

**PARLIAMENTARY INQUIRY QUESTION ON NOTICE**

**Department of Health**

**Senate Select Committee on COVID-19**

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

**26 May 2020**

**PDR Number: IQ20-000270**

**Question Subject:** ACQSC complaint data by provider

**Type of Question:** Spoken

**Hansard Page number:** 8

**Senator:** James Paterson

**Question:**

**Senator PATERSON:** Does your data give you sufficient visibility to identify whether there were particular providers or categories of providers that were subject to more complaints and that had more issues?

**Ms Anderson:** We haven't done that analysis. I could have a look and see whether that level of drill down is possible.

**Senator PATERSON:** Yes, thank you. On notice, that would be helpful.

**Answer:**

An analysis of complaints data by provider has not identified any particular categories of providers which were the subject of more complaints or issues.

# 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: IQ20-000269

**Question Subject:** Additional checks on masks

**Type of Question:** Spoken

**Hansard Page number:** 19-20

**Senator:** Murray Watt

#### Question

**Senator WATT:** Did the Department of Health make the additional checks on the 100 million masks that had been purchased?

**Ms Edwards:** All checks and standards are absolutely checked in a post-market way on everything that comes into the National Medical Stockpile, yes.

**Senator WATT:** How rigorous are these checks?

**Ms Edwards:** I can take on notice exactly what we do, but they're rigorous. We are absolutely committed to making sure that they're safe and effective, or we wouldn't want anything to be dispatched. But we did want to ensure we could take advantage of what supply lines were available and get things in quickly—so, in effect, risk managing, making sure we were going to have sufficient product in country. We still did checks before we bought things from wherever they came, checking that they provided the appropriate documentation and they were as described and so on, but they were exempted from some of the processes in order to get them into the stockpile. Then we do post-market checks to make sure they're appropriate and fit for purpose before dispatch.

#### Answer:

The Department of Health has stringent safeguards for procurement for the National Medical Stockpile (NMS). The Department seeks products that meet the TGA regulatory requirements, which means they meet the same standards of quality, safety and performance as those approved for supply in Australia.

The product specifications are required upfront, and masks must comply with national standards or an equivalent international standard before a purchase is agreed.

There are conditions written into contracts to allow for recourse should products not meet the agreed specifications and certifications.

To date, the Department is not aware of any inadequate stock provided to the NMS.

In addition, a post market review of face masks by the TGA commenced on 1 May 2020 to:

- validate the declarations of conformity including labelling, audited certificates and standards claimed for those devices included in the Australian Register of Therapeutic Goods (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 post market review is ongoing and the TGA will take action in relation to non-compliance.

All the ARTG listed masks are subject to the Therapeutic Goods Administration's post market review of Class 1 medical devices, including those purchased for the NMS.

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 personal protective equipment (PPE) by the Australian Government Department of Health for the NMS. 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 Department's mask procurement for the NMS has only utilised the exemption for three suppliers as at 30 June 2020.

- For one supplier, a small number of surgical masks was purchased. The Department has significant stocks of surgical masks, and the masks provided under the exemption will not be deployed until appropriate testing or authentication has been approved.
- For the second supplier, independent equivalent testing information has been provided and will be thoroughly assessed to ensure compliance with appropriate specifications before consideration given to deployment.
- The third supplier has also provided a range of detailed specification information which will be thoroughly assessed to ensure compliance with appropriate specifications before consideration given to deployment.