From: Withheld under section 9(2)(a)
Sent: Monday, 13 July 2020 3:25 PM
To: Procurement <procurement@Pharmac.govt.nz>
Subject: Feedback on PHARMAC's proposal to modify it's approach to procurement

Dear PHARMAC,

Here is my feedback as follow:

Regarding: "We are proposing to shift to using Principal Supply Status, with an allowance for other brands of 5%, for the 2020/21 Invitation to Tender and expect it would be used in other competitive supply processes (e.g. Requests for Proposals) in the future. "

Feedback: Allowing the principal supplier to supply 95%, is essentially a sole supplier arrangement, leaving little room for any other suppliers to supply medicines and little incentive for them to do so. There are many NZ patients who do not do well on the PHARMAC funded medications and need alternative brands and nonfunded medicines. 30-45% would be a better and fairer allowance for other brands and better cater for the wide variation in individual patient need.

When adverse reactions are reported by patients to pharmac funded medicines in significant numbers, PHAR<MAC should independently have those medicines tested and not rely on what the manufacturers tell them in their claims about the medicine's bio-equivalency etc. PHARMAC are quick to blame patients for their adverse reactions and this needs to change Many patinets I know won't report adverse reactions to CARM because it won't be taken seriously

I would like to see PHARMAC develop funding criteria for bio identical hormones; and work with Medsafe to agree Medsafe approval criteria suited to compounded medicines.

KInd regards
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Withheld under section 9(2)(a)

15th July 2020

Craig Butler,
Procurement and Contracts Manager,
PHARMAC,
Level 9, 40 Mercer Street,
Wellington 6143

Dear Craig,

Re; Modification to Competitive Procurement Process

Thank you for providing Juno the opportunity to provide feedback on PHARMAC's proposal to modify your approach to competitive procurement.

Given the current issues surrounding availability and supply of Pharmaceuticals due to COVID-19, it is appropriate that PHARMAC review their procurement process, particularly in light of the fact that the vast majority of pharmaceutical products sold in NZ are sourced from overseas In the current environment many active ingredients and finished products are difficult to source due to COVID 19 outbreaks in areas of countries where these products are manufactured or due to government directives to ensure local markets are supplied before export markets This of course constitutes a major problem for suppliers and subsequently patients and consumers in NZ.

Juno Pharmaceuticals primarily provides products distributed within the hospital supply chain and hence the proposals from PHARMAC appear to have little impact on the procurement process for our products Hence we don't have any direct comments on the proposal put forward.

Having said that, if the goal of PHARMAC is to ensure supply when the awarded product cannot be supplied for whatever reason, then we feel that the general 1- 5% DV limit is rarely sufficient incentive for a second supplier to provide product to the NZ market when there is a need to recoup costs of registration, labelling, and the cost to bring the product to the NZ market.

Two suggestions that we feel may be worth considering in future with regards to changes in the procurement process are as follows;

- Run more than one tender process, probably staggered, with each tender covering a certain proportion of the NZ market, whether this be geographical or by other means. This may incentivise multiple companies to supply in the market. It may be that this needs to be addressed on a product by product basis

  Run the tenders according to fixed timelines in terms of when the tenders are announced, when bids are provided, results awarded and supply begins This removes a great deal of uncertainty for the industry with regards to supply chain

Juno Pharmaceuticals NZ Pty Ltd | PO Box 76261, Manukau City | P +61 3 8888 1206 | info@junopharm.com.au
NZBN 9429041319567 | Auckland 2241, New Zealand | F + 61 3 8888 1299 | junopharm.com.au

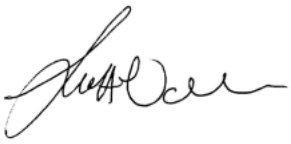
planning and hence greater capacity to maintain supply within the tender period. Currently the ad hoc and lengthy timing of awarding tender outcomes and supply start dates makes it very difficult for suppliers to plan.

We understand that multiple tenders may be difficult in a reasonably small pharmaceutical market such as New Zealand but we feel this is worth considering in an effort to incentivise companies to sell their products in NZ and as a result help reduce the current reliance on s29 products.

We are happy to discuss this further and elaborate on our ideas, as discussions such as these assist everyone including the supplier, the clinician, the consumer and the government.

We look forward to hearing from you.

Yours sincerely,



Scott Voller,
Director ANZ Scientific Affairs, Country Manager New Zealand,
Juno Pharmaceuticals ANZ
Withheld under section 9(2)(a)
M: Withheld under section 9(2)(a)

From: John Wickens <Withheld under section 9(2)(a)>
Sent: Tuesday, 21 July 2020 1:06 PM
To: Procurement <procurement@Pharmac.govt.nz>
Cc: Nicholas Cox <Withheld under section 9(2)(a)>
Subject: RE: Consultation feedback: sole supply arrangements

To - procurement@pharmac.govt.nz

We refer to the Proposal to modify PHARMAC's approach to competitive procurement issue on the 10 July 2020

We note that the current annual tenders contain DV limits for most products which allows for supply of an alternative brand if required and available

We note that the current tender includes specific allowance for PHARMAC to arrange a back-up supply for any pharmaceutical within Schedule 3 of the annual tender document.

> *8. Back up supply Back up Supply Agreements*
> *(a) PHARMAC may at any time negotiate a Back-up Supply Agreement with another supplier for any Tender Item.*
> *(b) PHARMAC may, at its sole discretion, seek proposals for Back up Supply Agreements under a separate process to this Invitation to Tender.*
> *PHARMAC does not seek submissions for Back-up Supply Agreements in response to this Invitation to Tender and is not obliged to consider proposals or bids for back-up supply submitted as part of the tender process.*

We see a number of potential issues with this proposal including but not limited to the following.

- The ability or commercial viability for suppliers of alternative brands to make available what for most products will be a very low volume of product into the NZ market.
- How alternative brands will be funded and whether they will be subject to the same or similar contractual agreements as the Principal Supply Status brand.
- With the declining numbers of companies and registrations of pharmaceuticals in the NZ market whether there will be viable alternative brands that are able to be supplied as an alternative brand.

Sincerely

John Wickens
Tel: Withheld under **Cell:** Withheld under
Teva Pharma (New Zealand) Ltd
Level 14, 41 Shortland St, Auckland 1010,
New Zealand
Withheld under section 9(2)(a) www tevapharm com

Canterbury District Health Board
Te Poari Hauora ō Waitaha

MEDICINES UTILISATION SERVICE
Department of Clinical Pharmacology
Christchurch Hospital
PO Box 4710, Christchurch
e: medicines@cdhb health nz
t: 03 364 1858

22 July 2020

PHARMAC
PO Box 10 254
Wellington 6143
e: procurement@pharmac.govt.nz

RE: PHARMAC proposal to modify approach to competitive procurement **Due 24 January 2020**

Summary of proposal
PHARMAC is seeking feedback on a proposal to amend the way they contract for pharmaceuticals as a result of competitive procurement. The predominant change is to replace community Sole Supply Status (SSS) and Hospital Supply Status (HSS) with Principal Supply Status This would be similar to HSS, however, could be applied in either the community or hospital settings (or both) If accepted, this change will not be applied retrospectively (will not impact current contracts, however, will apply to new contracts)

CDHB response:

Benefit: A common and more flexible approach for community and hospital procurement, such that variation for individuals or patient groups may be managed within contractual arrangements.

Harm: A risk of 'brand preference' cost increases

Comment: PHARMAC note that brand changes are generally well tolerated. PHARMAC know that events can occur at the time of brand changes and that brand changes require health professionals and support services to mitigate possible harm. The proposal outlines increased flexibility to meet clinical needs, and this is welcome where the need is substantiated by evidence and clear rationale, for example an alternate formulation, where there are utility challenges (e g tablet size or coating) This amendment may compromise the purpose of PHARMAC, to fund the best health outcomes for New Zealander, if it increases the funding of medicine brands based on individual preference

Question: What criteria will PHARMAC use to select those for whom particular brands will be selected or approved for greater discretional variance that the nominal 5%?

Response from: Clinical Pharmacology Department

Regards,

Judy Dalrymple | Medicine Utilisation Pharmacist
Matthew Doogue | Clinical Pharmacologist

Medicines New Zealand

Procurement Team
PHARMAC
Wellington

23 July 2020

Re: Proposal to modify PHARMAC's approach to competitive procurement

To whom it may concern,

Medicines New Zealand is the industry association for the modern prescription pharmaceutical sector in New Zealand, and in that capacity, we are responding with our feedback to PHARMAC's proposal.

Firstly, we support PHARMAC in its efforts and rationale to modify its competitive procurement processes around tendered products. This we assume has a focus on assuring patient safety, improving access to medicines for both patients and their clinicians, providing positive health outcomes, and enhancing New Zealand's public health system.

We do have significant comments on both the procedural and technical aspect of the consultation and proposal, which we have outlined below. We expect PHARMAC will address these comments in its response.

From a procedural basis and given both the nature of the proposed changes to PHARMAC fundamental procurement model, we do question why this consultation process seems to be undertaken in a very short timeframe of only two weeks. Furthermore, the lack of detailed information in our view, makes it hard for submitters to make anything other than high-level speculative views/comments rather than informed feedback on the proposal.

A solution to this may have been to provide a mock-up of the tender documentation around the proposed Principal Supply Status (PSS), so that differences between the existing procurement system and the PSS system can be better elucidated and commented on.

Also, if the intent is to incorporate this PSS approach in the 2020/21 tender round, which we assume will be initiated in August 2020 we assume with the Draft Tender Document release, then the tight timeframe for this consultation process also must be questioned.

From the information provided in the PHARMAC proposal we make the following technical comments:

Medicines New Zealand
Level 10, 117 Lambton Quay, PO Box 10-447, Wellington 6143, New Zealand
Tel 04 499 4277 www.medicinesnz.co.nz

(1) PHARMAC have indicated that there will be a Discretionary Variance (DV) allowance of 5% for other brands for the 2020/21 Invitation to Tender process – it is noted that currently under the Hospital Supply Status arrangement the DV limits are variable between 1-20% for medicines.

Comment: What is the risk-benefit justification for instituting a flat DV of up to 5% (with some case-by-case pharmaceuticals having different DV levels) rather than allowing full flexibility in the setting of the DV across the entire portfolio of tendered products?

(2) In the rationale for the proposal PHARMAC indicate a wish to have greater flexibility to address two different patient situations where provision of an alternative brand is necessary - i.e. firstly to enable someone to revert to their original brand (following an initial change) and secondly to avoid a brand change altogether.

Comment: PHARMAC do not address the overall issue of clinician discretion in terms of deciding the best medicine for a specific patient based on the individual's clinical particulars.

- *Will clinicians be able to prescribe the alternative DV product to people who have never received it before? i.e. patients who have been newly diagnosed and patients who have started on the Principal Supply Status product who may find it unsuitable due to adverse effects or lack of therapeutic benefit?*

- *What is the potential impact of this restriction of the DV to 5% on hospital specialists' ability to prescribe in the patient's best interests?*

(3) Irrespective of whether it is a community or hospital medicine, giving a Principal Supplier 95-100% of the market and setting the back-up product DV limit at 5% will create additional unforeseen issues for PHARMAC, and the patients and health system.

Comment: It is hard to see what the commercial attraction would be for suppliers of the alternative product to tender support a product in the NZ market (i.e. maintain registration, sales and distribution costs, production minimum order requirements, forecasting etc) when they can only have up to 5% of supply.

The unattractiveness of this approach would seem particularly evident if the back-up product is either a low margin/value product in terms of unit price or a product with very limited market potential in terms of the nature of the patient population (e.g. uncommon health conditions or acute conditions so no ongoing sales from repeat prescriptions etc). It would seem even less likely that PHARMAC would have the option of more than one other brand in the market under these circumstances if the 5% DV had to be split between alternative brands (it is not clear from the proposal if the DV of 5% may be split to allow more than one alternative product either).

This poses the question – is this 5% DV approach feasible for supply of alternative medicines for some conditions?

In conclusion, shifting to the proposed "Principal Supply Status" arrangement for competitive procurement would appear to do little to alleviate the supply risk that the current Sole Supply Status arrangements present in the Community Pharmaceuticals area. They may potentially increase the risk to supply in the hospital setting in the case of products where the DV has dropped to 5%. This is going to be particularly true for any products that are large volume and/or critical medicines where supply issues would have a large impact.

Put simply, and from the information provided in the Consultation, it appears that the proposed new approach to competitive procurement is going from "all eggs in the one Community Supply basket" to "95% of the eggs in the one Community Supply basket" .

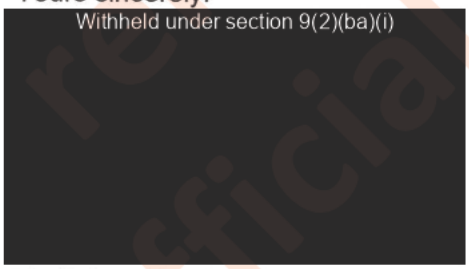
The question remains of what happens when either global circumstances (like a pandemic) or other events, like the withdrawal of the main supplier from the market interfere with supply?

As noted, Medicines New Zealand is supportive of the flexibility shown by PHARMAC as regards looking at alternative approaches to sole supply for competitive procurement, but the way in which the current consultation has been initiated is unfortunately sub-optimal in our view.

As a solution, Medicines New Zealand propose that perhaps a way to enhance this consultation process would be to run an on-line workshop with suppliers to discuss the proposal in more detail. This solution would allow PHARMAC's proposed approach to be both better understood and accepted by suppliers. It may also provide PHARMAC with improvements or alternatives which would enhance PHARMAC's stated goals in the Proposal document.

We hope you find our submission useful, and we would welcome the opportunity to work with PHARMAC to organise a collaborative workshop on this topic too.

Yours sincerely.



Medicines New Zealand

Unicorn Foundation New Zealand

23 July 2020

By Email: procurement@pharmac govt nz

Tēnā koe

The Unicorn Foundation NZ is grateful for the opportunity to provide input on the proposed changes to PHARMAC's competitive procurement process. The Unicorn Foundation NZ's position is set out below.

We support the proposal *with amendments*.
Overall, we support PHARMAC's proposal to shift to using *Principal Supply Status*, as we see significant patient benefits from a dual supply approach. However, we **strongly urge** two further amendments to the current proposal:

- **Increase the allowance for other brands from 5% up to 20%** (in line with the current discretionary variance limit for hospitals).
- **Expand the discretionary variance** to enable funding of another brand to help meet the needs of individuals or groups of patients who would benefit from an alternative treatment (at an equivalent price).

Why Unicorn Foundation NZ has an interest in PHARMAC procurement
The Unicorn Foundation NZ is a registered charity that is dedicated to revolutionising the way that NET cancers are diagnosed and managed in New Zealand. Neuroendocrine tumours (NETs) are a family of cancers that are hard to diagnose and complex to treat. On average one New Zealander is diagnosed with a NET cancer every day and the incidence is rising. There are currently around 2,000 New Zealanders living with NETs that we can help The Unicorn Foundation NZ provides support and information to patients, families and medical professionals involved in the treatment of NET cancers

Why treatment *options* are critical for NET cancer patients
NET cancers can occur almost anywhere in the body, and cause a wide variety of symptoms that are often mistaken for other, more common conditions like digestive disorders That means diagnosis can takes years, and sadly almost half (47%) of all New Zealand NET patients have metastases by the time they are diagnosed. Such cases can rarely be cured, although the symptoms can often be managed successfully for a number of years. The difficulty stems from the fact that NET cancers are incredibly diverse – each patient's condition is unique. This calls for personalised management of symptoms and tailored treatment of the disease. To support clinicians dealing with the challenges of NET patients, the District Health Boards have recently implemented a nationwide multidisciplinary meeting so that leading specialists can review NET patient histories and provide expert guidance on treatment plans The purpose is to provide the best outcomes possible for each patient. This requires the ability to prescribe the most effective treatment/s for each patient. Unlike other conditions that follow a typical trajectory, the unique nature of each patient's disease means that NET cancers do not benefit from a 'one size fits all' approach.

Therefore, we urge PHARMAC to consider expanding the discretionary variance for treatment beyond adverse clinical outcomes due to brand change Unicorn Foundation NZ strongly advocates that PHARMAC also funds alternative/s to the primary brand where the alternative offers better outcomes for sub groups of patients as recommended by the NET multi disciplinary meeting, or offers cost advantages to the overall health sector (e.g. self administration or home based treatment). Specifically, clinicians treating NET cancer patients see significant patient benefits to have access to lanreotide (Ipsen) as an alternative to octreotide (Novartis) for patients who don't tolerate octreotide

Unicorn Foundation New Zealand

Should PHARMAC proceed with the proposed procurement changes, including implementation of *Principal Supply Status*, then Unicorn Foundation NZ would be pleased to provide further information on NET cancer treatments and which products have a particular need that should be considered in any funding decisions.

Ngā mihi

Michelle Sullivan *PhD*
Chief Executive
E: Withheld under section 9(2)(a)
P: Withheld under section 9(2)(a)

From: [redacted]
Sent: Friday, 24 July 2020 1:54 PM
To: Procurement <procurement@Pharmac.govt.nz>
Subject: “Competitive” procurement submission

I do not support the proposed changes to the pharmacy tendering system from 2021

I wish for the rest of my submission to be treated as confidential

[redacted]

[redacted]

[redacted]

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With

From: Andy Watson <Withheld under section 9(2)(a)>
Sent: Friday, 24 July 2020 2:00 PM
To: Procurement <procurement@Pharmac.govt.nz>
Subject: PHARMAC consultation: proposal to modify our approach to competitive procurement - feedback

Dear Sir

I am the Supply Chain Manager for ProPharma Wholesalers and I would ask that you take the following feedback into consideration when progressing the above proposal

As a wholesaler in the current supply chain , I would make the following observations regarding the proposals:

- Operational Challenges : potentially having to list the backup brand across our prescription medicine portfolio would lead to a doubling of our current lines stocked from 1800> 3600 if applied across the board
    - That would create capacity issues at most of our sites having to provide the additional number of slots
        - I seriously doubt we would be able to do that in all sites – that would increase logistics costs shipping from the bigger central warehouses
        - Consideration also would need to go into special storage items where there would be the potential to also double both our Controlled Drugs & Cold Chain Items, this would come at a considerable cost as we would need to invest in chillers and build new bunkers . In the smaller sites there would be limitations in installing bigger chillers and controlled drug bunkers – which again will lead to greater logistics costs shipping from the bigger central warehouses
    - This would add to the number of lines being picked across our prescription medicine portfolio(inwards goods and customer order processing) and that would require more labour- with the secondary brand orders we would also need to watch for inefficient pick quantities/order value which could drive up charges for some suppliers
    - Net net , both of the above will drive up cost for the wholesaler with no return

- Demand Management Challenges:
    - Predicting demand with 2 brands in the frame is more challenging from a customer service perspective and would likely increase overall inventory investment to cover both products(greater total combined safety stock versus the single brand approach) and again will increase capacity requirements in the warehouse to hold extra volume
    - Conversely there could be an aging of stock challenge if the market routinely pulls the primary brand – both the backup supplier and wholesaler could be left with an aging stock/write off situation unless there is a guaranteed pull on the secondary brand(or sale or return agreements)
    - Contingency solution at 5% has limited ability to sustain supply – in the event the primary brand were to be out of stock , the backup supplier won't have sufficient stock to cover the gap if they are planning on supplying no more than 5% in business as usual circumstances I note that the Pharmac brief does make reference to being able to flex the backup brand %age as they do now with Hospital agreements (up to 30% in some categories) but even that level wouldn't plug the gap for very long if the primary supplier went down

- Contract Transition Challenges :
    - Currently we have to manage the run down from one incumbent brand to the new brand at the end/beginning of each 3 year sole supply agreement

- On the one hand having a second product supply to help bridge the transition would lessen the risk on being a gap on supply to trade during the transition (as sometimes now the incumbent runs out of stock before the new supplier is on stream)
- But it will also make the transition messier having to potentially co-ordinate 2 incumbent suppliers products with new suppliers products if the proposal is fully implemented again as a wholesaler we don't want to be left holding stock of the incumbent that has no demand

- Financial Management Challenges :
  - Because as a wholesaler we are not a signatory to the contracts , we already need to put in place a significant amount of governance on the existing sole supply agreements to ensure that as a wholesaler we are not being financially disadvantaged and as such we would now need to police double the number of contracts to check price change protocols
  - Where price support is involved in a price reduction scenario, we are also potentially going to be chasing up two supplier claims where as currently we are only doing that with the sole supplier
  - Where a price increase is going to be triggered then we need to check with two suppliers to confirm on which date the purchasing price change is effective in the month leading up to the retail price change to trade

Conceptually I understand the need to provide flexibility and sustainability of supply and that the sole supply agreements don't provide that ideal solution but as you can see from the above , there are quite a few consequences to be considered in moving to a dual supply solution.

Yours sincerely
Andy

Andy Watson
National Supply Chain Manager
ProPharma
Withheld under section 9(2)(a)
Withheld
Mob : Withheld under
DDI : Withheld
E Mail : Withheld under section 9(2)(a)

From: Quincy Liu <Withheld under section>
Sent: Friday, 24 July 2020 5:28 PM
To: Procurement <procurement@Pharmac.govt.nz>
Subject: Feedback: Proposal relating to modifying PHARMAC's approach to competitive procurement.

Dear PHARMAC,

Thank you for the opportunity provide feedback to the proposal relating to modifying PHARMAC's approach to competitive procurement issued on 10 July 2020.

While we agree that standardising the way that PHARMAC contract for pharmaceuticals as a result of competitive procurement processes, we have certain concerns as a key supply partner of medicines and vaccines in New Zealand

The "allowance" for alternative/secondary brands in a competitive procurement process in your proposal may create an unrealistic expectation to both prescribers and patients that the secondary supplier(s) will supply the NZ market. But often the situation for secondary suppliers is that low volumes may not be commercially viable and/or sustainable given the cost of regulatory maintenance as well as increasing freight costs from COVID, and therefore exit the market.

We suggest that PHARMAC consider entering into supply contract arrangements with the secondary suppliers as part of the procurement process. This will ensure that secondary suppliers will supply products for patients that need it, and that PHARMAC has certainty of the availability of alternative brands.

In addition to the above, it will be beneficial to patients and prescribers to know that PHARMAC has a robust (but simple) process for applying for funding of the secondary or alternative brand(s) of medicine if the brand switch is unsuccessful.

We hope that PHARMAC will take into consideration our feedback

If you have any questions on our Feedback, please contact me directly.

Ngā mihi (kind regards)

Quincy Liu
Head of Market Access
Commercial in Confidence

GSK
Zurich House, Level 11, 21 Queen St, Private Bag 106600, Downtown Auckland 1143 New Zealand
Email Withheld under section
Mob + Withheld under
GlaxoSmithKline NZ Limited - Co.No 1235481

gsk.com | gsk.co.nz | Twitter | YouTube | Facebook | Flickr

Janssen Cilag Pty Ltd
(inc. in NSW)

507 Mt Wellington Highway
Mt Wellington, Auckland 1060
PO Box 62185, Sylvia Park 1644
Tel: +649.588.1300 / 0800.800.806
Fax: +649.588.1398

Pharmac
Level 9 Simpl House
40 Mercer Street
Wellington 6011

24 July 2020

Re: Consultation response to the Proposal to modify PHARMAC's approach to competitive procurement

To whom it may concern,

Janssen is the Pharmaceutical Companies of Johnson & Johnson. We have been operating in New Zealand for over 50 years and have held many community sole supply and hospital supply contracts during this time. We specialize in the following therapy areas; Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.
Johnson & Johnson Medical Devices company represents the surgical and medical devices provided in New Zealand by Johnson & Johnson family of companies.

We understand that Pharmac are proposing to replace both Sole supply and Hospital supply arrangements with Principal Supply Status

You state that the proposal would mean that PHARMAC would have greater flexibility to respond to the needs of specific groups of patients or individuals who may experience, or are at heightened risk of, adverse clinical outcomes as a result of a brand change And that having the right contractual arrangements in place is necessary to enable this.

Janssen response:

- It is not clear to us whether Pharmac plan to tender for the DV limit or indeed how you intend to secure supply for a DV limit supply?
- With DV limits representing such low volumes it makes it very difficult and potentially costly to secure this supply and may not be feasible
- Most countries address the risk associated with out of stock situations or patient tolerability or efficacy issues by enabling personalized medicine and certainty of

supply, by ensuring an open market with multiple suppliers.

Pharmac state that they are also working to move to a common approach between the community and hospital markets over time.

Also, that through competitive procurement processes such as PHARMAC's annual Invitation to Tender, Requests for Proposals (RFPs), and Requests for Tenders (RFTs) suppliers compete for exclusive or preferential access to the funded pharmaceutical market for a set period of time. Such processes can result in significant savings for off patent medicines, freeing up funding that can be used for spending on other medicines.

Janssen response:

Our concern in standardizing the process by which Pharmac tenders for medicines is:

- limitations in clinical choice and patient choice
- the inconsistency in procurement pricing options which affect competition

Clinical and patient choice

- Whilst Pharmac has adopted sole supply or hospital supply +DV limits for the past 30 years, the innovation in medicines is making this approach increasingly out of date and needs an overhaul
- Medicines should be personalized to the patient and choice allowed
- A process that can be introduced to improve that customer choice, whilst still managing pharmaceutical spend is by bringing back in part charge or co payments for patients Have a level of reimbursement and enable alternative suppliers to provide choice on the market, with or without co payments from the patient

Lack of competition

- The process of the National Tender often excludes competition from originator suppliers due to the fact confidential rebates are not permissible, unless via an RFP or RFT.
- Suppliers with originator molecules often lose Intellectual Property (IP) rights in NZ years before other countries This means NZ suppliers cannot engage in significant drops in public List prices when it could impact much larger markets where IP remains. The longer IPs in other countries enable the suppliers to recoup R&D costs, invest in more R&D and support developing countries access to medicines at affordable prices.
- The National Tender should therefore enable confidential Net prices to be used in order to improve competition and increase the likelihood of continuity of supply from originator suppliers/manufacturers.

Pharmac state Principle Supply agreements are also a very successful way of ensuring continuity of supply for medicines in New Zealand this is because a supplier has mo**re** certainty

of the share of the funded market they will gain, so they are more able to accurately forecast demand and order stock from their manufacturers

Janssen response:

Supply risk

- We disagree with this statement.
  Certainty of market volume does not increase a supplier's ability to supply. It serves only to secure a better price in return for volume, not certainty of supply The predominant reasons for supply issues are:
    a) unforeseen source material supply issues,
    b) unforeseen manufacturing issues
    c) freighting issues including deviations in the Risk Mitigation Practices or transportation requirements, most frequently cold chain requirements.
  Having a sole or principle supplier is a risk to supply certainty. This has been demonstrated throughout the Covid 19 pandemic response and demonstrated currently with bortezomib
  We fundamentally disagree that the proposed 'Principle supply status' is likely to improve certainty of supply.
  Should a Principle supplier be out of stock, there is significant risk to patients. This risk must not be made at the expense of managing a budget.
  Additionally, there is risk and cost to supplier or to the NZ Pharmaceutical Schedule to secure an alternative supplier, if that supply can be secured at all

  It is not clear whether Pharmac plan to tender for the DV limit, but it is only likely to be successful if DV volumes are high i.e. ~>40%
  Due to the very low volumes associated with DV limits of 5 20%, very few, if any, suppliers will be in a position to maintain stock in country when volumes are so low.

  Many countries address this out of stock risk by ensuring an open market with multiple suppliers.
  A process that can be introduced to increase certainty of supply is to increase the number of medicines in a market and improve patient and clinician choice. This can be achieved whilst still managing pharmaceutical spend.
  We propose introducing the option of a part charge or co payments for patients. Have a level of reimbursement and enable alternative suppliers to provide choice in the market, with or without co payments from the patient

Finally, an important perspective from Johnson & Johnson Medical Devices NZ who supply thousands of different SKUs of surgical and medical devise to New Zealand hospitals.

The last few months have demonstrated the importance of a strong and diverse medicines and medical device sector which has the capacity and resources to provide extra support when managing crises. It has highlighted the importance of having multiple suppliers in place who can manage and respond to shortages in periods of high demand.
These high demands situations have been demonstrated during the Christchurch and Kaikoura earthquakes, The Christchurch terrorist attack and White island Eruption. Of

course, currently, Johnson & Johnson has been central in preparing hospitals for COVID 19 and will continue to play a key co ordination role in ensuring supply of medicines and medical devices during the pandemic.

In recognition of the current review and the need to modify PHARMAC's approach to competitive procurement, we reiterate our recommendation that the roll out of the PHARMAC model to medical devices be delayed until necessary changes have been made to the model (such as any changes of sole supply contracts) and a review is conducted to determine whether those changes have been sufficient to improve supply chain consistency and patient access.

We also believe that recent experiences with supply chain shortages should result in a revision to PHARMAC's stated goal of saving $1 billion from medical devices by 2025. With this as the target, there will inevitably be an overriding emphasis on the lowest unit cost device, rather than the quality of the device or the benefit it could provide to patients. We also reiterate our request that, prior to implementation a review into international best practice be undertaken which will consider methods of assessing the true value of medical devices and develop a clear evaluation methodology

Recent experience has demonstrated that both sole supply contracts and restrictive market share agreements are equally detrimental to market diversity through unsuccessful RFP/RFT applicants exiting the market. Even with DV targets in place it is unlikely that a 5 20% market share would be sufficient to allow for a supplier to have an in market presence that would enable them to provide rapid support in response to a medicines or medical device shortage

We thank you for the opportunity to respond to this proposal. Please note however that this has been a very short consultation period and given more consultation Pharmac may indeed gain more detailed and wider perspectives that they would find valuable.

Yours sincerely

Liz Naylor
Market Access and Government Affairs Group Manager
Janssen
A Johnson & Johnson Family Group of Companies

24 July 2020

Response to "Proposal to modify PHARMAC's approach to competitive procurement" dated 10 July 2020

Thank you for the opportunity to respond to the proposal to standardise the way PHARMAC contracts pharmaceuticals.

Having discussed the proposal internally there was agreement that we should request clarification from PHARMAC around the objectives for this proposal – is it to ensure continuity of supply or is the aim to manage brand switch issues?

Continuity of Supply

Sanofi understand the issue of continuity of supply and note that this has been highlighted recently by the withdrawal of a major generic company from New Zealand.

COVID-19 has also highlighted issues around the site of manufacture for active pharmaceutical ingredients as well as finished medicines, freight delays, lack of product etc

It is Sanofi's position that innovative companies take the responsibility (moral and ethical) to supply very seriously when winning a sole supply tender We note that Sanofi have maintained supply across all products on the Pharmaceutical Schedule throughout 2020 through careful management by our supply team. Sanofi ship the vast majority of product by sea during COVID19 we note there was less disruption to sea-freight shipments than those sent by air freight however in the event of disruption to our supply we utilise air freight to avoid out of stock situations wherever possible. We understand that some generics companies have refused to ship goods by air to alleviate supply disruptions

Sole supply is attractive because the winning product is guaranteed 100% of the market (community supply) and generally 95 99% of the hospital market There is no discounting required, no promotional costs, no risk that the subsidy and price will be changed etc.

Changes to the sole supply tender such that the principal brand has 95% of the market and the alternative brand has 5% will not, in our opinion, improve continuity of supply as no product will be able to maintain supply at 5% of NZ volumes.

It is Sanofi's position that the Principal Supply Status proposal will not improve continuity of supply.

sanofi-aventis new zealand limited trading as SANOFI
Level 8, 56 Cawley Street, Ellerslie, Auckland 1051, New Zealand; P.O Box 12851, Penrose, Auckland 1642
Tel: +64 (0) 9 580 1810 Fax: +64 (0) 9 580 1811 www sanofi com au

Brand Switch Issues

We understand completely the risk to patients of a loss of clinical control or adverse effects as a result of a brand switch, we have been highlighting this for years since patients were first forced to switch brands due to a change in funding.

Obviously for the vast majority of patients there is no significant issue but for those patients that cannot tolerate the subsidised brand Sanofi will endeavour to supply via the private market For example we have maintained supply of Cardizem CD 240mg and 360mg (but not 120mg which was NZ specific) along with Imovane i.e. products with harmonised packs to help patients achieve their desired health outcomes. This ongoing, low volume medicine supply comes at a cost to Sanofi the logistics involved being at least as time consuming as required for a large volume (sole supply) product.

It is important to note too that moving forward global rationalisation of low volume medicines will ultimately see them being discontinued.

Managing the preferred "Principal Supply" and alternative supplier volumes

Managing the DV limit in Community will be difficult making the principal supplier status potentially less attractive PHARMAC have been able to secure low prices for medicines largely because sole supply guarantees the entire market – in both Community and basically also Hospital as most products that are not the sole supply winner will withdraw from the market.

By introducing a DV limit of anywhere between 5% and 20% competition is potentially being reintroduced and with it an element of uncertainty. That said, it is highly unlikely that the alternative product will be commercially viable. In fact we would suggest that the alternative product would need to have a guaranteed 35 to 40% of the total market (and be in a harmonised pack) to be able to remain on the New Zealand market. Obviously this makes the principal supply status even less attractive.

Contractual obligations for the alternative supplier

Contractual obligations for the alternative supplier need to be very clearly outlined before a final decision about this proposal can be made. If for example a product with sole supply status is in a NZ specific pack and at tender it is not awarded the principal supply status does the company with the alternative product have the option to stop supply? This is basically what happens now – we manage our stocks to minimise write offs but once we are no longer the sole supply product we will cease marketing the product and will NOT purchase additional stock

Will this proposal require the outgoing sole supply product to maintain supply and if so for how long? What penalties do PHARMAC intend to apply to the alternative supplier for failure to supply?

Can the alternative product maintain it's existing pricing if that is at a premium to the principal supply? Can the alternative product increase price? It is unlikely that a price increase will guarantee ongoing commercial viability of a product, but there may be instances where it does.

In the event that PHARMAC impose ongoing supply requirements on an alternative product it is likely that fewer companies will be interested and prepared to enter in to tender agreements due to the financial penalties that could be applied when the "alternative product" becomes commercially non-viable and has to be withdrawn from the market.

Vaccines

Whilst not immediately relevant to this consultation and proposal for pharmaceuticals we would like to take this opportunity to highlight the following points with respect to the National Immunisation Schedule and funded vaccines in general:

1. *A sole supplier arrangement provides significantly less security of supply, and the potential for disruption to immunisation programs.*
2. *Bundling has the potential to reduce the number of vaccine suppliers that are able to compete in New Zealand and makes it less attractive to dedicate future resources to NZ.*
3. *Vaccines are different to pharmaceuticals:*
    a. *time to manufacturing is significantly longer and less flexible*
    b. *there are only 5 global vaccine manufacturers in the world and*
    c. *demand from large countries with a fast growing middle class leads to increasing global supply constraints.*
4. *Driving prices down inhibits manufacturers ability to secure ongoing allocation of supply to NZ and/or resources to register new innovative products.*
5. *The proposed changes for pharmaceuticals should also apply to vaccines – i.e. at least 20% of NIP contracts can be left open for a second manufacturer to supply.*

Sanofi welcomes the increased investment in the funding of vaccinations programs, which recognises the broader societal benefits that these programs often deliver. As Pharmac continues to make decisions with respect to the appropriate allocation of its budget to optimise the health outcomes for New Zealanders, we think it is essential that these broader benefits be considered in order to appropriately rank interventions by capturing the total benefit they are expected to deliver

Sanofi trust that these comments are of interest and our concerns are heard.

We look forward to receiving clarification around the points raised:

1. What is the objective of the proposal?
2 How will the DV limits be managed?
3. What ongoing supply requirements will apply to the alternative product?
4. What financial penalties will apply to the alternative product?

Yours sincerely
Sanofi-aventis new zealand limited

Alan Carter
General Manager

Merck Sharp & Dohme (New Zealand) Limited
Level 3, 123 Carlton Gore Road
Newmarket, Auckland 1023
PO Box 99851 Newmarket Auckland 1149
T 09 523 6000
msd.co.nz

24 July 2020

PHARMAC
Level 9, 40 Mercer Street
Wellington 6011

By email: consult@pharmac.govt.nz

Re: Proposal to modify PHARMAC's approach to competitive procurement

Thank you for the opportunity to respond to the proposed changes to the competitive procurement process. Our main concerns stem from the lack of detail on how the procurement changes would be implemented from a process and contractual perspective We hope that more details will be forthcoming after this initial consultation process.

We understand the primary reason for this change is to make it easier for clinicians and patients to access alternate brands when the principal supply medicine is not appropriate for the patient. For this objective to be achieved at least one other brand would need to remain in the market, registered, with supplies in order to support these patients Our main concern is that a market share of 5% or less may not be commercially viable for a generic or innovator company to maintain a brand in New Zealand, thus not solving for the key problem identified. Alternate commercial arrangements may need to be considered to maintain an alternative supplier in the market.

Our second concern relates to the terms and subsequent contracting under new procurement rules This includes questions such as;

- Will suppliers not successful as a Principal Suppliers also be contracted during a tender process?
- Does PHARAMC expect suppliers to submit a single price for either Principal or Alternate supplier contracts at time of tender?

Would an alternate supplier be subject to similar contractual restrictions and penalties found in a typical principal or sole supply contract?
What are the expectations of an alternative supplier if the principal supplier is unable to supply the market?

- Will PHARMAC have the power to unilaterally modify existing tender contracts or special authority criteria where a situation arises that a sub population (greater than 5% of total population) requires an alternate brand?

We feel these detailed questions would need to be clarified with suppliers prior to any change to annual tender rules to enable suppliers to bid with clarity and certainty.

Yours sincerely,

Jared Poppelbaum

Health of Market Access and Policy
M Withheld under

abbvie

24 July 2020

AbbVie response to PHARMAC's proposal to modify its approach to competitive procurement

AbbVie welcomes the opportunity to respond to this proposal. We acknowledge that PHARMAC has requested feedback on the "general direction of this proposed change", however AbbVie would be able to provide a more meaningful response once further details are provided by PHARMAC. The response below outlines the details that AbbVie wishes to understand further AbbVie acknowledge that PHARMAC are planning to undertake further consultation but would also encourage PHARMAC to hold a supplier meeting to allow further collaboration on this proposal.

Decision making on the alternative brand and access criteria

- AbbVie acknowledges that this proposal would broaden patient and prescriber choice, although based on the 5% allowance AbbVie expects that this would be limited.
- AbbVie wishes to understand if an alternative brand would only be made available if or when PHARMAC is proposing a brand switch.
- AbbVie is also interested to understand how the alternative brand will be chosen, for example, will a competitive process be used to select the funded alternative brand.
- It is not clear to AbbVie how or by whom the criteria will be determined regarding how the patient/prescriber will be able to access the alterative brand, and if the criteria will be publicly available.
- AbbVie recommends that the supplier of the alternative brand be involved in the decision around which process is used (i.e. Special Authority, exceptional circumstances etc.) and determining the criteria that will enable access to the alternative brand.
- It is not clear if both brands and prices be listed on Section B so pharmacies could claim appropriately.
- AbbVie is also interested to understand how PHARMAC will actively monitor the usage of the alternative brand, and if there will be any repercussions on prescribers that use more than 5% of this alternative brand.

Supplier considerations in supplying the alternative brand

- From a supplier perspective, there may be concerns around the commercial viability of supplying 5% of the NZ market, in particular when the market is small
- The size of the market is unlikely to correlate with the need for an alternative brand and therefore more may be needed to be done to encourage supply of an alternative brand. This could be mitigated by PHARMAC guaranteeing reimbursement payment of 5% of the market for the supplier of the alternative brand in the event that share is <5%. This may also assist in minimizing the write-off risk of supplying the alternative brand and associated regulatory maintenance costs.
- Suppliers may also need to consider minimum order quantities when determining the viability of supplying the alternative brand

AbbVie Limited
Level 6, Stephenson & Turner House
156-157 Victoria St
Wellington
NEW ZEALAND 6011

0800 900 030 (OFFICE)
+64 4 802 2981 (FAX)
www abbvie co nz

Market share level of the alternative brand

- With regards to the share of the alternative brand, it is not clear to AbbVie how the 5% level was determined AbbVie would be interested to understand the evidence that supports this level.
- It would also be useful to know how PHARMAC proposes to identify appropriate allowances for medicines that require a level other than 5%.

Implementation in the annual tender and future RFP/RFTs

- If this proposal is implemented, AbbVie would recommend that PHARMAC allow suppliers to submit a separate bid for the 95% share versus the 5% share in any competitive procurement process. Suppliers may have different pricing considerations depending on the market share
- AbbVie also seek to have the opportunity to comment on any proposed terms in the annual tender prior to this document being finalised.
- AbbVie is also interested to understand when the proposed change (if implemented) would apply to other competitive procurement processes such as RFPs and RFTs.

AbbVie Limited
Level 6, Stephenson & Turner House
156-157 Victoria St
Wellington
NEW ZEALAND 6011

0800 900 030 (OFFICE)
+64 4 802 2981 (FAX)
www abbvie co nz

Pfizer New Zealand Limited
Level 1, Suite 1 4, Building B,
8 Nugent Street, Grafton, Auckland 1023
PO Box 3998, Shortland Street, Auckland, 1140
Tel: 09 354 3065 Fax: 09 374 7630

Pfizer New Zealand Limited

24 July 2020

PHARMAC
Level 9 Simpl House
40 Mercer Street
Wellington 601
email: procurement@pharmac govt nz

Dear Sir / Madam

PHARMAC proposal to modify its approach to competitive procurement

Thank you for the opportunity to provide feedback on PHARMAC's proposal to modify its approach to competitive procurement, as posted on your website on 10 July 2020

Pfizer New Zealand Limited (**Pfizer**) believes PHARMAC's choice of procurement strategies is critical to the future range of medicines available to New Zealanders, the reliability of medicines supply, and the competitiveness of the options presented to PHARMAC. With this in mind, we offer the following feedback on the current proposal by PHARMAC.

General feedback:

1. The issues with the current PHARMAC procurement strategies and contracts run much deeper than the amendments proposed in this consultation. Pfizer proposes a collaborative review process involving all stakeholders, and in particular suppliers of medicines, who currently carry total financial and reputational risk under PHARMAC's sole-supply policy. The review should address issues such as:
    a. Allowing prescriber choice to accommodate individual patient needs
    b. Recognition of the continuity of supply risk that PHARMAC's sole supply strategy imposes on medicines supply and apportioning of that risk between PHARMAC and suppliers
    c. Consideration of the dynamic global supply environment and the potential need to amend contractual terms at the sole supply End Date.
2. The consultation timeline for this proposal of two weeks is too short for meaningful dialogue with and among stakeholders
3. The current consultation contains insufficient detail for suppliers to understand and provide in depth feedback on the proposed amendments
4. If the proposed changes are to be included in the draft ITT scheduled for release in two weeks' time, the purpose and additional value of the current consultation is unclear

Pfizer Supports:

5 Pfizer supports combining the current Sole Supply Status and Hospital Supply Status regimes in principle. This has the potential to streamline and simplify the standard contractual terms of supply.

Pfizer does not support:

6. Pfizer does not support the proposed general "allowance for other brands" of 5%. We believe it is not realistic as:
    a. In relation to supply of the 5% discretionary product, the value and volume of business this would equate to for individual SKUs is impractical and unworkable unless supported by a PHARMAC stock guarantee. Many items included in PHARMAC's ITTs have very low volume and/or revenue streams even with sole supply; 5% of that business would not be viable unless the price of the discretionary product was very high, especially if suppliers were required to accept indemnities and penalties for stock outages.
    b 5% variance cannot be expected to cater for individual patient needs in many cases, such as the recent lamotrigine and venlafaxine examples.
    c It is not clear what decision criteria would be used to select the discretionary product. Would it, for example, be based on anticipated individual patient needs, on product cost, or on supply reliability?
    d. Pfizer believes estimating variances, particularly in relation to patient needs, will be difficult within the framework PHARMAC is proposing. We would like to understand the rationale for determining 5% to be the appropriate allowance given the range of medicines and clinical scenarios where an alternative option is considered medically necessary?
    e It is not clear whether separate tenders would be invited for secondary supply (i e for the 5% discretionary product) or whether there would be provision for suppliers to tender different prices for specified market shares.
    f. It is not clear whether there would be penalties imposed on secondary suppliers if demand exceeded the proposed allowance, resulting in stock outages
    g. It is not clear how the 5% allowance would be administered. How would physicians and patients will be aware of the secondary option? Would the alternative brand be subject to an exceptional circumstances process? If so, that appears cumbersome. How would prescribers and dispensers otherwise know if the variation limit had been reached?
    h It is not clear where compensation for the primary supplier would come from should funded use of alternative brands exceed 5%; would the supplier of the alternative brand be required to contribute to it?

Specific Feedback on PHARMAC's current standard terms of supply

7. Pfizer believes the wording of the current standard PHARMAC agreement template is heavily weighted against the interests of suppliers, and requests changes to the following clauses:
    a Throughout the standard Agreement, there are various references to, *"(other than for reasons that PHARMAC considers to be wholly outside your control)" (e.g. clause 7(b)(ii) of Annex 3).* Pfizer believes that this subjective element in the Agreement is unreasonable, and requests that all instances of this wording be amended to read *"(other than for reasons wholly outside your control)"*
    b. Annex Three (A) Clause 7(b)and Annex Three Clause 7 (b)(ii)
    Pfizer's obligation here should be limited to "*reasonable additional costs that are directly related to the purchase of Alternative Pharmaceuticals*". Further, PHARMAC should have an obligation to use its best endeavours to mitigate any costs incurred by it, and by any relevant DHB Hospitals, in the circumstances outlined in clause 7(b)(ii)

c. *Annex Three (A)(13) and (B)(15) Confidentiality*

PHARMAC ~~may~~ will consult with you before deciding whether to disclose Confidential Information for the purpose described in the paragraphs (a) to (d) above, in order to ascertain any objections you may have to the disclosure of the Confidential Information and PHARMAC will provide reasonable notice to you if Confidential Information is to be disclosed pursuant to paragraphs (a) (d) above. You acknowledge, however, that it is for PHARMAC to decide, ~~in its absolute discretion~~ acting reasonably, whether it is necessary or appropriate to disclose information for any of the above purposes, provided that PHARMAC shall act in good faith in disclosing any Confidential Information.

d *Annex Three (B)(17)(a): Invoicing and Payment*

You are to invoice the DHB ~~at the end of each month~~ after delivery of product to the Designated Delivery Point, but no later than the second Business Day following the month to which the invoice in respect of the Pharmaceutical relates, specifying for all the Delivery of Pharmaceutical that month:

e. *Annex Three A (11) and Three B (9): Consents*

You warrant that you have, and will maintain, all consents (including Ministry of Health market approval) necessary for you to supply a Pharmaceutical in New Zealand for the treatment of each indication for which it is subsidised (at the date of signing of this agreement) with the exception of Unapproved Indications indicated as such in Sections C and H of the Pharmaceutical Schedule (each a "Consent").

f. *Annex Four*

Crown direction – We request that the following new paragraph (d) be inserted at the end of this clause: "*If the effect of any such Crown Direction on this Agreement is adverse to your interests, you may give PHARMAC not less than 30 days' written notice of termination of this Agreement with respect to any or all of the Pharmaceuticals.*"

As mentioned in the introduction, Pfizer recommends a stakeholder task force be convened by PHARMAC to discuss the wider problems with PHARMAC's current procurement strategy, and to develop a sustainable supply model that ensures New Zealanders have timely, affordable and reliable access to medicines offering safety and efficacy that aligns with the international standard of care.

Pfizer would welcome the opportunity to contribute to this conversation to create change and solutions that provide value to patients, and to our wider society and economy.

Yours faithfully

Ross Hunt
Market Access Manager
Pfizer New Zealand Limited

Anne Harris
Country Manager
Pfizer Australia and New Zealand

Withheld under section 9(2)(ba)(i)

Manager, Procurement and contracts
PHARMAC
40 Mercer Road
Wellington

24 July 2020

Dear Craig,

Consultation response – Proposal to modify PHARMAC's approach to competitive procurement

Thank you for the opportunity to comment on the consultation released 10 July 2020 around the proposal to modify PHARMAC's approach to competitive procurement

The proposal seeks to replace Sole Supply Status (SSS) and Hospital Supply Status (HSS) with Principal Supply Status (PSS), applied to either the community or hospital setting (or both), where there would be an allowance for other brands of a tendered pharmaceutical for 5% of the market volume

Withhel is a responsible and patient-centric organisation, placing the interest of patients at the heart of our actions and decisions In this respect we welcome and support, in principle, the objectives of the proposed amendment to PHARMAC's competitive procurement process where alternative brands of a tendered pharmaceutical would be made available to patients who cannot tolerate or develop an adverse reaction to the sole subsidised brand.

We are however cognisant of the incentives and risks associated with the proposal and have some questions and concerns we would like to share with PHARMAC around the workings of the proposed model

Determining the appropriate split between the primary brand and 'other' brands

The proposal seeks to award the primary brand with 95% market share, with a variable allowance of up to 5% for other brands of the same chemical and formulation intended for patients who cannot tolerate the primary brand.

It is unclear from the proposal if all winning tender bids would be awarded PSS with 5% brand variance, and if not, how and using what criteria PHARMAC would decide whether the 5% brand variance is required.

In theory, the magnitude of this variance should be proportionate to the perceived or likely risk associated with a brand switch, taking into account the nature of the medicine. For example, the risk associated with the initial switch from an innovator brand of a medicine to a generic medicine is arguably higher than switching patients from one brand of a genericised medicine to another brand of a generic medicine

In this respect, PHARMAC may wish to consider a higher variance allowance for medicines that are considered higher risk, or the first time that a generic medicine is awarded HSS, than in instances where brand switches have occurred without issue in the past.

Price control for pharmaceuticals supplied outside of Principal Supply Status

There remains a question of how PHARMAC would control the price and subsidy of medicines used outside of the Principle Supply Status

Whilst the proposal outlined three mechanisms whereby alternative brands may be accessed (listing, DV, or exceptional circumstances), from a supplier perspective, what incentives are there for a non primary supplier to enter into a contract with PHARMAC and fix a price for medicines sold outside of the Principle Supply Status In addition, how might PHARMAC ensure that use of medicines outside of the primary brand does not exceed the 5% allowance.

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Incentives for suppliers of non-primary brands

The proposed model may incentivise suppliers of non primary brands of medicines to promote the prescribing and dispensing of its brands.

The 5% market may prove a reasonable incentive for suppliers to directly advertise or promote its brand to prescribers or pharmacies (through free-stock arrangements), or to raise awareness of the adverse event profile of competing pharmaceuticals, to increase brand specific uptake and market share. Given that non-primary brands may not be contracted, PHARMAC may be faced with materially higher expenditure on generic pharmaceuticals in future

The increased cost pressures on PHARMAC would likely come from a combination of factors: subsidizing higher priced non primary brands, non primary brands obtaining a market share of greater than 5%, and topping up the primary-brand to the guaranteed 95% market share.

Augmenting competition in tender markets

There may be instances where suppliers with products which have high brand recognition and brand loyalty would be incentivised not to submit a tender bid for Principle Supply Status, and instead focus its attention and promotional efforts on the higher margin 5% market. Such a scenario may result in reduced competitiveness of bids in certain tender markets, and result in higher generic pharmaceutical prices.

Increased choice of generic medicines balanced against reduced investment into new innovative medicines

Relative to the status quo, the proposal would result in an increase in the brands of subsidised generic medicines. However, the proposed model would inevitably result in an increase in the expenditure on generic medicines as a whole

Given that PHARMAC manages a fixed pool of funds from which existing and new treatments are reimbursed, how would the likely increase in generic medicines expenditure impact the funds available for new and innovative medicines, and what would the fiscal cost, and foregone QALY cost of this proposal be? Is PHARMAC going to receive additional funding to offset this increase in generic medicines expenditure to maintain the headroom of funds available for new investments.

Medicines continuity considerations

This proposal is likely to incentivise suppliers who have not been awarded the Principle Supply Status to maintain registration and keep a small supply of a particular medicine in New Zealand

However, given the relatively small 5% total market offered to alternative brands together with the lack of contractually obligated minimum stock holding requirements, it would be unreasonable to expect or anticipate that such suppliers could materially bridge the gap or meet the demands of the total New Zealand market should a stock issue affect the primary contracted brand

An alternative approach

Given that PHARMAC is considering a review of its existing competitive procurement process, we also encourage PHARMAC to explore alternative approaches to awarding competitive contracts. One such example is the Australian model whereby generic brands are listed and subsidised using the lowest bid as a ceiling price, applied across all brands of that pharmaceutical. This may promote and encourage generic suppliers to remain and supply the New Zealand market

Concluding remarks

While we support the objectives of the proposal to amend PHARMAC's approach to competitive procurement, we are aware of the types of behaviors that the proposal may incentivise and are concerned at the material impact this proposal may have on generic pharmaceutical expenditure We

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urge PHARMAC to explore options to reduce exposure to the above mentioned risks prior to moving ahead with a decision

Please note that should this document be released in its entirety or in-part as part of an Official Information Act request, we wish to have the sender and organisation's details redacted

Sincerely,

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