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Department of Health and Aged Care

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Two anti-viral COVID-19 treatments approved

The Australian Government welcomes the Therapeutic Goods Administration's (TGA) provisional approval of the first oral treatments for COVID-19 in Australia, Lagevrio® (molnupiravir) and Paxlovid® (nirmatrelvir + ritonavir)

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The Australian Government welcomes the Therapeutic Goods Administration's (TGA) provisional approval of the first oral treatments for COVID-19 in Australia, Lagevrio® (molnupiravir) and Paxlovid® (nirmatrelvir + ritonavir).

Lagevrio and Paxlovid are oral anti-viral treatments that have been found to be effective in treating people with mild to moderate COVID-19 who have a high risk of progressing to severe disease, reducing admissions to hospital and ICU and potential death.

The Government has secured access to 300,000 treatment courses of Merck Sharp & Dohme's (MSD) Lagevrio® and 500,000 courses of Pfizer's Paxlovid® for supply throughout the course of 2022, with the first deliveries of both medicines anticipated over the coming weeks.

These oral antiviral treatments need a prescription and are taken every 12 hours for five days. They are designed to interfere with the virus' ability to multiply.

The clinical trials of these treatments show they reduce the risk of hospitalisation or death in patients with COVID-19 who are at high risk of progressing to severe disease.

Lagevrio and Paxlovid will supplement the existing National Medical Stockpile supplies of Xevudy (sotrovimab) and Veklury (remdesivir) and future supplies of Evusheld (tixagevimab with cilgavimab), the later pending a final TGA decision on registration.

Xevudy is an intravenous monoclonal antibody that can also be used to treat people with mild to moderate COVID-19 who have a high risk of progressing to severe disease. It has proven effective against the omicron variant with additional supply also secured for delivery over the coming months.

Veklury is being used for the clinical care of people with moderate to severe COVID-19 symptoms who have been admitted to hospital but do not require ventilation assistance in line with the recommendations of the National COVID-19 Clinical Evidence Taskforce.

As with other TGA approved COVID-19 treatments not everyone who contracts COVID-19 will require access to Lagevrio and Paxlovid and these treatments will be of most benefit for people most at risk of severe disease and through the oversight from a healthcare professional.

We are working to target access to those most vulnerable including the elderly and those in aged care through the National Medical Stockpile (NMS) with the view to transition to the Pharmaceutical Benefits Scheme (PBS) arrangements as supply continues to grow.

By law medicines can only be listed on the PBS following a positive recommendation from the Pharmaceutical Benefits Advisory Committee (PBAC).

Whilst vaccination remains the best protection against COVID-19 our Government continues work to ensure that Australians have early access to safe and effective treatments as they are approved for use by the medical experts. These agreements reinforce our strong response to managing COVID-19 outbreaks and ensures that Australia benefits from new pharmaceutical technologies.

As with all COVID-19 treatments, both of these medications have been rigorously assessed by the TGA for safety, quality and effectiveness before being provisionally registered for use in Australia.

The TGA is treating all COVID-19 treatment applications with the greatest priority as part of the Department of Health's response to the pandemic.

Tags:

Communicable diseases | Medical research | Medicines

Former ministers:
The Hon Greg Hunt MP