

CK Surgitech issued \$25,200 in infringement notices for alleged breaches in relation to COVID-19 test kits

24 April 2020

The Therapeutic Goods Administration (TGA) has issued two infringement notices totalling \$25,200 to Queensland company CK Surgitech Pty Ltd for alleged breaches of the [Therapeutic Goods Act 1989 \(the Act\)](#).

It is alleged the company made a false or misleading statement in an application to have their [IVD](#) Rapid Test kits for SARS-CoV2 (the COVID-19 virus) included in the Australian Register of Therapeutic Goods (ARTG).

The company also allegedly breached a condition of the [Therapeutic Goods \(Medical Devices—Accredited Pathology Laboratories\) \(COVID-19 Emergency\) Exemption 2020](#) (the Exemption) by importing COVID-19 test kits that were not included in the ARTG and were not being imported in relation to an authorised pathology laboratory as required by the Exemption.

COVID-19 test kits must not be imported into Australia, or manufactured or supplied in Australia, unless they are included in the ARTG or are subject to a relevant exemption, approval or authority.

Where medical devices are covered by the Exemption, the conditions of the Exemption must be complied with. A failure to do so is a criminal offence under section 41MNB of the Act and exposes the company or any relevant individual to a civil penalty under section 41MNC of the Act. For further information, see the TGA's advice on the [legal supply of COVID-19 test kits](#).

The TGA takes action concerning unlawful conduct

The TGA regulates all medicines, medical devices and biologicals under the Act. Considering the current COVID-19 pandemic, these contraventions are a cause of serious concern for the TGA. Any alleged breaches relating to products supplied as part of Australia's response to the pandemic will be given the highest priority by the TGA.

The regulatory scheme is important to the safety of Australians and the TGA investigates suspected illegal activity related to therapeutic goods. A range of [compliance and enforcement](#) actions detect, deter and address unlawful trade in unapproved therapeutic

goods. Where appropriate this can involve criminal or civil court proceedings, which may result in substantial penalties, fines or imprisonment.

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