Media Release

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Director-General's Statement Under Section 98 of the Medicines Act 1981

Director-General of Health Dr Karen Poutasi is today warning people against taking two herbal products after testing revealed they contained undeclared prescription medicines for weight loss and erectile dysfunction.

Tests by the Ministry of Health Medicines Safety Authority (Medsafe) have shown that the herbal weight loss product Li Da contains the prescription medicine sibutramine, which is prescribed for overweight (obese) patients who have not been able to lose weight using a low calorie diet and exercise.

Sibutramine can cause increased blood pressure and heart rate and cannot safely be taken by a range of people, including those with glaucoma, mental illness and severe liver or kidney problems. It should not be used in combination with other medicines such as some antidepressants and migraine treatments, Dr Poutasi says.

A second herbal product Nasutra, has been found to contain the prescription medicine Sildenafil, which is prescribed for the treatment of erectile dysfunction.

Sildenafil is known to interfere with some heart medication and could be fatal to some individuals.

"Consumers should immediately stop taking these two products," Dr Poutasi says. "People who have taken Li Da or Nasutra should seek medical advice from their doctor if they are: taking other medicines; have felt unwell when taking the products; or if they have become unwell after they stopped taking the products."

The two products were discovered following routine testing, surveillance activities and through information received by Medsafe.

Action is being taken with respect to the distributors of these products and further investigations by Medsafe are underway into the importation and supply of the products.

"It is illegal to sell or supply prescription medicines without the purchaser having a prescription from a registered medical practitioner. Distributors, importers and sellers are responsible for ensuring the products they import or sell do not contain any undeclared prescription medicines," Dr Poutasi says.

"It is also illegal for an individual to possess personal supplies of a prescription medicine without first having obtained a medical practitioner's prescription for them."

"Consumers need to be cautious as there may be other herbal products at risk of containing prescription medicines or toxic substances. There are many examples in the international literature where ‘herbal’ products for the treatment of impotence or for weight loss have been found to contain prescription medicines."

Further information and photos of the two products are available on the Medsafe website

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Background information

The products Li Da and Nasutra were investigated following information received by Medsafe and through surveillance activities carried out at the border. Subsequent testing showed that Li Da contained the prescription medicine sibutramine, and Nasutra contained the prescription medicine sildenafil.

As these products contain a prescription medicine and are clearly for a therapeutic use, they are considered to be a medicines distributed without the consent of the Minister, in contravention of the Medicines Act 1981. Before the Minister gives consent to the distribution of a medicine, its quality, safety and efficacy must be assessed against and meet international guidelines. This application process for approval has not occurred with either product.

Consequently, Medsafe has required known sellers of Li Da and Nasutra to immediately stop supplying these products. Further investigations are underway into the importation and supply of the product in New Zealand.

Why are these products a problem?

Li Da was investigated following complaints received by Medsafe about side effects of the product and because border surveillance had indicated increased attempts to import the product. Testing showed that it contained the prescription medicine sibutramine. Reductil is the only brand of sibutramine approved for sale in New Zealand and is used for managing overweight (obese) patients. Sibutramine can cause increased blood pressure and heart rate. Patients using sibutramine must see their doctor for a check-up every two weeks during the first three months of treatment in order to monitor the effects of use.

Additionally, sibutramine must not be given to certain persons (for example, those with glaucoma, mental illness, severe liver or kidney problems) nor should it be used in combination with medicines such as some antidepressants and migraine treatments. Li Da is labelled in Chinese characters, information about it indicates that it is claimed to be a herbal product.

The product Nasutra contains the prescription medicine sildenafil. Viagra is the only brand of sildenafil approved for sale in new Zealand and is used for managing erectile dysfunction. Sildenafil is known to interfere with some heart medication and could be fatal to some individuals. Nasutra is labelled as a herbal supplement and lists only herbal materials as ingredients.

It is a breach of the Medicines Act 1981 for so-called herbal products to contain undeclared prescription medicines. There is a real potential for harm to occur when prescription medicines are unknowingly used by consumers, particularly in the absence of medical supervision.

Is there information available for consumers about the active ingredient?

Sibutramine is the active ingredient in *Reductil* and Sildenafil is the active ingredient in *Viagra*. Consumers seeking general information about sibutramine or sildenafil can access the Consumer medication information about Reductil and Viagra on the Medsafe web site.

Are these products being removed from the market?

Known distributors are being warned that these products cannot be sold. Medsafe believes that no further supplies remain with these distributors.

Distributors, importers and sellers are responsible for ensuring products they import or sell that are not approved medicines do not contain any prescription medicines.

Also, it is illegal to sell or supply prescription medicines without the purchaser having a prescription from a registered medical practitioner.

Under the food and medicine legislation, sponsors/distributors/importers are required to list all active ingredients on the packaging, and to include the strength of each active ingredient.

If a consumer is taking Li Da or Nasutra what should they do?

Consumers are being warned to immediately stop taking these products.

Consumers should seek medical advice from their doctor:

- if they are taking other medicines
- if they felt unwell when taking Li Da or Nasutra
- if they become unwell after they stopped taking Li Da or Nasutra

How many people take these products in New Zealand?

There is no reliable information about how many people have taken these products.

How were these illegal products being sold?

Li Da appears to have been imported by individuals either for personal use or for supply to other individuals. Some traders appear also to have imported for retail supply. Nasutra was being sold by retail.

Can these products still be sold?

No. Medsafe has required the distributors of these products to immediately cease supplying it. Stocks have been seized from known sellers.

General warning for consumers about any products making therapeutic claims

Medsafe warns consumers that products making therapeutic claims being sold through websites may not be legal in New Zealand. All products for which a therapeutic benefit is being claimed must first be 'approved' by the Minister of Health before they can be marketed.

Consumers should also be alert to complementary healthcare products that appear to be of poor quality, cause side effects, or appear to be unusually effective or are available from unusual sources.

Any concerns should be reported to Medsafe. See the Medsafe website for contact details.

Adverse reactions to these products or to any herbal product should be reported to the Centre for Adverse Reactions Monitoring http://carm.otago.ac.nz/. This is a very important means of picking up issues with herbal medicines at an early stage.

Important advice to traders

Medicines are products sold or supplied principally for a therapeutic purpose. Selling, distributing or advertising the availability of a medicine which has not been given a consent or provisional consent by the Minister is in breach of section 20 of the Medicines Act 1981.

On conviction, the maximum penalty for an individual who sells a medicine without first having it registered through the regulatory process administered by Medsafe is $20,000 or up to 6 months in prison.

Unless a product is an approved medicine, sellers must ensure that claims of a therapeutic purpose are not made for products they advertise or sell AND they must ensure that their products do not contain scheduled medicines. It may, for instance, be prudent to test products prior to distribution.

The Ministry of Health advises traders that it takes breaches of the medicines legislation very seriously where patient / consumer safety is put at risk.

Related information

Medsafe website
