

2 August 2019

2019/20 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 2019/20 Invitation to Tender (2019/20 Tender); and
- Commercial proposals as an alternative to tendering.

PHARMAC welcomes all feedback on the draft 2019/20 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 26 AUGUST 2019**

**ALL OTHER CONSULTATION RESPONSES DUE BY
5 PM, FRIDAY 30 AUGUST 2019**

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: Emma Clarke (04) 830 1987
Nerissa Ramlall (04) 830 3824

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 2019/20 Tender

In general, the proposed 2019/20 Tender process would be similar to the 2018/19 Tender. In addition to Alternative Commercial Proposals (discussed below), we seek comments on all sections of the draft 2019/20 Tender, in particular on:

- The proposed changes in the draft 2019/20 Tender;
- An indication of any pharmaceuticals, whether or not they are included in Schedule Two of the draft 2019/20 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 2019/20 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 2019/20 Tender being issued.

Draft Invitation to Tender

We are seeking feedback on the composition of the draft 2019/20 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 2019/20 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 2019/20 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 bids)
- 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 2019. The figures included are indicative only and are provided on the basis set out in clause 1.3 of Schedule 2 of the draft 2019/20 Tender.

The final list of products, which may change following consultation, would be released as part of the 2019/20 Tender, following Board (or its Delegate) approval. You may provide feedback on the inclusion of any additional pharmaceuticals after the 2019/20 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 2019.

Proposed inclusion of the following provisions in the 2019/20 Invitation to Tender

Supplier Code of Conduct

The New Zealand Government is committed to sustainable and inclusive government procurement and the Supplier Code of Conduct outlines the Government's expectations of suppliers in this respect.

PHARMAC expects suppliers to meet or exceed the minimum standards set out in the Supplier Code of Conduct and a provision has been included in Schedule 4 of the draft 2019/20 Tender as follows:

"You shall comply with the New Zealand Government's Supplier Code of Conduct (see <https://www.procurement.govt.nz/assets/procurement-property/documents/supplier-code-of-conduct.pdf>)".

Additional Special Terms

PHARMAC proposes to include additional special terms in Schedule 7 of the 2019/20 Tender for the supply of lacosamide as follows.

In respect of the identified Tender Items in Schedule 2 (lacosamide (current access) tab 50 mg, 100 mg, 150 mg and/or 200 mg or lacosamide (widened access) tab 50 mg, 100 mg, 150 mg and/or 200 mg) ("Lacosamide Tender Items") and notwithstanding any other provision in this Agreement concerning the Sole Supply Status of the Lacosamide Tender Items, and without limiting any other actions that it may be necessary or appropriate for PHARMAC to take in response to patient safety concerns, PHARMAC may grant subsidised access, on a strictly limited basis, to an alternative brand of the relevant Lacosamide Tender Items during the Sole Supply Period to the extent that this is necessary to enable a limited number of patients to continue treatment following adverse effects or efficacy concerns in their treatment with the relevant Lacosamide Tender Items, in accordance with the following condition:

The maximum number of patients who are treated with the alternative brand of Lacosamide Tender Items shall not exceed 30 patients per calendar year, unless otherwise agreed, during the Sole Supply Period.

For the avoidance of doubt, this clause does not apply to the lacosamide (current access) inj 10 mg per ml, 20 ml Tender Item.

Key Dates and Timeframes for the 2019/20 Tender:

The timelines for the 2019/20 Tender are envisaged to be similar to the 2018/19 Tender; we propose to release the final 2019/20 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
2 August 2019	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft 2019/20 Tender.
26 August 2019	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
30 August 2019	Final date for all consultation to be received.
September 2019	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 2019	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2019	Consultation and decisions on Alternative Commercial Proposals.
Early November 2019	Issuing of the 2019/20 Tender.
13 December 2019	Invitation to Tender closes.
From end of January 2020	Announcements on Tender decisions will commence.

Unresolved Tender Bids

We intend to review any unresolved Tender Bids from the 2017/18 Tender and the 2018/19 Tender prior to issuing the 2019/20 Tender. The following Tender Bids remain unresolved:

2017/18 Invitation to Tender

Chemical Name	Line Item
Amoxicillin clavulanate	Grans for oral liq amoxicillin 400 mg with potassium clavulanate 57 mg per 5 ml
Bumetanide	Tab 1 mg
Chlorhexidine gluconate	Mouthwash 0.2%
Colchicine	Tab 500 mcg
Diclofenac sodium	Eye drops 0.1%
Dorzolamide hydrochloride	Eye drops 2%
Ibuprofen	Tab long-acting 800 mg
Lidocaine [lignocaine] hydrochloride with adrenaline	Inj 2% with adrenaline 1:80,000, 2.2 ml dental cartridge
Methotrexate	Inj 7.5 mg prefilled syringe
Methotrexate	Inj 10 mg prefilled syringe
Methotrexate	Inj 15 mg prefilled syringe

Chemical Name	Line Item
Methotrexate	Inj 20 mg prefilled syringe
Methotrexate	Inj 25 mg prefilled syringe
Methotrexate	Inj 30 mg prefilled syringe
Midodrine	Tab 2.5 mg
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
Norethisterone	Tab 5 mg
Oxycodone hydrochloride	Oral liq 1 mg per ml

Chemical Name	Line Item
Tobramycin	Solution for inhalation 60 mg per ml, 5 ml

Chemical Name	Line Item
Zoledronic acid	Inj 4 mg per 100 ml

2018/19 Invitation to Tender

Chemical Name	Line Item
Aciclovir	Eye oint 3%
Adapalene	Crn 0.1%
Adapalene	Gel 0.1%
Adenosine	Inj 3 mg per ml, 10 ml
Amoxicillin clavulanate	Grans for oral liq amoxicillin 125 mg with potassium clavulanate 31.25 mg per 5 ml
Amoxicillin clavulanate	Grans for oral liq amoxicillin 250 mg with potassium clavulanate 62.5 mg per 5 ml
Amoxicillin clavulanate	Inj 500 mg with clavulanic acid 100 mg
Amoxicillin clavulanate	Inj 1000 mg with clavulanic acid 200 mg
Anagrelide hydrochloride	Cap 0.5 mg
Beclomethasone Dipropionate	Metered aqueous nasal spray, 50 mcg per dose
Beclomethasone Dipropionate	Metered aqueous nasal spray, 100 mcg per dose
Bendamustine	Inj 25 mg vial
Bendamustine	Inj 100 mg vial
Bortezomib	Inj 3.5 mg
Brinzolamide	Eye drops 1%
Bupivacaine hydrochloride with fentanyl	Inj 1.25mg with 2 mcg fentanyl per ml, 15 ml syringe
Bupivacaine hydrochloride with fentanyl	Inj 1.25mg with 2 mcg fentanyl per ml, 20 ml syringe
Bupivacaine hydrochloride with fentanyl	Inj 0.625 mg with fentanyl 2 mcg per ml, 200 ml bag
Bupivacaine hydrochloride with glucose	Inj 0.5% with glucose 8%, 4 ml ampoule
Calcium folinate	Inj 50 mg
Calcium folinate	Inj 1 g

Chemical Name	Line Item
Capecitabine	Tab 500 mg
Capecitabine	Tab 150 mg
Captopril	Oral liq 5 mg per ml
Cefalexin monohydrate	Cap 500 mg
Chloramphenicol	Eye oint 1%
Cyclizine lactate	Inj 50 mg per ml, 1 ml
Dapsone	Tab 100 mg
Dapsone	Tab 25 mg
Doxorubicin	Inj 50 mg
Enalapril	Tab 5 mg
Enalapril	Tab 10 mg
Enalapril	Tab 20 mg
Ethambutol hydrochloride	Tab 100 mg
Ethambutol hydrochloride	Tab 400 mg
Fentanyl	inj 10 mcg per ml, 50 ml prefilled syringe
Fentanyl	inj 10 mcg per ml, 10 ml syringe
Fentanyl	inj 20 mcg per ml, 100 ml bag
Fluorouracil sodium	Inj 50 mg per ml, 50 ml
Ganciclovir	Inj 500 mg
Hydrocortisone	Inj 50 mg per ml, 2 ml
Hydrocortisone	Crn 1% (pack size greater than or equal to 15 g and less than or equal to 100 g)
Hydrocortisone	Crn 1% (pack size greater than 100 g)
Iron sucrose	Inj 20 mg per ml, 5 ml ampoule
Levonorgestrel	0.75 mg - 1.5 mg
Levosimendan	Inj 2.5 mg per ml, 5 ml
Lidocaine [Ligocaine] hydrochloride with chlorhexidine	Gel 2% with 0.05% chlorhexidine, 10 ml urethral syringe
Loperamide hydrochloride [split market]	Tab 2 mg
Loratadine	Oral liq 1 mg per ml
Macrogol 3350 with ascorbic acid, potassium chloride and sodium	Powder for oral soln 755.68 mg with

Chemical Name	Line Item
chloride	ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 210 g sachet
Macrogol 3350 with ascorbic acid, potassium chloride and sodium chloride	Powder for oral soln 755.68 mg with ascorbic acid 85.16 mg, potassium chloride 10.55 mg, sodium chloride 37.33 mg and sodium sulphate 80.62 mg per g, 70 g sachet
Methylprednisolone aceponate	Crn 0.1%
Minocycline hydrochloride	Cap 100 mg
Minocycline hydrochloride	Tab 50 mg
Moxifloxacin	Inj 400 mg
Moxifloxacin	Tab 400 mg
Noradrenaline	Inj 0.06 mg per ml, 50 ml syringe
Noradrenaline	Inj 0.12 mg per ml, 100 ml bag
Noradrenaline	Inj 0.16 mg per ml, 50 ml syringe
Octreotide (somatostatin analogue)	LAR 10 mg pre-filled syringe
Octreotide (somatostatin analogue)	LAR 20 mg pre-filled syringe
Octreotide (somatostatin analogue)	LAR 30 mg pre-filled syringe
Olopatadine	Eye drops 0.1%
Ornidazole	Tab 500 mg

Chemical Name	Line Item
Pantoprazole	Inj 40 mg
Pegfilgrastim	Inj 6 mg per 0.6 ml prefilled syringe
Pemetrexed	Powder for infusion, 100 mg
Pemetrexed	Powder for infusion, 500 mg
Phenoxymethylpenicillin (Penicillin V)	Grans for oral liq 125 mg per 5 ml
Phenoxymethylpenicillin (Penicillin V)	Grans for oral liq 250 mg per 5 ml
Promethazine hydrochloride	Inj 25 mg per ml, 2 ml
Rocuronium bromide	Inj 10 mg per ml, 5 ml
Sodium chloride	Aqueous nasal spray isotonic
Sodium citrate	Oral liq 8.8% (300 mmol/l)
Sodium nitroprusside	Inj 50 mg
Spironolactone	Tab 25 mg
Spironolactone	Tab 100 mg
Sumatriptan	Inj 12 mg per ml, 0.5 ml
Tamsulosin [Current Access]	Tab 400 mcg
Tamsulosin [Widened Access]	Tab 400 mcg
Tenoxicam	Inj 20 mg
Teriparatide	Inj 250 mcg per ml
Tigecycline	Inj 50 mg
Tolcapone	Tab 100 mg
Urea	Crn 10%
Vitamin B complex (strong)	Tab
Zinc oxide	Powder

Should any unresolved Tender Bids be declined prior to the release of the 2019/20 Tender, PHARMAC would consider re-tendering those pharmaceuticals when the 2019/20 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 2019/20 Tender are not currently listed in Section B of the Pharmaceutical Schedule:

Chemical Name	Line Item
Alprostadil	Inj 10 mcg
Alprostadil	Inj 20 mcg
Amiloride	Tab 5 mg
Benzoyl peroxide	Soln/gel/cream/lotn 5%
Betamethasone	Inj 4 mg per ml, 1 ml
Betamethasone	Tab 500 mcg
Buserelin acetate	In 1 mg per ml, 5.5 ml
Carmellose sodium	Eye drops 0.5%
Carmellose sodium	Eye drops 1%
Ciprofloxacin	Ear drops 0.3%
Clobazam	Liq
Condoms	Female, non-latex
Condoms	Male, non-latex, 55 mm – 58 mm
Fexofenadine	Tab 180 mg
Fulvestrant	Inj 250 mg per ml
Gefitinib	Tab 250 mg
Glucose [Dextrose]	Soln 15 g
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 4 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 6 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 4 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 6 mm needle
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 4 mm needle
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 6 mm needle
Lamivudine	Tab 300 mg
Metaraminol tartrate	Inj 0.5 mg per ml, 10 ml
Metaraminol tartrate	Inj 0.5 mg per ml, 6 ml
Metoclopramide hydrochloride	Oral liq 5 mg per 5 ml
Metronidazole	Gel 0.75%
Mitomycin C	Inj 10 mg – 20 mg
Mupirocin	Intra-nasal oint 2%
Nitazoxanide	Tab 500 mg
Nitrofurantoin	Tab modified-release

Chemical Name	Line Item
Noradrenaline	Inj 0.1 mg per ml, 50 ml syringe
Paliperidone (three-monthly depot injection)	Inj 175 mg syringe
Paliperidone (three-monthly depot injection)	Inj 250 mg – 300 mg syringe
Paliperidone (three-monthly depot injection)	Inj 350 mg syringe
Paliperidone (three-monthly depot injection)	Inj 500 mg or greater syringe
Palonosetron	Inj 250 mcg
Paraffin	Eye oint with soft white paraffin
Perindopril	Tab 8 mg – 10 mg
Pivmecillinam	Tab 200 mg
Potassium citrate	Tab
Pravastatin	Tab 10 mg
Pregnancy tests – HCG urine	Pregnancy tests – HCG urine - Dipstick
Pregnancy tests – HCG urine	Pregnancy tests – HCG urine - Midstream
Rasagiline	Tab 1 mg
Rosuvastatin	Tab 5 mg
Rosuvastatin	Tab 10 mg
Rosuvastatin	Tab 20 mg
Rosuvastatin	Tab 40 mg
Selexipag	Tab 200 mcg
Selexipag	Tab 400 mcg
Selexipag	Tab 600 mcg
Selexipag	Tab 800 mcg
Selexipag	Tab 1000 mcg
Selexipag	Tab 1200 mcg
Selexipag	Tab 1400 mcg
Selexipag	Tab 1600 mcg
Sodium acid phosphate	Enema 16% with sodium phosphate 8%
Sodium alginate with magnesium alginate	Powder for oral soln
Tacrolimus	Oint 0.03%
Tacrolimus	Oint 0.1%
Tadalafil	Tab / cap 2.5 mg
Tadalafil	Tab / cap 5 mg

Chemical Name	Line Item
Tadalafil	Tab / cap 10 mg
Tadalafil	Tab / cap 20 mg
Thiamine hydrochloride	Tab 100 mg
Trimethoprim	Tab 100 mg
Water-based lubricant	Single use sachets, 4 ml/g or larger
Zinc	Crm (pack size 50 g or less)
Zinc	Crm (pack size greater than 50 g)
Zinc	Oint (pack size 50 g or less)
Zinc	Oint (pack size

Chemical Name	Line Item
	greater than 50 g)
Zinc	Paste (pack size 50 g or less)
Zinc and castor oil	Crm (pack size 50 g or less)
Zinc and castor oil	Crm (pack size greater than 50 g)
Zinc and castor oil	Oint (pack size 50 g or less)
Zolmitriptan	Nasal spray
Zopiclone	Tab 3.75 mg
Zuclopenthixol decanoate	Inj 500 mg per ml

Electronic Tender (eTender) system

The 2019/20 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 2019/20 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, 27 September 2019**.

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 2019/20 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 2019/20 Tender;
- ACPs may not propose awarding Sole 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 26 August 2019**. PHARMAC may not consider any ACPs that are submitted after this date.

Usage data for 'PCT only' injectable products

The table below contains 'PCT only' usage data for items included in the 2019/20 Tender. 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 and description	Total usage (mg)*
Calcium folinate – tab 15 mg	9,870,441
Docetaxel	6,828,032
Etoposide	30,697,084
Etoposide phosphate	13,051,754
Hydroxyurea	22,287,281,250
Ketoconazole	6,480,000
Methotrexate	698,018,233
Mitomycin C	79,588
Paclitaxel	17,256,857
Thiotepa	409,249
*Usage in mg, for period between 1 January 2018 to 31 December 2018	