PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Inquiry into Australian Government's response to the COVID-19 Pandemic

Written Question on Notice, 8 October 2021

PDR Number: IQ21-000263

Antiviral treatment molnupiravir

Written

Senator: Katy Gallagher

Question:

With reference to the Commonwealth's purchase of 300,000 courses of molnupiravir –

1. What is the current regulatory status of the antiviral treatment molnupiravir?
2. When does the TGA anticipate full regulatory approval of molnupiravir?

Answer:

- Molnupiravir, sponsored by Merck Sharp and Dohme (Australia) Pty Ltd, is a proposed oral antiviral treatment for COVID-19.
- Molnupiravir was granted provisional determination by the Therapeutic Goods Administration (TGA) on 9 August 2021.
- Provisional determination is the first step in the process that enables the sponsor to apply to the TGA for provisional registration in the Australian Register of Therapeutic Goods (ARTG).
- Merck Sharp and Dohme (Australia) Pty Ltd have since submitted an application for provisional registration.
- Like other COVID-19 treatments, molnupiravir is being evaluated by the TGA in a rolling review, which means data is evaluated as it comes to hand. Only part of the required data has been submitted so far, and more data is expected to be submitted in the coming weeks and months.
- The evaluation of molnupiravir is being work-shared through the Access consortium of regulatory authorities (Australia, Canada, Singapore, Switzerland, United Kingdom), with the TGA taking the lead on the quality component and Health Canada taking the lead on the clinical component.

- The TGA can only make a regulatory decision on molnupiravir once the complete data package has been provided by the sponsor. Therefore, it is not possible to provide specific timeframes.
- Provisional registration balances the benefits of early access where additional data are required for full registration.
- Once provisionally registered, the sponsor has two years (with two possible extensions, up to six years) to provide the required data to the TGA in order to become fully registered.