PHARMAC
Pharmaceutical Management Agency

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19 July 2017

Dear Supplier

**REQUEST FOR PROPOSALS – SUPPLY OF ENTECAVIR AND TENOFOVIR DISOPROXIL TABLETS OR CAPSULES**

PHARMAC invites proposals for the supply of entecavir and tenofovir disoproxil 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 via the Government Electronic Tenders Service (**GETS**) (www.gets.govt.nz) no later than **4.00 p.m**. on **16 August 2017**.

If you have any questions about this RFP, please post these on GETS or alternatively contact Chloë Dimock by email at procurement@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 proposals from suppliers of entecavir and tenofovir disoproxil (in its various salt forms) for supply for treatment of hepatitis B virus (**HBV**) and, for tenofovir disoproxil only, human immunodeficiency virus (**HIV**) infection.

### 2. Definitions

**First Line** - where the pharmaceutical is funded for use as the first treatment for chronic hepatitis B (**CHB**) infection.

**Second Line** - where the pharmaceutical is funded for use in treatment for CHB infection only after another funded treatment has been tried first or where a patient meets additional criteria for use.

**Equal Access** - funding access criteria for CHB treatment naïve patients would be the same for entecavir and tenofovir disoproxil.

### 3. Background to RFP

The background to this RFP is as follows:

Entecavir is a guanosine nucleoside analogue with selective activity against HBV polymerase and is used in the treatment of CHB. Tenofovir disoproxil is an oral prodrug of tenofovir, a nucleoside monophosphate (nucleotide) analogue and obligate chain terminator with activity against HIV reverse transcriptase and HBV polymerase and is used in the treatment of both CHB and HIV infection.

*Funding history*

PHARMAC funds a variety of treatment options for CHB infection, some of which are also indicated and funded to treat HIV. Patients receiving treatment for CHB are treated most frequently with one of the funded oral pharmaceuticals (lamivudine, adefovir dipivoxil, entecavir and tenofovir disoproxil fumerate). Lamivudine was the first oral agent funded for treatment of CHB in June 2000 (it had been funded for the treatment of HIV since 1996) followed by adefovir in May 2006, entecavir in August 2009 and tenofovir in December 2009 (tenofovir has been funded for the treatment of HIV since April 2007).

Funding for these oral pharmaceuticals is restricted by Special Authority criteria which varies between each chemical. Expert clinical advice has been sought when setting Special Authority criteria. Changes to the criteria have been made over time with emerging new treatment options, clinical evidence and updated clinical guidelines. Use of these chemicals in DHB hospitals is similarly restricted. Please refer to the Pharmaceutical Schedule for further details:

- Section B (community)- entecavir and tenofovir disoproxil fumarate; and
- Part II of Section H (Hospital Medicines List)- entecavir and tenofovir disoproxil fumarate.

Consistent with the clinical advice PHARMAC has received and the recognised clinical practice guidelines,[1,2] most New Zealand CHB patients are now being treated with either entecavir or tenofovir disoproxil (in its fumerate salt form) (see Schedule 3 below for further usage details). Currently lamivudine remains the preferred agent for treatment of CHB in children under 12.

Entecavir is funded for **First Line** treatment for CHB treatment naïve patients, and tenofovir disoproxil is restricted to **Second Line** treatment for CHB or to patients who have been listed for or have undergone liver transplant for HBV, have decompensated liver cirrhosis or are pregnant, likely to become pregnant or are breastfeeding (for full details please refer to the Special Authority criteria attached via links above). There is also a small number of patients who continue to receive tenofovir disoproxil as part of their HIV treatment regime. The number of patients using tenofovir disoproxil for HIV diminished significantly after the introduction of tenofovir disoproxil combination products (efavirenz with emtricitabine and tenofovir disoproxil (Atripla), and emtricitabine with tenofovir disoproxil (Truvada)) in December 2012.

*Current funding*

Currently there is only one brand of entecavir (Baraclude) and one brand of tenofovir disoproxil fumarate (Viread) listed on the Pharmaceutical Schedule. The table below outlines the current Pharmaceutical Schedule listings of these two chemicals with web links to the restriction criteria applying in the community (Section B) and DHB Hospitals (Part II of Section H (Hospital Medicine List)).

| | | Subsidy/ Price | Per | Fully Subsidised | Brand or Generic Manufacturer |
|---|---|---|---|---|---|
| **Hepatitis B Treatment** | | | | | |
| **ENTECAVIR** | Special Authority see SA1361 below – Retail pharmacy | | | | |
| Tab 0.5 mg | …… | 400.00 | 30 | ✓ | **Baraclude** |
| **Section B of the Pharmaceutical Schedule** SA1361 Special Authority for Subsidy<br>**Hospital Medicine List of the Pharmaceutical Schedule** Hospital restrictions | | | | | |
| **Hepatitis B/ HIV/AIDS Treatment** | | | | | |
| **TENOFOVIR DISOPROXIL FUMARATE** Subsidy by endorsement; can be waived by Special Authority see SA1362 below<br>Endorsement for treatment of HIV: Prescription is deemed to be endorsed if tenofovir disoproxil fumarate is co-prescribed with another anti-retroviral subsidised under Special Authority SA1364 and the prescription is annotated accordingly by the Pharmacist or endorsed by the prescriber.<br>Note:<br>Tenofovir disoproxil fumarate prescribed under endorsement for the treatment of HIV is included in the count of up to 4 subsidised antiretrovirals for the purposes of Special Authority SA1364 | | | | | |
| Tab 300 mg | …… | 531.00 | 30 | ✓ | **Viread** |
| **Hepatitis B**<br>**Section B of the Pharmaceutical Schedule** SA1362 Special Authority for Subsidy<br>**Hospital Medicine List of the Pharmaceutical Schedule** Hospital restrictions | | | | | |
| **HIV**<br>**Section B of the Pharmaceutical Schedule:** SA1364 Special Authority for Subsidy<br>**Hospital Medicine List of the Pharmaceutical Schedule** Hospital restrictions | | | | | |

[1] American Association for the Study of Liver Diseases (AASLD) Guidelines for Treatment of Chronic Hepatitis B. available here.

[2] European Association for the Study of the Liver (EASL) Clinical Practice Guidelines: Management of chronic hepatitis B virus infection. Available here.

Details on the current Pharmaceutical Schedule listing arrangements for the other oral CHB treatments can be accessed via the web links provided below:

**Adefovir dipivoxil***

Section B of the Pharmaceutical Schedule SA0829 Special Authority for Subsidy
Hospital Medicine List of the Pharmaceutical Schedule Hospital restrictions

**Lamivudine***

Section B of the Pharmaceutical Schedule: SA1650 Special Authority for Subsidy
Hospital Medicine List of the Pharmaceutical Schedule Hospital restrictions

*PHARMAC notes that these other two oral CHB treatment markets may be impacted by funding changes resulting from proposals progressed through this RFP. Any proposed changes resulting from this RFP would be subject to consultation.

*Pharmacology and Therapeutics Advisory Committee (PTAC) and Subcommittee Advice*

PHARMAC has sought clinical advice on CHB treatments including entecavir and tenofovir disoproxil on a number of occasions. PHARMAC has also specifically sought clinical advice on commercial activities which could leverage competition between chemicals and within chemicals in the CHB treatment area.

Listed below is the most recent clinical advice received and web links to the relevant minutes.

- **26 February 2014** the Anti-infective Subcommittee considered access criteria, reviewed requests for widened access and considered current prescribing practices for CHB treatments. The February 2014 Anti-Infective Subcommittee minutes are available on the PHARMAC website.

- **12 December 2014** the Anti-infective Subcommittee made recommendations to change the renewal/continuation criteria for lamivudine. The December 2014 Anti-Infective Subcommittee minutes are available on the PHARMAC website.

- **4 November 2015** the Anti-infective Subcommittee recommended that lamivudine be funded for HBV reactivation prophylaxis for immunocompromised patients with a high priority. The November 2015 Anti-Infective Subcommittee minutes are available on the PHARMAC website.

- **13 October 2016** the Anti-infective Subcommittee discussed potential commercial activities that could be initiated in the CHB market relating more specifically to entecavir and tenofovir. The Subcommittee provided clinical advice related to possible commercial activity in the CHB market which included further discussion and recommendations on access criteria. The October 2016 Anti-Infective Subcommittee minutes are available on the PHARMAC website.

*Reason for running the RFP*

Under current restrictions both entecavir and tenofovir disoproxil represent significant expenditure to the Combined Pharmaceutical Budget (**CPB**). Table One below details the approximate gross expenditure for the last three calendar years.

**Table One Community gross expenditure of entecavir and tenofovir disoproxil by calendar year**

| Chemical | Presentation | Expenditure | | |
|---|---|---|---|---|
| | | 2014 | 2015 | 2016 |

| | | | | |
|---|---|---|---|---|
| **Entecavir *** | Tab 0.5 mg | $5,037,000 | $6,006,000 | $6,751,000 |
| **Tenofovir disoproxil fumarate** | Tab 300 mg | $4,445,000 | $4,801,000 | $5,065,000 |
| ***A confidential rebate currently applies: Entecavir Notification<br>DHB hospital usage of both entecavir and tenofovir disoproxil fumerate is <1% of total use. | | | | |

PHARMAC is aware that there are a number of entecavir and tenofovir disoproxil products currently approved through Medsafe, undergoing Medsafe approval and approved by regulatory bodies overseas. As a result of this potential competition, the purpose of this RFP is to:

(a) reduce the total expenditure of the entecavir and tenofovir CHB oral treatment market (and HIV treatment market for tenofovir disoproxil);

(b) determine if it is possible to achieve pricing for both entecavir and tenofovir disoproxil which would enable both treatments to be funded as a first line CHB treatment. This would be PHARMAC's preference;

(c) determine if widening funded access to entecavir and/or tenofovir disoproxil to enable use of entecavir and/or tenofovir for the prevention of HBV reactivation in surface antigen negative/core antibody positive patients receiving rituximab would be possible from within the available budget; and

(d) determine if widening funded access to tenofovir disoproxil to include all women of child bearing potential who need treatment for CHB would be possible from within the available budget (should tenofovir disoproxil remain a Second Line treatment).

Any proposals progressed for consideration for funding would be assessed using PHARMAC's decision-making framework as outlined in its Operating Policies and Procedures (**OPPs**) with reference to the Factors for Consideration.

## 4. Types of proposals sought

(a) Suppliers wishing to submit proposals **MUST** submit proposals for community and DHB hospitals supply at the chemical level for either:

- entecavir tab 0.5 mg; or
- tenofovir disoproxil (in its various salt forms) tab 300 mg (note: these **MUST** be inclusive of the CHB market **AND** HIV market)**.**

(b) Suppliers wishing to submit proposals for either entecavir tab 0.5 mg or tenofovir disoproxil (in its various salt forms) tab 300 mg **MUST** submit pricing for the following **THREE** Pharmaceutical Schedule listing scenarios:

1. pricing for either entecavir or tenofovir disoproxil tablets for use as a first line treatment for CHB infection (**First Line**), where the alternative chemical (entecavir or tenofovir disoproxil as applicable) would be listed as a second line treatment for CHB infection*;

2. pricing for either entecavir or tenofovir disoproxil tablets for use as a second line treatment for CHB infection (**Second Line**), where the alternative chemical

(entecavir or tenofovir disoproxil as applicable) would be listed as a first line treatment for CHB infection*; and

3. pricing for entecavir or tenofovir disoproxil tablets in a scenario where both chemicals were funded as a first line treatment for CHB infection (**Equal Access**)*.

*For the avoidance of doubt the chemical **MUST** be the same chemical under each pricing scenario stated above. A supplier wishing to submit proposals for both entecavir and tenofovir disoproxil would need to provide pricing for both chemicals as stated above i.e. First Line entecavir price, Second Line entecavir price, Equal Access entecavir price, First line tenofovir disoproxil price, Second Line tenofovir disoproxil price and Equal Access tenofovir disoproxil price, each capable of being accepted on its own.

(c) PHARMAC is willing to consider the following types of proposals:

(i) proposals that include supply of both tenofovir disoproxil and entecavir for **Equal Access**, in the strengths stated in paragraph 4 (a) above, provided the supplier who submits a proposal for supply of both tenofovir disoproxil and entecavir **MUST** also submit two individual proposals for each chemical with pricing for the three scenarios stated in 4 (a) above, each capable of being accepted on its own;

(ii) proposals that involve a period of sole subsidised supply of the pharmaceutical in the community and hospital supply status with a discretionary variance (DV) limit of 1% in DHB hospitals (hereinafter referred to as "**Sole Supply**") for a period of time, provided that the Sole Supply period does not extend beyond 30 June 2021;

For the avoidance of doubt Sole Supply would be at the chemical level (not for indication). The DV Limit would apply to other products of the same chemical. For example, if an entecavir tab 0.5 mg product (entecavir-brandX) was selected to be the First Line treatment and was awarded Sole Supply, it would be funded as a First Line treatment for CHB and be the only brand of entecavir listed on the Pharmaceutical Schedule. Tenofovir disoproxil would remain listed as a Second Line treatment for CHB (and remain funded for HIV). In DHB hospitals, the DV Limit of 1% would apply to other entecavir tablet products (entecavir-brandY and entecavir-brandZ).

(iii) proposals which include differential pricing for a scenario where access is widened to include prevention of HBV reactivation, similar to the access currently in place for lamivudine tab 100 mg and oral liq 5 mg per ml.

(iv) proposals which include pharmaceuticals which 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). In these circumstances, suppliers may be required to demonstrate their ability to obtain those consents within a time frame acceptable to PHARMAC.

(d) PHARMAC is not willing to consider the following types of proposals:

(i) proposals that include pharmaceuticals other than entecavir or tenofovir disoproxil (in its various salt forms). This includes pharmaceuticals which

combine more than one active ingredient including entecavir or tenofovir disoproxil (in its various salt forms);

(ii) proposals that include expenditure caps, rebates or other expenditure risk-sharing mechanisms (including volume base tiered pricing);

(iii) proposals that involve listing entecavir or tenofovir disoproxil with a partial subsidy;

(iv) 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; and

(v) parity pricing, whereby PHARMAC may reduce the subsidy payable for a pharmaceutical in a particular therapeutic sub-group to the level of the subsidy payable for a pharmaceutical in any other sub-group.

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

Suppliers should provide PHARMAC with samples of the entecavir / tenofovir disoproxil product(s) included in the proposal(s) (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 10 business days from the dated specified in Schedule 2, clause 1 (b).

## 5. Patents

(a) PHARMAC is aware that there are current patents in New Zealand which may be relevant to entecavir (potentially including, but not necessarily limited to **NZ520024**).

(b) PHARMAC is aware that there are current patents in New Zealand which may be relevant to tenofovir disoproxil (potentially including, but not limited to, **NZ333687** (expiry date 25 July 2017)**, NZ501287, NZ569349, and NZ588796**).

(c) PHARMAC makes no representation as to the patent status of entecavir and tenofovir disoproxil, or any particular synthetic methods or formulations of entecavir and tenofovir disoproxil, and it is the responsibility of the supplier to ensure its product does not infringe any third party intellectual property rights. PHARMAC accepts no liability for any patent infringement that might occur as a result of this RFP process or PHARMAC's acceptance of a proposal, including infringement of process patents.

## 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 to PHARMAC via GETS no later than **4.00 p.m. (New Zealand time) on 16 August 2017.** 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 submit them on GETS or alternatively contact Chloë Dimock, Procurement Manager, by email at procurement@pharmac.govt.nz

### 2. Evaluation

(a) Following the deadline for submitting proposals an Evaluation Committee comprising of 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 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 proposals 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 entecavir and/or tenofovir disoproxil following the closing of this RFP;

(iii) 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).

(e) 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.

(f) 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 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 criteria 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.

**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 the Board's delegate.

(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 entecavir or tenofovir disoproxil 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 August/September 2017;

(ii) negotiating with submitter(s) of one or more preferred proposals in September 2017;

(iii) consulting on a provisional agreement in September/October 2017; and

(iv) PHARMAC's Board, or the Board's delegate, considering this provisional agreement in or after October/November 2017,

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 January 2018.

(c) Please note that if a proposal for sole supply is accepted, the date of implementation may be later 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 CHB oral treatments. 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 entecavir or tenofovir disoproxil 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 Two Community usage of CHB oral treatments and tenofovir combination treatments by calendar year**

| Chemical | Presentation | Usage (tablets or ml) | | | Approximate portion of usage from patients with CHB without HIV |
|---|---|---|---|---|---|
| | | 2014 | 2015 | 2016 | 2016 |
| **Adefovir dipivoxil** | Tab 10 mg | 30,470 | 21,267 | 15,560 | 100% |
| **Entecavir** | Tab 0.5 mg | 377,775 | 450,474 | 506,310 | 100% |
| **Lamivudine** | Oral liq 5 mg per ml | 13,820 | 15,450 | 11,040 | 100% |
| **Lamivudine** | Tab 100 mg | 196,304 | 185,993 | 182,224 | 100% |
| **Tenofovir disoproxil fumarate** | Tab 300 mg | 251,133 | 271,256 | 286,149 | 74% |

**Table Three Community gross expenditure of CHB oral treatments and tenofovir combination treatments by calendar year**

| Chemical | Presentation | Expenditure | | |
|---|---|---|---|---|
| | | 2014 | 2015 | 2016 |
| **Adefovir dipivoxil** | Tab 10 mg | $680,500 | $475,000 | $347,500 |
| **Entecavir *** | Tab 0.5 mg | $5,037,000 | $6,006,300 | $6,750,800 |
| **Lamivudine** | Oral liq 5 mg per ml | $9,100 | $17,400 | $12,400 |
| **Lamivudine** | Tab 100 mg | $193,600 | $39,900 | $39,000 |
| **Tenofovir disoproxil fumarate** | Tab 300 mg | $4,445,100 | $4,801,200 | $5,064,800 |
| ***A rebate currently applies:** Entecavir Notification | | | | |

**Table Four: 2016 FYR CHB funded oral treatments patient demographic data**

| | Total patients | Chronic patients (3+ dispensings, over 4+ months) | New patients | Male:female | Māori | Pacific | Asian | Patients under 10 years | Women aged 10-49 |
|---|---|---|---|---|---|---|---|---|---|
| **Adefovir dipivoxil- Tab 10 mg** | 62 | 56 | 0 | 52:10 | 13 | 6 | 17 | 0 | 3 |
| **Entecavir Tab 0.5 mg** | 1,668 | 1,430 | 286 | 1,186:482 | 431 | 296 | 708 | 0 | 202 |
| **Lamivudine Tab 100 mg** | 698 | 554 | 142 | 459:239 | 175 | 166 | 203 | 1 | 65 |
| **Lamivudine oral liquid 5 mg per ml** | 8 | 3 | 1 | 6:2 | 4 | 1 | 2 | 2 | 0 |
| **Tenofovir disoproxil fumerate Tab 300 mg** | 968 | 839 | 116 | 646:322 | 193 | 172 | 393 | 1 | 18 |

**Table Five: Number of Special Authority Initial Applications for Lamivudine in the 2016 FYR**

| Special Authority Criteria Description | Total number of approved applications for each criteria |
|---|---|
| HBV DNA positive cirrhosis prior to liver transplantation | 9 |
| HBsAg positive and have had a liver, kidney, heart, lung or bone marrow transplant | 5 |
| Hepatitis B surface antigen (HbsAg) positive patient who is receiving chemotherapy for a malignancy, or high dose steroids (at least 20mg/day for at least 7 days), or who has received such treatment within the previous two months | 74 |
| Hepatitis B surface antigen positive patient who is receiving anti tumour necrosis factor treatment | 2 |
| Hepatitis B core antibody (anti-HBc) positive patient who is receiving rituximab plus high dose steroids (e.g. R-CHOP) | 62 |
| HBV DNA positive cirrhosis prior to liver transplantation | 9 |

**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*]**

Sarah Fitt, Director of Operations
C/- Chloe Dimock

Dear Sir/Madam

**Proposal for the supply of entecavir or tenofovir disoproxil**

In response to your request for proposals (**RFP**) dated **19 July 2017**, we put forward the following proposal in respect of [***insert pharmaceutical***].

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:

| | **First Line** | **Second Line** | **Equal Access** |
|---|---|---|---|
| Chemical name | | | |
| Strength (e.g. tab 0.5 mg) | | | |
| Form (e.g. tablet) | | | |
| Colour, Shape and Markings (e.g. white triangular tablet embossed with ENT 500) | | | |
| Brand name | | | |
| Pack size (e.g. 30's) | | | |

| | | | |
|---|---|---|---|
| Packaging type (e.g. blister) | | | |
| Shelf life (e.g. 36 months from date of manufacture stored at or below 30°C) | | | |

(c) Details of pharmaceutical manufacture:

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

(d) Key features of our proposal:

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| **Second Line** |
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| **Equal Access** |
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(e) 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.):

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| **Second Line** |
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| **Equal Access** |
| |

(f) 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 | |

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

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(h) Information about our ability to ensure the continuity of supply of the pharmaceutical (if not currently supplying in New Zealand please detail any other markets which you supply your product):

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

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(j) 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:

| **First Line** |
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(k) Reasons why PHARMAC should accept our proposal:

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(l) Additional information that PHARMAC should consider when evaluating our proposal [Please include information you consider relevant under PHARMAC's Factors for Consideration decision making framework]:

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| **Second Line** |
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| **Equal Access** |
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