



MEDSAFE

NEW ZEALAND MEDICINES
AND MEDICAL DEVICES
SAFETY AUTHORITY

A BUSINESS UNIT OF
THE MINISTRY OF HEALTH

www.medsafe.govt.nz

Dear Sir / Madam

WARNING LETTER CONCERNING THE ADULTERATION OF SEXUAL PERFORMANCE PRODUCTS WITH PRESCRIPTION MEDICINES

Background

Medsafe is a business unit of the Ministry of Health and is responsible for the regulation of the *Medicines Act 1981* ("the Act") and the *Medicines Regulations 1984*.

Medsafe is concerned at the number of sexual performance products adulterated with prescription medicines that have been intercepted at New Zealand's border, advertised for sale on New Zealand-based websites, or discovered for sale in retail stores in New Zealand.

Within the past five months Medsafe has required the mandatory recall and advised the public of up to 14 erectile dysfunction and sexual performance products found to contain undeclared prescription medicines, such as, sildenafil, tadalafil and various analogues of active pharmaceutical ingredients.

The recalled products have included:

SZM Formula for Men, Stallion, Volcanic, Tomcat Ali, So Hard for Men, Pulse8 for Women, The Rock, Tonic 66, Shaguar, Signature Signergy, VIGRX (green capsule), VIGRX (white capsule), VigRx (tablet) and VigRX Plus (caplet) .

Suspected breaches of the Act

The following are details of some of the offences that may be committed by persons involved with the importation, possession, sale or supply of products adulterated with prescription medicines.

Importation / Possession of prescription medicines

The importation of prescription medicines without reasonable excuse is an offence against in **section 43** of the Act and is punishable upon conviction to a term of imprisonment not exceeding three months or a fine not exceeding \$500.

Section 43 states:

No person shall, without reasonable excuse, import, procure, receive, store, use or otherwise have in his possession any prescription medicine.

Sale of prescription medicines

The sale of pharmacy-only, pharmacist-only (restricted) and prescription medicines by retail (except at a licensed pharmacy or when otherwise exempted) is an offence against **section 18** of the Act and is punishable upon conviction by a term of imprisonment not exceeding 6 months or a fine not exceeding \$40,000.

Section 18 states:

No person shall in the course of any business carried on by that person, sell by retail, or supply in the circumstances corresponding to retail sale, or distribute by way of gift or loan or sample or in any other way

(a) any prescription medicine unless

- (i) the medicines is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or*
- (ii) the medicine is supplied in accordance with a standing order by a person who is authorised to supply and administer any specified class or description of prescription medicine under that standing order.*

(b) Any restricted medicine unless the medicine is sold, supplied, or distributed by a pharmacist in a pharmacy or hospital; or

(c) Any pharmacy-only medicine unless the medicine is sold, supplied, or distributed by –

- (i) a person under the supervision of a pharmacist in a pharmacy or a hospital; or*
- (ii) a person who sells, supplies, or distributes the medicine in any shop described in section 51(2) and in accordance with a licence issued under Part 3.*

Sale & advertisement of new medicines

Adulterated sexual performance products are medicines that have not been 'approved' for distribution in New Zealand. The approval process requires assessment of the product by the Ministry of Health (via Medsafe) and the consent to sell and distribute the products by the Minister of Health.

Sale, distribution or advertising of a product that has not been approved through this process is a breach of **section 20** of the Act. The penalties for this offence upon conviction are: for an individual, a term of imprisonment not exceeding six months or a fine not exceeding \$20,000; and, in the case of a body corporate a fine not exceeding \$100,000.

Section 20 states:

No person shall

(a) sell; or

(b) distribute by way of gift or loan or sample or in any other way; or

(c) advertise the availability of

any medicine to which this section applied before the consent or provisional consent of the Minister to the distribution of the medicine has been notified in the Gazette, or otherwise than in accordance with such conditions as may be imposed by the Minister on giving his consent or provisional consent and notified in the Gazette.

“Strict liability” considerations

Prosecution for selling a medicine contrary to the Act may be proceeded with on a “strict liability” basis under section 80(1) of the Act, which means that it is not necessary for the prosecution to prove that the defendant intended to commit the offence.

All sellers and distributors, at all levels of the distribution chain, may be prosecuted for selling or distributing products in contravention of the Act. A lack of knowledge of the medicines legislation and/or what is contained in the products is not a defence to a prosecution for selling a medicine contrary to the Act.

Warning

Importers, distributors and retailers are responsible for the products they sell under the medicines legislation, including being cognisant of all the active ingredients contained in the products and are required to seek approval under the Act, if required, prior to selling them.

Recently we have tested various sexual performance products and have found many of them to be adulterated with prescription medicine adulterants. Some of them have had the adulterants contained within the capsule shell itself.

Note that assurances, documents and samples supplied by manufacturers and distributors may not always be accurate or correctly describe the content of the products. Some suppliers may appear legitimate but could be selling the products illegally for which you may become liable to prosecution in New Zealand.

This is a general warning letter to importers, distributors and retailers of sexual performance products in New Zealand.

Medsafe intends to continue to closely monitor the importation, sale and supply of sexual performance products and to prosecute, if the circumstances require it, any breaches of the Act.

If you require further advice concerning any general regulatory issues raised in this letter, please contact the Compliance Management Branch at Medsafe. If you require advice on how to comply with the legislation with respect to products you wish to market, the Regulatory Consultants listed on the Medsafe website www.medsafe.govt.nz may be able to assist you.

Yours sincerely

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