Australian Government

Department of Health
Therapeutic Goods Administration

Name & Address
Withheld

URGENT RESPONSE NEEDED

Our Reference: **RC-010706**

Importation and Supply of Unregistered Therapeutic Goods

Dear [redacted]

The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health (Department) and is responsible for monitoring, and enforcing where necessary, compliance with the legislation, regulations and rules for therapeutic goods including import, manufacture, advertising and supply.

Therapeutic goods, including traditional and over the counter medicines, must not be imported, supplied or advertised in Australia, unless they are included in the Australian Register of Therapeutic Goods (ARTG) or are otherwise the subject of a relevant exemption, approval or authority under the *Therapeutic Goods Act 1989* (the Act).

Australian Border Force (ABF) has held a parcel, and informed us that you are attempting to import the following therapeutic goods into Australia:

Description	Each containing	Category of medicine
1000 IVERBEST 12 Tablet	12.00 Milligram of ivermectin	(S4) Prescription Only Medicine

The goods you have attempted to import are *therapeutic goods*, as defined in the *Therapeutic Goods Act 1989* (the Act)

Ivermectin falls within the definition of a medicine under the *Therapeutic Goods Act 1989,* and is included in Schedule 4 to the Poisons Standard, meaning it is a prescription only medicine.

It is an offence under section 19B of the Act to import therapeutic goods without the relevant registration, listing, approval, authority or exemption. In addition, civil penalties can be imposed for the importation of such goods under section 19D of the Act.

The personal importation exemption may apply to allow you to import these products. To be eligible for this exemption, required evidence as specified in Item 1 of Schedule 5 of the *Therapeutic Goods Regulations 1990* must be provided.
However, the Personal Importation Scheme is unlikely to apply in this circumstance as the importation is addressed to a company and/or the quantity is in excess of a personal volume.

You should be aware that in Australia these products require entry in the Australian Register of Therapeutic Goods (ARTG) prior to import, export, manufacture or supply for human therapeutic use.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
02 6232 8444 02 6232 8605 info@tga.gov.au

TGA Health Safety Regulation

Our records indicate that neither you nor your business have not registered these products in the Australian Register of Therapeutic Goods (ARTG).

What you need to do

You are required to provide further information, including:

- If your company believes it should be exempt from the registration process, information on why this is believed to be the case
- Any other information that you feel may be relevant to assist us in making a decision regarding if your products should be included on the ARTG or exempt from regulation by the TGA.

You are required to immediately cease all importation and supply of these products, together with any other unregistered or unlisted product not exempted from this requirement.

You may apply to have your goods listed on the ARTG by following instructions available at https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia or by phoning 1800 020 653.

You are to provide written confirmation by **28 March 2022** that you are legally authorised to import (and supply) these products, or that you have ceased the import and any supply until such time as the products have been included in the ARTG for human therapeutic use.

Failure to comply with this request to cease and desist or continued importation, and any subsequent supply of therapeutic goods may result in the TGA pursuing further enforcement action against you. This may include issuing of infringement notices, commencing legal proceedings against you seeking payment of civil penalties in relation to the alleged unlawful conduct or referring the matter to the Commonwealth Director of Public Prosecutions for criminal prosecution.

Where applicable, the TGA may also raise the matter with, or work in conjunction with, other regulatory agencies, which may have legislative jurisdiction over such matters, such as State or Territory Police and/or State Health Regulators.

Do you need further assistance?

You may wish to seek independent legal advice or the assistance of a regulatory affairs consultant to address non-compliance with your importation, supply and/or online advertising of the goods. You can find a list of organisations that may be able to assist you in finding an adviser or consultant on the TGA website.[1] The TGA does not endorse any of the consultants on our website.

Any correspondence on this matter should be addressed to myself, Sam and emailed to RC@health.gov.au, or mailed to PO Box 100 Woden ACT 2606. If you need any further assistance or clarification on this matter please do not hesitate to contact me on (02) 6289 1683

Yours sincerely

Sam
Compliance Officer
Therapeutic Goods Administration
16 March 2022

[1] See https://www.tga.gov.au/regulatory-affairs-consultants

What the law says

In Australia, if you import, manufacture, advertise or supply products with claims for human therapeutic use, they are classified as therapeutic goods under the *Therapeutic Goods Act 1989*.

This requires the goods to be registered on the ARTG prior to import, export, manufacture or supply for human therapeutic use.

It is an offence under section 19B of this Act for a person to import, export, supply, or manufacture therapeutic goods for use in humans unless those goods are listed or registered in the ARTG by the sponsor, or the goods are exempt or are subject of an approval or authority under Sections (18A) (19) or (19A) of the Act.

"Sponsor" includes persons who import or arrange for the importation of therapeutic goods, or who manufacture or arrange for another person to manufacture the goods for supply.

Sponsors are subject to the requirements of the Act if they are trading corporations or, in the case of individuals and corporations generally, trade goods between Australia and another country or among States within Australia.

The maximum penalty upon conviction is Imprisonment for 5 years or a fine of $888,000 or both for an individual, or a fine of $4,440,000 for a body corporate in respect of each offence.

Please also note that Section 19D of the Act, may also subject sponsors of therapeutic goods not included in the Australian Register of Therapeutic Goods to the civil penalties provisions contained in the legislation. Contravention of a civil penalty can attract maximum fines of $1,110,000 for individuals and $11,100,000 for a body corporate.

Further information

- Application forms for Listing or Registration of Therapeutic Goods are available from the TGA website: https://www.tga.gov.au/overview-supplying-therapeutic-goods-australia or by phoning 1800 020 653
- Further information regarding advertising and endorsements can be found on the TGA website at https://www.tga.gov.au/book-page/advertising-and-endorsements.
- The *Therapeutic Goods Act 1989, Therapeutic Goods Regulation 1990* and Poisons Act are available at www.legislation.gov.au
- TGA guidance on the Excluded Goods Order is available at http://www.tga.gov.au/industry/legislation-excluded-goods-order-1101-guidance-4opqr.htm.