PARLIAMENTARY INQUIRY QUESTION ON NOTICE

Department of Health

Senate Select Committee on COVID-19

Australian Government's Response to the COVID-19 Pandemic

2 June 2020

PDR Number: IQ20-000358

Question Subject: Testing and quality of face masks

Type of Question: Written

Senator: Stirling Griff

Question:

A Sydney Morning Herald article from 26 May 2020 reported there are fears that doctors and nurses treating patients infected with COVID-19 in some Australian hospitals are wearing counterfeit face masks that have been registered with the TGA.

1. Can the Department confirm that the TGA relaxed the scrutiny it provides for medical equipment such as surgical masks because of the COVID-19 crisis?
   (A) Does the TGA maintain a list of all items that were given this rapid approval without testing?
   (B) Are manufacturers and suppliers required to maintain a list of where they have been supplied?

Answer:

1. There has been no change to the approval process for including medical devices such as surgical masks that meet the definition of a medical device in the Australian Register of Therapeutic Goods (ARTG).

However, the TGA is prioritising and expediting all applications seeking regulatory approval to supply medical devices used in the prevention, detection and treatment of COVID-19. Information about the approval processes are published on our website.

Additional surveillance of Class I medical devices, including face masks is occurring to identify any inclusions in the ARTG that do not comply with regulatory requirements. A post market review of face masks commenced on 1 May 2020 to:

- validate the declarations of conformity including labelling, audited certificates and standards claimed for those devices included in the ARTG;

- validate the performance of those devices included in the ARTG by TGA laboratory testing;
- validate the devices that have utilised the emergency exemption to supply to the National Medical Stockpile.

The TGA will take action in relation to non-compliance, and encourages reporting of non-compliance via the TGA website.

The *Medical Devices—Face Masks and Other Articles COVID-19 Emergency Exemption* was made to support the purchase of PPE by the Australian Government Department of Health for the National Stockpile. The approval processes have not changed in that all PPE must meet the standards set for inclusion in the ARTG. The TGA continues to review evidence relating to the devices purchased under the exemption. To date, none have failed to meet appropriate manufacturing standards or have failed to comply with the requirements for inclusion in the ARTG.

(A) The TGA does not perform pre-market laboratory testing of medical devices. To include a device in the ARTG, the sponsor and manufacturer are required to demonstrate their compliance with the Essential Principles for safety and performance.

(B) Yes this is a condition of approval.