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SEA View

The TGA and the Iron Mask

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In 2020, heightened demand for health care resulted in an influx of therapeutic goods being included on the Australian Register of Therapeutic Goods (ARTG). A large portion of these goods are manufactured in China however, due to the significant spike in demand from around the world many businesses have modified their usual operations, for example apparel manufacture, to instead manufacture personal protective equipment in order to capitalize on the opportunity. This has been evident across Southeast Asia and in particular Vietnam. Whilst speed of entry onto the ARTG assisted sponsors and manufacturers to capitalize on demand, the Therapeutic Goods Administration (TGA) has now shifted its focus from including therapeutic goods on the ARTG to verifying that these goods comply with relevant regulatory requirements. Notably this has led to a post market review into the efficacy of face masks (class 1 medical devices), and action being taken against sponsors.

Post market review

The TGA can undertake a post market review of products listed on the ARTG at any time. The purpose of a post market review is to confirm that goods included on the ARTG comply with

regulatory requirements, including the essential principles as set out in *Therapeutic Goods (Medical Devices) Regulations 2002* (Cth) (Schedule 1), and perform as intended.

In mid-2020 the TGA announced it was conducting a post market review of face masks. The main driver behind this review was the explosion of face masks in the Australian market in 2020 and issues being raised about their effectiveness. The TGA has recently indicated that its face mask post market review has identified some face masks do not meet regulatory requirements (e.g. non-conformance with the essential principles including labelling, failed TGA laboratory testing), and/or are not performing as intended, i.e. as claimed by the manufacturer. To date, the TGA has cancelled, or procured sponsor initiated cancellation, of 827 face masks.

As part of the post market review process, the TGA is collecting information about the medical devices from sponsors and manufacturers. In some instances, the TGA is also carrying out its own testing on registered face masks to determine compliance with relevant standards. If the face masks fails the TGA's testing, the sponsor may seek a review pursuant to regulation 30 of the Therapeutic Goods Regulations 1990.

Information/documentation requested by the TGA

The TGA has the power to request information from sponsors. Using this power, the TGA can request information from sponsors about (amongst others) the characteristics and manufacturing procedures of medical devices. If sufficiently concerned, the TGA may request large amounts of information with a relatively short deadline.

In respect to the recent post market review of masks, the TGA has outlined that sponsors should have the following documents readily available:

- Declaration of conformity from the manufacturer (conformity assessment certificate).
- A list of models of masks, supply numbers by model and year (if applicable), and the states within Australia where you have distributed the face masks.
- Details of the manufacturing standards the devices conform to and appropriate evidence of compliance.
- A copy of all packaging and labelling.
- A copy of the instructions for use that are supplied with the product (if applicable).
- Where the intended purpose of the device claims to protect the wearer from COVID-19, either specifically or by implication, appropriate evidence to support such a claim.

Takeaway for Sponsors

It is crucial that all sponsors are able to swiftly collate and supply conformity and compliance documentation when requested by the TGA. It is also crucial that manufacturers are similarly able to quickly produce relevant compliance documentation when called upon by the sponsor.

Maintaining detailed and transparent communication with the TGA, or any regulator, is often key to resolving such issues.

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