News Release

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Australian health assessment system needs a check up

Analysis reveals conservative approach to valuing oncology medicines affects PBS access

A new analysis has shown that Australian bureaucrats are underestimating the value of immuno-oncology medicines which could then be delaying the ability for patients to access medicines on the PBS.

Two research reviews presented at this week's ISPOR Asia Pacific 2020 conference revealed that:

1. A comparison of similar health technology assessment (HTA) processes in the UK, France, Canada and Australia, showed that **Australia applies the most conservative approach to analysing new medicines, and was the slowest to reimburse immuno-oncology therapies**; and
2. **Methodology applied** by Australia's Pharmaceutical Benefits Advisory Committee **(PBAC) underestimated longer-term trial data on patient outcomes**.

Australia applies the most conservative approach to analysing new medicines

This research, *Predicting the unknown – how health technology assessment agencies deal with uncertainty, and the impact this has on patient access for immuno-oncology therapies,* which was commissioned by bio-pharmaceutical company MSD examined how the HTA of immuno-oncology therapies is becoming increasingly challenging. The distinct clinical profile of these therapies, which requires analysing long-term responses in patients, means that HTA agencies are increasingly relying on modelling to predict cost-effectiveness of these medicines for governments who are considering funding these medicines[1].

The study, which focused on melanoma and non-small cell lung cancer therapies, explored how different HTA agencies, including Australia's PBAC, manage the uncertainty of patient outcomes and the impact this has on the ability for patients to access these immuno-oncology therapies[1].

There were significant differences in how HTA agencies dealt with 'uncertainties' in clinical data such as the role of biomarkers to define the eligible population; surrogate endpoints and the impact of the need for re-treatment. The four HTA agencies analysed in the research had

different systems for evaluation, as well as different information needs to help inform their decision-making process. Interestingly, the length of time for a patient to access medicines under consideration varied greatly – in some instances registration to reimbursement took as little as four months, in some cases, such as Australia, up to 20 months[1].

The research concluded that differences in how uncertainly is managed in the HTA process impacts a patient's ability to access immuno-oncology medicines. Report author Carmel Spiteri, from MSD's Center for Observational and Real World Evidence said that, "Further analysis of how HTA agencies differently manage uncertainty could help accelerate decision-making processes for future medicine assessments, leading to improved access for patients[1]."

Methodology applied by the PBAC was conservative and underestimated longer-term clinical trial data on patient outcomes

This review, authored by MSD and Health Technology Analysts Australia, examined how the PBAC modelled patient outcomes compared to long term, clinical trial data for immuno-oncology therapies indicated for advanced melanoma and non-small cell lung cancer[2].

The analysis revealed that, in line with findings in the above-mentioned research, Australia's PBAC applied conservative modelling methodology which underestimated overall survival data between 5 and 18 per cent, compared to longer-term clinical trial data[2]. As a result, the analysis reported that the PBAC under-estimated the value of immuno-oncology therapies for Australian cancer patients[2].

"Overall survival is a key analysis tool to understand clinical effectiveness and cost effectiveness of immuno-oncology therapies. Submissions to reimbursement authorities such as the PBAC require the extrapolation of observed overall survival data from key clinical trials to project patients' survival beyond the trial period[2]", said Kevin Phan, Senior Consultant at Health Technology Analysts and one of the authors of the report.

"We hope that the findings of this study reveal the opportunity for the PBAC to use early trial data to model a longer time horizon, as well as explore the use of alternative methods for understanding survival outcomes of immuno-oncology therapies[2]," continued Mr Phan.

Mr Michael Azrak, Managing Director of MSD Australia and New Zealand, said that it is concerning that the Australian method to valuing medicines is conservative: "We can see from these two reports that the current approach applied by healthcare decision makers

undervalues these medicines for Australian patients, which also then affects patients' ability to access medicines on the PBS."

"In addition, a report recently issued by IQVIA Institute for Human Data Science showed that Australian government spending on medicines hasn't increased in more than a decade, and that government expenditure on the PBS is not on par with other areas of the health system[3]."

"When combined with the current conservative method for valuing medicines, all the data points to the fact that our health care decision makers are not supporting investment in innovative medicines for Australian patients," continued Mr Azrak.

"Medicines of all kinds, especially cancer medicines, must be seen as an investment in human capital and as an integral part of the health care ecosystem."

"We would welcome the opportunity to work with Government to drive reform in the PBAC decision making process so that the committee can have more tools available to analyse the value of innovative medicines for Australian cancer patients, the healthcare system, and the broader community."

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About MSD

For more than 125 years, MSD has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. MSD is a trade name of Merck & Co., Inc., with headquarters in Kenilworth, N.J., U.S.A. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, MSD continues to be at the forefront of research to prevent and treat diseases that threaten people and animals — including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases — as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.msd-australia.com.au and connect with us on Twitter and LinkedIn.

References

[1] Spiteri C et al: *Predicting the unknown – how health technology assessment agencies deal with uncertainty, and the impact this has on patient access for immuno-oncology therapies*; ISPOR Asia 2020.
[2] Phan K et al: *Comparison of Long-Term Overall Survival With Extrapolated Overall Survival for Pembrolizumab Assessed by Australian Reimbursement Authorities*; ISPOR Asia 2020
[3] https://www.iqvia.com/insights/the-iqvia-institute/reports/understanding-medicine-spending-in-australia Accessed 4 Sept 2020.