News release

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Bewildering PBAC decision a missed opportunity to ensure Australian cancer patients not left behind

MSD Australia & New Zealand is astonished that after eight years of dialogue and consideration, the Pharmaceutical Benefits Advisory Committee (PBAC) which advises the Federal Government on medicines access has outright rejected a funding proposal that would have removed inequities of access to a cancer-treating immunotherapy in Australia.

The company is concerned that this decision will leave some cancer patients bereft of reimbursed treatment options, while foregoing an opportunity to deliver equity of cancer care to thousands of Australians, including those with certain rare cancers.

The MSD 'multi-cancer funding model' proposed that all usages of KEYTRUDA® (pembrolizumab) registered on the Australian Register of Therapeutic Goods (ARTG) for advanced or metastatic cancers be converted into immediate access via the Pharmaceutical Benefits Scheme (PBS).[1]

In rejecting MSD's proposal, the PBAC said that because the funding model *"was restricted to the indications for which pembrolizumab was registered with the Therapeutic Goods Administration"* it *"would not provide access to some patient groups in which there is a significant unmet clinical need, such as rare cancers."*

This assertion is bewildering given the proposal was developed with the explicit intention of removing immunotherapy access barriers, including for certain rare cancers, where the number of patients involved in a study is often too small to meet requirements for a PBS subsidy.[2]

Following ongoing consultation throughout 2024-25 with Rare Cancers Australia and leading oncologists, as well as the PBAC and Department of Health, Disability and Ageing, it was considered inappropriate for the proposed funding model to include medicines or indications that had not been registered on the ARTG.

Under the multi-cancer proposal, an estimated 700 Australian eligible cancer patients could have been suitable for reimbursed access to KEYTRUDA.[1] An additional 5,200 eligible cancer patients could have had reimbursed access over the next four years.[1] This would have facilitated funded access for certain patients with 11 rare or less common cancer sub types where there is currently no other immunotherapy on the PBS.[1]

Currently, each new indication registered on the ARTG requires a separate assessment by the PBAC to qualify for government funding. Of the 35 KEYTRUDA registered indications,[3] 15 are partially or fully funded through the PBS despite 40 reimbursement submissions.[1,4] The average time from a new ARTG registration to a successful PBS listing has been 447 days.[1]

MSD notes that it is eight years since the Federal Government first sought PBAC advice on the reimbursement of immunotherapies across different cancer types in response to a direct request from the then Minister for Health.[5]

MSD's initial multi-cancer funding proposal was deferred by the PBAC in December 2023, with the committee noting that "*it would be appropriate and desirable to have a simplified process for listing future indications.*"[6] In September 2024 the PBAC advised that a simplified process would only be considered within certain tumour types. At both these milestones, the PBAC raised concerns with providing broad access that was not linked to registered indications and was supportive of a restriction which limited funded access to the registered indications.[1,7]

The PBAC again considered a broad multi-cancer funding proposal for KEYTRUDA at its July 2025 meeting where it issued a rejection. Throughout this process, the PBAC consistently raised Quality Use of Medicines (QUM) concerns about medicines being used outside their registered indications and stated its preference for the proposal to be aligned with TGA registrations.[1,7]

Multi-cancer or 'pan-tumour' funding models were introduced in Europe in 2017 and have been adopted by several countries.[8] These models are noted for increasing speed of access and budget predictability.[8]

A pan-tumour funding model was first considered in Australia in 2017[9], followed by a multi-cancer proposal in 2023.[1] After eight years, Australia's pharmaceutical reimbursement advisory committee has now closed this opportunity.

"It's simply not good enough that after eight years of churn, the committee's answer to the pleas of the Australian cancer community for more affordable and equitable access to cancer care is an outright 'no'," said Chifumi Umeda, Managing Director, MSD Australia & New Zealand.

"For almost a decade the PBAC has continually shifted the goal posts on multi-cancer funding, making it impossible to find an equitable solution for Australian cancer patients."

"Without a clear change in approach by the Federal Government, there does not appear to be a path forward for multi-cancer funding in Australia," she said.

"Sadly, Australian cancer patients remain at the mercy of a painfully slow, inequitable and inefficient medicines funding system. It's a sad day when innovation and equity are dismissed in favour of the status quo."

"MSD is also deeply uneasy that the committee appears to be using Australians with rare cancers as a justification for the rejection, at a time when the rare cancer community has been the most vocal advocate for multi-cancer funding."

KEYTRUDA has been assessed by the Therapeutic Goods Administration (TGA) more than 30 times[3] since it was first reimbursed for advanced metastatic melanoma on 1 September 2015.[10]

"Today's decision means that some Australian cancer patients will not have equitable funded access to this registered treatment," said Ms Umeda.

– ENDS –

KEYTRUDA® (pembrolizumab) Minimum Consumer Medicine Information Selected Safety Information.[11] KEYTRUDA contains the active ingredient pembrolizumab. KEYTRUDA is a medicine that may treat certain cancers by working with the immune system. KEYTRUDA may be given in combination with other anticancer medicines with or without radiation therapy. Not everybody is suitable to have KEYTRUDA as a treatment for their cancer. Before using KEYTRUDA, a doctor will check if a person with cancer has a disease of the immune system like Crohn's, ulcerative colitis, or lupus; had an organ transplant (like a kidney transplant) or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic); have pneumonia or swelling of the lungs (called pneumonitis); have liver damage. If you are pregnant or plan to become pregnant, tell your health care provider as KEYTRUDA can cause harm or death to your unborn baby. Effective birth control must be used during treatment and for at least 4 months after the last dose of KEYTRUDA. Tell your health care provider if you are breastfeeding or intend to breastfeed. Tell your doctor or pharmacist if you are taking any other medicines, vitamins, or supplements, particularly medicines that can make your immune system weak such as steroids. Like all medicines, KEYTRUDA can cause side effects, although not everybody gets them. KEYTRUDA can cause the immune system to attack normal organs and tissues in any area of the body and can affect the way they work. Sometimes these problems can become

severe or life-threatening. More than one side effect can occur at the same time and side effects can arise at any time during treatment and even after the treatment has ended. These can include immune system problems affecting: the lungs; intestines; liver, kidneys; skin, hormone glands (especially thyroid, pituitary, and adrenal glands) and blood sugar levels. Rejection of a transplanted organ; and complications in people with a bone marrow transplant that uses donor stem cells (allogeneic) can occur. Very common side effects include diarrhoea, nausea, itching, rash, joint pain, back pain, feeling tired, cough, patches of skin which have lost colour, stomach pain, decreased sodium levels in the blood, fever, infections of the upper respiratory tract, low levels of thyroid hormone, a decreased number of white blood cells (which are important in fighting infection) in patients with primary mediastinal B-cell lymphoma. These are not the only side effects that occur with KEYTRUDA.

For further information read the KEYTRUDA (pembrolizumab) Consumer Medicine Information and speak to your doctor. Patients should discuss treatment options with their doctor.

PBS information: KEYTRUDA (pembrolizumab) is available on the Pharmaceutical Benefits Scheme (PBS) for certain cancer types. Further criteria apply. Consult the Pharmaceutical Benefits Scheme at www.pbs.gov.au for full information.

Issued by Ethical Strategies on behalf of MSD Australia. For more information contact Max Weber on 0452 213 513.

About MSD

At MSD, known as Merck & Co., Inc., Rahway, NJ, USA in the United States and Canada, we are unified around our purpose: We use the power of leading-edge science to save and improve lives around the world. For more than 130 years, we have brought hope to humanity through the development of important medicines and vaccines. We aspire to be the premier research-intensive biopharmaceutical company in the world – and today, we are at the forefront of research to deliver innovative health solutions that advance the prevention and treatment of diseases in people and animals. We foster a diverse and inclusive global workforce and operate responsibly every day to enable a safe, sustainable, and healthy future for all people and communities. For more information, visit www.msd.com and connect with us on Twitter and LinkedIn.

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AU-KEY-01565v1. Issued August 2025.

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