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**Royal Australasian College of Physicians
submission to PHARMAC**

Declining inactive applications

Introduction

The Royal Australasian College of Physicians (RACP) welcomes the opportunity to submit feedback on PHARMAC's proposal to decline inactive applications for pharmaceuticals in New Zealand.

The RACP works across more than 40 medical specialties to educate, innovate and advocate for excellence in health and medical care. Working with our senior members, the RACP trains the next generation of specialists, while playing a lead role in developing world best practice models of care. We also draw on the skills of our members, to develop policies that promote a healthier society. By working together, our members advance the interest of our profession, our patients and the broader community.

The RACP acknowledges that the PHARMAC model continues to achieve positive health outcomes for many New Zealanders. We do recognise, however, that significant barriers to improve access to medicines and medical devices remain for many people in our communities, particularly for Māori, Pasifika, people living with chronic disease and people experiencing high levels of deprivation.

Comments on the decision-making criteria

The RACP supports policy and decision-making informed by evidence, efficacy and equity. We note the current consultation (PHARMAC's proposal to decline a number of medicines due to inactive funding applications) covers a range of medicines and conditions. Further, PHARMAC cites a number of factors which have contributed to these medicines being considered as having inactive funding applications:

1. Clinical advice has recommended the application be declined more than two years ago
2. Other medicines for the same condition are funded and have greater clinical preference
3. The medicine would provide no additional benefits over other funded medicines, or may cause harm
4. No company is willing to supply the medicine in New Zealand.

Not every rationale applies to every medicine listed in the consultation. Some are clear; for example Simeprevir for chronic hepatitis C genotype one; and Sibutramine (Reductil) for severe obesity. Maviret, which covers all genotypes of hepatitis C was funded by PHARMAC from February 2019, meaning that medicines which only treat one or two genotypes was no longer necessary; additionally, Marivet and other direct-acting antiviral agents have shown reduced risk of significant side effects, administration of complex medicine regimens and costs^{1 2}. Sibutramine was withdrawn in 2010 by Medsafe, following evidence of increased harm to people using the medication, including stroke and not-fatal cardiovascular events³.

Other medicines and their respective clinical indications listed in this consultation, namely melatonin, Trastuzumab (Herceptin), Temozolomide and Methylphenidate are under consideration to be declined due to insufficient clinical evidence, or evidence of poor quality. If the rationale to decline the application is based on the available evidence, this should be explicitly stated. We encourage

¹ PHARMAC funding decision gives Kiwis with hepatitis C access to a potential cure. Media release. 17 December 2018. Wellington: PHARMAC. Available from <https://www.pharmac.govt.nz/news/media-2018-12-17-hepatitis-treatment/>. Accessed 14 May 2019

² Ahmed M. Era of direct-acting antiviral agents for the treatment of hepatitis C. World J Hepatol. [Internet] 2018; 10(10):670-684. Available from <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6206157/>. Accessed 14 May 2019.

³ Medsafe. Withdrawal of Sibutramine (Reductil) in New Zealand. Media release. 11 October 2010. Wellington: Medsafe. Available from <https://medsafe.govt.nz/hot/media/2010/SibutramineOct2010.asp>. Accessed 14 May 2019.

PHARMAC to amend the first bullet point in the list of reasons to include reference to available evidence, for example:

- Our expert clinical advisors recommended that the funding application be declined more than two years ago *based on available evidence*

The RACP sees this aspect important, as we note that one of the purposes of this consultation is as a test case: “it will also help us determine if this consultation approach works for people who are interested in and want to contribute to our decision-making”. The consultation approach used by PHARMAC here provides greater transparency of decision-making at all stages of the process, which we believe would be welcomed by interested parties, including prescribers, clinicians, consumers and whānau.

Cost as a factor

Medicines, medical devices and other therapeutic products are expensive to research, develop, test and eventually bring to market; as such, medicines, particularly those under patent may incur significant costs to the consumer. PHARMAC’s role is in part to negotiate subsidies on behalf of the New Zealand government, contributing to its legislated 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”⁴.

While there are several ways for cost to be a factor in decision-making, applications for funding which have not progressed due to the high costs of some medicines set by the pharmaceutical industry should be stated explicitly where possible. For example, the consultation document details in the background for Cisapride that “there is no supplier with a Medsafe approved supplier of Cisapride willing to supply Cisapride in New Zealand”. One conclusion would be no supplier was willing to receive less than the current market rate in exchange for supplying this medicine to New Zealand. Although it cannot be deduced from the consultation document whether or not this is the case, the public discourse around why this is the outcome is often construed negatively towards PHARMAC’s own decision-making, not the demands of industry.

The RACP acknowledges the complexity of PHARMAC’s negotiations and recognises specific details will have a degree of commercial sensitivity. Recent examples of industry actions and their contribution to increasing inequities in access to health care and medicines should be called out – and equally examples of collaboration, goodwill and innovation to improve health outcomes should also be profiled in the sector and civil society.

Reducing harm through Choosing Wisely

The RACP is a supporter of the Choosing Wisely movement in New Zealand and Australia and have developed a number of top 5 lists in collaboration with specialty societies through our EVOLVE initiative⁵. There are several points of alignment between PHARMAC’s proposal to decline the stated inactive applications and the Choosing Wisely and EVOLVE principles of reducing harm, eliminating waste in the system and changing practice.

⁴ New Zealand Public Health and Disability Act 2000, s47 (a).

⁵ Royal Australasian College of Physicians. EVOLVE. Sydney: The Royal Australasian College of Physicians; 2019. Available from <https://evolve.edu.au/home>. Accessed 14 May 2019

Comments on specific inactive applications

Long-acting paracetamol

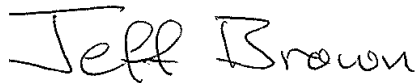
The RACP supports the 2010 recommendation of the Analgesic Subcommittee on 665mg paracetamol sustained release tablets only be funded if it were cost neutral compared to the daily cost per patient of funded immediate release 500mg tablets.

We note however that there may be instances where long-acting paracetamol is clinically indicated, for example in older, chronically or terminally ill patients where there is a significant pill burden or risk of polypharmacy.

Conclusion

The RACP thanks PHARMAC for the opportunity to provide feedback on this consultation, and looks forward to commenting on future consultations regarding PHARMAC's decision-making processes. To discuss this submission further, please contact the NZ Policy and Advocacy Unit at policy@racp.org.nz.

Nāku noa, nā



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