

## Drug Tracker Report: November 2011



**Pretium's** *Drug Tracker* is a special bi-monthly feature article in the online magazine *Pharma In Focus* which analyses trends in regards to ADEC, PBAC and PBS information relevant to the reimbursement of medicines in the Australian Health Care system.

The **Pretium** database houses PBAC recommendations and PBS listings and ADEC recommendations from the dates that these data were made public. The database includes sponsor names, drug names, PBS codes, brand names, strength and types of drugs, ATC codes down to level 5 and additional product by product detail.

Access to this depth of data allows *Drug Tracker* to expose clear trends in how regulators and reimbursement authorities affect the process of bringing new drugs to market.

### **November Summary: Probability of success for PBAC submissions – review of data for preparations for malignant neoplastic diseases and immunomodulating agents, June 2003 to July 2011**

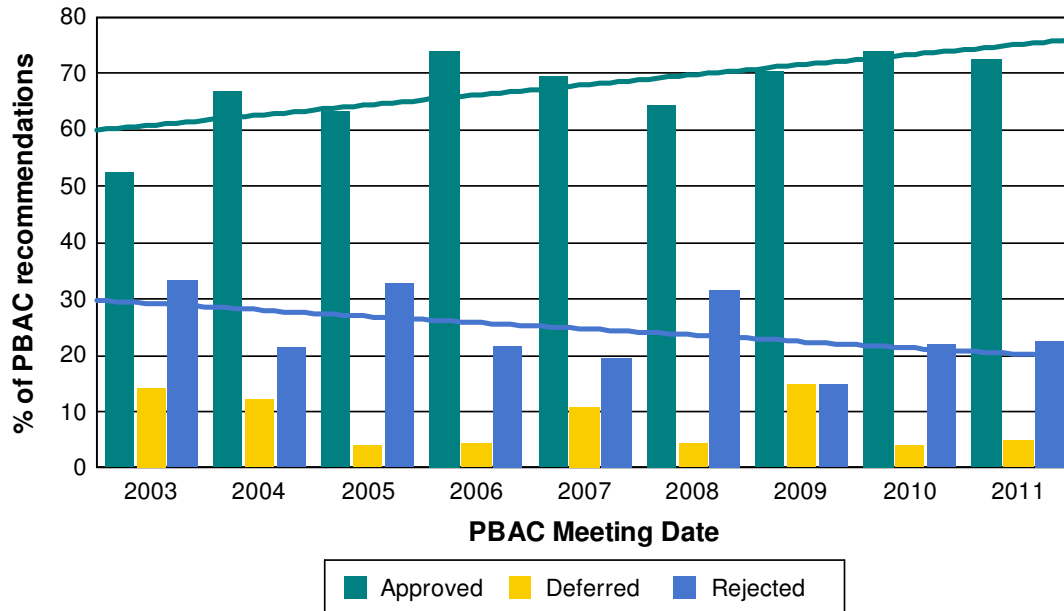
Oncology is an area of increasing disease burden in Australia and worldwide. The AIHW lists cancer as the leading cause of the burden of disease and injury in Australia. It also states that advances in cancer treatment areas are improving disease outcomes. As these advances in treatment become available PBAC subsidisation is sought. Herein we examine trends related to new oncology treatment subsidisation.

In this November 2011 issue of *Drug Tracker*, we present a trend analysis of the probability of success for a PBAC submission categorised under WHO ATC code L (preparations used in the treatment of malignant neoplastic diseases and immunomodulating agents) on an annual basis, from June 2003 to July 2011. Prior to June 2003 unsuccessful submissions to the PBAC were not made public.

A trend analysis was performed for all (major and minor) submissions made in the category of WHO ATC code L for this period to determine the proportions that were successfully recommended by the PBAC and those that were rejected. The analysis revealed an increasing trend in the proportion of approvals overall for antineoplastic and immunomodulating agents (**Figure 1**).

# PBAC Outcomes, 2003-2011

All Submissions with ATC code L



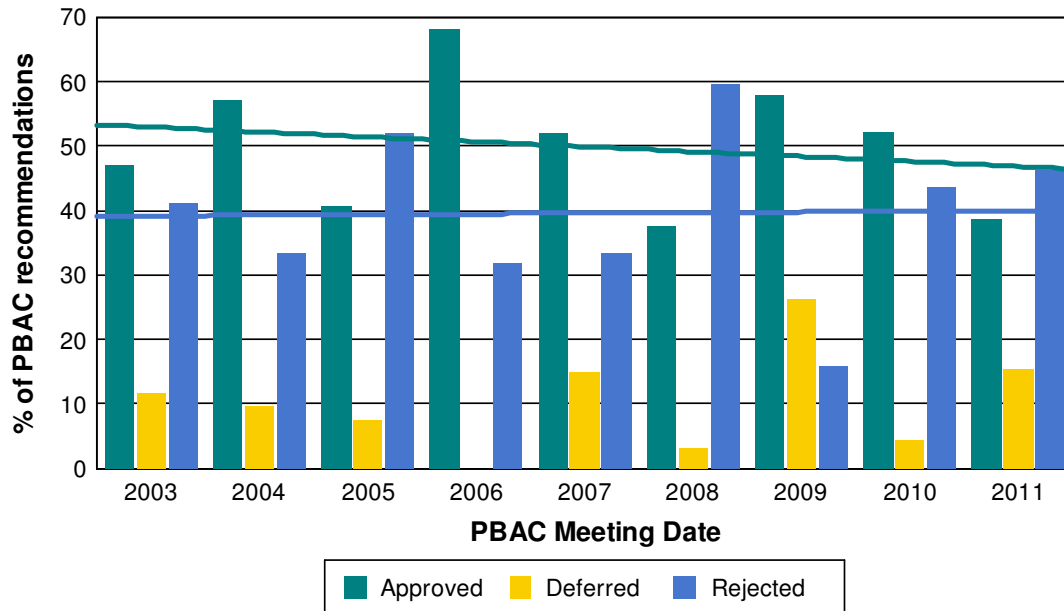
Note: This analysis is based on all PBAC submissions where a medication was submitted to the PBAC as an antineoplastic or immunomodulating agent (ATC code L)

**Figure 1 Figure 1 Probability of success at a PBAC meeting, PBAC submissions with ATC code L, June 2003-July 2011 (n=409)**

However, when stratifying the data to include only major submissions to the PBAC, a downward trend in the proportion of approvals was observed. To date in 2011 there have been thirteen major applications that have been submitted for antineoplastic and immunomodulating agents. Of these 5 have been approved (38%) and 6 have been rejected (46%) which is much reduced from approval rates of 57% and 52% in 2009 and 2010 respectively (**Figure 2**).

## PBAC Outcomes, 2003-2011

All major submissions with ATC code L



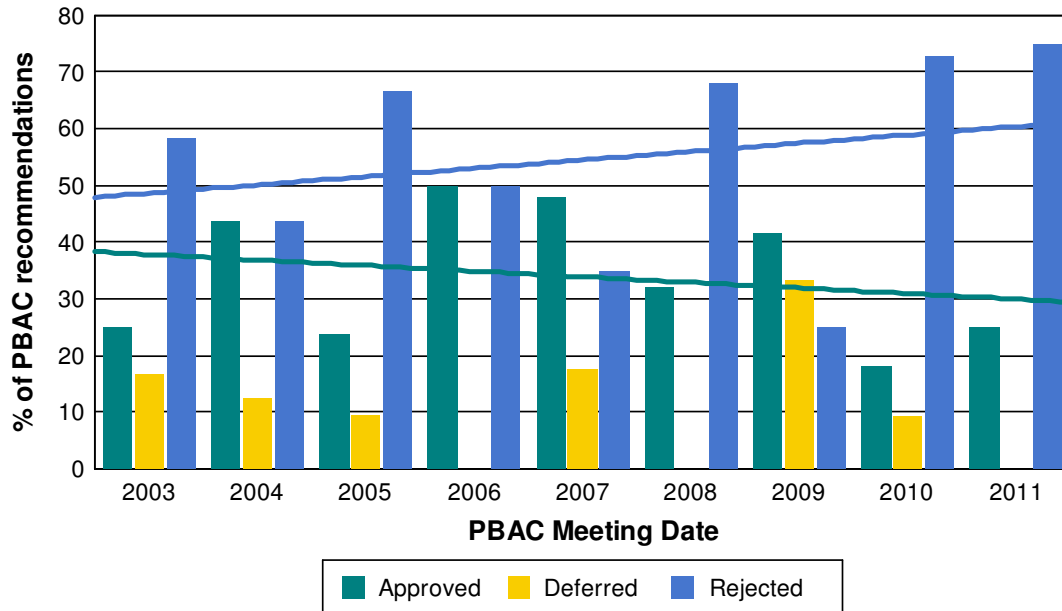
Note: This analysis is based on PBAC submissions where a medication was submitted as a major submission to the PBAC and associated with the ATC code L

**Figure 2 Probability of success at a PBAC meeting, major PBAC submissions with ATC code L, June 2003-July 2011 (n=201)**

When the data are further stratified to include only major submissions using a cost effectiveness analysis, the proportion of rejections has exhibited an upward trend with this year's figure the worst on record. To date in 2011 there have been 8 submissions made in this category, of which 6 (75%) have been rejected (**Figure 3**). In contrast, the 2 submissions that have been made on a cost minimisation basis (CMA) have been approved (data not shown). Overall, there have been 5 approvals for major submissions in ATC class L this year, 2 were immunomodulating agents and were approved based on a cost effectiveness analysis. The remaining 3 approvals were antineoplastic agents and were approved based on a cost minimisation analysis.

# PBAC Outcomes, 2003-2011

All major CEA submissions in ATC class L



Note: This analysis is based on PBAC submissions where a medication was submitted as a major submission to the PBAC using cost effectiveness as the economic approach and associated with ATC code L

**Figure 3 Probability of success at a PBAC meeting, major PBAC submissions using a cost-effectiveness analysis and ATC code L, June 2003-July 2011 (n=142)**

## Conclusion

The rising trend in approvals for antineoplastic and immunomodulating agents is being driven by the success of minor submissions. When major cost effectiveness submissions are analysed, the trend is for a greater number of rejections and fewer approvals.

Apart from *Drug Tracker's* bi-monthly publication in the online magazine *Pharma In Focus*, **Pretium** is able to offer *Drug Tracker* reports specific to your requirements which include, but are not limited to, competitor analyses, therapeutic class analyses, and drug or indication specific analyses. For more information on *Drug Tracker* or **Pretium's** data and services, contact Dr Munro Neville on 02 8088 1500 or email [info@pretium.com.au](mailto:info@pretium.com.au).