

Activity Indicators for the Pharmaceutical Benefits Scheme

Fourth Report: 2005 to 2010

Preamble

This report presents the fourth annual set of outcomes resulting from a collaborative project between Medicines Australia, the Department of Health and Ageing and the Pharmaceutical Benefits Advisory Committee (PBAC) to jointly develop indicators that can be used to monitor the listing processes as they apply to the Pharmaceutical Benefits Scheme (PBS) and National Immunisation Program (NIP). The primary purpose of these indicators is to facilitate the identification of trends in the process of adding items to the PBS/NIP that may provide the basis for further dialogue.

In developing the indicators, it was agreed that the data with which they are to be populated should, where possible, be publicly available and independently verifiable eg. in the form of the reporting of the PBAC agendas, PBAC outcomes and public summary documents (PSD, see web links below). This has necessitated a great deal of interaction and collaboration between all parties to ensure agreement on the definitions of the indicators and the data parameters utilised. Importantly, it is not possible to uphold the principle of independent verifiability with regard to outcomes based on the type of economic analysis reported in the submission for the period prior to the commencement of publication of PSDs (July 2005). Similarly, information regarding some non-sponsor-initiated matters and submissions relating to pricing matters is currently excluded from the publication of the PBAC agenda, outcomes and PSDs. Public release of information on some pricing matters is under discussion between the Department of Health and Ageing and Medicines Australia. In the meantime, submissions relating to pricing matters are included in the aggregate count for the first background and first core indicator graph but are excluded from the remaining indicators.

The intended perspective of these indicators is such that they reflect all published matters considered by the PBAC regardless of the source of the submission giving rise to those considerations, or the subsequent PBAC recommendation. Accordingly, the indicators are presented in aggregate (without differentiation of the source of the underlying submission) and relate to the inputs to the PBS/NIP listing process (hence matters which are subsequently withdrawn are captured in these indicators).

This fourth report provides data on outcomes pertaining to PBAC deliberations of submissions, including the overall PBAC recommendation, and recommendations stratified by type of submission (major/minor), and by the economic basis of the submission and subsequent PBAC recommendation (cost-effectiveness where a price advantage is justified over the comparator therapy, cost-minimisation where a price advantage is not justified over the comparator therapy). The information it contains relates to considerations by the PBAC over the years 2005 to 2010 inclusive. Issues regarding the definition and data requirements for additional indicators such as those encompassing timelines within the listing process will continue to be explored throughout 2011, although outcomes for a transitional timelines indicator are included in this report.

Transitional timelines indicator

In 2009, a transitional timelines indicator was added to the Activity Indicators. The data in this indicator show all initial major submissions by the calendar year in which they were considered by the PBAC, and then reports the cumulative percentage with a positive recommendation for each subsequent calendar year. For example, the current table shows that by the third year after the year of initial consideration, between 83% and 92% of major submissions for a 'drug-main indication' pairing have received a positive PBAC recommendation. In contrast to most other Key Activity Indicators, which are based on submissions per PBAC meeting, the cumulative recommendation

percentage over time follows submissions involving a 'drug-main indication' pairing forward as a cohort.

Archived data

To ensure that the graphical figures provided in this report continue to be legible, each figure is limited to presenting a maximum of six years worth of data. Accordingly, the data for the 2004 calendar year included in the earlier reports have been omitted when adding the 2010 calendar year data. However, a link to the earlier 2004-2009 information is provided below.

Explanatory notes: PBAC Outcomes

In viewing the report, it is important to recognise that most outcomes are presented on a per meeting basis. That is, the PBAC outcomes are reported as they pertained to each meeting with the submission date relating to the date of consideration not the date of lodgement. With the exception of the Transitional Timelines Indicator, the PBAC outcomes are not based on tracking serial submissions for related requests to the PBAC over time. Tracking across submissions requires pairing the particular drug involved with the main indication requested for its subsidised PBS use.

The terms "core" and "supportive" are used to classify the PBAC outcome indicators reported herein. There are four core and seven supportive indicators. Core indicators are those providing overarching information for the main elements of interest in the PBAC outcomes. The supportive indicators subsequently provide more detail regarding those core PBAC outcomes, and additional information not addressed by the core indicators. In addition to presenting information to populate the four core and seven supportive PBAC outcome indicators, an introductory background figure featuring the total number of PBAC submissions considered in each calendar year (classified as minor/major) and a transitional timelines indicator are presented.

The majority of the terms appearing within this report are self-explanatory or are defined within the *Guidelines for Preparing Submissions to the Pharmaceutical Benefits Advisory Committee* (Version 4.3, December 2008).

Type of submission – Major/Minor

Submissions to list a new drug on the Schedule of Pharmaceutical Benefits or to make substantial changes to current listings are classified as major submissions. Major submissions require presentation of an economic analysis. They are evaluated by the Pharmaceutical Evaluation Section, the Economics Sub-Committee, the Drug Utilisation Sub-Committee and the Australian Technical Advisory Group on Immunisation before consideration by the PBAC. Submissions that relate to new forms of previously listed products or changes to the conditions of use e.g. change in maximum quantity/repeats or clarifying the wording of a restriction (while not altering the intended use) are considered to be minor submissions. These do not usually require the presentation of an economic analysis. Typically, they are not evaluated by the Pharmaceutical Evaluation Section or relevant sub-committees prior to consideration by the PBAC.

Status of submission – Initial/Resubmission/Other

Major or minor submissions are classed as "initial" if it is their first presentation to the PBAC to add a new listing or to request a change to an existing listing. "Resubmissions" result in a re-consideration by the PBAC for a 'drug-main indication' pairing that has failed to be recommended on a previous occasion or has not proceeded to listing if it has been recommended. "Ever major" resubmissions result in a PBAC re-consideration of a 'drug-main indication pairing' which at some time was considered by the PBAC as a major submission. In such cases the initial presentation to the PBAC and/or the submission resulting in the PBAC outcome itself may have involved a minor submission. All submissions outside of these categories, for example deferrals or pricing matters, are classed as "other".

Basis of economic analysis

The economic basis of the submission may be identified using section 9 (Clinical Claim) and/or section 10 (Economic Analysis) of the relevant PSD, while the economic basis of the recommendation is available from the PBAC outcomes posting on the Department of Health and Ageing web-site, and section 12 (Recommendation and Reasons) of the PSD. Since PSDs are only available from July 2005, supportive indicators 1, 2, 5 and 6 begin from this time instead of the beginning of the 2005 calendar year seen with the other indicators.

The economic basis of the submission is that of the submission which generated the relevant PBAC outcome rather than the economic basis of the submission when it was first lodged. The two broad types of economic analysis presented in these indicators are cost-effectiveness and cost-minimisation. Submissions using a cost-utility analysis, cost-benefit analysis or a partial economic analysis (such as cost-analysis) have been included with those submissions having cost-effectiveness as the economic basis of submission. Submissions which do not contain an economic analysis are included in the total count of PBAC submissions (background graph), core indicators 1 and 2 and the transitional timelines indicator but are excluded from the supportive indicators 1, 2, 5 and 6 which relate to the basis of economic analysis.

Changes to PBS listing

The indicator presenting the number of PBAC recommendations to either tighten or broaden an existing restriction is sourced from the PBAC Short Minutes 'Changes to present (or recommended) PBS availability'. It reviews whether the change to listing was less restrictive (resulting in an increase in the eligible patient population), more restrictive (resulting in a reduction in the eligible patient population) or no change (where no change to the eligible patient population was anticipated). Block additions to this section, such as minor clarification changes to the restriction wording (or to the "Notes" attached to PBS listings) or access by new prescriber groups, are excluded. For the purposes of this analysis any change in maximum quantity and/or the number of repeats, and removal of grandfather clauses that might have applied to PBS restrictions are treated as 'no change'.

Web-links

General PBS information: www.pbs.gov.au

PBAC agenda: www.health.gov.au/internet/main/publishing.nsf/Content/PBAC-Meeting-Agenda-and-Consumer-Comments-lp

PBAC outcomes: www.health.gov.au/internet/main/publishing.nsf/Content/pbac-outcomes-info

Public summary documents:
www.health.gov.au/internet/main/publishing.nsf/Content/public-summary-documents

Guidelines for preparing submissions to the PBAC:
www.health.gov.au/internet/main/publishing.nsf/Content/pbacguidelines-index

PBAC Outcome activity indicators

Background figure: PBAC submissions.

Core indicator 1: PBAC submissions by outcome.

Core indicator 2: Initial major submissions by outcome.

Core indicator 3: Initial minor submissions by outcome.

Supportive indicator 1: Initial major cost-effectiveness submissions by outcome.

Supportive indicator 2: Initial major cost-minimisation submissions by outcome.

Supportive indicator 3: Number of submissions referred for independent review over past 12 months.

Supportive indicator 4: Percentage of submissions referred for independent review over past 12 months for which the PBAC reverses its decision.

Core indicator 4: Resubmissions of ever majors by outcome.

Supportive indicator 5: Ever major cost-effectiveness resubmissions by outcome.

Supportive indicator 6: Ever major cost-minimisation resubmissions by outcome.

Supportive indicator 7: Changes to PBS listing.

Timelines activity indicator

Transitional timelines indicator: Cumulative PBAC recommendation percentage for initial major submissions by calendar year, 2005-2010.

Archived 2004-2009 indicators

PBAC Outcomes

Transitional timelines indicator