

Pretium's *Drug Tracker* is a special bi-monthly analysis featuring trend analyses of ADEC, PBAC and PBS information relevant to the reimbursement of medicines in the Australian Health Care system. In the July 2010 *Drug Tracker* we conduct a review of the listing and recommendation trends from the past year.

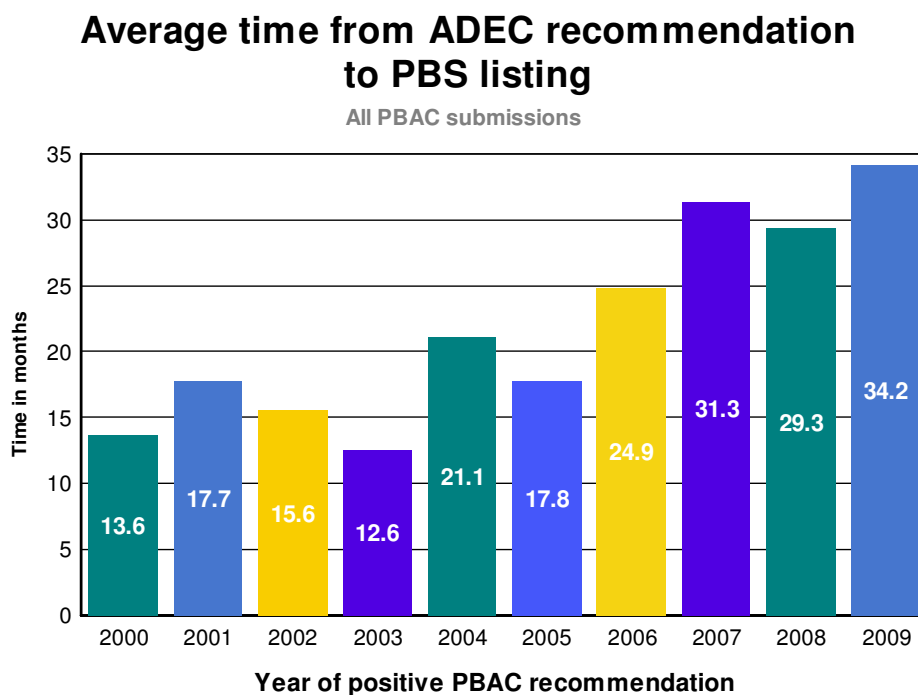
The **Pretium** database houses PBAC recommendations and PBS listings and ADEC recommendations from the dates that these data were made public. The database includes sponsor names, drug names, PBS codes, brand names, strength and types of drugs, ATC codes down to level 5 and additional product by product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

July Summary: Time from ADEC recommendation to PBS listing – Review of data spanning from June 2003 to July 2010

In the July 2010 issue of *Drug Tracker*, we present a trend analysis that reviews the average time to PBS listing following ADEC approval on a yearly basis, capturing data from the period 1998 to 2010. Note: as only 1 ADEC approved drug has received a PBS listing following a positive PBAC recommendation at the March 2010 meeting, these data have not been included in the analysis.

Figure 1 Average time from positive ADEC recommendation to PBS listing, all PBAC submissions, 2000-2009 (n=340; range per year = 27-38)

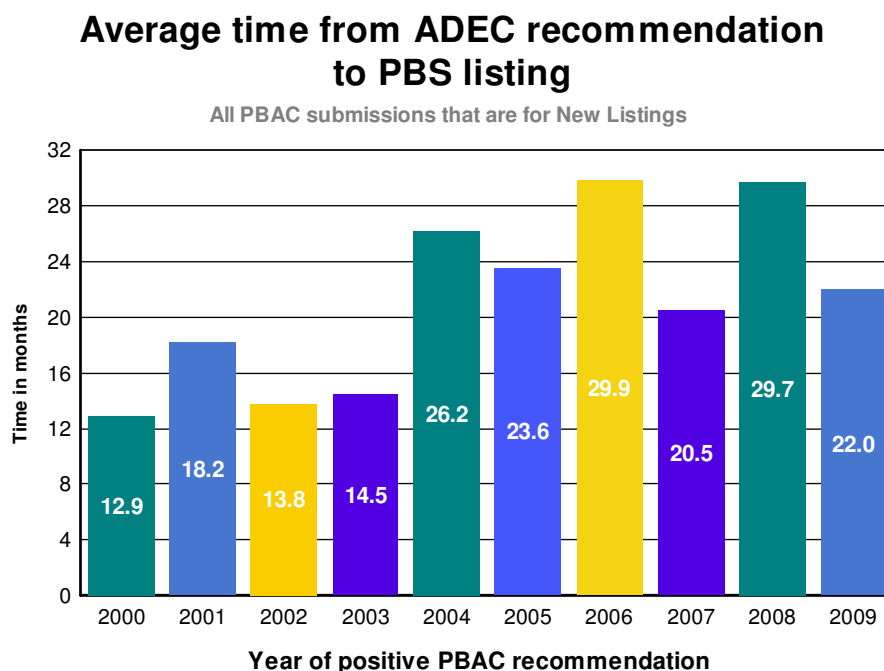


The data captured in this trend analysis indicate that the average time to achieve PBS listing post ADEC approval for all submission types has steadily increased over the period 2000-2009. The data in **Figure 1** show that there are spikes in the time to approval in 2004, 2007, and 2009. As the variation in the number of submissions per year is small and the minimum number of submissions is relatively large (27), these variations do not appear to have been influenced too heavily by individual submissions data not shown).

When stratifying the above trend report to include only submissions to the PBAC for new listings, a definite increase in time to listing can be seen when comparing the period 2000-2003 and 2004-2009 (**Figure 2**). The average time to PBS listing does not appear higher overall than the all submission analysis shown as **Figure 1**.

While, as **Figure 2** shows, there is a clear differentiation between time to listing and the year of the PBAC recommendation, there is no clear relationship between the PBAC analysis type, PBAC submission type, or ADEC recommendation type and the time to PBS listing post ADEC approval (data not shown).

Figure 2 Average time from positive ADEC recommendation to PBS listing, submissions to the PBAC for new listings, 2000-2009 (n=146; range per year = 11-20)



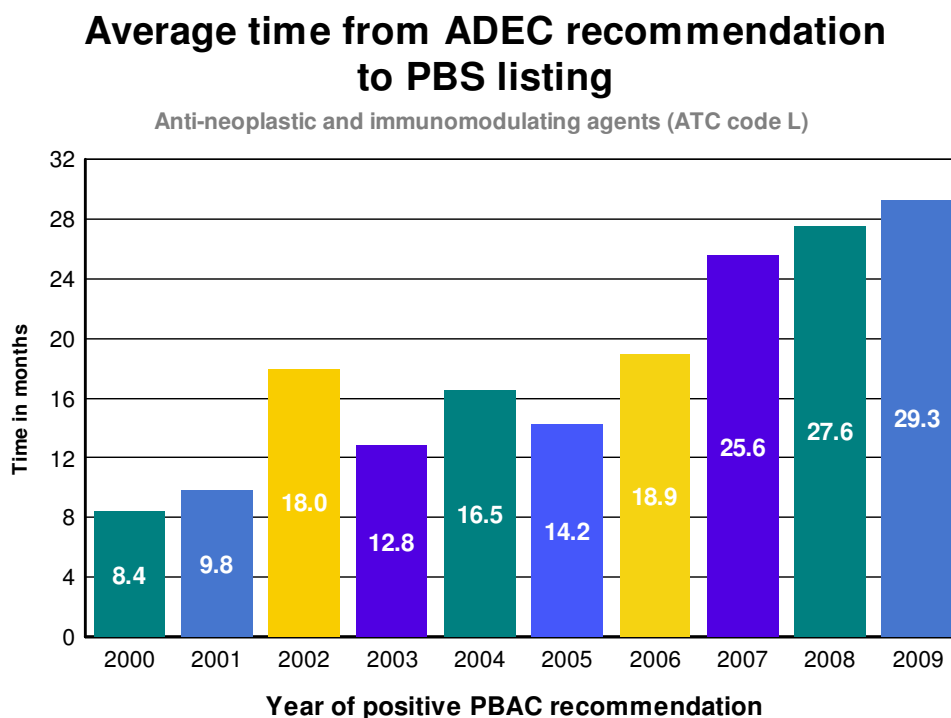
As can be seen in **Figure 1** and **Figure 2**, there are unexpected lengthy time span differences between time to PBS listing following ADEC approval for all submissions compared to new listings in 2007 and 2009. A review of the raw data indicates that these are due to a number of lengthy outliers that have taken longer than 50 months to receive PBS listing following ADEC recommendation. Examples from 2007 include: a new indication for **Dysport®** for the treatment of moderate-severe spasticity of the upper limb in adults following a stroke, which took 84 months to receive PBS listing; a new indication for **Remicade®** for the treatment of moderate to severe Crohn's disease, which took 90 months to receive

PBS listing; a new indication for **Ritalin LA®** for the treatment of ADHD in patients 6 to 18 years, which took 68 months to receive PBS listing; a new combination product for **Triasyn®** for the treatment of hypertension in patients, which took 108 months to receive PBS listing; and for a new indication for **Actonel®** for the prevention of first fracture in patients with osteoporosis aged ≥ 70 years with a T-score ≤ -3.0 , which took 88 months to receive PBS listing.

Examples from 2009 include: a new combination product for **Riamet®** for the treatment of suspected or confirmed uncomplicated malaria which received PBS listing 90 months after receiving a positive ADEC recommendation; an extended indication for **Zoladex Implant®** for use in early breast cancer in peri- or pre-menopausal women which took 101 months; a reinstatement for **Viramune®** for treatment of HIV which took 120 months; an extended restriction for **Sifrol®** to include use as monotherapy for idiopathic Parkinson's Disease which took 92 months to receive PBS listing from ADEC recommendation. It was also surprising to note that the average time to PBS listing post ADEC recommendation for new listings was lower for CEA than CMA submissions in 5 of the 10 years of data analysed (data not shown) given that previous Drug Tracker reports have indicated that time from PBAC to PBS listing was shorter for submissions recommended on the basis of cost-minimisation compared to cost-effectiveness. Earlier Drug Tracker reports have also shown that submissions recommended on a cost-minimisation basis also have a greater probability of success than submissions using a CEA; therefore negating multiple submissions to the PBAC.

When the data are stratified by ATC code, the ATC code with the most information is code L (anti-neoplastic and immunomodulating agents) with 91 PBAC submissions that fulfil the criteria for inclusion in this analysis (**Figure 3**).

Figure 3 Average time from positive ADEC recommendation to PBS listing, anti-neoplastic and immunomodulating agents, 2000-2009 (n=91; range per year = 5-15)



For this group, the average time to PBS listing has increased markedly between 2000 and 2009, with the majority of the increase occurring between 2005 (14 months) and 2007 (26 months).

A recent paper by Chim et al 2010 reviewed PSDs from July 2005 to March 2008, with a main aim of determining whether cancer drugs were less likely to be recommended for listing by the PBAC, concentrating on probability of success and QALY values. These objectives, along with the inclusion of only cancer drugs means that the results of the Chim et al 2010 paper cannot be directly reflected in the results of our analysis. However, Chim et al 2010 indicate that submissions with a modelled economic evaluation (that is, CEA and cost-utility analyses) and a higher cost per QALY tend to get approved less often than submissions that presented a CMA or used no modelling. In recent years, with the advances in technology, cancer treatments have become more common and subsequently, more targeted. Therefore, the cost of the drug has also increased, making it more difficult for cancer drugs to demonstrate an acceptable cost per QALY and subsequently a lower chance of obtaining a positive PBAC recommendation on initial application. As this has tended to occur more often in recent years, the success for these years has shown a decrease and the time to listing has consequently increased, as shown in **Figure 3** above.

Conclusion

As can be seen from the information analysed above, the time from positive ADEC recommendation to PBS listing has increased markedly between 2000 and 2009.

For more information on *Drug Tracker* or **Pretium's** data and services, contact Penny Reeves on 02 8088 1511 or email info@pretium.com.au.