

5 April 2016

Pharmaceutical Benefits Advisory Committee (PBAC)
PO Box 9848
Canberra ACT 2601
Via email: PBSPostmarket@health.gov.au

Re: Public consultation on the draft revised PBAC Guidelines

Thank you for the opportunity to respond to the public consultation on the draft revised *PBAC Guidelines*. NPS MedicineWise continues to support the high quality work of PBAC and their importance in supporting Quality Use of Medicines (QUM) principles. We are pleased to have organisational representation and participate in the process. Reviewing and refining the guidelines is an important piece of work which will enhance the evaluation and translation of clinical evidence to ensure appropriate PBS listings.

NPS MedicineWise is key to implementing the National Medicines Policy (NMP), of which QUM is one of the four pillars. We support the judicious, appropriate, safe and efficacious use of medicines. As a national, independent, evidence based, not-for-profit organisation, we work to improve the way medicines and other medical technologies are prescribed and used in practice. We create better health outcomes through behaviour change interventions, evidence based information to support decision making and targeted health communication campaigns for health professionals and consumers in Australia.

Given our work and experience in this area, we are particularly interested in section 5.1 *Quality use of medicines*. In order to improve QUM, reduce adverse events and reduce costs of medicine misuse in Australia, it is critical that PBAC guidelines are consistent with the objectives of the NMP. With this in mind, please find below some suggestions you may wish to take on board before finalising the guidelines.

1.1 Strengthening section 5

Section 5.1 asks for information on any activities the sponsor will undertake in supporting QUM. This section is currently optional. NPS MedicineWise is concerned that sponsors are not completing section 5.1 and therefore are not providing any documented consideration to the QUM implications of their application.

NPS MedicineWise believes section 5.1 should be strengthened to better support the NMP principles and practice. We strongly support either making this section compulsory or reframing it in such a way that sponsors are more encouraged to complete section 5.1.

Other options to improve the consideration of QUM impacts of proposals include:

- Moving section 5 to earlier in the guidelines document, which will make it stand out more
- Strengthening the language and highlighting the importance of sponsors considering QUM issues in their submission
- Sponsors could be required to respond to any QUM related issues raised in the commentary
- Upskilling sponsors to better respond to this section, as we note the current quality in sponsor's proposals is variable.

We strongly encourage the review to also consider additional options in which the importance of QUM is highlighted in the guidelines.

1.2 Follow up and compliance

Follow up and compliance with QUM plans is an important part of the guideline implementation process, to ensure that desired outcomes are achieved. NPS MedicineWise therefore recommends greater transparency regarding PBAC's process for monitoring and ensuring compliance with the QUM plans put forward by sponsors.

Please do not hesitate to contact Kerren Hosking, Executive Manager Corporate Affairs and Governance, on (02) 8217 8796 or email khosking@nps.org.au, should you wish to discuss this further.

We look forward to seeing the finalised guidelines in due course.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Lynn Weekes', written in a cursive style.

Dr Lynn Weekes AM
CEO