

**PARLIAMENTARY INQUIRY QUESTION ON NOTICE**

**Department of Health**

**Senate Select Committee on COVID-19**

**Australian Government's Response to the COVID-19 Pandemic**

**02 June 2020**

**PDR Number: IQ20-000360**

PPE standards and the approval process for hospitals and aged care facilities

**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.** Does the TGA believe that substandard PPE is better than no PPE? Is that why it changed its approval processes?
- 2.** Is the Department aware of any clinicians that have been put at risk because of substandard PPE that has been imported under this exemption?
- 3.** What steps does the TGA recommend hospitals and aged care facilities take to ensure that the PPE available to them meets necessary safety and quality standards?  
Has this advice been provided to hospitals and aged care facilities?

**Answer:**

- 1.** All Personal Protective Equipment (PPE) for therapeutic use is required to meet the standards set for inclusion in the Australian Register of Therapeutic Goods (ARTG).

Under the *Therapeutic Goods (Declared Goods) Order 2019* all PPE which is presented or claimed to be for therapeutic use are required to be in the ARTG (such as being labelled for surgical use, or to reduce or prevent the transmission of disease or microorganisms such as bacteria or viruses).

On 22 March 2020, the *Medical Devices—Face Masks and Other Articles COVID-19 Emergency Exemption* was put in place to support the purchase of PPE by the Australian Government Department of Health for the National Medical Stockpile. The exemption can only be used where a contract is in place with the Department of Health. The exemption is not for general use.

The approval processes have not changed in that all PPE must meet the standard set for inclusion in the ARTG.

2. The Department is not aware of any substandard PPE purchased by the Commonwealth for the National Medical Stockpile. A limited quantity of products under two supplier contracts have drawn on the exemption. None of that product has been dispatched for use pending post market assurance.

3. The Department of Health's website and the TGA website both have fact sheets and information about PPE. For example, specific information for the Health and Aged Care Sector [www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert](http://www.health.gov.au/news/health-alerts/novel-coronavirus-2019-ncov-health-alert).

The TGA website ([www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19](http://www.tga.gov.au/behind-news/regulation-personal-protective-equipment-and-covid-19)) includes detail about the relevant standards and information relating to particular types of products.

Information has also been provided directly to states and territories and private hospitals.

On 1 May 2020, the TGA commenced a post market review of face masks registered on the ARTG, and encourages reporting to the TGA of any concerns.

The Department is aware that some state health departments have quarantined stock which they have manufacturing or quality concerns about. We are working closely with these health departments to review and assess these products.

The TGA has encouraged any reports of suspected counterfeit medical devices to be made through the online form [www.tga.gov.au/report-perceived-breach-or-questionable-practices](http://www.tga.gov.au/report-perceived-breach-or-questionable-practices).

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**Department of Health**

**Senate Select Committee on COVID-19**

**Australian Government's response to the COVID-19 pandemic**

**02 June 2020**

**PDR Number: IQ20-000364**

Delegations to perform any functions under the Biosecurity Determination 2020

**Type of Question:** Written

**Senator:** Katy Gallagher

**Question:**

1. Was the NSW Commissioner of Police delegated by a Minister or authorised Commonwealth officer to perform any functions under the Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (Emergency Requirements) Determination 2020 made under S477 of the Biosecurity Act 2015 - Compilation No 1 of 27 March 2020 as registered on 2 April 2020 or any related Determination?
2. If yes to (1), what was the name of the instrument that gave that delegation to the NSW Commissioner of Police and who authorised that delegation?

**Answer:**

1. No, the NSW Commissioner of Police has not been delegated by the Minister for Health or an authorised Commonwealth officer to perform any functions under the Biosecurity (Human Biosecurity Emergency) (Human Coronavirus with Pandemic Potential) (Emergency Requirements for Cruise Ships) Determination 2020, or any other related Determination under the Biosecurity Act 2015.
2. Not applicable.