisine inj 100 u/ml</td>
<td>$27.03 per 10 ml vial</td>
<td>Apidra</td>
</tr>
<tr>
<td></td>
<td>$46.07 per 5 x 3 ml cartridges</td>
<td>Apidra</td>
</tr>
<tr>
<td></td>
<td>$46.07 per 5x 3 ml disposable pen</td>
<td>Apidra Solostar</td>
</tr>
<tr>
<td>Insulin lispro inj 100 u/ml</td>
<td>$34.92 per 10 ml vial (OP)</td>
<td>Humalog</td>
</tr>
<tr>
<td></td>
<td>$59.52 per 5 x 3 ml cartridges</td>
<td>Humalog</td>
</tr>
</tbody>
</table>

PHARMAC wish to receive proposals for funding of rapid acting insulin where the preferred insulin would be listed as a first line treatment for all new patients with type 1 diabetes and patients using rapid acting insulin for the first time. An endorsement would be required when prescribing other rapid acting insulin’s to confirm that patients were intolerant to or had an inadequate response to the first line insulin. Patients who are using any rapid acting insulin before the date of implementation would not be required to switch and prescriptions would be deemed to be endorsed. A decision to proceed with any proposal which defines access criteria would be the subject of consultation and would require Board approval.

**Insulin Pumps and Consumables**

PHARMAC does not currently provide funding for insulin pumps or consumables. A funding application generated by PHARMAC was reviewed by the Diabetes Subcommittee of PTAC at its 3 March 2011 meeting and by PTAC at its 6 May 2011 meeting - the minutes of which can both be found at www.pharmac.govt.nz/?q=insulin+pumps.

PHARMAC wishes to receive proposals to fund insulin pumps and consumables, however the decision to proceed with funding has not been made. We note that the cost effectiveness of insulin pumps and consumables is heavily dependent on price. The purpose of this RFP is to attempt to obtain the best possible pricing to determine whether the funding of insulin pumps and consumables would be favourable compared to other funding proposals currently being considered by PHARMAC (using our decision criteria which includes cost-effectiveness) and if funding of insulin pumps and consumables would be possible from within the available budget.
It is likely that any funded access would be targeted using eligibility criteria. The following Special Authority criteria have been proposed by the Diabetes Subcommittee of PTAC, however the final criteria would be in agreement with a successful bidder and subject to Board approval.

**Special Authority for Subsidy for insulin pump**

Initial application only from a relevant specialist. Approvals valid for three months for applications meeting the following criteria:

1. Patient has type 1 diabetes; and
2. has adhered to an intensive MDI regimen using analogue insulin’s for at least three months but still has either
   1.1. severe unexplained recurrent nocturnal hypoglycaemia; or
   1.1.2. severe unexplained recurrent hypoglycaemia requiring assistance; or
   1.1.3. chronically raised HbA1c despite optimal MDI therapy; or
2. is a child and in the opinion of the treating specialist a trial with a MDI regimen would be unsuitable and inappropriate; or
3. is already on pump treatment and before date (date Special Authority is initiated) met the above eligibility criteria for funded pumps and/or consumables and continues to benefit from pump treatment; and
4. has undertaken a carbohydrate counting course, and
5. has been evaluated for psychological suitability for a pump, and

Renewal only from a relevant specialist. Approvals valid for three months for applications meeting the following criteria:

1. Patient is continuing to derive benefit due to reduced hypoglycaemic events or maintaining similar or better glycaemic control (HbA1c is less than or similar to pre-initiation HbA1c); and
2. It has been at least 4 years since the last insulin pump received by the patient or in the case of patients qualifying under 1.3 the pump is due for replacement.

**Special Authority for Subsidy for insulin pump consumables**

Initial application only from a relevant specialist. Approvals valid for nine months for applications meeting the following criteria:

1. Patient has had a Special Authority for an insulin pump approved under SA xxx

Renewal only from a relevant specialist. Approvals valid for two years for applications meeting the following criteria:

1. Patient is continuing to derive benefit from insulin pump therapy as defined by:
2. stabilisation or reduction of hypoglycaemic events compared with pre-pump frequency; and/or
3. is maintaining better glycaemic control (HbA1c is stable or less than pre-initiation HbA1c); and
4. the patient continues to be part of a multidisciplinary team experienced in type 1 diabetes care; and
5. the patient continues to be compliant.

**3. Types of proposals sought**

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

- proposals for the Sole Subsidised Supply (provided that the Sole Subsidised Supply period does not commence before 1 June 2012 and does not extend beyond 1 July 2015) for the following products subject to 3.2 below;
  - blood glucose test strips and meters;
  - blood ketone test strips and meters;
  - urine ketone test strips;
  - insulin pumps and consumables;
proposals for Dual Subsidised Supply in the community (provided that the Dual Subsidised Supply period does not commence before 1 June 2012 and does not extend beyond 1 July 2015) that may involve reference pricing, subsidy and/or delisting protection for a period of no more than 3 years, of one or more of the following diabetes management products:

- blood glucose test strips and meters;
- blood ketone test strips and meters;
- urine ketone test strips;
- insulin pumps and consumables;

listing proposals for supply in the community that may involve reference pricing, subsidy and/or delisting protection for a period of no more than 3 years, of one or more of the following diabetes management products:

- blood glucose test strips and meters;
- blood ketone test strips and meters;
- urine ketone test strips;
- insulin pumps and consumables;

proposals that include blood glucose diagnostic test meters that provide additional technologies (e.g. voice readings, software functions) or additional diabetes management tools (e.g. lancet devices or blood ketone test strip functionality);

proposals that include a bundled package of diabetes management consumable products (e.g. lancets and test strips) subject to 3.2 below;

proposals for rapid acting insulin which involves first line access for all newly diagnosed patients with type 1 diabetes or patients being prescribed rapid acting insulin for the first time (no change would occur for existing patients already using rapid acting insulin);

cross-deal or bundling arrangements in respect of more than one chemical entity defined in this RFP as a diabetes management product, or may also include other types of insulin;

dynamic or simple caps or rebates, (note caps/rebates may be for > 3 years). Proposals involving caps and rebates must specify price arrangements, and any other terms, applicable at the end of the supply protection period and/or cap period.

3.2 Please note:

- If you submit a proposal for Sole Subsidised Supply for any diabetes management product, you must also submit a proposal for Dual Subsidised Supply for that same product.
- If you submit a bundle proposal for diabetes management products, you must submit individual proposals for each of the diabetes management products included in the bundle proposal.
- Any supplier that is awarded Sole Subsidised Supply or Dual Subsidised Supply shall be responsible for ongoing educational and operational support to patients and clinicians and the details of relevant service specifications should be submitted with any proposal for insulin pumps and consumables.
• PHARMAC reserves the right to consider blood glucose test strips for visually impaired patients to be a separate sub-group and therefore exempt from the restrictions of Sole or Dual Supply listing.

• In the event that Dual Subsidised Supply is awarded, PHARMAC reserves the right to contract with one supplier from 1 March 2012 or any subsequent date and contract with an alternative supplier at a later date.

• In the case of a sole or dual supply bid for blood glucose test strips and meters, a requirement would be to supply all patients who needed to switch brands with a new meter free of charge for a period of up to 12 months following listing.

• The award of any listing agreement for blood glucose diagnostic test meters is subject to the device meeting required performance standards. The protocol for assessment is set out on pages 51 and 52 of the PHARMAC Guidelines for Funding Applications to PHARMAC: www.pharmac.govt.nz/suppliers/fundingapps.

• Where the price offered by the preferred supplier of rapid acting insulin is matched by other suppliers of rapid acting insulin, maintaining first line access to one brand would not be feasible.

3.3 Proposals must include the following information:

• proposals for blood glucose test strips must include a proposal for an appropriate diagnostic test meter;

• proposals for blood ketone test strips must include a proposal for an appropriate diagnostic test meter;

• proposals for an insulin pump device must include a proposal for appropriate consumables;

• the proposed prices of the diabetes management products included in the proposal;

• Information about the supplier’s ability to ensure reliability and continuity of supply of diabetes management products (including replacement/repair policies, battery/device replacement services and customer services where applicable);

• length of the warranty for insulin pumps;

• which insulin pumps the insulin pump consumables are compatible with;

• information regarding the supplier’s ability to provide clinical and technical support for the diabetes management products (including 0800 line information and clinician and patient training information);

• details of packaging and pack size of diabetes management products;

• in relation to blood glucose test strips and blood glucose diagnostic test meters confirmation of whether information can be downloaded from meters to GP software systems and, where applicable, a list of the software with which the meters are compatible and technology required;
• in relation to lancets, the compatibility of the lancet device consumable with other lancet devices in the market or the proposed plans of supplying lancet devices to patients (i.e. would there be any costs to the patient);

• the supplier’s rationale as to why PHARMAC should accept their proposal; and

• any other information in support of your proposal contemplated by Schedule 4.
3.4 **PHARMAC is not willing to consider the following types of proposals:**

- Proposals for blood glucose test strips only.
- Proposals for blood glucose diagnostic test meters only.
- Proposals for blood ketone diagnostic test meters only.
- Proposals for blood ketone test strips meters only.
- Proposals for lancets only.
- Proposals for insulin pump devices only.
- Proposals for insulin pump consumables only.
- Numerical limits for patients to whom subsidy would be available.
- Proposals including the widening of funded access to other products currently listed on the Pharmaceutical Schedule.
- Proposals for part-funding of diabetes management products.
- Proposals which involve cross-deal or bundling arrangements which involve any chemical entity other than insulin or diabetes management products as defined in this RFP.
- 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 or diabetes management product(s) on specific terms.

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

3.6 PHARMAC may request samples of any diabetes management product included in a proposal and such samples must be provided within 10 working days of such a request.
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) Proposals must be submitted no later than 4.00 p.m. (New Zealand time) on 20 October 2011. Late proposals will only be considered at PHARMAC’s discretion.

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

(d) All proposals (including samples) must be submitted electronically by email to Natalie Davis at PHARMAC (natalie.davis@pharmac.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 basis on which the Evaluation Committee will evaluate proposals, and the weight to be given to the criteria and other matters that it considers, are to be determined by the Evaluation Committee at its sole discretion. The matters to be taken into account by the Evaluation Committee will, however, include:

(i) the decision criteria 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;

(ii) any clinical advice from PTAC or the Diabetes Sub-committee;

(iii) the ability of the supplier to ensure reliability and continuity of supply of diabetes management products including:

   o battery and device replacement and/or repair policies including warrantee

   o customer and clinician support and training services where applicable

(iv) 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) 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.
3. **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, which are available on request from PHARMAC, 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).

4. **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 PHARMAC’s Chief Executive 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 PHARMAC’s Chief Executive under delegated authority) in accordance with the decision criteria in PHARMAC’s then current OPPs.

(d) If the Board or the Chief Executive 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 Chief Executive’s decision to accept a negotiated agreement; or

(ii) the termination of the RFP process.

5. **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 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 in light of consultation, or alternatively we may request that new proposals be submitted;

(vii) 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;

(viii) to readvertise 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 Chief Executive.

(d) You must not at any time initiate any communication with PHARMAC’s directors or officers, the Ministry of Health, the Minister of Health or District Health Boards, 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 letter. PHARMAC may exclude your 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 is not an offer capable of being converted into a contract for the supply of diabetes management products 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.

6. Anticipated timetable

(a) Following receipt of proposals, PHARMAC anticipates:

(i) The Evaluation Committee evaluating proposals in November 2011.

(ii) Negotiating with submitter(s) of one or more preferred proposals in December 2011.

(iii) Consulting on a provisional agreement in January 2011.

(iv) PHARMAC’s Board or Chief Executive considering this provisional agreement in or after February 2012.

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 April 2012 (any agreement for Sole Subsidised Supply would not be effective before June 2012);

(c) Please note that if a proposal for sole supply is accepted, the date of implementation may be later than June 2012 to allow for an orderly transition to any sole supply arrangement.
Schedule 3: Current listing and market information

The following information relates to the estimated subsidised market size of diabetes management products. 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 diabetes management products 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.

The number of subsidised units for blood glucose and diagnostic meters, blood and urine ketone test strips in the community for the calendar years 2008, 2009, and 2010 is shown below:

<table>
<thead>
<tr>
<th>Pharmaceutical</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood glucose test strips *</td>
<td>42,823,225</td>
<td>44,946,265</td>
<td>48,590,478</td>
</tr>
<tr>
<td>Blood glucose diagnostic test meters</td>
<td>7130</td>
<td>5392</td>
<td>5009</td>
</tr>
<tr>
<td>Blood ketone test strips *</td>
<td>Not listed</td>
<td>10,510</td>
<td>32,750</td>
</tr>
<tr>
<td>Urine ketone test strips *</td>
<td>65,900</td>
<td>64,280</td>
<td>35,260</td>
</tr>
</tbody>
</table>

*1 unit = 1 test strip

The Optium Xceed meter is the only blood ketone testing meter available. It has dual functionality to test blood glucose also.

The number of subsidised units (one unit = one 10 ml vial or one 3 ml cartridge/prefilled pen) of rapid acting insulin in the community for the calendar years 2008, 2009 and 2010 is shown below:

<table>
<thead>
<tr>
<th>Pharmaceutical</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rapid acting insulin 10 ml</td>
<td>14,132</td>
<td>14,147</td>
<td>14,150</td>
</tr>
<tr>
<td>Rapid acting insulin 3 ml</td>
<td>526,069</td>
<td>571,112</td>
<td>620,353</td>
</tr>
</tbody>
</table>

Insulin Pumps and Consumables

PHARMAC staff conducted a Request for Information in December 2010. Based on the information received, we estimate that there are about 300 to 400 existing patients who currently receive varying amounts of funding from DHBs for insulin pumps and/or consumables, although it is possible that some of these patients may not meet the proposed criteria for funding on the Pharmaceutical Schedule.

We estimate that there could be 200 to 400 new patients per year initiating insulin pump therapy. The capacity for each multidisciplinary team to assess and train patients may limit the rate of patients beginning insulin pump therapy.
Schedule 4: Proposal form

An electronic version of this form is available from Natalie Davis. You should expand the boxes as necessary.

Date:

Chief Executive  
C/- Natalie Davis  
PHARMAC  
PO Box 10-254  
(or for courier delivery:  
Level 9  
40 Mercer Street)  
Wellington 6011  
New Zealand

Dear Natalie

Proposal for the supply of diabetes management products

In response to your request for proposals (RFP) dated 26 August 2011 we put forward the following proposal in respect of diabetes management products.

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

(a) Our contact details:

<table>
<thead>
<tr>
<th>Name of supplier</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Contact person</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Address</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Phone</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Facsimile</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Email address</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(b) Details of pharmaceutical presentation:

<table>
<thead>
<tr>
<th>Chemical name</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Strength (if applicable)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Form (e.g. strip)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Brand name</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pack size (e.g. 50)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Packaging type (e.g. foil or tube)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
(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, price in return for dual supply, reference price protection etc.):

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

<table>
<thead>
<tr>
<th>Date of Notification to WAND database</th>
<th>Evidence of any other approval required or otherwise obtained in relation to supply of the pharmaceutical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Device imprecision and inaccuracy levels (according to the 1996 American Diabetes Association standards for diabetes meters) judged in a recent (within the last 18 months) independent test (please attach results separately)</td>
<td></td>
</tr>
<tr>
<td>Date of market approval (as applicable - please attach copy of Medsafe Gazette notice)</td>
<td></td>
</tr>
</tbody>
</table>

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) Operating information about our brand of blood glucose test strips and diagnostic test meter and/or blood ketone test strips and diagnostic test meter:

<table>
<thead>
<tr>
<th>Volume of blood required</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Time taken for test</td>
<td></td>
</tr>
<tr>
<td>Temperature range of operation</td>
<td></td>
</tr>
</tbody>
</table>
(g) Information about our ability to ensure the continuity of supply of the diabetes management product:


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


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


(j) Other relevant information about our brand of diabetes management products:

<table>
<thead>
<tr>
<th>Availability of an 0800 number (incl. hours of operation)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Repair/replacement policy</td>
<td></td>
</tr>
<tr>
<td>Ability to download data and compatible software</td>
<td></td>
</tr>
<tr>
<td>Other customer services</td>
<td></td>
</tr>
<tr>
<td>Clinician and patient training services</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td></td>
</tr>
</tbody>
</table>

(k) Reasons why PHARMAC should accept our proposal and any additional information that PHARMAC should consider when evaluating our proposal:


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