

3 August 2018

2018/19 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 2018/19 Invitation to Tender (2018/19 Tender); and
- Commercial proposals as an alternative to tendering.

PHARMAC welcomes all feedback on the draft 2018/19 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 27 AUGUST 2018**

**ALL OTHER CONSULTATION RESPONSES DUE BY
5 PM, THURSDAY 6 SEPTEMBER 2018**

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: Heather Milne (04) 830 2658

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 2018/19 Tender

In general, the proposed 2018/19 Tender process would be similar to the 2017/18 Tender. In addition to Alternative Commercial Proposals (discussed below), we seek comments on all sections of the draft 2018/19 Tender, in particular on:

- The proposed changes to the 2018/19 Tender;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2018/19 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 2018/19 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 2018/19 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 2018/19 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 2018/19 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 Supply and/or Hospital Supply Status
- Schedule 5: Additional contract terms for Sole Supply Status
- Schedule 6: Additional contract terms for Hospital Supply Status
- Schedule 7: Additional special terms for particular pharmaceuticals

*The units provided in Schedule Two consist of market data for the year ended 30 June 2018. The figures included are indicative only and are provided on the basis set out in clause 1.3 of Schedule 2 of the draft 2018/19 Tender.

The final list of products, which may change following consultation, would be released as part of the 2018/19 Tender, following Board (or its Delegate) approval. You may provide feedback on the

inclusion of any additional pharmaceuticals after the 2018/19 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 2018.

Proposed inclusion of the following provisions in the 2018/19 Invitation to Tender

Proposal to modify the transition between funded brands in the Schedule

On 13 July 2018 PHARMAC released a consultation to seek feedback on the proposal to modify the transition between funded brands in the Schedule. The proposal is to remove the reference pricing period during brand changes and would result in the alignment of transition arrangements in the community and DHB hospitals by increasing the transition time in DHB hospitals to five months.

The consultation is available on our website (www.pharmac.govt.nz/news/consultation-2018-07-13-brand-transition) and closes at **5 pm on Friday, 10 August 2018**. Feedback can be emailed to Heather Milne at heather.milne@pharmac.govt.nz.

If the proposal was to be accepted it would result in changes to Schedule Three and Five in the 2018/19 Tender. Briefly it would result in the Second Transition Period being removed from the 2018/19 Tender which would result in the following changes;

- the Sole Supply Period would be modified to state that it relates to the period beginning on the day after the expiry of the First Transition Period and ending on 30 June 2022.
- the transition period in relation to community supply would be changed from three transition periods to two transition periods, this is the same as the current transition period for hospital supply.
- the subsidy payable for all other brands of the pharmaceutical will remain until the Sole Supply Period begins, this contrasts with the current process which decreases the subsidy to the price of the incoming brand on the first day of the Second Transition Period until the first day of the Sole Supply Period.

Additional Special Terms

PHARMAC proposes to include a new schedule in the 2018/19 Tender relating to special terms for the supply of intra-uterine copper device as follows.

You shall provide the following information when submitting a Tender Bid for the Pharmaceutical intra-uterine copper device ("IUCD Tender Item"):

- the size of the IUCD Tender Item, including length and width measurements as well as the diameter of the inserter;
- a description of the material the inserter is made of;
- the duration of the therapeutic effect of the IUCD Tender Item; and
- the metals which are contained in the IUCD Tender Item.

You shall provide the following Resources at no cost for the IUCD Tender Item:

- the provision of education, training and support to healthcare professionals in respect of the use of the IUCD Tender Item.

For the purposes of this clause "Resources" shall include but not be limited to the:

- provision of training materials (DVDs, pamphlets, leaflets, brochures) to healthcare professionals;
- provision of an information sheet explaining the differences between the current brand of intra-uterine device and your IUCD Tender Item; and
- provision of presentations and/or demonstrations on the use of your IUCD Tender Item to patients and/or healthcare professionals.

Key Dates and Timeframes for the 2018/19 Tender:

The timelines for the 2018/19 Tender are envisaged to be similar to the 2017/18 Tender; we propose to release the final 2018/19 Invitation to Tender in early November 2018 and consequently the closing date for tender submissions would be late December 2018. The proposed timeline is outlined in the following table:

Date	Event
3 August 2018	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft 2018/19 Tender.
27 August 2018	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
6 September 2018	Final date for all consultation to be received.
September 2018	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 2018	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2018	Consultation and decisions on Alternative Commercial Proposals.
Early November 2018	Issuing of the 2018/19 Tender.
14 December 2018	Invitation to Tender closes.
From end of January 2019	Decisions on the first Tender winners announced.

Unresolved Tender Bids

We intend to review any unresolved Tender Bids from the 2016/17 Tender and the 2017/18 Tender prior to issuing the 2018/19 Tender. The following Tender Bids remain unresolved:

2016/17 Invitation to Tender

Chemical Name	Line Item
Amantadine hydrochloride	Cap 100 mg
Benzylpenicillin sodium [Penicillin G]	Inj 3 g
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

Chemical Name	Line Item
Buprenorphine with naloxone	Tab sublingual 2 mg with naloxone 0.5 mg
Buprenorphine with naloxone	Tab sublingual 8 mg with naloxone 2 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

Chemical Name	Line Item
	(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)
Ephedrine	Inj 3 mg per ml, 10 ml prefilled syringe
Hyoscine N-butylbromide	Inj 20 mg, 1 ml

Chemical Name	Line Item
Iodine supplement	Tab 150 mcg elemental
Mebeverine hydrochloride	Tab 135 mg
Mercaptopurine	Tab 50 mg
Metoclopramide hydrochloride	Inj 5 mg per ml, 2 ml ampoule
Tenoxicam	Inj 20 mg
Trimethoprim with sulphamethoxazole [Co-trimoxazole]	Inj 16 mg with sulphamethoxazole 80 mg per ml, 5 ml
Zinc	Paste (pack size 50 g or less)

2017/18 Invitation to Tender

Chemical Name	Line Item
Ambrisentan (current access)	Tab 10 mg
Ambrisentan (current access)	Tab 5 mg
Ambrisentan (widened access)	Tab 10 mg
Ambrisentan (widened access)	Tab 5 mg
Amoxicillin clavulanate	Grans for oral liq amoxicillin 400 mg with potassium clavulanate 57 mg per 5 ml
Baclofen	Inj 0.05 mg per ml, 1 ml
Baclofen	Inj 2 mg per ml, 5 ml
Benzoyl peroxide	Soln/Gel 5%
Budesonide (current access)	Cap 3 mg modified release
Budesonide (widened access)	Cap 3 mg modified release
Bumetanide	Tab 1 mg
Bupivacaine hydrochloride	Inj 0.25%, 20 ml sterile pack
Bupivacaine hydrochloride	Inj 0.5%, 10 ml sterile pack
Bupivacaine hydrochloride	Inj 0.5%, 20 ml sterile pack
Calamine	Lotn, BP
Carboplatin	Inj 10 mg per ml, 15 ml
Carboplatin	Inj 10 mg per ml, 45 ml
Chloramphenicol	Inj 1 g
Chlorhexidine gluconate	Crn 1% obstetric

Chemical Name	Line Item
Chlorhexidine gluconate	Lotn 1% obstetric
Chlorhexidine gluconate	Mouthwash 0.2%
Chlorhexidine gluconate	Soln 4%
Colchicine	Tab 500 mcg
Daptomycin	Inj 350 mg- 500 mg
Diclofenac sodium	Eye drops 0.1%
Dorzolamide hydrochloride	Eye drops 2%
Doxorubicin	Inj 200 mg
Efavirenz	Tab 50 mg
Efavirenz	Tab 200 mg
Efavirenz	Tab 600 mg
Epirubicin	Inj 2 mg per ml, 100 ml
Febuxostat	Tab 80 mg
Febuxostat	Tab 120 mg
Ferrous fumarate	Tab 200 mg
Ferrous sulphate with ascorbic acid	Tab long-acting 325 mg (105 mg elemental) with ascorbic acid 500 mg
Filgrastim	Inj 120 mg per ml, 0.5 ml prefilled syringe
Filgrastim	Inj 300 mcg per ml, 0.5 ml prefilled syringe
Filgrastim	Inj 480 mcg per ml, 0.5 ml prefilled syringe
Furosemide	Tab 40 mg
Fusidic acid	Crn 2%
Fusidic acid	Oint 2%

Chemical Name	Line Item
Hydrocortisone butyrate	Lipocream 0.1% (pack size greater than 30 g)
Hydrogen peroxide	Crn 1%
Hydrogen peroxide	Soln 3% (10 vol)
Ibuprofen	Tab long-acting 800 mg
Imipenem with cilastatin	Inj 500 mg with cilastatin 500 mg
Irinotecan	Inj 20 mg per ml, 2 ml
Irinotecan	Inj 20 mg per ml, 5 ml
Lidocaine [lignocaine] hydrochloride with adrenaline	Inj 2% with adrenaline 1:80,000, 2.2 ml dental cartridge
Linezolid	Inj 2 mg per ml, 300 ml
Metaraminol tartrate	Inj 0.5 per ml, 20 ml prefilled syringe
Metaraminol tartrate	Inj 1 mg per ml, 1 ml
Metaraminol tartrate	Inj 1 mg per ml, 10 ml prefilled syringe
Metaraminol tartrate	Inj 10 mg per ml 1 ml
Methadone hydrochloride	Tab 5 mg
Methotrexate	Inj 7.5 mg prefilled syringe
Methotrexate	Inj 10 mg prefilled syringe
Methotrexate	Inj 15 mg prefilled syringe
Methotrexate	Inj 20 mg prefilled syringe
Methotrexate	Inj 25 mg prefilled syringe
Methotrexate	Inj 30 mg prefilled syringe
Midodrine	Tab 2.5 mg
Midodrine	Tab 5 mg
Mitozantrone	Inj 2 mg per ml, 10 ml
Mixed salt solution for eye irrigation	Eye irrigation solution calcium chloride 0.048% with

Chemical Name	Line Item
	magnesium chloride 0.03%, potassium chloride 0.075%, sodium acetate 0.39%, sodium chloride 0.64% and sodium acetate 0.17%, 450 ml - 550 ml
Moclobemide	Tab 150 mg
Moclobemide	Tab 300 mg
Nitrofurantoin	Tab 50 mg
Nitrofurantoin	Tab 100 mg
Norethisterone	Tab 5 mg
Oxaliplatin	Inj 50 mg
Oxycodone hydrochloride	Oral liq 1 mg per ml
Pizotifen	Tab 500 mcg
Povidone iodine	Antiseptic soln 10% (pack size 15 ml or less)
Povidone iodine	Antiseptic soln 10% (pack size greater than 100 ml)
Povidone iodine	Antiseptic soln 10% (pack size greater than 15 ml but less than or equal to 100 ml)
Povidone iodine	Oint 10%
Rivastigmine	Patch 4.6 mg per 24 hour
Rivastigmine	Patch 9.5 mg per 24 hour
Teicoplanin	Inj 400 mg
Tobramycin	Solution for inhalation 60 mg per ml, 5 ml
Valganciclovir	Tab 450 mg
Zoledronic acid	Inj 4 mg per 100 ml
Zoledronic acid (current access)	Inj 4 mg per 5 ml
Zoledronic acid (widened access)	Inj 4 mg per 5 ml

Should any unresolved Tender Bids be declined prior to the release of the 2018/19 Tender, PHARMAC would consider re-tendering those pharmaceuticals when the 2018/19 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 2018/19 Tender are not currently listed in Section B of the Pharmaceutical Schedule:

Chemical Name	Line Item
Ascorbic acid	Tab (chewable) 250 mg
Benzydamine hydrochloride	Spray 0.15%
Benzydamine hydrochloride	Spray 0.3%
Candesartan cilexetil with hydrochlorothiazide	Tab 16 mg with hydrochlorothiazide 12.5 mg
Candesartan cilexetil with hydrochlorothiazide	Tab 32 mg with hydrochlorothiazide 12.5 mg
Candesartan cilexetil with hydrochlorothiazide	Tab 32 mg with hydrochlorothiazide 25 mg
Cefalexin monohydrate	Cap 250 mg
Docusate sodium	Ear drops 0.5%
Lidocaine [Lignocaine] hydrochloride	Inj 2%, 5 ml, sterile pack

Chemical Name	Line Item
Lidocaine [Lignocaine] hydrochloride	Inj 1%, 5 ml, sterile pack
Macrogol 3350	Powder for oral soln
Methylprednisolone Acetate with Lignocaine	Inj 40 mg per ml with lignocaine 2 ml
Metoclopramide hydrochloride	Oral liq 5 mg per 5 ml
Nitrofurantoin	Modified-release 100 mg
Pimozide	Tab 2 mg or less
Pimozide	Tab 4 mg or more
Pivmecillinam	Tab 200 mg
Primidone	Tab 25 mg
Primidone	Tab 50 mg

Electronic Tender (eTender) system

The 2018/19 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 2018/19 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, 28 September 2018**.

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 2018/19 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 2018/19 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 27 August 2018**. 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 2018/19 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)*
Bendamustine	137,897
Bortezomib	24,938
Busulfan	60
Calcium folinate	3,804,695
Dacarbazine	65,485,756
Doxorubicin	462,934
Etoposide	1,196,534
Fludarabine phosphate	708,935
Fluorouracil sodium	44,671,283
Gemcitabine hydrochloride	9,758,248
Mesna	5,915,174
Methotrexate	5,688,348
Mitomycin	7,229
Pemetrexed	96,220
Vincristine sulphate	10,486
*Usage in mg, for period between 1 January 2017 to 31 December 2017	