PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Australian Government's response to the COVID-19 pandemic

Senate Select Committee on COVID-19

26 May 2020

PDR Number: IQ20-000289

Question Subject: National medical stockpile checks

Type of Question: Written

Senator: Katy Gallagher

Question:

In relation to the Department's evidence that some items have been procured for the National Medical Stockpile before their efficacy is confirmed (by the Commonwealth of independent testing), and are instead subject to post-market review:

- What is the total value and volume of such items? Please provide a breakdown of the value and volume of each type of item (e.g. type of PPE, type of medical equipment, type of medicine)
- Of this, what is the value and volume of items that have now been:
  - Subject to post-market review – where the manufacturer's claims on efficacy have been proven (please provide a breakdown as above)
  - Subject to post-market review – where the manufacturer's claims on efficacy have been disproven or brought into question (e.g. antibody tests from MD Solutions and Endo X) (please provide a breakdown as above)
  - Not yet subject to post-market review (please provide a breakdown as above)

Answer:

Personal Protective Equipment

Two of the 53 contracts to supply personal protective equipment to the National Medical Stockpile, totalling $22,971,687.50 and USD $7,880,000.00 respectively, were fully reliant upon the *Medical Devices—Face Masks and Other Articles COVID-19 Emergency Exemption*. A third contract included a component, valued at $19,500,000, which also used the exemption.

Prior to entering into a contract, the Department of Health undertook due diligence checks on the supplier and the goods. In addition to financial and supply chain checks, product specifications were reviewed to ensure they were fit for purpose, and compliant with the appropriate Australian Standards, or international equivalents.

In addition the National Medical Stockpile (NMS) has commissioned additional testing of products provided under contracts to ensure the delivered product meets the relevant standards.

On 1 May 2020, the Therapeutic Goods Administration (TGA) commenced a post market review of all face masks included in the Australian Register of Therapeutic Goods (ARTG), including those masks purchased by states and territories as well as the NMS. Details about the TGA face mask review and the outcomes are published on the TGA website.

Tests

To ensure that Australia had tests available to support the response to COVID-19, the TGA conducted expedited assessments of COVID-19 tests, based on the information and performance data available at the time applications were submitted to the TGA. All point of care serology tests for COVID-19 included in the ARTG were approved by the TGA under the expedited assessment process with conditions.

These conditions require the sponsor to provide additional evidence to the TGA that supports the on-going performance of these tests (i.e. the ability of the test to detect antibodies to SARS-CoV-2), with assessment of this evidence undertaken as a post market review. Supply of the tests was also limited to specified healthcare professionals, including medical practitioners, who can interpret the results and provide individuals with appropriate advice.

The Department has procured into the NMS 1 million point of care serology tests for COVID-19, at a cost of $18,900,000 (GST inclusive).

The Department also procured BGI pathology equipment and consumables to facilitate 4.86 million tests.

On 21 March 2020, the Minister for Health and Aged Care, the Hon Greg Hunt MP, announced the engagement of the Peter Doherty Institute for Infection and Immunity (PDI) to assist in the post market validation of COVID-19 tests. PDI studies to date (16 April 2021) include:

- post market validation of 27 point of care serology tests for COVID-19, including those procured by the Department, confirming that these tests, although not suitable for acute diagnosis of COVID-19, can help identify individuals who have developed detectable antibodies to SARS-CoV-2 as part of an immune response to the virus. This occurs approximately 10 to 14 days after the onset of symptoms.
- a validation study of the BGI SARS-CoV-2 Real time PCR test kit and associated instrumentation and reagents (collectively referred to as ‘the BGI platform’), reporting that the BGI platform is fit for purpose in Australian laboratories.

The PDI reports are available on the Department's website.

https://www.health.gov.au/resources/collections/post-market-validation-of-serological-point-of-care-tests-for-covid-19

www.health.gov.au/resources/publications/post-market-validation-of-the-beijing-genomics-institute-bgi-sars-cov-2-real-time-pcr-platform