

3 August 2016

2016/17 Invitation to Tender

PHARMAC is seeking feedback from pharmaceutical suppliers and interested parties on:

- A proposal to tender certain pharmaceuticals for sole supply;
- The draft process and terms and conditions for the 2016/17 Invitation to Tender (2016/17 Tender); and
- Commercial proposals as an alternative to tendering.

PHARMAC welcomes all feedback on the draft 2016/17 Tender. Feedback received by the deadline may be considered by the Tender Medical Evaluation Subcommittee of PTAC and would be considered by the PHARMAC Board (or its Delegate, where applicable) prior to making a decision on this proposal.

Feedback should be submitted by the following dates; late feedback may not be considered:

**ALTERNATIVE COMMERCIAL PROPOSAL RESPONSES DUE BY
5 PM, MONDAY 29 AUGUST 2016**

**ALL OTHER CONSULTATION RESPONSES DUE BY
5 PM, FRIDAY 2 SEPTEMBER 2016**

Feedback should be provided by submitting an email or letter to the Tender Analysts:

Email: tender@pharmac.govt.nz

Letter: Tender Analysts
PHARMAC
PO Box 10-254
Wellington 6143

DDI: Tim Nuthall: (04) 901 3233
Katie Brownless: (04) 916 7522

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly

state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request.

Details of the proposed 2016/17 Tender

In general, the proposed 2016/17 Tender process would be similar to the 2015/16 Tender. In addition to Alternative Commercial Proposals (discussed below), we seek comments on all sections of the draft 2016/17 Tender, in particular on:

- The proposed changes to the 2016/17 Tender;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2016/17 Tender, that you consider should be tendered, and the reasons for that view. If you wish, you may provide a non-binding confidential indication of the price or price range that you might be able to offer for a line item or group of line items you wish to have tendered;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2016/17 Tender, that you consider would be inappropriate to tender, and the reasons for that view, including any contractual constraints or patent protection that could restrict PHARMAC from awarding a tender on a particular pharmaceutical;
- For Hospital Pharmaceuticals, feedback on the appropriate Discretionary Variance Limit for each pharmaceutical, in the event that a 1% Discretionary Variance Limit is not considered clinically acceptable; and
- Feedback on any unresolved Tender Bid(s) from previous tenders that you consider should remain open for acceptance. Please note that some currently unresolved Tender Bids may be resolved prior to the consultation deadline and the final Tender being issued.

Draft Invitation to Tender

We are seeking feedback on the composition of the draft 2016/17 Tender. This is still under development and may change before it is taken to the Board (or its Delegate) for approval and subsequently issued. At this stage, but depending on the extent of any changes, PHARMAC does not intend to send out further drafts for consultation.

A complete copy of the draft 2016/17 Tender, including the proposed terms and conditions which successful tender bids would be subject to, is available on our website (www.pharmac.health.nz). The draft 2016/17 Tender comprises the following sections:

- Schedule 1: Definitions and interpretation
- Schedule 2: The list of pharmaceuticals proposed for tender* #
- Schedule 3: The Tender process (for both hospital and community Tenders)
- Schedule 4: Contract terms for Sole Subsidised Supply and/or Hospital Supply Status
- Schedule 5: Additional contract terms for Sole Subsidised Supply Status
- Schedule 6: Additional contract terms for Hospital Supply Status

*The market data for the year ended 30 June 2016 has not yet been finalised and the units provided in Schedule Two currently consist of market data for the year ended 30 June 2015; however, finalised 2016 market data would be included in the final 2016/17 Tender. The figures included are indicative only and are provided on the basis set out in clause 1.3 of Schedule 2 of the draft 2016/17 Tender.

The final list of products, which may change following consultation, would be released as part of the 2016/17 Tender, following Board (or its Delegate) approval. You may provide feedback on the inclusion of any additional pharmaceuticals after the 2016/17 Tender has been issued, and any such feedback would be considered by the Board (or its Delegate) before making a final decision on any product, provided that any feedback is given prior to the tender close date in late 2016.

Proposed inclusion of the following provisions in the 2016/17 Invitation to Tender

Pack size preference

PHARMAC propose to include a provision in the 2016/17 Invitation to Tender relating to pack size preference.

In summary, where a Tender Item is specified as being available for a Tender Bid for Sole Supply Status, it is the preference of PHARMAC that the pack size for such a Tender Item is a 30 or 90 day pack where the Tender Item is in a tablet or capsule form.

Notwithstanding the preference of PHARMAC for Tender Items to be in pack sizes as specified above, pack sizes may be specified in the comments column in the attached list or you may submit, and PHARMAC will consider and may accept, a Tender Bid for any pack size, including larger pack sizes, following its evaluation of Tender Bids under clause 5 of Schedule Three.

Matters for evaluation

PHARMAC propose to include a provision in the 2016/17 Invitation to Tender relating to matters for evaluation.

The Evaluation Committee will evaluate Tender Bids 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 Operating Policies and Procedures (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.

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.

Product identification codes

PHARMAC propose to include a provision in the 2016/17 Invitation to Tender relating to product identification codes.

The provision would require that, prior to the listing of a new pharmaceutical, the supplier must obtain and notify PHARMAC by submitting a notification of product changes form of the Pharmacode, the GTIN and the CTPP for the Pharmaceutical, no later than the earlier of:

- (a) 10 business days following the Market Notification Date; or
- (b) the 5th day of the month immediately prior to the Start Date.

For the avoidance of doubt, this requirement does not apply in relation to any Pharmaceutical that is a Medical Device.

Key Dates and Timeframes for the 2016/17 Tender:

The timelines for the 2016/17 Tender are envisaged to be similar to the 2015/16 Tender; we propose to release the final 2016/17 Invitation to Tender in early November 2016 and consequently the closing date for tender submissions would be late December 2016. The proposed timeline is outlined in the following table:

Date	Event
3 August 2016	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft Invitation to Tender.
29 August 2016	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
2 September 2016	Final date for all consultation to be received.
September 2016	PHARMAC considers feedback from consultation, negotiates with suppliers over any ACP proposals it considers would meet PHARMAC's Factors for Consideration, and enters into provisional contracts with suppliers where appropriate.
September 2016	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2016	Consultation and decisions on Alternative Commercial Proposals.
Early November 2016	Issuing of the 2016/17 Tender.
15 December 2016	Invitation to Tender closes.
From end of January 2017	Decisions on the first Tender winners announced.

Unresolved Tender Bids

We intend to review any unresolved Tender Bids from the 2014/15 Tender and the 2015/16 Tender prior to issuing the 2016/17 Tender. The following Tender Bids remain unresolved:

2014/15 Invitation to Tender

Chemical Name	Line Item
Atropine sulphate	Inj 600 mcg, 1 ml
Caspofungin	Inj 50 mg
Caspofungin	Inj 70 mg
Celiprolol	Tab 200 mg
Chloramphenicol	Inj 1 g
Clonidine	Inj 150 mcg per ml, 1 ml
Famotidine	Tab 20 mg
Granisetron	Inj 1 mg
Hyoscine N-butylbromide	Inj 20 mg, 1 ml
Lidocaine [Lignocaine] Hydrochloride	Inj 1%, 20 ml
Lidocaine [Lignocaine] Hydrochloride	Inj 1%, 5 ml
Lidocaine [Lignocaine] Hydrochloride	Inj 2%, 20 ml
Lidocaine [Lignocaine] Hydrochloride	Inj 2%, 5 ml
Lidocaine [lignocaine] hydrochloride with adrenaline	Inj 2% with adrenaline 1:80,000, 2.2 ml dental cartridge

Chemical Name	Line Item
Metformin Hydrochloride	Tab immediate-release 1 g
Naloxone Hydrochloride	Inj 400 mcg per ml, 1 ml
Propranolol	Cap long-acting 60 mg
Urokinase	Inj 10,000 iu
Urokinase	Inj 100,000 iu
Urokinase	Inj 500,000 iu

2015/16 Invitation to Tender

Chemical Name	Line Item
Ambrisentan	Tab 10 mg
Ambrisentan	Tab 5 mg
Amiodarone hydrochloride	Inj 50 mg per ml, 3 ml
Amoxicillin clavulanate	Grans for oral liq amoxicillin 250 mg with potassium clavulanate 62.5 mg per 5 ml
Amoxicillin clavulanate	Grans for oral liq amoxicillin 400 mg with potassium clavulanate 57 mg per 5 ml
Atomoxetine	Cap 10 mg
Atomoxetine	Cap 100 mg
Atomoxetine	Cap 18 mg
Atomoxetine	Cap 25 mg
Atomoxetine	Cap 40 mg
Atomoxetine	Cap 60 mg
Atomoxetine	Cap 80 mg
Azacitidine	Inj 100 mg
Azathioprine	Inj 50 mg
Azathioprine	Tab 25 mg
Azathioprine	Tab 50 mg
Bacillus Calmette-Guérin (BCG) vaccine	Inj containing equal to or greater than 500 million CFU
Baclofen	Inj 2 mg per ml, 5 ml
Cetomacrogol with glycerol	Crm 90% with glycerol 10%, 100 g
Cilazapril	Tab 0.5 mg - 1 mg
Clonazepam	Tab 2 mg
Clonazepam	Tab 500 mcg
Coal tar	Soln BP
Codeine phosphate	Tab 15 mg
Codeine phosphate	Tab 30 mg
Codeine phosphate	Tab 60 mg
Colchicine	Tab 500 mcg
Condom lubricating jelly	<200 ml

Chemical Name	Line Item
Condoms	Female condom
Cytarabine	Inj 1 g
Cytarabine	Inj 2 g
Dimethicone	Lotn 4% head lice suffocant
Dorzolamide hydrochloride	Eye drops 2%
Droperidol	Inj 2.5 mg per ml, 1 ml
Eptifibatide	Inj 0.75 mg per ml, 100 ml
Eptifibatide	Inj 2 mg per ml, 10 ml
Fludarabine phosphate	Inj 50 mg
Hexamine hippurate	Tab 1 g
Ibuprofen	Oral liq 20 mg per ml
Latanoprost with timolol	Eye drops 50 mcg per ml with timolol 0.5%
Levetiracetam	Inj 100 mg per ml, 5 ml
Levetiracetam	Oral liq 100 mg per ml
Levocabastine	Eye drops 0.5 mg per ml
Liquid paraffin with white soft paraffin	Liquid paraffin 50% with white soft paraffin 50% ointment (pack size 100 g or less)
Liquid paraffin with white soft paraffin	Liquid paraffin 50% with white soft paraffin 50% ointment (pack size greater than 100 g)
Mercaptopurine	Tab 50 mg
Mycophenolate mofetil	Cap 250 mg
Mycophenolate mofetil	Tab 500 mg
Nitrofurantoin	Tab 100 mg
Nitrofurantoin	Tab 50 mg
Nitrofurantoin	Tab modified-release 100 mg
Noradrenaline	Inj 1 mg per ml, 4 ml ampoule
Ondansetron	Tab 4 mg
Ondansetron	Tab 8 mg
Pemetrexed	Powder for infusion, 100

Chemical Name	Line Item
	mg
Pemetrexed	Powder for infusion, 500 mg
Piperacillin with tazobactam	Inj 4 g with tazobactam 500 mg
Propranolol	Tab 10 mg
Propranolol	Tab 40 mg
Risedronate sodium	Tab 35 mg
Salbutamol	Oral liq 2 mg per 5 ml
Sodium chloride	Inj 0.9%, 10 ml
Sodium chloride	Inj 0.9%, 20 ml
Sodium chloride	Inj 0.9%, 5 ml
Sodium chloride	Soln 0.9% for irrigation, 30

Chemical Name	Line Item
	ml
Starch	Powder
Sumatriptan	Tab 100 mg
Sumatriptan	Tab 50 mg
Tamsulosin	Tab 400 mcg
Tolcapone	Tab 100 mg
Voriconazole	Inj 200 mg
Water for Injection	Purified for inj, 10 ml
Water for Injection	Purified for inj, 20 ml
Water for Injection	Purified for inj, 5 ml
Zinc and castor oil	Oint BP (pack size greater than 30 g)

Should any unresolved Tender Bids be declined prior to the release of the 2016/17 Tender, PHARMAC would consider re-tendering those pharmaceuticals when the 2016/17 Tender is issued. Unresolved Tender Bids have not been included in the draft pharmaceutical list (Schedule Two).

Products not currently listed in Section B of the Pharmaceutical Schedule

The following products included in Schedule Two of the draft 2016/17 Tender are not currently listed in Section B of the Pharmaceutical Schedule:

Chemical Name	Line Item
Albendazole	Tab 200 mg
Apraclonidine	Eye drops 0.5%
Brimonidine	Gel 0.5%
Cefuroxime	Oral suspension 25 mg per ml
Cefuroxime	Oral suspension 50 mg per ml
Cetrimide	Solution 20% (pack size equal to or less than 100 ml)
Coal tar	Shampoo 4% (pack size equal to or less than 100 ml)
Dexamethasone with tobramycin	Eye drops 0.1% with tobramycin 0.3%
Doxycycline hydrochloride	Tab 20 – 40 mg
Fosfomicin	Powder for oral solution, 3 g sachet
Isotretinoin	Cap 5 mg
Ivermectin	Cream 1%
Lidocaine [lignocaine] hydrochloride with adrenaline and tetracaine hydrochloride	Soln 4% with adrenaline 0.1% and tetracaine hydrochloride 0.5%, 5 ml

Chemical Name	Line Item
Loteprednol etabonate	Eye drops 0.5% (pack size less than or equal to 5 ml)
Macrogol 3350 with potassium chloride, sodium bicarbonate and sodium chloride	Powder for oral soln 6.563 g with potassium chloride 23.3 mg, sodium bicarbonate 89.3 mg and sodium chloride 175.4 mg
Nitrofurantoin	Tab modified-release 50 mg
Pegylated interferon alpha-2b	Inj 100 mcg
Pegylated interferon alpha-2b	Inj 120 mcg
Pegylated interferon alpha-2b	Inj 150 mcg
Pegylated interferon alpha-2b	Inj 50 mcg
Pegylated interferon alpha-2b	Inj 80 mcg
Pegylated interferon alpha-2b with ribavarin	Inj 100 mcg x 4 with ribavarin cap 200 mg x 112
Pegylated interferon alpha-2b with ribavarin	Inj 120 mcg x 4 with ribavarin cap 200 mg x 140
Pegylated interferon alpha-2b with ribavarin	Inj 150 mcg x 4 with ribavarin cap 200 mg x

Chemical Name	Line Item
	168
Pegylated interferon alpha-2b with ribavirin	Inj 50 mcg x 4 with ribavirin cap 200 mg x 112
Pegylated interferon alpha-2b with ribavirin	Inj 80 mcg x 4 with ribavirin cap 200 mg x 168
Pivmecillinam	Tab 200 mg
Pregnancy tests – HCG urine	Dipstick
Pregnancy tests – HCG urine	Midstream
Primidone	Tab 25 mg
Primidone	Tab 50 mg
Ribavirin	Tab 200 mg

Chemical Name	Line Item
Ribavirin	Tab 400 mg
Ribavirin	Tab 600 mg
Rifampicin	Tab 600 mg
Sumatriptan	Nasal spray
Trimipramine maleate	Cap 25 mg
Trimipramine maleate	Cap 50 mg
Zidovudine [AZT]	Inj 10 mg per ml, 20 ml vial
Zinc	Paste (pack size equal to or less than 50 g)
Zolmitriptan	Nasal spray

Electronic Tender (eTender) system

The 2016/17 Tender will be distributed via PHARMAC's new electronic Tendering portal. The new portal requires companies to register for a user account and details of how to register will be distributed prior to the release of the final 2016/17 Invitation to Tender. Please let us know if the contact details for the person responsible for submitting tender bids have changed for your company by sending an email to the tender analysts at tender@pharmac.govt.nz by **5pm, 30 September 2016**.

Alternative Commercial Proposals

PHARMAC seeks any Alternative Commercial Proposals (ACPs) to tendering that you may wish to submit. An ACP may, for example, offer price reductions on one set of pharmaceuticals in return for PHARMAC agreeing to defer tendering on another group of pharmaceuticals for a period.

Please note the following points apply to ACPs for both the community and DHB hospital markets:

- ACPs may include more than one line item and may include pharmaceuticals not listed in Schedule Two of the draft 2016/17 Tender;
- ACPs may seek PHARMAC's agreement to defer tendering or application of reference pricing for a period of time for any pharmaceutical, whether or not it is listed in Schedule Two of the draft 2016/17 Tender;
- ACPs may not propose awarding Sole Subsidised Supply Status in the community or Hospital Supply Status in DHB Hospitals;
- PHARMAC reserves the right:
 - not to accept any ACPs; and/or
 - not to provide reasons for the acceptance or non-acceptance of any ACP; and/or
 - to enter into an agreement or arrangement that differs in a material respect from that envisaged in this letter; and

ACPs are due by **5pm, Monday 29 August 2016**. PHARMAC may not consider any ACPs that are submitted after this date.

Usage data for 'PCT only' injectable products

This year we will be providing 'PCT only' usage data prior to the release of the final 2016/17 Tender (as shown below). These volumes are approximate and indicative only. PHARMAC makes no representation as to the accuracy of these figures or as to the level of sales or likely sales of any tender item.

Chemical	Total usage (mg)*
Calcium folinate	3,047,600
Docetaxel	499,500
Gemcitabine hydrochloride	10,583,300
Paclitaxel	1,588,400

*Usage in mg, for period between 1 January 2015 to 31 December 2015

Changes to PHARMAC's decision making mechanism

The issues PHARMAC considers when it makes decisions is fundamental in order for PHARMAC to meet its statutory objective, so its important suppliers understand the new Factors for Consideration.

All decisions relating to the 2016/2017 Tender will be made under the Factors for Consideration.

More information on the Factors for Consideration can be found on the PHARMAC website:

<http://www.pharmac.health.nz/medicines/how-medicines-are-funded/factors-for-consideration/>

PHARMAC labelling preferences

In June 2016 PHARMAC established and released a document entitled '[PHARMAC labelling preferences for prescription pharmaceuticals](#)'.

The preferences stated in this document aim to provide guidance and transparency on PHARMAC's naming and labelling preferences.

The document addresses the most common naming and labelling issues that PHARMAC encounters, and PHARMAC's preferred approach.

We recommend suppliers familiarise themselves with the preferences stated in this document.