Delays in Access to New Medicines

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BACKGROUND

To save costs, the government recently deferred approval of seven new medicines recommended by the Pharmaceutical Benefits Advisory Committee (PBAC) for up to seven months. This decision impacted on the accessibility of affordable and appropriate medicines for patients.

Whilst criticism has focussed on this decision and delays at the end of the approval system, there are a number of other stages in the approval process where patient access may be delayed.

AIM

The aim of this research is to examine the timeline from registration of a drug by the Therapeutic Goods Administration to submission and review of a PBAC application for subsidised funding. This will allow a comparison of the delays in Cabinet decision making in the context of the overall medicines approval process.

METHODS

All new chemical entities and products for new indications approved in 2004 by the TGA Australian Drug Evaluation Committee (ADEC) were identified. The outcomes of PBAC meetings between March 2004 and August 2010 were then searched to identify if and when these products were considered.

RESULTS

There were six meetings of ADEC in 2004, at which 47 eligible products were recommended for registration. Twenty were new chemical entities and 27 were new indications.

Figure 1: Product Approval Status

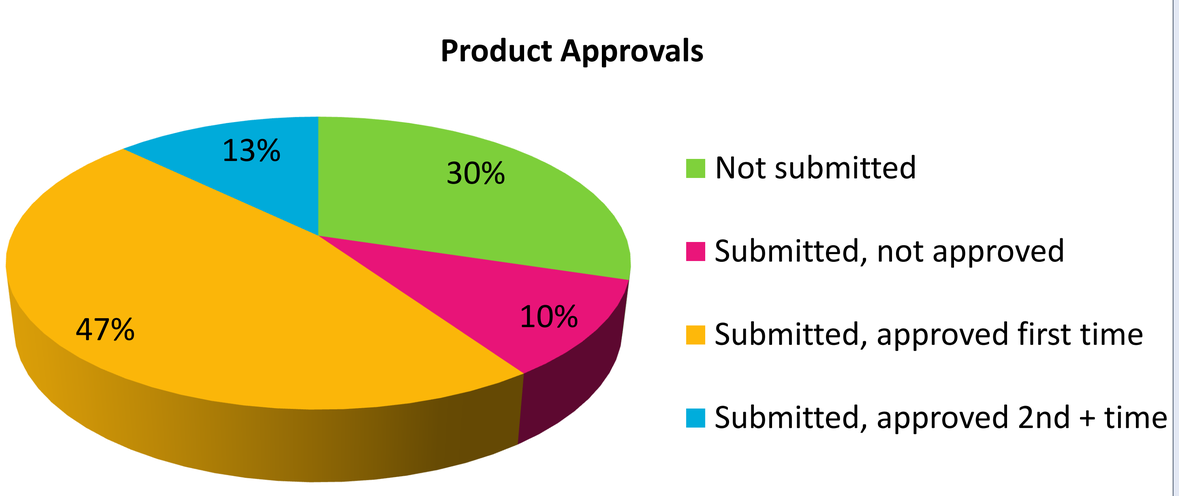


Figure 2: Number of Submissions per Product

Reviewed products were submitted to PBAC an average of three times (median twice), with a total of 100 submissions.

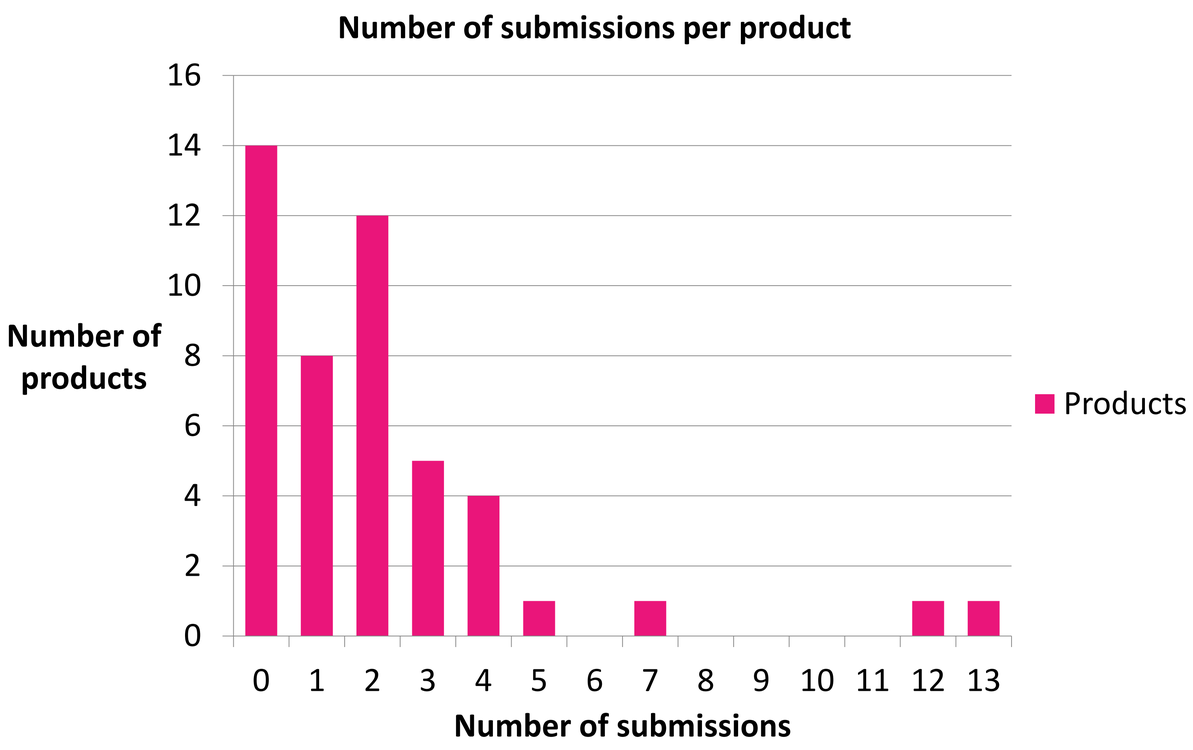


Figure 3: Time to PBAC review and approval of product

There was an average of 515 days (median 274 days, range 29 - 1675 days) from the ADEC approval date for a new indication or new chemical entity to its first review by the PBAC. Products which were approved had an average of 613 days (median 365 days, range 29 - 1675) to first approval.

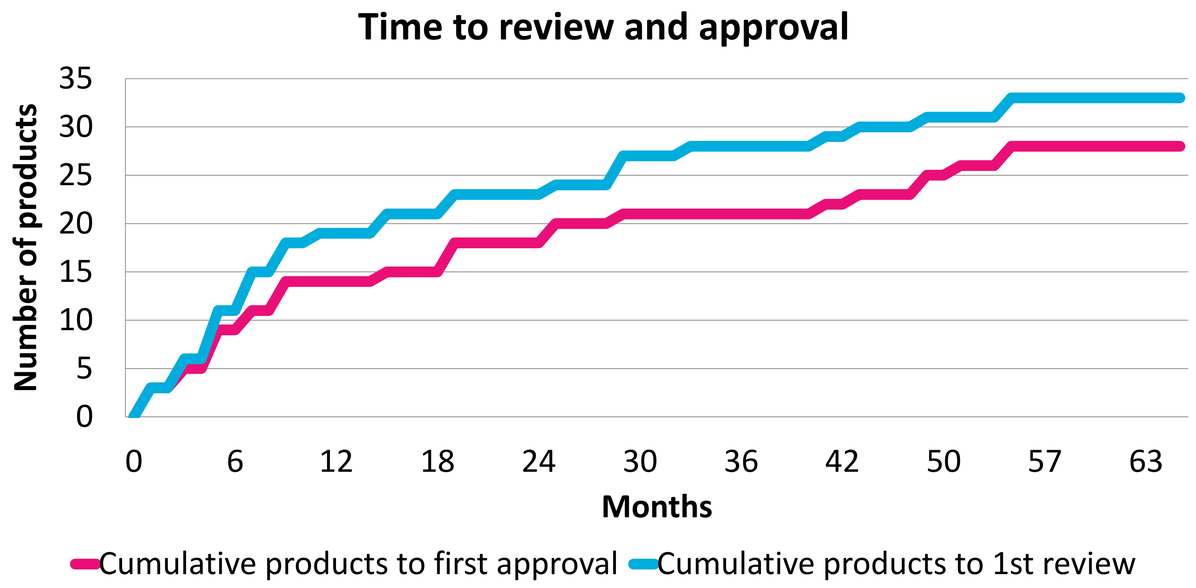
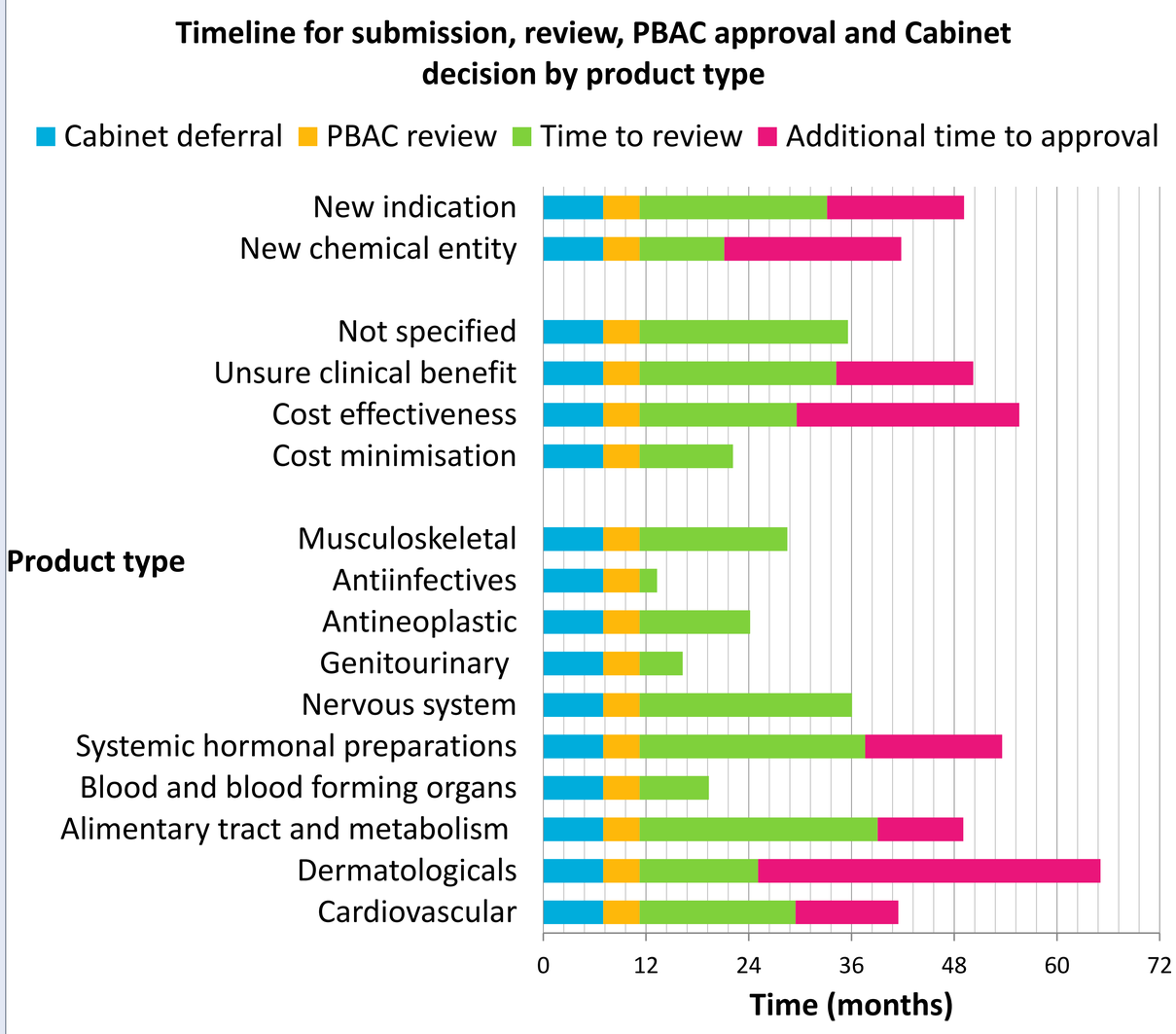


Figure 4: Overall Product Approval Timeline

In the overall timeline from TGA registration to PBAC recommendation, an additional seven month delay in Cabinet decision making represents a 29% increase in the time to approval.



CONCLUSIONS

This work puts the Cabinet decisions to defer listing of new medicines in the overall context of the approval process. There is no doubt that the seven month deferral time delayed the accessibility of new treatments to the Australian public. However, this work shows that there are additional delays earlier in the subsidised access approval process. These have a greater impact on the overall timeline, with delays of over four years for submission of products to PBAC for review.

CONTACTS AND ACKNOWLEDGEMENTS

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