

3 August 2015

2015/16 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 2015/16 Invitation to Tender (2015/16 Tender); and
- Commercial proposals as an alternative to tendering.

PHARMAC welcomes all feedback on the draft 2015/16 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, THURSDAY 27 AUGUST 2015**

**ALL OTHER CONSULTATION RESPONSES DUE BY
5 PM, THURSDAY 3 SEPTEMBER 2015**

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: Laurence Holding: (04) 901 2844
Chloe Dimock: (04) 916 7263

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 2015/16 Tender

In general, the proposed 2015/16 Tender process would be similar to the 2014/15 Tender. In addition to Alternative Commercial Proposals (discussed below), we seek comments on all sections of the draft 2015/16 Tender, in particular on:

- The proposed changes to the 2015/16 Tender;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2015/16 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 2015/16 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 2015/16 Tender. This is still under development and may change before it is taken to the Board 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 2015/16 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 2015/16 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 draft 2015/16 Tender template allows an option for medical devices to be included as part of the tender process for hospital supply, following the amendments made to the 2014/15 Tender. Note this is a template change only.

*The market data for the year ended 30 June 2015 has not yet been finalised and the units provided in Schedule Two currently consist of market data for the year ended 30 June 2014; however, finalised 2015 market data would be included in the final 2015/16 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 2015/16 Tender.

The final list of products, which may change following consultation, would be released as part of the 2015/16 Tender, following Board approval. You may provide feedback on the inclusion of any additional pharmaceuticals after the 2015/16 Tender has been issued, and any such feedback would be considered by the Board (or its Delegate under Delegated Authority) before making a final decision on any product, provided that any feedback is given prior to the tender close date in late 2015.

Proposed inclusion of the following provisions in the 2015/16 Invitation to Tender

Pharmaceutical Price

PHARMAC propose to include provisions in the 2015/16 Invitation to Tender that amend the terms and conditions relating to pharmaceutical price changes in the market.

In summary, PHARMAC propose to amend the price change date for a pharmaceutical that is currently listed and awarded a tender to the following:

- If the pharmaceutical is currently listed on the Schedule, then the price must change from the 12th of the month prior to the start date, and the supplier must provide price support to wholesalers (or other such distributors) to ensure pharmacy can purchase stock at the new price; or
- If the pharmaceutical is currently listed on the Schedule, then the supplier may reduce the price from the 1st of the month prior to the start date instead of price support to wholesalers (or other such distributors) provided there is more than 2 months lead time.

The incumbent supplier must note in its tender bid which of the above price change criteria would apply to its pharmaceutical. If there is no notification provided by a supplier then the price change on the 12th of the month prior to the start date with price support to wholesalers (or other such distributors) would be considered the default position.

If the pharmaceutical has a rebate, PHARMAC may at its option ask suppliers to reduce the price of the pharmaceutical on the 22nd of the month prior to the start date provided the supplier provides price support to wholesalers (or other such distributors) to ensure that pharmacy can purchase stock at the new price.

PHARMAC acknowledge that price support would require wholesalers (or other such distributors) to provide information on stockholding of a pharmaceutical to allow a supplier to provide price support which would include stock on hand of the pharmaceutical on the 12th of the month prior to the start date.

For pharmaceuticals that are not currently listed on the Schedule, the provisions stated in the terms and conditions of the draft 2015/16 Invitation to Tender will apply.

Pharmacode and NZMT numbers

PHARMAC propose to include a provision in the 2015/16 Invitation to Tender relating to the supply of product identification codes used throughout the health sector.

The provision would require that, prior to the listing of a new pharmaceutical, the supplier must provide both the Pharmacode and the New Zealand Medicines Terminology (NZMT) Containered Trade Product Pack (CTPP) number for that pharmaceutical to PHARMAC 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.

Key Dates and Timeframes for the 2015/16 Tender:

The timelines for the 2015/16 Tender are envisaged to be similar to the 2014/15 Tender; we propose to release the final 2015/16 Invitation to Tender in early November 2015 and consequently the closing date for tender submissions would be late December 2015. The proposed timeline is outlined in the following table:

Date	Event
3 August 2015	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft Invitation to Tender.
27 August 2015	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
3 September 2015	Final date for all consultation to be received.
September 2015	PHARMAC considers feedback from consultation, negotiates with suppliers over any ACP proposals it considers would meet PHARMAC's Decision Criteria, and enters into provisional contracts with suppliers where appropriate.
September 2015	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2015	Consultation and decisions on Alternative Commercial Proposals.
Early November 2015	Issuing of the 2015/16 Tender.
17 December 2015	Invitation to Tender closes.
From end of January 2016	Decisions on the first Tender winners announced.

Unresolved Tender Bids

We intend to review any unresolved Tender Bids from the 2013/14 Tender and the 2014/15 Tender prior to issuing the 2015/16 Tender. The following Tender Bids remain unresolved:

2013/14 Invitation to Tender

Chemical Name	Line Item
Aciclovir	Eye oint 3%
Ciprofloxacin	Eye Drops 0.3%
Hyoscine N-butylbromide	Tab 10 mg
Ornidazole	Tab 500 mg
Thiopental [Thiopentone] sodium	Inj 500 mg
Zinc	Crn BP
Zinc	Oint BP

2014/15 Invitation to Tender

Chemical Name	Line Item	Chemical Name	Line Item
Atorvastatin	Tab 10 mg	Atorvastatin	Tab 40 mg
Atorvastatin	Tab 20 mg	Atorvastatin	Tab 80 mg

Chemical Name	Line Item
Atropine sulphate	Inj 600 mcg, 1 ml
Baclofen	Inj 2 mg per ml, 5 ml
Bimatoprost	Eye Drops 0.03%
Bortezomib	Inj 3.5 mg
Brimonidine Tartrate with Timolol Maleate	Eye drops 0.2% with timolol maleate 0.5%
Buspirone hydrochloride	Tab 5 mg
Buspirone hydrochloride	Tab 10 mg
Calcipotriol	Crn 50 mcg per g (pack size 30 g or less)
Calcipotriol	Crn 50 mcg per g (pack size greater than 30 g)
Calcipotriol	Oint 50 mcg per g (pack size 30 g or less)
Calcipotriol	Oint 50 mcg per g (pack size greater than 30 g)
Candesartan with hydrochlorothiazide	Candesartan 8 mg, hydrochlorothiazide 12.5 mg tablet
Candesartan with hydrochlorothiazide	Candesartan 16 mg, hydrochlorothiazide 12.5 mg tablet
Caspofungin	Inj 50 mg
Caspofungin	Inj 70 mg
Celiprolol	Tab 200 mg
Chloramphenicol	Eye oint 1%
Chloramphenicol	Inj 1 g
Clonazepam	Tab 500 mcg
Clonazepam	Tab 2 mg
Clonidine	Inj 150 mcg per ml, 1 ml
Condoms	Latex-free 55 mm or greater (nominal width)
Crisantaspase	Inj 10,000
Dipyridamole	Tab long-acting 150 mg
Domperidone	Tab 10 mg
Eptifibatide	Inj 0.75 mg per ml, 100 ml
Eptifibatide	Inj 2 mg per ml, 10 ml
Famotidine	Tab 20 mg
Fludarabine phosphate	Inj 50 mg
Fondaparinux sodium	Inj 2.5 mg syringe
Granisetron	Inj 1 mg
Hyoscine N-butylbromide	Inj 20 mg, 1 ml
Ketamine	Inj 100 mg per ml, 2 ml vial
Latanoprost with timolol	Eye drops 50 mcg per ml with timolol 0.5%
Lidocaine [Lignocaine] Hydrochloride	Inj 1%, 5 ml
Lidocaine [Lignocaine]	Inj 1%, 20 ml

Chemical Name	Line Item
Hydrochloride	
Lidocaine [Lignocaine] Hydrochloride	Inj 2%, 5 ml
Lidocaine [Lignocaine] Hydrochloride	Inj 2%, 20 ml
Lidocaine [lignocaine] hydrochloride with adrenaline	Inj 2% with adrenaline 1:80,000, 2.2 ml dental cartridge
Metformin Hydrochloride	Tab immediate-release 1 g
Methadone hydrochloride	Inj 10 mg per ml, 1 ml
Midazolam	Inj 1 mg per ml, 5 ml
Midazolam	Inj 5 mg per ml, 3 ml
Milrinone	Inj 1 mg per ml, 10 ml
Mixed salt solution for eye irrigation	Eye irrigation solution calcium chloride 0.048% with magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium acetate 0.17%, 15 ml
Mixed salt solution for eye irrigation	Eye irrigation solution calcium chloride 0.048% with magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium acetate 0.17%, 250 ml
Mixed salt solution for eye irrigation	Eye irrigation solution calcium chloride 0.048% with magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium acetate 0.17%, 500 ml
Naloxone Hydrochloride	Inj 400 mcg per ml, 1 ml
Nitrofurantoin	Tab 50 mg
Nitrofurantoin	Tab 100 mg
Nitrofurantoin	Tab modified release 50 mg
Nitrofurantoin	Tab modified release 100 mg
Oestradiol	TDDS 25 mcg per day
Oestradiol	TDDS 50 mcg per day
Oestradiol	TDDS 75 mcg per day
Oestradiol	TDDS 100 mcg per day
Oxycodone hydrochloride	Inj 10 mg per ml, 1 ml
Oxycodone hydrochloride	Inj 10 mg per ml, 2 ml
Oxycodone hydrochloride	Inj 50 mg per ml
Oxycodone hydrochloride	Tab controlled-release 5 mg

Chemical Name	Line Item
Oxycodone hydrochloride	Tab controlled-release 10 mg
Oxycodone hydrochloride	Tab controlled-release 20 mg
Oxycodone hydrochloride	Tab controlled-release 40 mg
Oxycodone hydrochloride	Tab controlled-release 80 mg
Propranolol	Cap long-acting 160 mg
Pyrazinamide	Tab 500 mg
Tobramycin	Inj 40 mg per ml, 2 ml

Chemical Name	Line Item
Travoprost with timolol	Eye drops 0.004% with timolol 0.5%
Trimethoprim with sulphamethoxazole [Co-trimoxazole]	Tab trimethoprim 80 mg and sulphamethoxazole 400 mg
Urokinase	Inj 10,000 iu
Urokinase	Inj 100,000 iu
Urokinase	Inj 500,000 iu

Should any unresolved Tender Bids be declined prior to the release of the 2015/16 Tender, PHARMAC would consider re-tendering those pharmaceuticals when the 2015/16 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 2015/16 Tender are not currently listed in Section B of the Pharmaceutical Schedule:

Chemical Name	Line Item
Albendazole	Tab 200 mg
Aprepitant	Cap 40 mg
Baclofen	Oral liq
Benzoyl peroxide	Gel 2.5%
Benzoyl peroxide	Gel 5%
Betamethasone valerate with clioquinol	Oint 0.1% with clioquinol 3%
Cephalexin monohydrate	Cap 250 mg
Ciprofloxacin	Ear drops 0.3%
Condoms	Female condom
Dimethicone	Lotn 4% - head lice suffocant
Duloxetine	Cap modified-release 30 mg
Duloxetine	Cap modified-release 60 mg
Glycerol	Suppos 2.55 g
Glycerol	Suppos 1.27 g
Hydrocortisone	Oral liq 1 mg per ml
Hydrocortisone	Tab 1 mg
Hydrocortisone	Oint (pack size greater than 100 g)
Lamivudine	Tab 300 mg
Levetiracetam	Oral liq 100 mg per ml

Chemical Name	Line Item
Levetiracetam	Tab 1 g
Liquid paraffin with white soft paraffin	Liquid paraffin 50% with white soft paraffin 50% ointment (pack size greater than 100 g)
Liquid paraffin with white soft paraffin	Liquid paraffin 50% with white soft paraffin 50% ointment (pack size of 100 g or less)
Lymecycline	Cap 300 mg
Malathion	Crn 1%
Malathion	Lotn 0.5%
Medical lubricating jelly	<200 ml
Methadone hydrochloride	Tab 10 – 20 mg
Metoclopramide hydrochloride	Oral liq 5 mg per 5 ml
Minoxidil	Tab 2.5 mg
Minoxidil	Tab 5 mg
Mupirocin	Nasal oint 2% (pack size 5 g or less)
Natamycin	Eye drops 5%
Nitrofurantoin	Oral liq
Pyridostigmine bromide	Tab modified-release 180 mg
Starch	Powder
Sumatriptan	Nasal spray
Tetracaine [amethocaine]	Gel 4%

Chemical Name	Line Item
hydrochloride	
Trimethoprim	Oral liq
Trimethoprim	Tab 100 mg

Chemical Name	Line Item
Trimipramine maleate	Cap 25 mg
Trimipramine maleate	Cap 50 mg

Electronic Tender (eTender) system

The 2015/16 Tender will be distributed via PHARMAC's eTender system. Please let us know by **5pm, 30 September 2015** if the contact details for the person responsible for submitting tender bids have changed for your company or if you would like to register your company to use the eTender system.

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 2015/16 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 2015/16 Tender;
- ACPs may propose PHARMAC awarding Hospital Supply Status for Hospital Pharmaceuticals included in Schedule Two but not for Hospital Pharmaceuticals that do not appear in Schedule Two;
- ACPs may not propose awarding Sole Subsidised Supply Status in the community;
- 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, Thursday 27 August 2015**. 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 2015/16 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)*
Azacitidine	43,000

Dacarbazine	890,000
Liposomal daunorubicin	Not currently listed
Mesna	5,900,000
Pegylated liposomal doxorubicin	Not currently listed
Pemetrexed	Not currently listed
Topotecan	Not currently listed
*Usage in mg, for period between 1 January 2014 to 31 December 2014	

Ambrisentan, Filgrastim, and Levetiracetam

Due to the nature of these chemicals, longer transition times may apply to ambrisentan 5 mg and 10 mg tablets, filgrastim 300 mcg per ml, and 480 mcg per ml, 0.5 ml prefilled syringes, and 300 mcg per ml, 1 ml vials, and levetiracetam 250 mg, 500 mg, and 750 mg tablets.

Changes to PHARMAC's decision making mechanism

PHARMAC is changing the way it makes decisions. Currently, PHARMAC uses Decision Criteria to identify pharmaceuticals which best help it achieve PHARMAC's Statutory Objective:

“to secure for eligible people in need of pharmaceuticals, the best health outcomes that are reasonably achievable from pharmaceutical treatment within the funding provided”

PHARMAC has made a decision to move away from the Decision Criteria to 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/>

The issues PHARMAC considers when it makes decisions is fundamental to PHARMAC's work, so it's important suppliers understand what the new Factors for Consideration are, and how the change is going to occur. PHARMAC has intentionally not specified a 'go live' date, in order to be confident of effective implementation. However, PHARMAC anticipates this change may mean that some decisions relating to the 2015/2016 Tender may be made under the Decision Criteria and others will be made under the Factors for Consideration.

At the time of the release of the draft 2015/2016 Tender, PHARMAC anticipates that further information will be available relating to the timing of the transition and the effect that this change may have on the 2015/2016 Tender and PHARMAC will keep suppliers informed in this respect.