

Shannon Stewart

From: Simon England
Sent: Monday, 25 June 2018 10:30 AM
To: 'Justine Mecchia'
Subject: No surprises update - Updated policy settings for medicines for rare disorders

Hi Justine

This is a no surprises update about our ongoing work in medicines for rare disorders. At the end of 2017, PHARMAC agreed to update a set of policy settings for medicines for rare disorders, amongst other work including establishing a dedicated subcommittee for such medicines.

Today we are publishing adjusted policy settings on medicines for rare disorders on our website. The policy settings will help guide our work in this area and give clarity to stakeholders.

We have also begun seeking applications from suppliers of medicines for rare disorders. We hope that this process will lead to even better access to funded medicines for people with rare disorders.

The policy settings include three principles, which are based on the differences of medicines for the treatment of rare disorders. These differences address the current market challenges for these medicines, and enable (where appropriate) a different entry into the pharmaceutical funding process.

The principles are as follows:

1. The medicine has been approved by Medsafe, or an approved international regulatory authority, for the identified indication.
2. The disorder is a clinically defined disorder affecting an identifiable and measurable patient population with a prevalence of less than 1:50,000 in New Zealand.
3. The medicine is only registered for the treatment of the rare disorder, or if it is registered for other disorders (or is part of phase three clinical trials for other disorders), the cumulative prevalence across all indications still meets principle 2.

PHARMAC will determine whether funding applications meet the principles. Those that do will then be considered through the process determined by PHARMAC. Other applications that do not meet the principles can still be considered through our usual Schedule listing process.

We will be contacting key stakeholders ahead of the policy settings being published.

Please contact me if you require any further information.

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