APPENDIX 4

Excerpts from correspondence with TruVision

Letter to Truvision NZ dated 11 March 2016

Review of products

TruVision Gen 2 flat pack

This product contains blue capsules (truFIX) and green capsules (tru weight & energy).

The advertising on the promotional pack uses the words "Lose Body Fat". This wording is considered to be a therapeutic claim and therefore the product is for a therapeutic purpose.

The Supplemented Facts panel for the tru WEIGHT & ENERGY product states "yohimbine (98%)". Yohimbine is scheduled as a prescription medicine by schedule 1 of the Medicines Regulations 1984.

Truvision one week sample pack

This product contains blue capsules (truFIX) and green capsules (TruWeight & Energy).

The Supplemented Facts panel on the box for the tru WEIGHT & ENERGY product states "Bitter Orange Extract (synephrine 30%). Synephrine is also known as oxedrine. Oxedrine in medicines containing more than 30 milligrams per recommended daily dose is a prescription medicine.

TruELEVATE

According to the website information, truELEVATE contains DHEA. DHEA is also known as dehydroepiandrosterone or dehydroepiandrostenedione. In New Zealand it is known as prasterone and that is scheduled as a prescription medicine by schedule 1 of the Medicines Regulations 1984.

Extent of review performed by Medsafe

The three products discussed in this letter are the only products that have been reviewed for compliance with the medicines legislation; just because we have not identified or brought to your attention other products that may not be compliant does not mean that they are compliant.

Classification of products

Prescription medicines can only be prescribed by a New Zealand authorised prescriber (usually a registered medical practitioner) and sold by a licenced pharmacy or a health care professional authorised under the Act. Importing, wholesaling and distribution of medicines requires a licence from the Ministry of Health before the activity takes place.

Therapeutic purpose / therapeutic claim / herbal remedy

"Therapeutic purpose" is defined in Section 4 of the Medicines Act 1981 (the Act), and includes, amongst other things, the treatment, diagnosis and prevention of disease or the modification of a physiological function.

Products that are intended to be used for a therapeutic purpose can be categorised as *medicines, related products* or *medical devices*. A product is considered to be intended for a therapeutic purpose if:

- The product contains one or more ingredient(s) that have a pharmacological action
- A therapeutic purpose is claimed for the product (usually on the label or in promotional material)
- A therapeutic purpose is implied for the product (usually on the label or in promotional material)
- The product contains a medicine or substance listed in the Schedule 1 of the Medicines Regulations 1984 or a Notice in the *New Zealand Gazette* issued under section 106 of the Medicines Act (unless the product is in a form that cannot be administered to a human being for a therapeutic purpose).

Compliance with the Medicines Act 1981

The products identified that you have imported, distributed or have in your possession for sale or distribution are medicines by virtue of their intended use for a therapeutic purpose and the ingredients in the products are scheduled as prescription medicines which means that their route of supply is restricted and regulated by the Medicines Act 1981.

Section 17: manufacturers, wholesalers, packers of medicines and operators of pharmacies to be licenced

Selling any medicine by wholesale without a licence breaches section 17 of the Act. The penalty for doing so for an individual is a fine not exceeding $40,000. Section 17 states:

> **Except as provided in sections 25 to 34, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person,—**
>
> **(a) manufacture any medicine; or**

(b) sell any medicine by wholesale; or
(c) pack or label any medicine; or
(d) operate any pharmacy,—
otherwise than in accordance with a licence issued under Part 3.

Section 18: Sale of medicines by retail

Selling products containing prescription medicines direct to the public without the required legal authority breaches section 18 of the Act. The penalty for doing so for an individual is liable to imprisonment for a term not exceeding 6 months or a fine not exceeding $40,000. Section 18 states:

Except as provided in sections 25, 27, and 30 to 33, or as may be permitted by regulations made under this Act, no person shall, in the course of any business carried on by that person, sell by retail, or supply in 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 medicine 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; or
(aa) [Repealed]
(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.
(2) No person may sell by retail any prescription medicine otherwise than under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber.
(2A) No person may supply, in circumstances corresponding to retail sale, any prescription medicine otherwise than—
(a) under a prescription given by a practitioner, registered midwife, veterinarian, or designated prescriber; or
(b) in accordance with a standing order.

Section 20: Restrictions on sale or supply of new medicines

The Minister of Health has not given consent pursuant to section 20 of the Act for the sale, distribution or advertising of these products. It is important to note that even though medicines may be approved for sale in other countries they may not been approved in New Zealand. There is no provision in the New Zealand legislation for the parallel importing and selling of medicines.

Any products you may sell, advertise and distribute that are non-consented (unapproved) medicines are *new medicines*. Selling, advertising and supplying *new medicines* breaches section 20 of the Act. The penalty for doing so is; 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*.

Section 43: Restrictions on possession of prescription medicines

The importation, receiving, possession and storage of prescription medicines must be done with a 'reasonable excuse' in accordance with section 43 of the Act.

Persons or companies who are not licensed or otherwise authorised under the Act, to import, receive, possess or store prescription medicines may breach section 43 of the Act. The penalty for doing so is 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.

Action required

In order to avoid continuing offences, I advise you to take the following action:

1. Cease importing, advertising, selling and distributing all of the medicines identified in this letter and any other medicines you may identify within your operation
2. Quarantine all current stock of these medicines so no further sale or distribution can take place;
3. Immediately review any website or advertising associated with the sale and distribution of the products and business activity to ensure compliance with the relevant legislation regarding medicines

Recall of products

You should urgently review your position with respect to the legislation and in regard to the health and well-being of anyone supplied medicines by you and consider recalling these medicines from your customers.

Regulatory Guidance and advice

I encourage you to review your processes to ensure that any medicinal products that you purchase, import, advertise, sell or distribute comply with the Medicines Act 1981 and its regulations. Other legislation such as the Dietary Supplement Regulations 1985 should also be considered.

A number of regulatory consultants provide independent regulatory advice, clinical and other consultancy services to the therapeutic sector in New Zealand. A link to such consultants can be found on the Medsafe website www.medsafe.govt.nz or at the following link: http://www.medsafe.govt.nz/regulatory/consultants.asp.

I have also attached a guidance document for weight loss products which will give you some basic guidance should you import and distribute this type of products:

http://www.medsafe.govt.nz/profs/NaturalHealth.asp

The following link provides information regarding the categorisation of products and the Therapeutic Advertising pre-Vetting Service (TAPS):

http://www.medsafe.govt.nz/regulatory/categorisation-of-products.asp

The database of medicine classifications is available on the Medsafe website at the following link: http://www.medsafe.govt.nz/profs/class/classification.asp

Should you wish to view the full list of scheduled prescription, restricted and pharmacy only medicines the list is available in schedule 1 of the Medicines Regulations 1984. The link is http://www.legislation.govt.nz/regulation/public/1984/0143/latest/DLM95668.html

Letter to TruVision US dated 24 June 2016

You have advised us of your intention to comply with the Medicines Act 1981 (the Act) and New Zealand (NZ) law.

Current Importation of TruVision products

On 17 June 2016 the NZ Customs Service referred to Medsafe five boxes containing a total of 63 flat packs. The flat packs are mostly blue in colour and possibly generation 1. The flat packs contain a blisterpack of 15 blue capsules (truFIX) and a blisterpack of 15 green capsules Tru WEIGHT & ENERGY).

The importer of the boxes advised me that they logged into the TruVision website and used their credit card to purchase the products.

The invoices in the imported boxes show that they are from:

TruVision Health

6077 W Wells Park Road

West Jordan UT 84081

Bitter Orange Extract (synephrine 30%)

The Supplemented Facts panel on the flat pack for the tru WEIGHT & ENERGY product states "Bitter Orange Extract (synephrine 30%). Synephrine is also known as oxedrine. Oxedrine in medicines containing more than 30 milligrams per recommended daily dose is a prescription medicine.

You have previously advised me by email that the amount of synephrine is 24mg .

The labelling on the product is: "**Suggested use:** take one of each capsule before breakfast and again in the early afternoon". This indicates the recommended daily dose is two capsules and therefore the recommended daily intake would be 48 milligrams of oxedrine a day. This means that the product would be considered to be a prescription medicine as the recommended daily dose is over 30 milligrams.

Our testing of the tru WEIGHT & ENERGY green capsules from the generation 1 one week sample pack established that each capsule contained approximately 30mg of Oxedrine (Synephrine) per capsule (ESR report PHA16124/1).

Additionally, the ingredient oxedrine is included in schedule 1 of the Medicines Regulations 1984 and therefore any product that contains this medicine is considered to be for a therapeutic purpose and would be a general sale medicine if present in doses below those specified for a prescription medicine. For this product

to be sold, distributed or advertised in New Zealand the product must be consented by the Minister of Health pursuant to section 20 of the Medicines Act 1981.

Our opinion is that this product is a prescription medicine. I recommend that you do not ship any of this product to NZ.

Therapeutic Claim

The advertising on the promotional pack uses the words "Lose Body Fat". This wording is considered to be a therapeutic claim and therefore the product is for a therapeutic purpose.

Compliance with the Medicines Act 1981

I have contacted the importer and advised them that importing the Truvision product for the purpose of advertising, sale and distribution breaches the Medicines Act 1981.

Any person or company importing, advertising and selling any of the Truvision products identified in our correspondence including generation 1 and 2 products I believe will potentially breach sections 17, 18, 20 and 43 of the Act. This is outlined in previous correspondence.

We are aware that Truvision products are still being sold in New Zealand. I intend to contact known sellers and advise them that they cannot advertise and sell the products identified in this letter and other correspondence and if they do so they will potentially be breaching the Medicines Act 1981. Advertising includes facebook and websites.

It is my opinion that you were supplied sufficient information in the correspondence prior to this letter that would enable you to reasonably establish that the products that are continuing to be distributed in NZ are likely to breach the Act.

Any further non-compliant Truvision product that enters New Zealand that we believe is in breach of the Act are is likely to be the subject to regulatory action which may include seizure.

Action required

I strongly recommend that you cease sending this non-compliant product to New Zealand as any person, company or entity involved with any illicit advertising, selling and distribution of Truvision products that are not compliant with the Medicines Act 1981 may be liable.

Once again. I encourage you to review all of your products and ensure that they are all compliant with NZ law of you intend to market them in New Zealand.