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Are Australians Able to Access New Medicines on the Pharmaceutical Benefits Scheme in a More or Less Timely Manner? An Analysis of Pharmaceutical Benefits Advisory Committee Recommendations, 1999–2003

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ABSTRACT

Objective: Timely access to necessary medicines that Australians need is one of the four pillars of the Australian Government's National Medicines Policy. We were interested to determine whether there was a change in the time taken for medicines to be listed once recommended by the Pharmaceutical Benefits Advisory Committee (PBAC).

Methods: Descriptive statistics were used to show the pattern of recommendations for PBAC meetings from 1999 to 2003. For successful recommendations, we developed a linear regression model to analyze the time to list from the PBAC meeting to date of listing (time to list). The model determined whether this time had changed over the 4-year period, and the reasons for any changes.

Results: The PBAC made 307 positive recommendations at its 17 meetings over the study period. Ninety percent resulted in a Pharmaceutical Benefits Scheme (PBS) listing on or before April 1, 2005. Eighty-two percent of the recommendations made in 1999 and 2000 resulted in early or on-time listings. In 2001, 2002, and 2003, the comparable proportions were 67%, 68%, and 75%. Mean times to list for the years from 1999 to 2003 were similar (approximately 23 weeks), except in 2001 where it was 30 weeks.

Conclusions: Over the study period, 90% of all PBAC recommendations resulted in a PBS listing. In 2001 there was a statistically significant increase in the mean time to list. In addition, it appears that recommendations for new listings and new indications (medicines that are likely to result in substantial Government expenditure) were associated with a longer time to list.

Keywords: cost-effectiveness, decision-making, health economics, health policy.

Introduction

Australia has a national scheme to provide subsidized access to necessary medicines—the Pharmaceutical Benefits Scheme (PBS). The Pharmaceutical Benefits Advisory Committee (PBAC) was established as a statutory body to advise the Minister of Health and Ageing (Minister) on matters relating to the listing and availability of medicines on the PBS [1]. The PBAC is required by law to consider cost and effectiveness, among other factors, when reviewing an application to list a (new) medicine on the PBS ("value for money" assessment) [2]. The PBAC has produced Guidelines for the pharmaceutical industry on the preparation of applications [3]. For many years, the PBAC met on a quarterly basis. Since 2004, meetings occur three times a year.

The PBAC makes three types of decisions (outcomes):

- It can decide to recommend the listing of a medicine on the PBS (so-called recommendation);
- It can decide not to recommend the listing of a medicine on the PBS (rejection);
- It can defer a decision pending the provision of specific additional information that would be relevant and important to its decision (deferral).

Once a medicine has been recommended by the PBAC, it is referred to the Pharmaceutical Benefits Pricing Authority (PBPA) for consideration. The PBPA is a nonstatutory body that advises the Minister on matters relating to the pricing of medicines on the PBS [4]. The PBPA usually meets 4 to 5 weeks after each PBAC meeting.

Recommendations are referred to the Minister, or to Cabinet if the estimated annual cost to the PBS is greater than AU$10 million in any of the first 4 years of listing, for approval. It is most unusual for a Min-

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Conflicts of interest: M.W. is employed by a pharmaceutical company that made numerous applications to the PBAC during the study period. A.M.N. and R.P. acted as consultants to the local pharmaceutical industry on PBAC application issues.

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ister not to accept a PBAC recommendation. The listing process, from PBAC application to listing, takes a minimum of 8 months. The PBS listing of a PBAC-recommended medicine can be delayed if the sponsor and the PBPA cannot agree on price; the recommendation is referred to Cabinet and its consideration is delayed or deferred; or there are supply issues.

For many years PBAC decisions were not made public. Following an agreement between the PBAC and the pharmaceutical industry in mid-1999, all positive PBAC recommendations have been made public since the December 1999 PBAC meeting. Further agreement has been reached such that from its June 2003 meeting, all PBAC "decisions" (recommendations, rejections, and deferrals) will be made public, although the extent of disclosure will be limited.

Objectives

Our aim was to determine whether, over a period of 4 years, new necessary medicines that were recommended by the PBAC were made available on the PBS in a more or less timely manner—one of the objectives of the Government's National Medicines Policy [5]. Our primary objective was to determine whether the proportion of recommendations that resulted in a PBS listing at any time varied with the year of recommendation or other key variables. Our secondary objective was to determine whether any of these variables were associated with a prolonged time to list.

The time period of our analysis (December 1999–December 2003) was chosen on the basis of currency and sample size (no a priori power calculations were conducted). Other than the introduction in June 2001 of the mandatory requirement for Cabinet approval of recommendations that are estimated to involve considerable Government expenditure, there were no new policy/procedural initiatives that required consideration during the study period [6].

Methods

We extracted the following information for each recommendation from the PBS Web site: meeting date; (generic) name of medicine; presentation/s and strengths; medicine use/type (indication or medicinal class); type of listing; PBAC recommendation and comments [7]. The information provided on medicine type/use was used to determine the Anatomical Therapeutic Chemical Classification (ATC) system main group for each medicine [8].

We created the following categories to classify the recommendations by listing type:

1. New listing—a new medicine.
2. New indication—extend a current listing of a medicine to include its subsidized use in/by a completely new patient population.
3. New combination product—a new medicine with two or more active substances that are listed on the PBS as individual entities.
4. Restriction change—revise the wording of the restrictions of a listed medicine.
5. New strength—a new strength of a listed medicine.
6. New formulation—a new presentation of a listed medicine.
7. Therapeutic relativity—price increase for a currently listed medicine by way of a changed (improved) therapeutic relativity.

Where a recommendation was made for more than one listing type, we used the higher of the two categories (e.g., a new indication took precedence over a new formulation). Information on which medicines were referred to Cabinet for consideration was obtained from Ministerial media releases and press articles [9]. Information on what medicines had been designated as orphan drugs was obtained from the Register of Orphan Drugs [10].

We classified all recommendations as being either resolved or unresolved. The resolved recommendations were further classified as having been either accepted or rejected by the Minister (or Cabinet).

We confirmed the type of listing for all accepted recommended medicines and the date of their PBS listing using the issues of the Schedule of Pharmaceutical Benefits for the period from February 1, 2000 to April 1, 2005 inclusive [11]. New issues of the Schedule were released every 3 months during the study period. Most listings became effective on the date of issue of the Schedule; some became effective in between issues. The time (in weeks) from the date of PBAC recommendation to the date of PBS listing (time to list) was measured.

Descriptive statistics were used to determine the proportion of recommendations made at each PBAC meeting that achieved a PBS listing at any time. A logistic regression model was developed to determine whether the annual proportion was associated with the year of recommendation ("year") and other variables (medicine type, type of listing, Cabinet review, and orphan drug status). "Year" was included as a categorical variable to ascertain whether there had been any change over time in the proportion of successfully listed recommendations. Recommendations were considered successful if they resulted in a PBS listing at any time, regardless of the breadth of the patient population and/or the degree of restrictions applied.

For those recommendations that resulted in a PBS listing on or before April 1, 2005, we determined with a further logistic regression model if the time to list was associated with any of the variables used in the first model. The listing of each PBAC recommendation was then classified as being either "early" (less than

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