

LATEST NEWS

## Post-PBAC Listing Times For High-Cost Medicines Have Improved Under The MoU – Pradaxa The Exception

o November 28, 2012

An analysis by PharmaDispatch has found that post-PBAC listing times for high-cost medicines requiring Cabinet approval have generally improved under the MoU. However, the delayed listing of PRADAXA, currently almost 640 days since PBAC approval, already over twice as long as the MoU average, remains an unresolved issue that could have a significant impact on confidence in the process.

The analysis shows that, while the total number of days from PBAC approval to actual listing has improved, the improvement is entirely due to one part of the process. The average number of days taken from PBAC approval to Ministerial announcement of Cabinet approval has more than halved, reflecting the “best endeavours” clause under the MoU.

The analysis is based on the PBS listing of four high-cost medicines approved by the PBAC before the MoU and three during the MoU. While PRADAXA is stuck in the post-PBAC process, and not included in the calculation, including it would significantly reduce the improvement in listing times under the MoU.

Under the MoU, the Government will use its “best endeavours” to secure a Cabinet decision on high cost medicines within six months of notification from the Department of Health and Ageing to the sponsor company that pricing is agreed.

The timing of the actual Cabinet meeting at which a medicine is approved is not publicly available. However, the Minister’s announcement of the approval is the best indicator that the relevant medicine was approved at a recent meeting.

Information on when price agreements are reached is not publicly available and could be subject to significant variation. An industry source told PharmaDispatch that, while the “best endeavours” clause was definitely a contributing factor, another factor is that both the industry and the Department of Health and Ageing have become significantly better at negotiating price agreements.

The analysis has found that the two medicines for Hepatitis C, MSD’s VICTRELIS and Janssen-Cilag’s INCIVO, which were both approved at July’s PBAC meeting, are currently 150 days into the post-PBAC process. While the timing of when the relevant price agreements were agreed is not disclosed, PharmaDispatch understands that the six months “best endeavours” clause has been triggered for both drugs, but at different times.

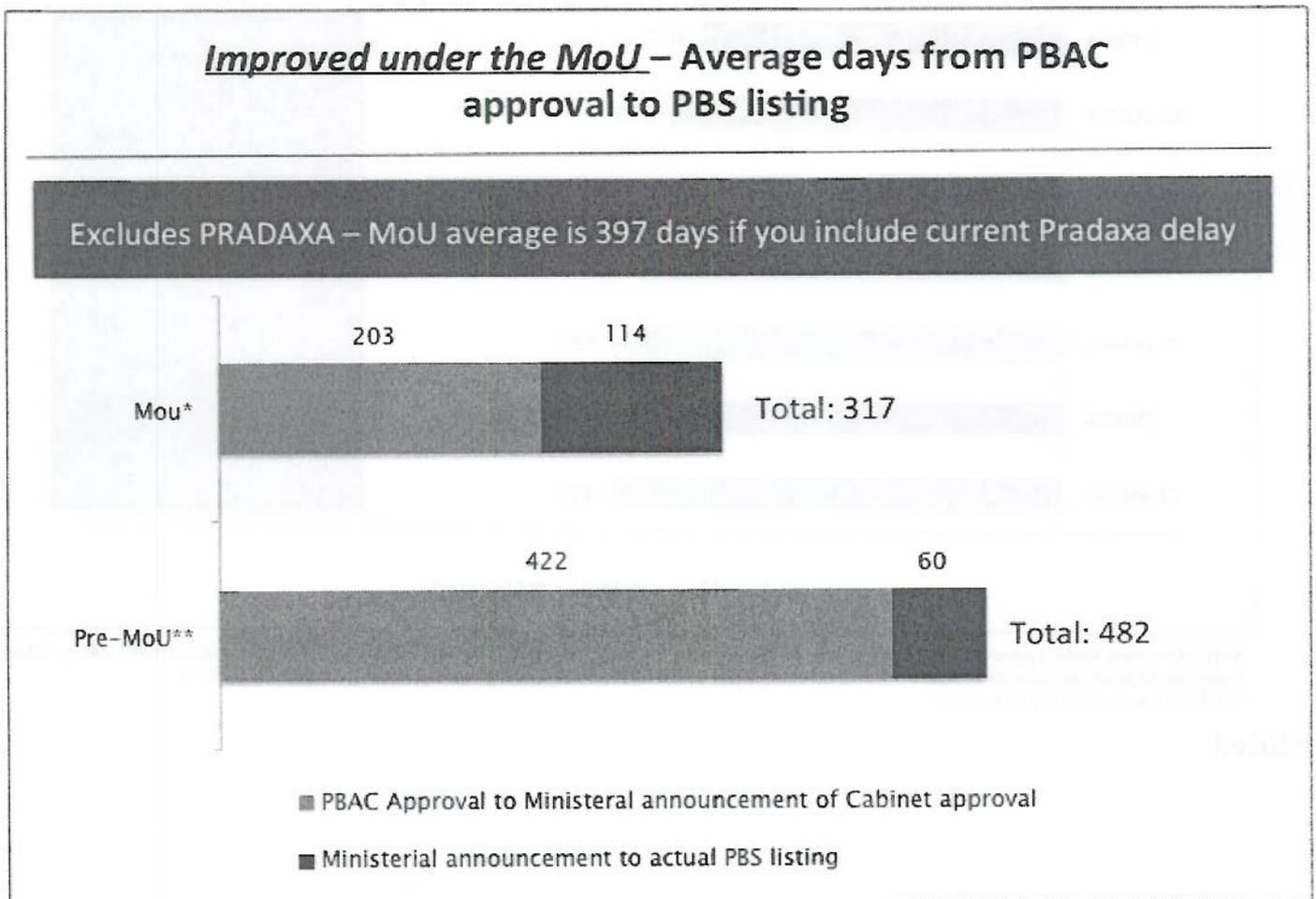
2012-13 Additional Estimates  
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The “best endeavours” clause does not restrict the Cabinet from considering the listing of a high-cost medicine much earlier. However, the analysis shows that, under the MoU, the average number of days taken from PBAC approval to Ministerial announcement has been 203, meaning they could have more time to wait.

The analysis also found that some of the improvement in the number of days from PBAC approval to Ministerial announcement has been offset by an increase in the number of days taken to actually list a medicine post-Ministerial announcement of its approval.

## Slide1

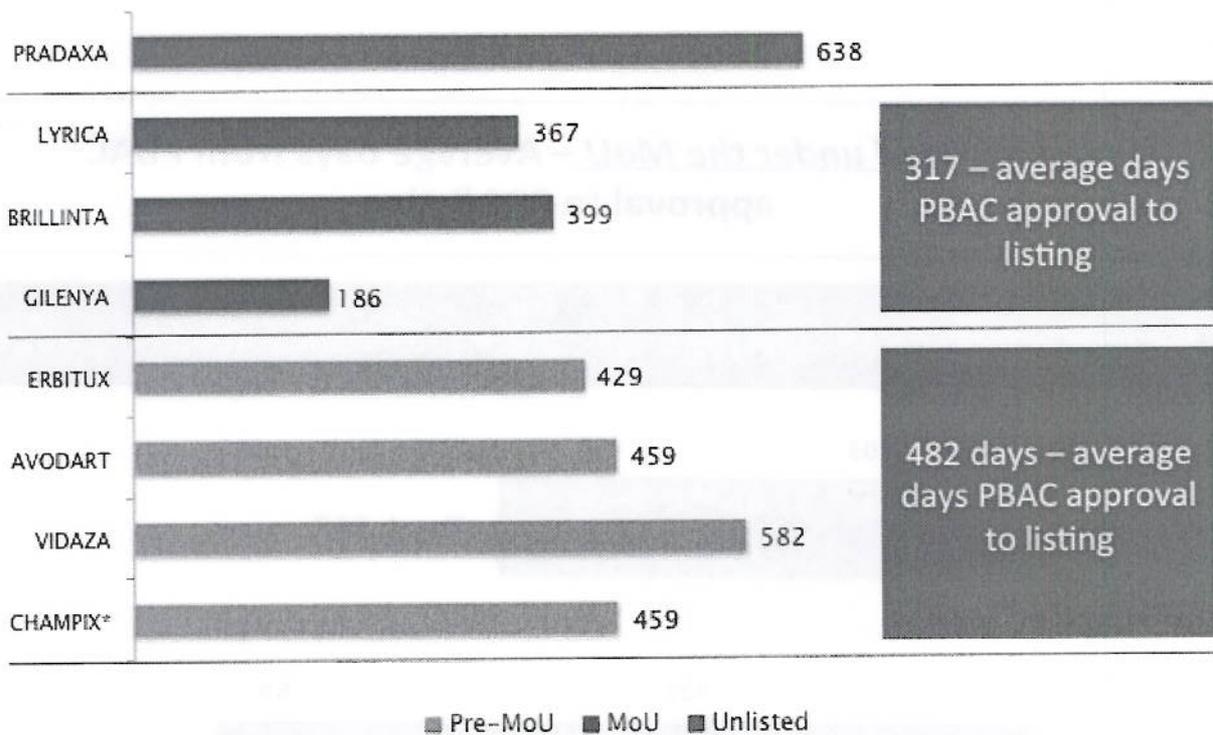


\*Based on the average days from PBAC approval to PBS listing (Gilenya, Brillinta and Lyrica)

\*\* Based on the average days from PBAC approval to PBS listing (Champix, Vidaza, Avodart and Erbitux)

## Slide2

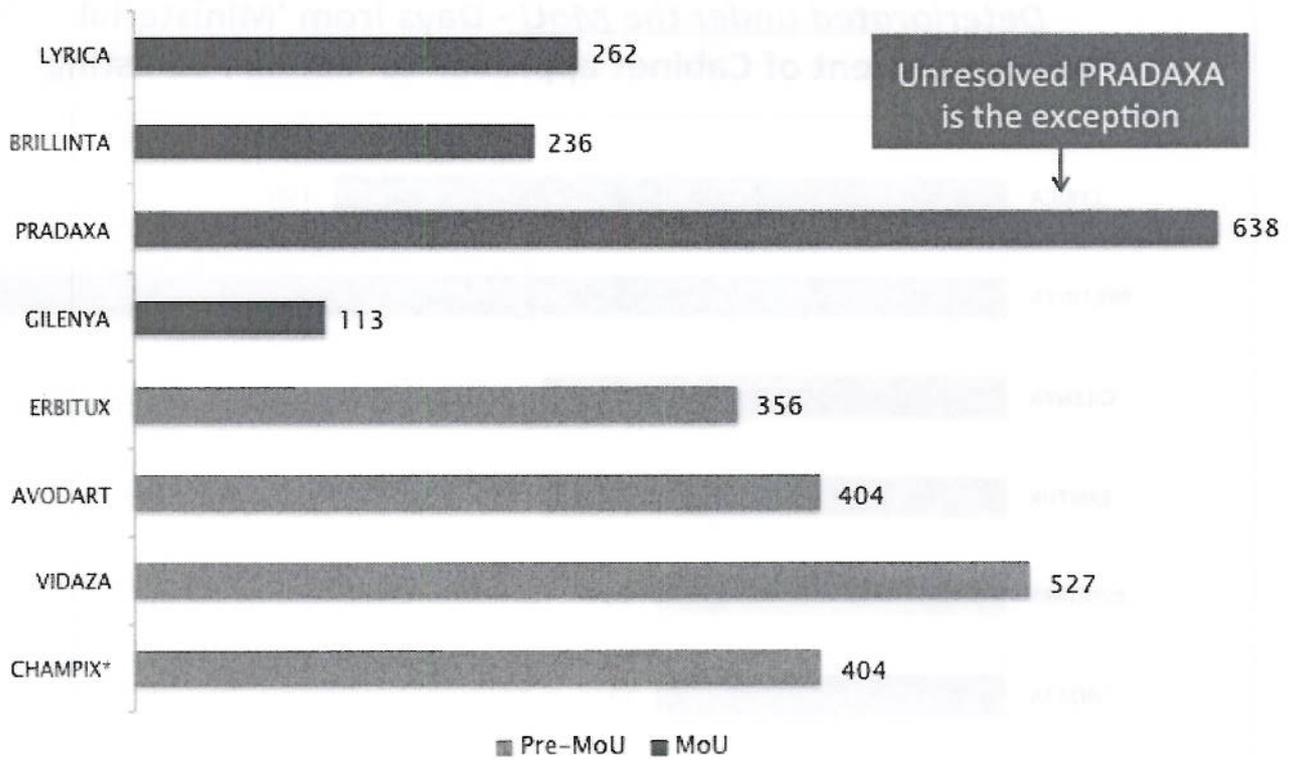
## Days to list post-PBAC approval has improved under the MoU – the unlisted PRADAXA remains a significant exception



*Note: Assumes PBAC approved on the first day of the month in which the PBAC meeting was held. Listing announcement day is taken from the date of the relevant media release issued by the Minister for Health and Ageing. Date of actual PBS listing*  
 \*CHAMPIX was a listing extension

**Slide3**

***Improved under the MoU - Days from 'PBAC approval' to  
'Ministerial announcement of Cabinet approval'***

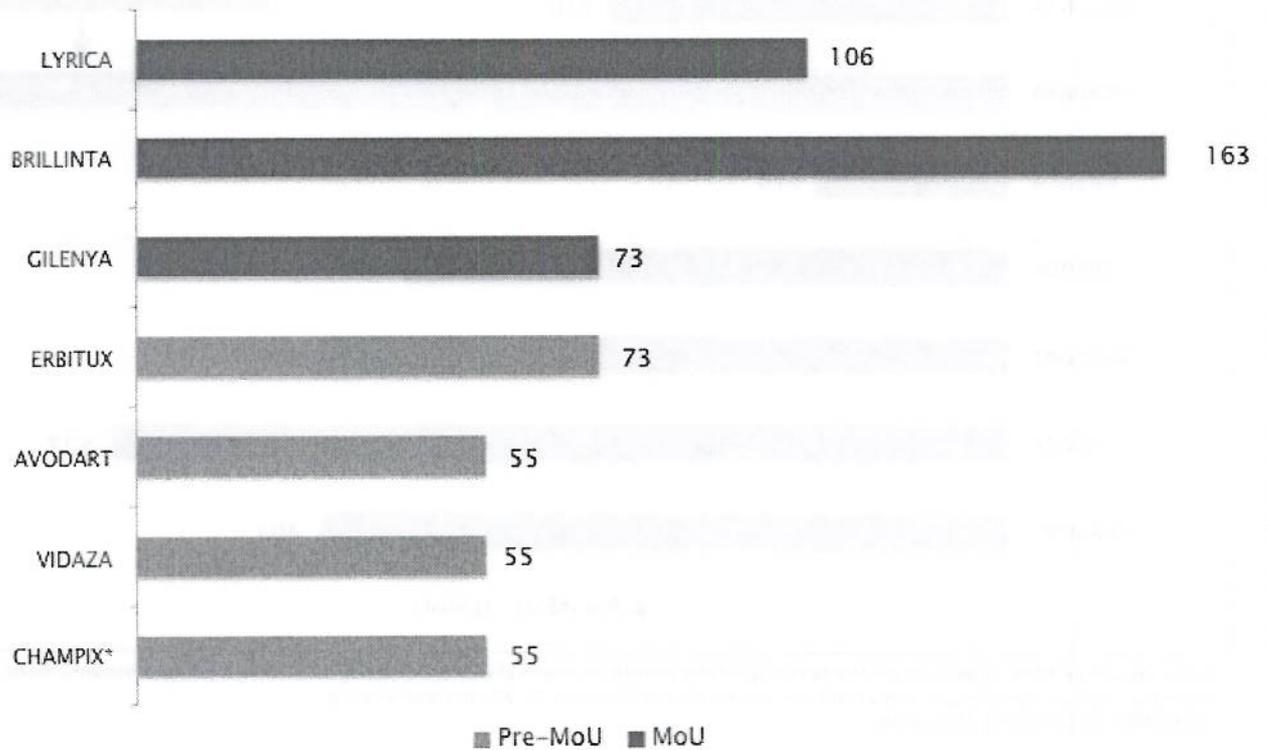


*Note: Assumes PBAC approved on the first day of the month in which the PBAC meeting was held. Listing announcement day is taken from the date of the relevant media release issued by the Minister for Health and Ageing*  
 \*CHAMPIX was a listing extension

**Slide4**

Ministerial announcement of Cabinet approval  
Days from 'Ministerial announcement of Cabinet approval' to actual PBS listing

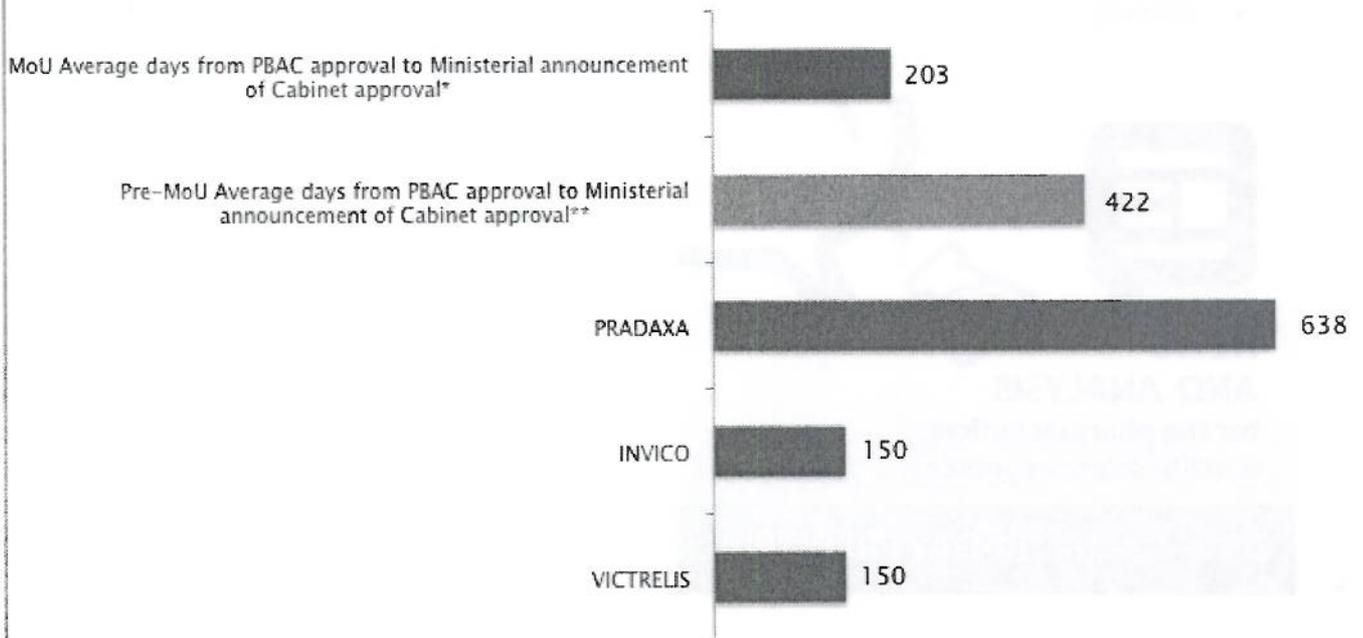
### ***Deteriorated under the MoU - Days from 'Ministerial announcement of Cabinet approval' to 'actual PBS listing'***



Note: Listing announcement day is taken from the date of the relevant media release issued by the Minister for Health and Ageing. Date of actual PBS listing  
\*CHAMPIX was a listing extension

Slide5

## Three medicines waiting for Ministerial announcement of Cabinet approval – days since PBAC approval



*Note: Assumes PBAC approved on the first day of the month in which the PBAC meeting was held.*

\*Based on the average days from PBAC approval to Ministerial announcement (Gilenya, Brillinta and Lyrica)

\*\* Based on the average days from PBAC approval to Ministerial announcement (Champix, Vidaza, Avodart and Erbitux)

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