



5 August 2020

Therapeutic Goods Administration

Via email: email:info@tga.gov.au

cc: John.Skerritt@health.gov.au

Dear TGA

RE: Complaint about therapeutic hand sanitisers

CHOICE writes to ask the Therapeutic Goods Administration (**the TGA**) to investigate SIQURA for potential breaches of TGA regulations.

SIQURA was reported to CHOICE by a concerned member of the community. We believe that the company may be engaging in advertising of their therapeutic hand sanitiser products, despite being unregistered on the Australian Register of Therapeutic Goods (the **Register**). SIQURA makes potentially misleading advertising claims about the protection offered by quaternary ammonium compound (QAC) based hand sanitisers. The Australian Government and public health experts have doubted the effectiveness of QAC hand sanitisers in mitigating the risk of COVID-19.¹

Complaint about SIQURA hand sanitiser products

CHOICE asks that TGA investigate SIQURA for potentially selling unregistered therapeutic hand sanitisers, and for a possible breach of the *Therapeutic Goods Advertising Code (No.2) 2018 (the Code)*.

TGA guidelines state that any product that makes claims for use in a health care setting is “regulated as therapeutic goods”.² SIQURA makes therapeutic advertising claims that their hand sanitiser products are suitable for use in healthcare settings. Under a section on their website titled, “Protect your hands for 24 hours”, SIQURA advertises that “The Best Places to Use SIQURA” includes, “Aged & child care” and “Hospitals”³ The image attached to the text includes two medical professionals in scrubs washing their hands in a medical setting (**Appendix 1**).

¹ Australian Commission on Safety and Quality in Health Care, 2020, COVID-19

<https://www.safetyandquality.gov.au/covid-19/#%3Cstrong%3Eon-healthcare-settings:-use-of-non-alcohol-based-hand-rub-%3C/strong%3E>

² TGA, 2020, “Hand sanitisers: Information for manufacturers, suppliers and advertisers”

<https://www.tga.gov.au/hand-sanitisers-information-manufacturers-suppliers-and-advertisers>

³ SIQURA 2020, “Your Skin”, <https://siqura.com.au/pages/your-skin>, viewed 29 July 2020, screenshot in Appendix 1

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TGA guidelines also state any advertising that claims to be “active against viruses, fungi or other microbial organisms (other than bacteria)” means the product is marketed as therapeutic and will be regulated as a therapeutic good.⁴ SIQURA prominently advertises on their homepage that their products are, “proven to kill up to 99.999% of microbes within 1 to 5 minutes”.⁵ (Appendix 2) This advertising clearly extends beyond claiming hand sanitiser is active against bacteria. It is evident that SIQURA is making therapeutic claims about their hand sanitisers, both about the product’s use in healthcare settings as well as being active against microbial organisms.

We note that on 1 July 2020, SIQURA’s “Hospital grade surface disinfectant” was registered by Fresche Bioscience Pty Ltd on the Australian Register of Therapeutic Goods (ARTG).⁵ However, SIQURA’s hand sanitiser products are not registered on the ARTG. We are concerned that SIQURA is unlawfully manufacturing and marketing unregistered therapeutic hand sanitisers to Australian consumers.

Claims of QAC-based hand sanitisers

CHOICE is concerned about the veracity of SIQURA’s advertising claims on their hand sanitiser products. SIQURA advertises that their product’s, “ongoing protection makes it more effective than disinfection alone, by protecting surfaces from bacteria & germs for 24 hours or up to 30 days” (Appendix 3). Online advertising claims that, “one application in the morning helps to protect you for 24 hours” (Appendix 4).

This issue was brought to CHOICE’s attention by a concerned member of community, who happens to be a doctor:

“I purchased this brand of hand sanitiser at my local Amcal chemist. I am concerned that their claims about 24 hour protection against germs is extraordinary, and potentially misleading.”

SIQURA is an alcohol-free hand sanitiser. It uses antimicrobial agents, such as quaternary ammonium compounds (QAC), including benzalkonium chloride. The Australian government does not recommend QAC-based hand sanitisers for use against COVID-19, saying that current evidence indicates that these compounds have limited activity against viruses such as COVID-19.⁶ The advice aligns with the official WHO recommendation which states that if you don’t have access to soap and water, alcohol-based hand rubs are “the only known means for rapidly and effectively inactivating a wide array of potentially harmful microorganisms on hands” – including COVID-19.⁷ Professor Andrew McLachlan, Dean of Pharmacy at Sydney University’s School of Pharmacy states that,

⁴ TGA, 2020, “Hand sanitisers: Information for manufacturers, suppliers and advertisers”

<https://www.tga.gov.au/hand-sanitisers-information-manufacturers-suppliers-and-advertisers>

⁵ ARTG Entry: 338686,

[https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=7A31C8FE758CC447CA25859800422F6D&agid=\(PrintDetailsPublic\)&actionid=1](https://www.ebs.tga.gov.au/servlet/xmlmillr6?dbid=ebs/PublicHTML/pdfStore.nsf&docid=7A31C8FE758CC447CA25859800422F6D&agid=(PrintDetailsPublic)&actionid=1)

⁶ Australian Commission on Safety and Quality in Health Care, 2020, COVID-19

<https://www.safetyandquality.gov.au/covid-19/#%3Cstrong%3Eon-healthcare-settings:-use-of-non-alcohol-based-hand-rub-%3C/strong%3E>

⁷ World Health Organization, WHO Guidelines on Hand Hygiene in Health Care,

https://apps.who.int/iris/bitstream/handle/10665/44102/9789241597906_eng.pdf;jsessionid=A8D8B125A210C31036999654E904CE06?sequence=1

"There is limited evidence to suggest benzalkonium chloride is effective to inactive viruses and it's probably not effective against coronaviruses such as COVID-19."⁸

It is concerning that the Australian Government and leading public health experts suggest that the research into the effectiveness of QAC hand sanitisers in preventing COVID-19 is unproven at best, and ineffective at worst. We urge the TGA to investigate the advertising claims of SIQURA hand sanitiser products. In particular, we hold concerns about advertising that suggests "one application in the morning helps to protect you for 24 hours." There is an implication from this advertising that a person who applies from this sanitiser, will be protected from any new viral loads in the next 24 hours. This may lead people to believe they are protected from COVID-19, when may not be.

Given the limited research behind QAC hand sanitisers, the TGA should investigate whether there has been a breach of section 9(a) and 9(b) of the Code.⁹ In particular, whether the marketing of QAC-based hand sanitisers have breached code obligations to offer "valid and accurate" or "truthful" advertising given the lack of evidence about their effectiveness.

A stronger enforcement approach is needed

As a result of COVID-19, there has been a significant increase in the volume and range of hand sanitisers sold in Australia. Now more than ever, we need strong enforcement and compliance to ensure that unscrupulous companies do not illegally market hand sanitiser products.

We strongly support the TGA's recent actions against Australian Chemical Research Pty Ltd and Stapit Medical and Sports Supplies Pty Ltd for alleged breaches of the *Therapeutic Goods Act 1989*.¹⁰ We strongly urge the TGA to consider civil and criminal penalties for businesses who illegally sell hand sanitisers.

For further information please contact Patrick Veyret at pveyret@choice.com.au.

Yours sincerely,



Erin Turner
Director - Campaigns and Communications
CHOICE

⁸ CHOICE 2020, 'Are alcohol-free hand sanitisers effective against COVID-19?'

<https://www.choice.com.au/health-and-body/beauty-and-personal-care/skin-care-and-cosmetics/articles/alcohol-free-hand-sanitiser>

⁹ TGA 2020, 'Therapeutic goods advertising code', <https://www.tga.gov.au/publication/therapeutic-goods-advertising-code>

¹⁰ <https://www.tga.gov.au/media-release/australian-chemical-research-fined-25200-alleged-breaches-relation-hand-sanitiser>
<https://www.tga.gov.au/media-release/stapit-fined-37800-alleged-advertising-breaches-disinfectant-and-hand-sanitiser-relation-covid-19>

Appendix 1: SIQURA healthcare setting claims¹¹



PROTECT YOUR HANDS FOR 24 HOURS

THE BEST PLACES TO USE SIQURA

- Kitchens
- Bathrooms
- Cafes & restaurant counters
- Store fronts
- Workplaces & offices
- Gyms & fitness centres
- Aged & child care
- Hospitals
- While travelling

SHOP HAND SANITISER

Appendix 2: SIQURA claims to “kill up to 99.999% of microbes within 1 to 5 minutes”¹²

WHY SIQURA?

SIQURA is a simple and intelligent way to kill tough bacteria and protect surfaces, by staying bonded to skin for up to 24 hours and surfaces for up to 30 days.
Proven to kill up to 99.999% of microbes within 1 to 5 minutes*.

Appendix 3: SIQURA’s advertising claims¹³

¹¹ SIQURA 2020, “Your Skin”, <https://sigura.com.au/pages/your-skin>, viewed 29 July 2020

¹² SIQURA 2020, <https://sigura.com.au/>, viewed 29 July 2020

¹³ SIQURA 2020, <https://sigura.com.au/>, viewed 29 July 2020

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LONG LASTING

SIQURA'S ongoing protection makes it more effective than disinfection alone, by protecting surfaces from bacteria & germs for 24 hours or up to 30 days.

Appendix 4: SIQURA's advertising claims¹⁴

KEEP IT WITH YOU AT ALL TIMES

Keep our Hand Sanitiser & Protectant with you at all times. One application in the morning helps to protect you for 24 hours. You can also foam and wipe clean surfaces including cars, door handles, office equipment, airplane seats & gym equipment. Our 50ml bottle is perfect for travelling - lasting up to 100 applications.

¹⁴ SIQURA 2020, "Your Skin", <https://siqura.com.au/pages/your-skin>, viewed 29 July 2020

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