

4 August 2020

2020/21 Invitation to Tender

PHARMAC has released the draft 2020/21 Invitation to Tender for consultation and is welcoming feedback from patient groups and the public by 4 pm (New Zealand time), 31 August 2020. For the medicines we are considering tendering, PHARMAC wants feedback from patient groups and the public about:

- A proposal to tender certain medicines 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).

Demand for medicines we fund, and for new and innovative medicines, is always increasing. PHARMAC's Annual Tender is key in making sure we're able to keep up with that demand. PHARMAC releases the draft Invitation to Tender each year at this time to consult on products which may be included in the Annual Tender. The Annual Tender is invaluable in ensuring we secure medicines (and some medical devices) for New Zealanders, manage spending on medicines and make sure the medicines we fund through the Tender are suitable for people to use.

The consultation on the draft 2020/21 Invitation to Tender is the first step in this process, and is a chance for our stakeholders to provide feedback on the proposed products that could be included in the Annual Tender process. 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.

You can view the draft 2020/21 Invitation to Tender and full product list on the [PHARMAC website](#), and provide feedback via email to tender@pharmac.govt.nz.

Background

Since 1997 PHARMAC has been using the strategy of tendering medicines for sole supply of medicines for a fixed period of time. Regular tendering has proven to be an effective way to encourage competition among suppliers of medicines. As in the past, the community and hospital tender processes would be run in unison, however, the medicine 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 would 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 medicines listed in Schedule Two, particularly the impact of a brand switch on patients, their families and whānau;
- Your views on which medicines 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

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). 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 medicines for supply to community pharmacies and/or DHB hospital pharmacies. If PHARMAC awards a tender for these products, the awarded brand would be the principal funded brand in the community and hospitals.

The full product list (Schedule Two) is a list of medicines that we are considering tendering. Medicines are sorted into therapeutic groups and then listed alphabetically in each group by chemical, form and strength. Each medicine 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 proposed change will allow PHARMAC greater flexibility to respond to the needs of specific groups of patients or individuals. 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, 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 an additional patient charge (above that of the patient co-payment) in Section B would become fully subsidised if a tender was awarded for that pharmaceutical.

Alternative brands

- The proposed shift to Principal Supply Status would enable PHARMAC 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.

- PHARMAC would gain the ability to fund alternative brands in the community. 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 would vary by product and would not always be predictable. With that in mind, we are interested in receiving feedback on:
 - Which medicines (or medical conditions) might have particular need for funding of an alternative brand (and why).
- Our preliminary view is that alternative brand funding might be needed in three different circumstances:
 - If a patient has previously 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 as a result of 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. 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:

Date	Event
4 August 2020	Consultation with suppliers, medical groups, patients and interested parties on the proposed medicine list and draft 2020/21 Tender.
24 August 2020	Final date for receipt of Alternative Commercial Proposals (ACPs) to tendering by PHARMAC.
31 August 2020	Final date for all consultation to be received.
September 2020	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 2020	Meeting of the Tender Medical Evaluation Subcommittee of PTAC to consider clinical issues in relation to the proposed Tender list.
September/October 2020	Consultation and decisions on Alternative Commercial Proposals.

Early November 2020	Issuing of the 2020/21 Tender.
17 December 2020	Invitation to Tender closes.
From end of January 2021	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.

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.

Schedule Two: Possible medicines for tender for principal supply

Order of medicines in this Schedule

Medicines 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. Medicines with indications that may apply to multiple therapeutic groups will only appear in one group.

<i>Therapeutic Group</i>	Page Numbers
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 medicine

For each medicine (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 medicine list:

Symbol	Explanation
Underlined	Medicine line items where a sole supply contract is in force are underlined. The price and subsidy for these medicines 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 medicines).
H	To be tendered for Principal Supply Status (DHB hospital medicines).
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 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 Medicine, marked with an “@”, for which the supplier of the successful Tender Bid would be required to hold additional stock.
#	A rebate currently exists.