

3 August 2017

2017/18 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 2017/18 Invitation to Tender (2017/18 Tender); and
- Commercial proposals as an alternative to tendering.

PHARMAC welcomes all feedback on the draft 2017/18 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 28 AUGUST 2017**

**ALL OTHER CONSULTATION RESPONSES DUE BY
5 PM, FRIDAY 1 SEPTEMBER 2017**

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
Laura Baker: (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 2017/18 Tender

In general, the proposed 2017/18 Tender process would be similar to the 2016/17 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 2017/18 Tender;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2017/18 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 2017/18 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 2017/18 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 2017/18 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 2017/18 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
- Schedule 7: Additional special terms for particular pharmaceuticals

*The market data for the year ended 30 June 2017 has not yet been finalised and the units provided in Schedule Two currently consist of market data for the year ended 30 June 2016; however, finalised

2017 market data would be included in the final 2017/18 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 2017/18 Tender.

The final list of products, which may change following consultation, would be released as part of the 2017/18 Tender, following Board (or its Delegate) approval. You may provide feedback on the inclusion of any additional pharmaceuticals after the 2017/18 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 2017.

Proposed inclusion of the following provisions in the 2017/18 Invitation to Tender

Matters for evaluation

Further information that will be considered in applying the Factors for Consideration by the Evaluation Committee when evaluating products included in the 2017/18 Tender will include;

- (i) alternative manufacturers of the finished product and active ingredients (if any); and
- (ii) other markets in which you currently supply the Pharmaceutical.

Tender Submission Form

PHARMAC propose to include a provision in the 2017/18 Tender relating to information that must be supplied regarding a Tender Item.

The provision will state that, as well as the existing information required to be submitted in the tender submission form, additional detail and information regarding pharmaceuticals which do not require consent from Medsafe will be required as follows;

- (i) Evidence and justification as to why Consent from Medsafe is not required for the Tender item(s);
- (ii) Confirmation that the Tender Items(s) you are submitting a Tender Bid in respect of meet the relevant standards and/or regulatory requirements for its intended use and details on what those standards and/or regulatory requirements are; and
- (iii) Details on the Tender Item(s) including excipients and shelf life.

In addition, further information regarding other markets in which the pharmaceutical or medical device is currently provided by you, may be included in the tender submission form at the supplier's discretion.

Price Change

PHARMAC propose to include a provision in the 2017/18 Tender that amends the terms and conditions relating to price changes in the event of award of a tender item for sole supply and/or hospital sole supply as follows.

Where your brand of the pharmaceutical is currently listed on the Pharmaceutical Schedule, if the price would result in a price increase for your brand of the pharmaceutical you must supply the pharmaceutical at the new price from the 22nd day of the month prior to the start date, and the pharmaceutical will be subsidised at the new price from the start date (as defined in the 2017/18 Tender).

PCTs

PHARMAC propose to include a provision in the 2017/18 Tender relating to a preference for PCT products that have post-compounding stability data greater than 48 hours.

Stock Reporting

PHARMAC proposes the inclusion of a provision in the 2017/18 Tender relating to a supplier providing reports to PHARMAC on pharmaceutical stock levels upon PHARMAC's request during the sole supply and/or hospital supply status periods.

Additional Special Terms

PHARMAC proposes to include a new schedule in the 2017/18 Tender relating to special terms for the supply of somatropin as follows.

A tenderer who submits a tender bid for somatropin, should note that special terms will also apply to the supply of somatropin. In this respect, successful tenderers shall provide the following resources and related products at no cost:

- The provision of education, training and support Resources to endocrinologists, paediatric endocrinologists, pharmacies and patients in respect of the use of somatropin.
- The Resources shall be provided to all endocrinologists, paediatric endocrinologists, pharmacies and patients in New Zealand or upon request by any relevant party.
- The Resources shall be provided to patients when their prescription is filled and directly to all endocrinologists, paediatric endocrinologists and pharmacies before the commencement of any sole supply period.
- The provision of Related Products for your proposed brand of somatropin for the benefit of patients, in respect of the use of somatropin. The Related Products shall be delivered to the nominated delivery address of the prescribed patient.

For the purposes of this paragraph:

"Resources" shall include but not be limited to the:

- provision of patient training and medical education and support for endocrinologists, paediatric endocrinologists and pharmacies on the use of somatropin devices, including a preference for clinical educators to talk specifically with patients and for an 0800 number to be available for patients to contact with any further queries;
- provision of training materials (DVDs, pamphlets, leaflets, brochures) to new patients; and
- provision of presentations and/or demonstrations on the use of somatropin devices to patients and/or healthcare professionals.

"Related Products", which shall be inclusive of the replacement of any defective Related Product, shall include but not be limited to devices, needles, needle clippers, sharps bins, vials and other products which are required for the safe treatment of your brand of somatropin.

PHARMAC may request tenderers to provide a proposal and evidence of the Resources and Related Products after the submission of a tender bid for somatropin

Key Dates and Timeframes for the 2017/18 Tender:

The timelines for the 2017/18 Tender are envisaged to be similar to the 2016/17 Tender; we propose to release the final 2017/18 Invitation to Tender in early November 2017 and consequently the closing date for tender submissions would be late December 2017. The proposed timeline is outlined in the following table:

Date	Event
3 August 2017	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft Invitation to Tender.
28 August 2017	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
1 September 2017	Final date for all consultation to be received.
September 2017	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 2017	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2017	Consultation and decisions on Alternative Commercial Proposals.
Early November 2017	Issuing of the 2017/18 Tender.
15 December 2017	Invitation to Tender closes.
From end of January 2018	Decisions on the first Tender winners announced.

Unresolved Tender Bids

We intend to review any unresolved Tender Bids from the 2015/16 Tender and the 2016/17 Tender prior to issuing the 2017/18 Tender. The following Tender Bids remain unresolved:

2015/16 Invitation to Tender

Chemical Name	Line Item
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
Clonazepam	Tab 2 mg
Clonazepam	Tab 500 mcg
Cytarabine	Inj 1 g
Cytarabine	Inj 2 g
Pemetrexed	Powder for infusion, 100 mg
Pemetrexed	Powder for infusion, 500 mg
Salbutamol	Oral liq 2 mg per 5 ml
Tamsulosin	Tab 400 mcg

2016/17 Invitation to Tender

Chemical Name	Line Item
Adapalene	Crn 0.1%
Adapalene	Gel 0.1%

Chemical Name	Line Item
Albendazole	Tab 200 mg
Amantadine hydrochloride	Cap 100 mg

Chemical Name	Line Item
Beclomethasone Dipropionate	Metered aqueous nasal spray, 100 mcg per dose
Beclomethasone Dipropionate	Metered aqueous nasal spray, 50 mcg per dose
Benzylpenicillin Sodium [Penicillin G]	Inj 3 g
Brinzolamide	Eye drops 1%
Budesonide	Metered aqueous nasal spray, 100 mcg per dose
Budesonide	Metered aqueous nasal spray, 50 mcg per dose
Bupivacaine hydrochloride with adrenaline	Inj 2.5 mg per ml with adrenaline 1:400,000, 20 ml sterile pack
Bupivacaine hydrochloride with adrenaline	Inj 5 mg per ml with adrenaline 1:200,000, 20 ml sterile pack
Buprenorphine with Naloxone	Tab sublingual 2 mg with naloxone 0.5 mg
Buprenorphine with Naloxone	Tab sublingual 8 mg with naloxone 2 mg
Calcipotriol	Soln 50 mcg per ml (pack size 30 ml or greater)
Calcium folinate	Inj 1g
Calcium folinate	Inj 100 mg
Calcium folinate	Inj 50 mg
Caspofungin	Inj 50 mg
Caspofungin	Inj 70 mg
Cetirizine hydrochloride	Oral liq 1 mg per ml
Cetrimide	Solution 20% (pack size of 100 ml or less)
Chlorhexidine with ethanol	Soln 2% with ethanol 70%, non-staining (pink) 100 ml
Chlorhexidine with ethanol	Soln 2% with ethanol 70%, non-staining pink (pack size less than 50 ml)
Chlorhexidine with ethanol	Soln 2% with ethanol 70%, staining (red) 100 ml
Chlorhexidine with ethanol	Soln 2% with ethanol 70%, staining red (pack size less than 50 ml)
Ciprofloxacin (current access)	Eye drops 0.3%
Ciprofloxacin (widened access)	Eye drops 0.3%

Chemical Name	Line Item
Colestimethate	Inj 150 mg
Ephedrine	Inj 3 mg per ml, 10 ml prefilled syringe
Gemcitabine hydrochloride	Inj 1 g
Gemcitabine hydrochloride	Inj 200 mg
Granisetron	Inj 1 mg per ml
Hyoscine N-buylbromide	Inj 20 mg, 1 ml
Imiquimod	Crm 5%
Lamivudine	Oral liq 5 mg per ml
Lamivudine	Tab 100 mg
Levodopa with Carbidopa	Tab 100 mg with carbidopa 25 mg
Levodopa with Carbidopa	Tab 250 mg with carbidopa 25 mg
Levodopa with Carbidopa	Tab long-acting 200 mg with carbidopa 50 mg
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	Spray – 10 mg dose per spray
Losartan with hydrochlorothiazide	Tab 50 mg with hydrochlorothiazide 12.5 mg
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
Mebeverine hydrochloride	Tab 135 mg
Mercaptopurine	Tab 50 mg
Meropenem	Inj 1 g
Meropenem	Inj 500 mg
Methylphenidate Hydrochloride	Tab immediate-release 10 mg
Methylphenidate Hydrochloride	Tab immediate-release 20 mg
Methylphenidate Hydrochloride	Tab immediate-release 5 mg
Methylphenidate Hydrochloride	Tab sustained-release 20 mg
Metoclopramide hydrochloride	Inj 5 mg per ml, 2 ml ampoule

Chemical Name	Line Item
Minocycline hydrochloride	Cap 100 mg
Minocycline hydrochloride	Tab 50 mg
Moxifloxacin	Tab 400 mg
Nitrofurantoin	Tab 100 mg
Nitrofurantoin	Tab 50 mg
Nitrofurantoin	Tab modified-release 100 mg
Ondansetron	Tab disp 4 mg
Ondansetron	Tab disp 8 mg
Paraffin (current access)	White soft – 500g
Paraffin (widened access)	White soft – 500 g
Pregnancy tests	HCG urine – Pregnancy test – HCG urine – Dipstick
Pregnancy tests	HCG urine – Pregnancy test – HCG urine – Cassette
Pregnancy tests	HCG urine – Pregnancy test – HCG urine – Midstream
Ribavirin	Tab 200 mg

Chemical Name	Line Item
Ribavirin	Tab 400 mg
Ribavirin	Tab 600 mg
Tamoxifen citrate	Tab 10 mg
Tamoxifen citrate	Tab 20 mg
Tenoxicam	Inj 20 mg
Tetracaine [amethocaine] hydrochloride	Gel 4%
Thiamine hydrochloride	Tab 50 mg
Tigecycline	Inj 50 mg
Trimethoprim with sulphamethoxazole [Co-trimoxazole]	Inj 16 with sulphamethoxazole 80 mg per ml, 5 ml
Zinc	Paste (pack size 50 g or less)
Zinc and castor Oil	Oint 5% or less (pack size greater than 30 g)
Zinc and castor Oil	Oint BP (pack size greater than 30 g)
Zinc sulphate	Cap 50 g elemental
Zolmitriptan	Nasal Spray

Should any unresolved Tender Bids be declined prior to the release of the 2017/18 Tender, PHARMAC would consider re-tendering those pharmaceuticals when the 2017/18 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 2017/18 Tender are not currently listed in Section B of the Pharmaceutical Schedule:

Chemical Name	Line Item
Alpha Tocopheryl Acetate	Oral liq 156 u per ml
Asenapine	10 mg sublingual wafer
Asenapine	5 mg sublingual wafer
Baclofen	Oral liq
Eplerenone	Tab 25 mg
Eplerenone	Tab 50 mg
Ferrous Gluconate with Ascorbic Acid	Tab 170 mg with ascorbic acid 40 mg
Ferrous Sulphate with Ascorbic Acid	Tab long-acting 325 mg (105 mg elemental) with ascorbic acid 500 mg
Fexofenadine	Tab 180 mg
Fosfomycin	Powder for oral solution, 3 g sachet

Chemical Name	Line Item
Furosemide	Tab 20 mg
Glucose [Dextrose]	Gel 40%
Glucose [Dextrose]	Tab 1.5 g
Glucose [Dextrose]	Tab 3.1 g
Glucose [Dextrose]	Tab 4 g
Hydrocortisone	Oint 1% (pack size 100 g or less)
Hydrocortisone	Oint 1% (pack size greater than 100 g)
Hydrogen Peroxide	Crn 2%
Indomethacin	Inj 1 mg
Indomethacin	Cap 25 mg
Indomethacin	Cap 50 mg
Indomethacin	Cap long-acting 75 mg
Indomethacin	Suppos 100 mg

Chemical Name	Line Item
Isotretinoin	Cap 5 mg
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)
Macrogol 3350	Powder for oral soln
Metformin Hydrochloride	Tab immediate-release 1 g
Oil in Water Emulsion (pack size 100 g or	Crn

Chemical Name	Line Item
less)	
Potassium citrate	Tab 99 mg
Ramipril	Cap 1.25 mg
Ramipril	Cap 2.5 mg
Ramipril	Cap 5 mg
Ramipril	Cap 10 mg
Somatropin	Inj 0.05 mg per ml – 2.5 mg per ml, including overage
Zidovudine [AZT]	Inj 10 mg per ml, 20 ml vial
Zopiclone	Tab 3.75 mg

Electronic Tender (eTender) system

The 2017/18 Tender will be distributed via PHARMAC's electronic tendering portal. The 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 2017/18 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, 29 September 2017**.

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 2017/18 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 2017/18 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.

ACPs are due by **5pm, Monday 28 August 2017**. 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 2017/18 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	456,072
Bleomycin Sulphate	11,364,795,800 **
Calcium Folate	3,241,932
Carboplatin	3,330,505
Carmustine	2,746,622
Cisplatin	368,760
Cyclophosphamide	10,707,600
Doxorubicin Hydrochloride	493,800
Epirubicin	262,362
Fluorouracil sodium	39,202,900
Idarubicin Hydrochloride	4,072
Irinotecan	1,168,805
Mitozantrone	5,340
Oxaliplatin	998,351
Paclitaxel	1,526,710
Vinorelbine	117,450
*Usage in mg, for period between 1 January 2016 to 31 December 2016	
** Usage shown in IU (international units)	