Dreamtime: Version 5.0 of the Australian Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC)

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abstract

In September 2016 the Australian Department of Health published Version 5.0 of the Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee (PBAC). These guidelines, which were first published for comment in 1990, set out how to prepare a submission to list a new medicine or medicinal product on the Pharmaceutical Benefits Schedule (PBS). The guidelines give instructions on the information required by the PBAC and the Economic Sub-Committee (ESC), the most appropriate form for presenting clinical evidence and the standards for an economic evaluation. The purpose of this commentary is to consider whether or not the evidence standards proposed and the consequent modeled claims for economic effectiveness meet the standards of normal science: are the claims presented to support PBS listing credible, evaluable and replicable. The review concludes that the PBAC guidelines do not meet the standards expected in normal science. The absence of empirically evaluable claims means there is no way of judging whether they are right or even if they are wrong. If the Guidelines were never intended to support experimentation and

systematic observation to generate feedback to health system decision makers, then this should be made clear by the PBAC. If not, then consideration should be given to redrafting the guidelines to ensure they conform to these standards. Hopefully, future versions of the guidelines will address this issue and focus on a rigorous research program of claims assessment and feedback.

Type: Commentary

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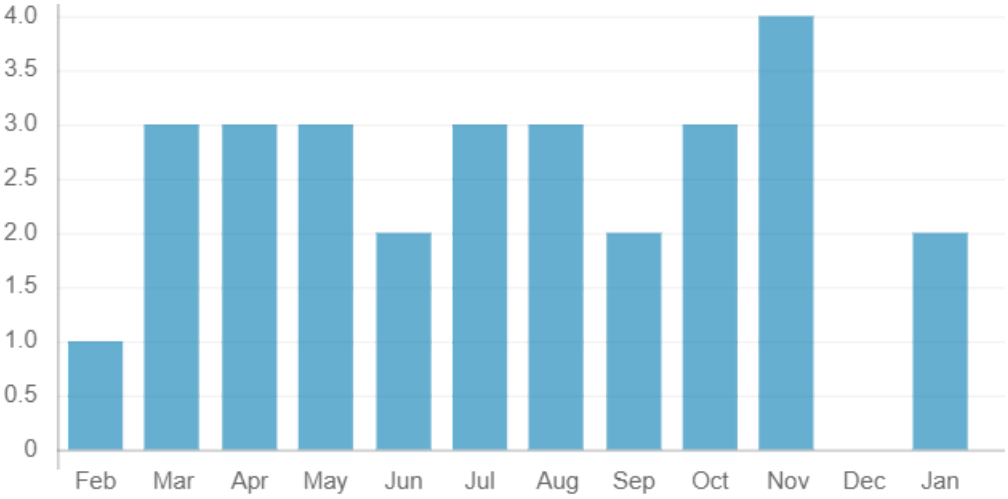

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