

## ***THERAPEUTIC GOODS ACT 1989***

Undertaking to the Secretary of the Australian Department of Health and Ageing given for the purposes of section 42YL of the Act

By

T & D TRADING CO PTY LIMITED

ACN: 104 234 040

And

VAN DUNG NGUYEN (DAVID NGUYEN)

### **Persons giving this undertaking**

- (1) This undertaking is given to the Secretary of the Australian Department of Health and Ageing (DoHA), by T & D Trading Co Pty Limited (T & D Trading) of 17-23 Chadderton Street, Lansvale, NSW 2166 and David Nguyen for the purposes of section 42YL of the *Therapeutic Goods Act 1989* (the Act).

### **Background**

- (2) T & D Trading carries on the business of importation and wholesale distribution in Australia of diverse consumer goods including cosmetic products. Some of these products are therapeutic goods within the meaning of the Act by virtue of the claims made on the product labelling.
- (3) David Nguyen is the sole director and the secretary of T & D Trading and a director of a number of other Australian registered companies that are also involved, either directly or indirectly, in the importation into Australia of products that are therapeutic goods within the meaning of the Act by virtue of the claims made on the product labelling.
- (4) The Therapeutic Goods Administration (TGA) is a division of the Australian Government Department of Health and Ageing, and is responsible for the national regulation of therapeutic goods including medicines, biologicals and medical devices.
- (5) The meaning of 'sponsor' in the Act includes a person (including a corporation) who is resident of or carrying on business in Australia, who imports or arranges the importation of therapeutic goods into Australia.

- (6) Unless otherwise exempt or excluded, therapeutic goods must be included in the Australian Register of Therapeutic Goods (ARTG) by a sponsor prior to importation. Criminal offences and/or civil penalty provisions may apply if goods are imported and are not included in the ARTG.
- (7) In 2011, the TGA Regulatory Compliance Unit warned T & D Trading three times in relation to the importation into Australia variously of toothpaste, sunscreen, condom and eye wash products not included in the ARTG in the name of T & D Trading as sponsor as required by the Act.
- (8) Between 1 May 2012 and 22 June 2012, T & D Trading twice imported into Australia a quantity of antiseptic mouthwash products (the Contravening Goods) which were therapeutic goods which were not included in the ARTG in the name of T & D Trading or any of its subsidiaries as sponsor.
- (9) Consequently representatives of the TGA Regulatory Compliance Unit commenced investigations into the alleged importation by T & D Trading of the Contravening Goods not included in the ARTG in the name of T & D Trading or any of its subsidiaries as sponsor. A total of 1671 one litre bottles of the Contravening Goods were seized as a result of these investigations.
- (10) The TGA considers that the importation of the Contravening Goods into Australia by T & D Trading constitutes a criminal offence against section 19B(4) of the Act by reason of coming within section 19B(4)(a)(i) of the Act, and/or breaches the civil penalty provisions contained in section 19D(1) of the Act by reason of coming within section 19D(1)(a)(i) of the Act as T & D Trading were the "sponsor" of the Contravening Goods within the meaning of the Act, the Contravening Goods were not included in the ARTG in the name of T & D Trading as sponsor, and no exemptions or exclusions applied.
- (11) Since becoming aware of the TGA investigation, T & D Trading has ceased the importation into Australia, and distribution within Australia, of the Contravening Goods.
- (12) T & D Trading acknowledges that its conduct described at paragraph 8 above, involved the commission or the likely commission of a criminal offence and/or involved a breach or likely breach of the civil penalty provisions as described in paragraph 10 above.

#### **Period of undertaking**

- (13) This undertaking comes into effect when all of the following are satisfied:
  - (i) the undertaking is executed by T & D Trading; and

- (ii) the undertaking is executed by David Nguyen both in his personal capacity and in his capacity as director and secretary of T & D Trading; and
  - (iii) the Delegate of the Secretary signs the executed undertaking.
- (14) Upon the commencement of this undertaking, T & D Trading and David Nguyen undertake to assume the obligations set out in paragraphs 16 - 20 below.
- (15) This undertaking terminates on the third anniversary of the day on which it comes into effect.

## Undertakings

- (16) T & D Trading undertakes for the purposes of section 42YL of the Act that within one month from the date of this undertaking it will, at its own expense, engage a qualified compliance professional to advise and assist with the implementation of regulatory procedures to ensure that T & D Trading does not commit any future breaches of the Act.
- (17) For the purposes of this Undertaking a 'qualified compliance professional' will be someone with a minimum of 5 years experience in advising on regulatory compliance matters concerning therapeutic goods in Australia.
- (18) T & D Trading further undertakes for the purposes of section 42YL of the Act that it will at its own expense:
  - (i) establish and implement a Therapeutic Goods Compliance Program, within 3 months of the commencement of this undertaking in accordance with Australian Standard AS 3806-2006 and the requirements set out in **Annexure A** to this Undertaking, being a program designed to minimise T & D Trading and its subsidiaries risk of future breaches of sections 19B, 19D, 41MI and 41MIB<sup>1</sup> of the Act and to ensure their awareness of their responsibilities and obligations in relation to the requirements of sections 19B, 19D, 41MI and 41MIB of the Act; and
  - (ii) maintain and continue to implement the Compliance Program for a period of 3 years from the commencement of this Undertaking; and
  - (iii) provide a copy of any documents required by the TGA in accordance with **Annexure A**.

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<sup>1</sup> Sections 41MI and 41MIB being the equivalent offence and civil penalty provisions to sections 19B and 19D, respectively, but in relation to medical devices.

- (19) T & D Trading also undertakes for the purposes of section 42YL of the Act that it will:
- (i) at its own expense, within 2 months of the commencement of this Undertaking have caused the Contravening Goods to be collected from the TGA, transported and destroyed in accordance with the standard for the handling and destruction of drugs AS/NZS4757:2002 and provide the TGA with a Certificate of Destruction; and
  - (ii) pay to the TGA (on behalf of the Commonwealth) an amount of \$2307.00 as reimbursement for transportation and 3 months storage costs incurred by the TGA in connection with the Contravening Goods.
- (20) David Nguyen undertakes for the purposes of section 42YL of the Act that he will:
- (i) at his own expense, ensure that within 3 months of the Undertaking coming into effect, he attends practical training focusing on the identification of categories of consumer goods likely to be imported by T & D Trading or any of its subsidiaries that, being therapeutic goods, may be subject to regulation by the TGA, and the statutory obligations applicable to importers (sponsors) of therapeutic goods; and
  - (ii) ensure that the training is administered by a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation; and
  - (iii) within 14 days of completion of training, provide the TGA with a written statement from the qualified compliance professional or legal practitioner that conducted the training, confirming the completion of the training and that it was conducted as required by 20(i) – 20(ii) above.

## Acknowledgements

- (21) T & D Trading and David Nguyen acknowledge that:
- (i) this Undertaking is given voluntarily; and
  - (ii) the Secretary may make this Undertaking publicly available on a public register and is obliged under the Act to publish details of the undertaking, as in force from time to time, on the internet; and
  - (iii) the Secretary and/or the Commonwealth or officers thereof may from time to time, publicly refer to this Undertaking including through, but not limited to, news media statements, and in TGA or DoHA publications; and

- (iv) this Undertaking in no way derogates from the rights and remedies available to the Secretary, the Commonwealth or any other person arising from the conduct of T & D Trading or David Nguyen.

**Executed by**

**T & D Trading Co Pty Limited (ACN 104 234 040)**     )  
by its authorised officers pursuant to                                     )  
section 127(1) of the Corporations Act                                     )

.....  
Van Dung Nguyen (David Nguyen) (Director)  
for and on behalf of T & D Trading Co Pty Limited  
ACN: 104 234 040

.....  
**Van Dung Nguyen (David Nguyen)**

This 21<sup>st</sup> day of February 2013

**ACCEPTED BY THE NATIONAL MANAGER OF THE THERAPEUTIC GOODS ADMINISTRATION  
AS DELEGATE OF THE SECRETARY OF THE DEPARTMENT OF HEALTH AND AGEING, UNDER  
SECTION 42YL OF THE *THERAPEUTIC GOODS ACT 1989*.**

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**Dr John Skeritt**  
**TGA National Manager**  
**Delegate of the Secretary**

This 7<sup>th</sup> day of March 2013

## **THERAPEUTIC GOODS COMPLIANCE PROGRAM (see clause 18)**

T & D Trading Co Pty Ltd (T & D Trading) will, in order to meet its obligations under clause 18 of the Undertaking, establish a Therapeutic Goods Compliance Program (Compliance Program) in accordance with AS 3806-2006 that also complies with each of the following requirements:

### **Appointment**

- (1) Within one month of the date of the Undertaking coming into effect T & D Trading will appoint a director, or one of the directors or a senior manager, of the company to be responsible for the development, implementation and maintenance of the Compliance Program (the Compliance Officer).
- (2) T & D Trading will within 14 days of the Compliance Officer's appointment notify the Therapeutic Goods Administration (TGA) of the Compliance Officers name and contact details.
- (3) T & D Trading, for a period of 3 years from the date of the Undertaking coming into effect, will advise the TGA within 28 days of any change of Compliance Officer or the Compliance Officer's contact details.

### **Compliance Officer Training**

- (4) T & D Trading will at its own expense, ensure that within 3 months of the Undertaking coming into effect, the Compliance Officer attends practical training focusing on the identification of categories of consumer goods likely to be imported by T & D Trading or any of its subsidiaries that, as therapeutic goods, may be subject to regulation by the TGA, and the statutory obligations applicable to importers (sponsors) of therapeutic goods.
- (5) T & D Trading shall ensure that the training is administered by a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation.
- (6) T & D Trading will within 14 days of that completion of training provide the TGA with a written statement from the qualified compliance professional or legal practitioner who conducts the training, confirming the completion of the training and that it was conducted as required by paragraphs 4 - 5 above.

### **Staff Training**

- (7) For the period of 3 years from the date of this undertaking T & D Trading shall, at its own expense, cause all employees of T & D Trading and its subsidiaries whose duties could result in them being concerned with conduct that may contravene sections 19B, 19D, 41MI and 41MIB of the Act to receive regular (at least once a year) practical training focusing on the identification of categories of consumer goods likely

to be imported by T & D Trading or any of its subsidiaries that, being therapeutic goods, may be subject to regulation by the TGA and the statutory obligations applicable to importers (sponsors) of therapeutic goods. This training is to be administered by the Compliance Officer (once trained) or a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation.

## **Review**

- (8) T & D Trading shall, at its own expense, cause two annual reviews of the Compliance Program (the Review) to be carried out by a qualified compliance professional or legal practitioner with expertise in Australia's therapeutic goods legislation and T & D Trading shall ensure that the Review is broad and rigorous enough to:
  - (i) Provide T & D Trading and the Therapeutic Goods Administration (TGA) with a supportable verification that the Compliance Program complies with the requirements of this Undertaking and is suitable for the size and structure of T & D Trading and its subsidiaries; and
  - (ii) Provide the Compliance Program Review Report and opinions detailed at paragraph 10 below.
- (9) T & D Trading shall ensure that the first review is completed within one year and one month of this Undertaking coming into effect and that a second review is completed one year after the first review.

## **Reporting**

- (10) T & D Trading shall require the person undertaking an annual review ('the Reviewer') to set out the his or her findings in a Compliance Program Review Report, which will provide particular and specific information regarding the scope of the review and the effectiveness of the Compliance Program including:
  - (i) details of the evidence gathered and examined during the review; and
  - (ii) the name and relevant experience of the person appointed as T & D Trading's Compliance Officer; and
  - (iii) the Reviewer's opinion on whether T & D Trading has in place effective staff training that comply with the requirements of this Undertaking; and
  - (iv) actions recommended by the Reviewer to ensure the continuing effectiveness of T & D Trading's Compliance Program.
- (11) T & D Trading shall require that each Compliance Program Review Report is completed and provided to T & D Trading within one month of completion of the review.
- (12) T & D Trading will cause the Compliance Program Review Report to be provided to the TGA within 14 days of its receipt from the Reviewer.

- (13) T & D Trading shall implement promptly and with due diligence any recommendations made by the Reviewer or required by the TGA that are reasonably necessary to ensure that T & D Trading maintains and continues to develop the Compliance Program elements in accordance with this Undertaking and effectively implements and follows the Compliance Program.
- (14) If requested by the TGA, T & D Trading shall, at its own expense provide copies of documents and information in respect of matters which are the subject of the Compliance Program.
- (15) In the event the TGA has reason to suspect that the Compliance Program is not being implemented effectively, T & D Trading shall, at its own expense and if required by the TGA, cause an interim or additional review to be undertaken to which paragraphs 10 to 13 above apply as if it were an annual review.



**THERAPEUTIC GOODS ACT 1989 - SECTION 42YL**

**Enforcement of undertakings**

- (1) The Secretary may accept a written undertaking given by a person in connection with a matter in relation to which the Secretary has a power or function under this Act or the regulations.
- (2) The person may withdraw or vary the undertaking at any time, but only with the consent of the Secretary.
- (3) The Secretary must publish details of the undertaking, as in force from time to time, on the internet.
- (4) If the Secretary considers that the person who gave the undertaking has breached any of its terms, the Secretary may apply to the Federal Court for an order under subsection (5).
- (5) If the Court is satisfied that the person has breached a term of the undertaking, the Court may make all or any of the following orders:
  - (a) an order directing the person to comply with that term of the undertaking;
  - (b) an order directing the person to pay to the Commonwealth an amount up to the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach;
  - (c) any order that the Court considers appropriate directing the person to compensate any other person who has suffered loss or damage because of the breach;
  - (d) any other order that the Court considers appropriate.