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, 27 August 2021

PDR Number: IQ21-000210

Daily Insights Media Report - AusTender contract CN3808018

Written

Senator: Katy Gallagher

Question:

With reference to AusTender contract CN3808018 published by the Department of Health engaging Isentia Pty Limited under the description "Daily Insights Media Report - COVID-19".

1. Are the "Daily Insights Media Report - COVID-19" produced by Isentia shared beyond the Department of Health? If yes, with which agencies?
2. Is the report limited to Australian domestic media or does it extend to international reportage?

Answer:

This report is not shared outside the Department of Health. It includes domestic and international news.

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Department of Health

Senate Select Committee on COVID-19

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

Written Question on Notice, 27 August 2021

PDR Number: IQ21-000216

Progress on the assessment of monoclonal antibody treatments for COVID-19

Written

Senator: Katy Gallagher

Question:

1. Where is the TGA up to in its assessment of monoclonal antibody treatments for COVID-19
   a.) Specifically, please update on the assessment and any advice to government about the Sotrovimab and Regeneron treatments

Answer:

- The Australian Government is committed to providing all Australians with access to safe and effective COVID-19 treatments as soon as they are available and the Therapeutic Goods Administration (TGA) is assessing COVID-19 treatments with the greatest priority.
- The TGA granted provisional approval to sotrovimab (XEVUDY), a monoclonal antibody treatment, on 20 August 2021. Australia is the first OECD country to issue a formal regulatory approval for sotrovimab.
- Sotrovimab, manufactured by GlaxoSmithKline, is provisionally approved in Australia for the treatment of adults and adolescents (aged 12 years and over and weighing at least 40 kg) with COVID-19 who do not require initiation of oxygen due to COVID-19 and who are at increased risk of progression to hospitalisation or death.

- The TGA also granted provisional determination to another two monoclonal antibody treatments on 20 August 2021:
    - The combination therapy casirivimab + imdevimab (RONAPREVE), sponsored by Roche Products Pty Ltd. This is the Regeneron treatment mentioned in the question above. RONAPREVE is proposed for the treatment of confirmed COVID-19 in patients aged 12 years and older and weighing at least 40 kg that do not require supplemental oxygen for COVID-19 and who are at high risk of progressing to severe COVID-19. RONAPREVE will also be considered for the prevention of COVID-19 in patients of the same age who have been exposed to or are at high risk of exposure to SARS-CoV-2 and/or have a medical condition that makes them unlikely to be protected by vaccination. This product is known as REGN-COV2 in the United States.
    - Regdanvimab, sponsored by Celltrion Healthcare Australia Pty Ltd, for treatment of mild-to-moderate COVID-19 in adults who are confirmed to be infected with SARS-CoV-2.
- The granting of a provisional determination means that the TGA has made a decision that these medicines are eligible to apply for provisional registration in the Australian Register of Therapeutic Goods (ARTG).
- Provisional registration applications have recently been received for COVID-19 treatments RONAPREVE and regdanvimab and these products are currently under expedited rolling review by the TGA. The timeframes for evaluation in each case are largely dependent on when the sponsors provide the required data and respond to the TGA's requests for information. Depending on receipt of the required information from the sponsor, it is hoped that a meeting of the TGA Advisory Committee on Medicines to consider the RONAPREVE application will be able to be held in early October.
- The TGA is proactively meeting with sponsors of other potential COVID-19 treatments to discuss the regulatory process and encourage future applications.
- The TGA also continues to work very closely with international regulators to harmonise regulatory approaches, share information and where it speeds up evaluation, collaboratively review new treatments.