multiplemyeloma.org.nz
admin@multiplemyeloma.org.nz

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Pharmac
consult@pharmac.govt.nz

Dear Pharmac

Proposal to increase access to lenalidomide and pomalidomide through a brand change for lenalidomide

Myeloma New Zealand is very pleased Pharmac is proposing to fund pomalidomide and widen access to lenalidomide. This will benefit patients, their loved ones, our wider society, and New Zealand's health system.

Better access to treatments
New Zealand myeloma patients need these medicines so the proposal is welcomed. However, we are deeply concerned at the length of time taken to fund them:

- Pharmac's tracker shows the application for lenalidomide first line was submitted in April 2016 and the pomalidomide application submitted in November 2015 - . eight and nine years respectively for these medicines to be funded, until the generic is off patent. This callous waiting until a medicine is off patent is shocking. Patients, too many patients, have died while waiting.
- In those nine years the myeloma world has continued to move. Those medicines are still needed, but patients need the other treatments with which they are now being combined.
- It is well known that New Zealand is considerably behind with funded myeloma treatments compared with other countries. We are concerned patients will have to wait for other medicines to come off patent before they have access to them. That is distressing and discouraging for patients and the people who care about and for them.
- Myeloma is a relapsing remitting disease. New Zealand patients and clinicians need, and should have, access to a range of treatments and particularly to myeloma treatments that are standard of care in comparable countries.
- The delays to fund medicines mean patients are dying earlier than they need to. In addition, the lack of modern treatments compromises the work of our haematologist community. It means New Zealand is losing haematologists to overseas and it will be difficult to recruit haematologists in New Zealand. We are now left ineligible for myeloma trials as we do not have funded drugs such as daratumumab which are standard of care overseas.

Myeloma New Zealand is also concerned at the low number of myeloma treatments that are Medsafe approved. While this may not seem like Pharmac's responsibility, we believe your

decisions influence willingness (or not) to submit medicines and treatments to Medsafe for approval. We find it unfortunately understandable that the consistent lack of funding for new myeloma treatments suggests to pharmaceutical companies that there is little point in progressing through the approval process.

Section 68 subsection 1 of the Pae Ora (Healthy Futures) Act 2022 states the intention of Pharmac is 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"*. We ask Pharmac advocate stronger for sufficient budget to achieve "best health outcomes that are reasonably achievable from pharmaceutical treatment", with 'best health outcomes' recognising the wider benefits of medicines beyond patients to their families, society, and the wider health system.

Supply and safety/efficacy

As noted later in this response, we are concerned the data around efficacy and safety has not been provided as part of this proposal. We ask that Pharmac include it in any future proposals.

The proposal does not set out alternative plans in the event of problems with supply. Anecdotally, there have been issues with supply of lenalidomide generics in the United States. If that happened in New Zealand, would Pharmac provide Revlimid/Pomalyst branded lenalidomide/pomalidomide? What steps has Pharmac has taken to secure supply of these medicines and what assurances have you been given around supply?

Feedback to proposal

Our feedback to specific parts of the proposal follows.

Pharmac proposal	**Myeloma New Zealand comment**
This proposal results from a competitive procurement process for the Principal Supply of lenalidomide and pomalidomide. Changing the funded brand of lenalidomide would enable increased access to treatments for people with multiple myeloma and MDS and result in cost savings.	We are pleased to see Pharmac say this process would enable increased access to treatments for people with myeloma. From a patient's point of view it is exciting to think this process could lead to medicines like daratumumab and carfilzomib being funded. However, we do not think that is actually your intention as we understand any cost savings go back "into the pot" at Pharmac and are not tied to myeloma specifically. Language like this escalates the emotional roller coaster patients experience about their lack of access to good medicines.

	The statement also prompts the question: are we always going to have to wait for generics to get any medicine in the future?
From 1 August 2024 lenalidomide (branded as Lenalidomide Viatris) supplied by Viatris would be funded for anyone with multiple myeloma who has not previously received funded treatment with lenalidomide. This means people would be able to access lenalidomide treatment earlier in the course of their disease, without having to try other funded treatments or receive a stem cell transplant first.	We are very pleased the proposal does not exclude those currently paying privately for lenalidomide and pomalidomide. As written, it appears to exclude patients who: - have chosen to take a break from the medicine for whatever reason - travel or fora break from side effects such as fatigue, - may have been paying privately and stopped because the cost became untenable, - wanted to be strategic about use of treatment because of the limited myeloma treatments e.g. stopping lenalidomide maintenance after three years while not refractory, so it is an option to reuse in the future, - may have used the treatment in the past and the clinician wants to use it again in combination with other treatments because of the synergistic advantages of doing so. We ask you to change the criteria so both medicines are available for anyone with myeloma if their specialist believes they need them, including those who have been on them before previously. (See comments further below on the specific criteria for funding).
Our clinical advisors told us that it would be appropriate to consider ongoing funding of the Revlimid brand for people on an individual, case-by-case basis. An individual's prescriber would need to apply via Pharmac's Exceptional Circumstances framework for this. The application would need to demonstrate that the individual transitioned from the Revlimid brand of lenalidomide to the generic Lenalidomide Viatris brand, and then experienced a hypersensitivity	Reactions may be rare but they do happen and our understanding is they are more common with generics. Accordingly, we are expecting Pharmac's process will be considerate in these situations.

reaction that could be reasonably attributable to the generic lenalidomide. Our clinical advisors have told us that this would be extremely rare. This application would be different to our Named Patient Pharmaceutical Applications (NPPA) pathway. We would provide more information about this process, if this proposal is approved.	
Support for people with multiple myeloma or MDS Pharmac would work alongside advocacy and support groups and the suppliers of lenalidomide (Viatris) and pomalidomide (Juno) to provide information and resources about these treatments to support the transition and new listing. This would include educational material about lenalidomide and pomalidomide in English, Māori and Pacific languages. We would have a dedicated webpage on the Pharmac website for people with multiple myeloma and MDS that would include the key dates for the transition and where to find more information. We are interested to hear what other activities would support a smooth transition for people to Viatris Lenalidomide and the introduction of Pomolide.	We suggest provision of information about efficacy and safety data is provided to patients as part of the rollout to give some reassurance during the change. Although myeloma patients and their loved ones have provided feedback to Myeloma New Zealand on the proposal, there has been nothing specific on this point. We hope Pharmac will be flexible if ideas come up during the rollout process.
Support for healthcare professionals Pharmac and the suppliers of these treatments would work together to provide specific information about the proposed brands (Lenalidomide Viatris and Pomolide), including: • clinical data about efficacy and safety • practical prescribing / dispensing information including risk management programme support. We would have a dedicated webpage on the Pharmac website for healthcare	We have been unable to find anything online about the efficacy and safety of the proposed brands of generics, only about other generics. That information should have been provided as part of the proposal. We cannot give a fully informed response without that. The proposed support for healthcare professionals is good. However, we think this information should also be available to patients, as many of them need this to be active participants in their treatment plan. We assume patients will be able to access the

professionals. This would include information regarding the transition to a new risk management programme. It would also include the key dates for the transition, where to find more information, and how to apply to our Exceptional Circumstances Framework for individuals who may need to return to the previously funded brand of lenalidomide (Revlimid).	proposed page and that it is not locked to public access.
In New Zealand, around 400 new cases of multiple myeloma are diagnosed each year. Māori and Pacific peoples who develop myeloma are diagnosed at a younger age but are less likely to receive first-line treatment or an autologous stem cell transplant (ASCT). They experience poorer outcomes than non-Māori and non-Pacific populations.	We agree with this comment with regard to the current proposal, but we remind Pharmac that this is why we need newer and better treatments for myeloma such as carfilzomib and daratumumab.
Lenalidomide and pomalidomide Lenalidomide is an immunomodulatory drug that is indicated for the treatment of multiple myeloma and myelodysplastic syndrome (MDS) associated with a deletion 5q cytogenetic abnormality. It works by stimulating part of the immune system to attack the cancer cells and stop them developing. It is supplied as an oral capsule and is used in combination with a medicine called dexamethasone as part of a 28-day cycle. Further information can be found in the lenalidomide Medsafe Datasheet [PDF](external link). Pomalidomide works in a similar way to lenalidomide. It is a more potent medicine than lenalidomide. It is indicated for the treatment of people with relapsed and refractory multiple myeloma. It is also supplied as an oral capsule and is used in combination with dexamethasone as part of a 28-day cycle.	We assume that both treatments can be used as a monotherapy without dexamethasone and ask that this be clarified.

There are several brands of lenalidomide and pomalidomide approved by Medsafe for use in Aotearoa New Zealand. A generic medicine has the same active ingredient and works the same way as the original reference brand. When there are generic brands available, Pharmac can use the opportunity to promote competition. This can release significant funds to increase access to more medicines. We understand there would still be unmet health needs for people with multiple myeloma, even if we widen access to lenalidomide and pomalidomide. We would continue to assess funding applications for other treatments for multiple myeloma and engage with suppliers about their treatments. Read more about the funding process on the Pharmac website.	Similar to our comment above, does this process release significant funds for myeloma? If not, why is this comment included? If this process does release funds for myeloma, then we urgently need treatments like daratumumab funded. If not, including this comment here, like the one at the beginning, is misleading and upsetting for patients.
Initial application – (Multiple myeloma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both: 1. Patient has multiple myeloma requiring treatment; and 2. Patient has not received prior funded lenalidomide. **Renewal application – (Multiple myeloma)** from any relevant practitioner. Approvals valid for 12 months where there is no evidence of disease progression.	As above, we are pleased the proposal does not exclude those currently paying privately for lenalidomide and pomalidomide. As written, it appears to exclude patients who: - have chosen to take a break from the medicine for whatever reason - travel or fora break from side effects such as fatigue, - may have been paying privately and stopped because the cost became untenable, - wanted to be strategic about use of treatment because of the limited myeloma treatments e.g. stopping lenalidomide maintenance after three years while not refractory, so it is an option to reuse in the future, - may have used the treatment in the past and the clinician wants to use it again in combination with other treatments because of the synergistic advantages of doing so.

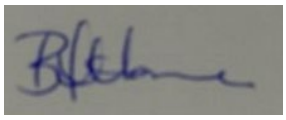
	Given the serious lack of treatments in New Zealand, we believe it is up to clinicians as they are best place to make the decision if the treatment has benefit for a particular patient. We ask you change the criteria so both medicines are available for anyone with myeloma if their specialist believes they need them, including those who have been on them previously. We suggest the following wording: **Initial application – (Multiple myeloma)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both: ~~1.~~ Patient has multiple myeloma requiring treatment. ~~and~~ ~~2. Patient has not received prior funded lenalidomide.~~
Initial application – (Relapsed/refractory multiple myeloma) from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both: 1. Patient has relapsed or refractory multiple myeloma with progressive disease; and 2. Patient has not received prior funded pomalidomide. **Renewal - (Relapsed/refractory multiple myeloma)** from any relevant practitioner. Approvals valid for 12 months where there is no evidence of disease progression.	As above, we are pleased the proposal does not exclude those who are currently paying privately for lenalidomide and pomalidomide. As written, it appears to exclude patients who: - have chosen to take a break from the medicine for whatever reason - travel or fora break from side effects such as fatigue, - may have been paying privately and stopped because the cost became untenable, - wanted to be strategic about use of treatment because of the limited myeloma treatments e.g. stopping lenalidomide maintenance after three years while not refractory, so it is an option to reuse in the future, - may have used the treatment in the past and the clinician wants to use it again in combination with other treatments because of the synergistic advantages of doing so.

	Given the serious lack of treatments in New Zealand, we believe it is up to clinicians as they are best placed to make the decision if the treatment has benefit for a particular patient. We ask you change the criteria so both medicines are available for anyone with myeloma if their specialist believes they need them, including those who have been on them previously. We suggest the following wording: **Initial application – (Relapsed/refractory multiple myeloma)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria: Both: 1. Patient has relapsed or refractory multiple myeloma with progressive disease requiring treatment. 2. ~~Patient has not received prior funded pomalidomide.~~
The proposed eligibility criteria may allow wider funded access than the Medsafe approved indications. Prescribing of pomalidomide outside of Medsafe approved indications would need to follow Section 25 of the Medicines Act 1981.	We are pleased to see this in the proposal and hope that daratumumab will soon be available and able to used in combination with pomalidomide and dexamethasone.
Your feedback may be shared Feedback we receive is subject to the Official Information Act 1982 (OIA). Please be aware that we may need to share your feedback, including your identity, in response to an OIA request. This applies to anyone providing feedback, whether they are providing feedback themselves or for an organisation, in a personal or professional capacity. We can only keep feedback confidential as allowed under the OIA and other related laws. If you want any part of your feedback treated as confidential, you	We are aware of patients who are not public about their myeloma and are concerned about their details being made public. We do not believe the wording in the proposal is correct. The Privacy Act still applies when providing information under Official Information Act. We ask that all names are redacted if there was an Official Information Act request about submissions. We are concerned that this section of the proposal could restrict the number of people who feel comfortable putting in a submission.

need to tell us. Please let us know if you want to keep part of your feedback confidential, and why. Is it commercially sensitive, confidential or proprietary, or personal information? Clearly state this and tell us which parts of your feedback you want to keep confidential for these reasons. We will consider your request under our OIA requirements.	

Thank you for the opportunity to provide this feedback. Myeloma patients, and Myeloma New Zealand, look forward to a time when the medicines and treatments available here mean myeloma can be treated more like the chronic condition that it is already in other countries – and one day there may be a curative treatment. Pharmac plays a critical role in achieving that goal.

Yours sincerely



Barbara Horne
Chair
Myeloma New Zealand