

4 August 2020

## 2020/21 Invitation to Tender

PHARMAC is seeking feedback from medical groups, DHB hospital pharmacies and other interested parties on:

- A proposal to tender certain pharmaceuticals for principal supply;
- The implications of awarding Principal Supply Status; and
- The draft process and terms and conditions for the 2020/21 Invitation to Tender (2020/21 Tender).

PHARMAC welcomes all feedback on the draft 2020/21 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.

### Background

Since 1997 PHARMAC has been using the strategy of tendering pharmaceuticals for sole supply of pharmaceuticals for a fixed period of time. Regular tendering has proven to be an effective way to encourage competition among suppliers of pharmaceuticals. As in the past, the community and hospital tender processes would be run in unison, however, the pharmaceutical list for community and hospital supply may be different.

The Draft 2020/21 Tender proposes awarding Principal Supply Status rather than Sole Supply Status or Hospital Supply Status. In previous tenders, DHB hospitals were able to purchase alternative brands under the *Discretionary Variance* provisions. For this tender, we are proposing to extend this to cover community pharmaceuticals as well. We consider this change will allow PHARMAC to better support healthcare professionals when prescribing medicines for their patients.

We are seeking feedback on the approach outlined in the following pages, in particular on:

- The proposed tender process and timeline;
- The actual or potential clinical implications of awarding PSS to the pharmaceuticals listed in Schedule Two, including the impact of a brand switch on patients and clinical staff;
- Your views on which chemicals included in Schedule Two (or associated medical conditions) might have a particular need for funding of an alternative brand, and what the criteria for funding an alternative brand should be; and
- Your views on whether any product included in Schedule Two might have more than 5% of patients needing to access an alternative brand.

**ALL RESPONSES ARE DUE BY 4 PM (NEW ZEALAND TIME), MONDAY 31 AUGUST 2020**

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

Email: [tender@pharmac.govt.nz](mailto:tender@pharmac.govt.nz)

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

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.

### **Distribution of Consultation Documents**

Although this consultation letter has been widely distributed, should you consider that a particular person, group or agency should receive this letter and/or future tender documents, please feel free to contact PHARMAC or refer it on directly. All tender documents and consultations are also available from the PHARMAC website at [www.pharmac.govt.nz/news/consultation](http://www.pharmac.govt.nz/news/consultation). We also invite any person or group to contact PHARMAC should you wish to meet to discuss the proposals contained in this consultation letter.

### ***Details of the proposed 2020/21 Tender***

In accordance with PHARMAC's objective (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), PHARMAC is consulting on a proposal to tender certain pharmaceuticals for Principal Supply Status (PSS) to community pharmacies and/or DHB hospital pharmacies.

Attached to this letter (as Schedule Two) is a list of pharmaceuticals that we are considering tendering for Principal Supply Status. Pharmaceuticals are sorted into therapeutic groups and then listed alphabetically in each group by chemical, form and strength. Each pharmaceutical has a 'C' and/or 'H' next to it to indicate whether it is proposed to be tendered for community and/or hospital supply.

In general, the proposed 2020/21 Tender process would be similar to previous tenders. However, the 2020/21 Tender would result in awarding Principal Supply Status (PSS), instead of Sole Supply Status and/or Hospital Supply Status. This will provide PHARMAC with greater flexibility to fund alternative brands where clinically indicated. We have outlined the key aspects of Principal Supply Status and our preliminary views on how/when we may utilise the alternative brand allowance.

A copy of the draft 2020/21 Invitation to Tender is available on our website: [www.pharmac.govt.nz](http://www.pharmac.govt.nz), or by contacting PHARMAC.

### **Key Aspects of Principal Supply Status:**

- PSS could be applied across community and/or hospital markets (as detailed in Schedule Two).
- The tender winning brand would be the only brand subsidised in the community and/or purchased by DHB hospitals (subject to any alternative brand allowance) for up to approximately 3 years. The PSS period would conclude on 30 June 2024 for all Tenders awarded from the 2020/21 Tender.
- Other brands could continue to be marketed, sold and dispensed during the PSS period, but they would not necessarily receive a subsidy in the community.
- Any pharmaceutical that currently carries a manufacturer's surcharge in Section B (that is, the additional patient charge above that of the patient co-payment) would become fully subsidised if a tender was awarded for that pharmaceutical.

### **Alternative brands**

- The proposed shift to PSS would enable PHARMAC greater flexibility to fund alternative brands for those who may experience, or are at heightened risk of, adverse clinical outcomes as a result of a brand change. Use of alternative brands under the current tender agreements only exists in relation to DHB hospital purchases.
- DHB hospitals would continue to be able to purchase alternative brands up to a certain percent of volume, as they currently do under the Discretionary Variance provisions of Hospital Supply Status.
- PSS would allow PHARMAC the flexibility to fund alternative brands in the community:
  - In some cases, this would be through listing (or maintaining the listing of) other brands under Special Authority criteria.
  - In others, we would manage case-by-case approvals through our exceptional circumstances framework.
  - Regardless of the mechanism used, we intend to develop and communicate clear clinical criteria for funding of alternative brands.
- Brand changes are generally well-tolerated, and we expect that the need for funding of alternative brands will vary by product and will not always be predictable. With that in mind, we are interested in receiving feedback on:
  - Which chemicals (or indications for a chemical) or patient groups might have particular need for funding of an alternative brand (and why), and
  - For those situations, whether you consider that clinical destabilisation can be objectively determined, and if so, how.
- Our preliminary view is that alternative brand funding might be needed in three different circumstances:
  - If a patient has experienced adverse clinical outcomes as a result of a brand change,

- If a patient has unique clinical circumstances that would put them at heightened risk of adverse clinical outcomes, and wishes to avoid a brand change, or
- If a patient's circumstances mean that they require a temporary delay to the brand switch (e.g. pregnancy or pending surgery).
- We are interested in receiving feedback on what the criteria for those circumstances should be, and whether there are other circumstances that we need to consider as well.
- The draft contractual terms for the 2020/21 tender do not put a cap on the number of patients for whom PHARMAC might fund an alternative brand, however the draft contractual terms include a threshold (indicated by the "ABA Limit" in Schedule Two) at which be reimbursed for lost market share. Accordingly, we are interested to understand if you consider that there are any products that we are proposing to tender where more than 5% of patients might need access an alternative brand.
- Note that although these changes would give PHARMAC the option to fund alternative brands, continued supply of a particular alternative brand is not always able to be guaranteed.

#### **Key Dates and Timeframes for the 2020/21 Tender:**

The proposed timelines for the 2020/21 Tender are as follows:

<b>Date</b>	<b>Event</b>
<b>4 August 2020</b>	Consultation with suppliers, medical groups and interested parties on the proposed pharmaceutical list and draft 2020/21 Tender.
<b>24 August 2020</b>	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
<b>31 August 2020</b>	Final date for all consultation to be received.
<b>September 2020</b>	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.
<b>September 2020</b>	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
<b>September/October 2020</b>	Consultation and decisions on Alternative Commercial Proposals.
<b>Early November 2020</b>	Issuing of the 2020/21 Tender.
<b>17 December 2020</b>	Invitation to Tender closes.
<b>From end of January 2021</b>	Announcements on 2020/21 Tender decisions will commence.

#### **Contractual obligations for suppliers**

A copy of the draft terms and conditions which would form the terms of the 2020/21 Tender contract is available on the PHARMAC website: [www.pharmac.govt.nz](http://www.pharmac.govt.nz).

## Additional Special Terms

Additional Special Terms have been included in the draft 2020/21 Tender contract for somatropin injections. This clause would require any potential suppliers to offer education, training and support resources to patients and healthcare professionals, and related products required for the safe treatment of the supplier's somatropin product (such as associated devices, needles, needle clippers, sharps bins). The full Additional Special Terms for somatropin can be found in the draft 2020/21 Tender contract on the PHARMAC website.

## Unresolved Tender Bids

PHARMAC would review any unresolved Tender Bids from the 2018/19 Tender and the 2019/20 Tender prior to issuing the 2020/21 Tender and may close the tender for some of these tender items and reissue them as part of the 2020/21 Tender. The following Tender Bids remain unresolved and may potentially be added to the 2020/21 Tender following consultation. We are interested in your views as to whether any of these pharmaceuticals would not be appropriate for PSS and, as outlined above, when we may need to consider funding an alternative brand.

### *2018/19 Invitation to Tender*

Chemical Name	Line Item
Aciclovir	Eye oint 3%
Cefalexin monohydrate	Cap 500 mg
Cyclizine lactate	Inj 50 mg per ml, 1 ml
Levonorgestrel	0.75 mg - 1.5 mg
Loperamide hydrochloride [split market]	Tab 2 mg
Loratadine	Oral liq 1 mg per ml
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

Chemical Name	Line Item
	mg and sodium sulphate 80.62 mg per g, 210 g sachet
Minocycline hydrochloride	Tab 50 mg
Sodium nitroprusside	Inj 50 mg
Spironolactone	Tab 25 mg
Spironolactone	Tab 100 mg
Tenoxicam	Inj 20 mg
Teriparatide	Inj 250 mcg per ml
Tigecycline	Inj 50 mg
Vitamin B complex (strong)	Tab

2019/20 Invitation to Tender

Chemical Name	Line Item
Acetazolamide	Tab 250 mg
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
Brimonidine Tartrate with Timolol Maleate	Eye drops 0.2% with timolol maleate 0.5%
Bupivacaine hydrochloride	Inj 2.5 mg per ml, 20 ml ampoule
Carbimazole	Tab 5 mg
Carmellose sodium	Eye drops 1%
Clobazam	Liq
Clotrimazole	Crn 1%
Colistin Sulphomethate	Inj 150 mg
Condoms	Female, non-latex
Condoms	Male 55 mm - 58 mm, non-latex
Disulfiram	Tab 200 mg
Docetaxel	Inj 20 mg
Docetaxel	Inj 80 mg
Ephedrine	Inj 3 mg per ml, 10 ml prefilled syringe
Erlotinib hydrochloride	Tab 100 mg
Erlotinib hydrochloride	Tab 150 mg
Escitalopram	Tab 10 mg
Escitalopram	Tab 20 mg
Ethinylestradiol with levonorgestrel	Tab 30 mcg with levonorgestrel 150 mcg
Ethinylestradiol with levonorgestrel	Tab 20 mcg with levonorgestrel 100 mcg
Exemestane	Tab 25 mg
Febuxostat	Tab 80 mg
Febuxostat	Tab 120 mg
Fludrocortisone Acetate	Tab 100 mcg
Glucose [Dextrose]	Solution 15 g
Glyceryl trinitrate	Inj 5 mg per ml, 10 ml ampoule
Hydrocortisone	Powder

Chemical Name	Line Item
Insulin pen needles	29 g x 12.7 mm
Insulin pen needles	31 g x 8 mm
Insulin pen needles	31 g x 5 mm
Insulin pen needles	31 g x 6 mm
Insulin pen needles	32 g x 4 mm
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 29 g x 12.7 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 29 g x 12.7 mm needle
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 12.7 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.3 ml with 31 g x 8 mm needle
Insulin syringes, disposable with attached needle	Syringe 0.5 ml with 31 g x 8 mm needle
Insulin syringes, disposable with attached needle	Syringe 1 ml with 31 g x 8 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 6 mm needle
Insulin syringes, disposable with attached needle	Syringe 1 ml with 29 g x 6 mm needle
Irbesartan	Tab/Cap 75 mg
Irbesartan	Tab/Cap 150 mg
Irbesartan	Tab/Cap 300 mg
Irbesartan with hydrochlorothiazide	Tab/Cap 150 mg with hydrochlorothiazide 12.5 mg
Irbesartan with hydrochlorothiazide	Tab/Cap 300 mg with hydrochlorothiazide 12.5 mg
Irbesartan with hydrochlorothiazide	Tab/Cap 300 mg with hydrochlorothiazide 25 mg
Ivabradine (current access)	Tab 5 mg
Ivabradine (current access)	Tab 7.5 mg
Ivabradine (widened access)	Tab 5 mg
Ivabradine (widened access)	Tab 7.5 mg
Lamivudine	Tab 300 mg
Latanoprost with timolol	Eye drops 0.005% with timolol 0.5%
Levosimendan	Inj 2.5 mg per ml, 5 ml
Lidocaine [lignocaine] hydrochloride with adrenaline and tetracaine hydrochloride	Soln 4% with adrenaline 0.1 % and tetracaine hydrochloride 0.5%, 5

Chemical Name	Line Item
	ml syringe
Magnesium sulphate	Inj 2 mmol per ml, 5ml
Metaraminol tartrate	Inj 0.5 mg per ml, 10 ml
Metaraminol tartrate	Inj 0.5 mg per ml, 5 ml prefilled syringe
Metaraminol tartrate	Inj 0.5 mg per ml, 10 ml prefilled syringe
Morphine	Inj 10 mg per ml, 1 ml
Morphine	Inj 15 mg per ml, 1 ml
Morphine	Inj 30 mg per ml, 1 ml ampoule
Morphine	Inj 20 mg per ml
Morphine	Inj 50 mg per 5 ml
Morphine	Inj 100 mg per 5 ml
Mupirocin	Topical oint 2% (pack size 5 g or less)
Mupirocin	Intra-nasal oint 2%
Neostigmine metisulfate	Inj 2.5 mg per ml, 1 ml
Nitrofurantoin	Tab modified-release
Noradrenaline	Inj 0.1 mg per ml, 100 ml bag
Noradrenaline	Inj 0.1 mg per ml, 50 ml syringe
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
Noradrenaline	Inj 0.06 mg per ml, 50 ml vial
Noradrenaline	Inj 0.12 mg per ml, 50 ml vial
Octreotide (somatostatin analogue)	Inj 100 mcg per ml, 1 ml
Octreotide (somatostatin analogue)	Inj 50 mcg per ml, 1 ml
Octreotide (somatostatin analogue)	Inj 500 mcg per ml, 1 ml
Omeprazole	Cap 10 mg
Omeprazole	Cap 20 mg
Omeprazole	Cap 40 mg
Ondansetron hydrochloride	Inj 2 mg per ml, 2 ml
Ondansetron hydrochloride	Inj 2 mg per ml, 4 ml
Phenylephrine hydrochloride	Inj 10 mg per ml, 1 ml vial
Piperacillin with tazobactam	Inj 4 g with

Chemical Name	Line Item
	tazobactam 500 mg
Progesterone	Cap 100 mg
Rifaximin	Tab 200 mg - 550 mg
Rosuvastatin	Tab 5 mg
Rosuvastatin	Tab 10 mg
Rosuvastatin	Tab 20 mg
Rosuvastatin	Tab 40 mg
Silver Sulphadiazine	Crm 1% (pack size of 100 g or less)
Sodium alginate with sodium bicarbonate and calcium carbonate	Oral liq 500 mg with sodium bicarbonate 267 mg and calcium carbonate 160 mg per 10 ml
Tacrolimus	Oint 0.1%
Tadalafil	Tab/Cap 5 mg
Tadalafil	Tab/Cap 10 mg
Tadalafil	Tab/Cap 20 mg
Tadalafil	Tab/Cap 2.5 mg
Talc	Dusting Powder BP
Teriflunomide (current access)	Tab 14 mg
Teriflunomide (widened access)	Tab 14 mg
Thiamine Hydrochloride	Tab 50 mg
Thiotepa	Inj 15 mg
Thiotepa	Inj 100 mg
Ticagrelor	Tab 90 mg
Tramadol hydrochloride	Oral soln 10 mg per ml
Travoprost	Eye drops 0.004%
Vitamins	Cap/tab (fat soluble vitamins A, D, E, K)
Water-based lubricant	Single use sachets, 4 ml/g or larger
Zinc	Paste (pack size 50 g or less)
Zinc	Crm (pack size greater than 50 g)
Zinc	Crm (pack size 50 g or less)
Zinc	Oint (pack size greater than 50 g)
Zinc	Oint (pack size 50 g or less)
Zinc and castor oil	Oint (pack size greater than 50 g)
Zinc and castor oil	Oint (pack size 50 g or less)

Should any unresolved Tender Bids be declined prior to the release of the 2020/21 Tender, PHARMAC would consider including those pharmaceuticals in the 2020/21 Tender. Currently unresolved Tender Bids have not been included in the draft pharmaceutical list set out in Schedule Two.

## **Schedule Two: Possible pharmaceuticals for tender for principal supply**

### **Order of pharmaceuticals in this Schedule**

Pharmaceuticals have been listed in groups according to the therapeutic group classification system used in the Pharmaceutical Schedule. Below is a list of these groups, and the corresponding page numbers for your ease of reference. Pharmaceuticals with indications that may apply to multiple therapeutic groups will only appear in one group.

<b><i>Therapeutic Group</i></b>	<b>Page Numbers</b>
Alimentary Tract and Metabolism	1-2
Blood and Blood Forming Organs	2-3
Cardiovascular System	3-5
Dermatologicals	5-7
Genito-Urinary System	7
Hormone Preparations – Systemic Excluding Contraceptives	8-10
Infections – Agents for Systemic Use	10-12
Musculoskeletal System	12-14
Nervous System	14-17
Oncology and Immunosuppressants	18-20
Respiratory System and Allergies	20
Sensory Organs	20-21
Various	21

### **Information provided for each pharmaceutical**

For each pharmaceutical (as defined by chemical name, form and strength) we have provided the following information:

- the current ex-manufacturer subsidy per unit of measure as at 1 July 2020;
- the number of subsidised or partially subsidised units sold in the community in the year ending 30 June 2020;
- an estimate of the annual community market value at current subsidies (estimated by multiplying the volume of units subsidised in the year ending 30 June 2020 by the relevant listed unit subsidy as at 1 July 2020); and
- comments specifically relating to the Tender Item and/or its current listing on the Pharmaceutical Schedule.

### **Explanation of terms, symbols and abbreviations**

Most terms and abbreviations used are self-explanatory: “tab” means tablet, “cap” means capsule, “liq” means liquid, “inj” means injection, “suppos” means suppository, “grans” mean granules and “OP” means original pack to be dispensed.



The following table explains the symbols used in the draft pharmaceutical list:

<b>Symbol</b>	<b>Explanation</b>
Underlined	Pharmaceutical line items where a sole supply contract is in force are underlined. The price and subsidy for these pharmaceuticals are fixed until 30 June 2021 unless otherwise stated in the Comments column and a listing of a new brand could only occur after that date.
C	To be tendered for Principal Supply Status (community pharmaceuticals).
H	To be tendered for Principal Supply Status (DHB hospital pharmaceuticals).
PCT	A reference in the Invitation to Tender that denotes the pharmaceuticals for which DHB hospitals may claim a subsidy through Section B of the Pharmaceutical Schedule.
+	PHARMAC has been advised of the possible existence of a patent.
*	There is no fully funded product available for this line item (in relation to community supply).
@	Additional Stock Pharmaceuticals (ASP) means a Pharmaceutical, marked with an "@", for which the supplier of the successful Tender Bid would be required to hold additional stock.
#	A rebate currently exists.