

**Notice Information: Human Medicines - Warning
21 April 2008**

Part 1. Product Information

- a) Title: Potentially Harmful Traditional Chinese and other Medicinal Products
- b) Product Name/Type: There are four products in relation to this warning: 1. Power 1 Walnut Tablets 2. Cialis Tablets (Suspected counterfeit Product)* 3. Santi Bovine Penis Erecting Capsules 4. Zhong Hua Niu Bian Capsules
- c) Active Substance: ¶ Products 1, 2 & 3 above have been found to be adulterated with high doses of glibenclamide (40-90mg per tablet) and small amounts of sildenafil (1-2 mg per tablet). Note that glibenclamide and sildenafil are active substances that are under prescription control in Ireland. ¶ Product No. 4 above has been found to be adulterated with sildenafil, glibenclamide (14.3mg per capsule) and sibutramine. Note that sildenafil, glibenclamide and sibutramine are active substances that are under prescription control in Ireland.
- d) Serial/Batch Number & Expiry Date: Serial/Batch Number(s): All batches may be adulterated
Expiry Date: Various
- e) Authorisation Number: None
- f) Manufacturer/Supplier: For products 1, 2 and 4 the manufacturer/supplier is unknown. For product 3 the manufacturer is suspected to be Santi Medical and Health Products Company, located in Anhui Province, China.
- g) Recall Classification: Recall Required: Yes, if product is identified on the Irish Market

Part 2. Target Audience

- a) Target Audience: ¶ The General Public and Users of Traditional Chinese and other Medicinal Products ¶ Suppliers and Retailers of Traditional Chinese and other Medicinal Products ¶ Practitioners of Traditional Chinese Medicine ¶ Pharmacists

Part 3. Problem/Issue

a) Problem/Issue:

The Irish Medicines Board (IMB) wishes to advise that it has recently learned that the above adulterated products have been found in the Singapore marketplace. While there is no evidence at this time that these products are on the Irish market, it is possible that one or more of them is on sale or in use in Ireland, and as a precautionary measure, we are issuing this statement. The IMB is also aware of one Irish resident who suffered an adverse reaction following the ingestion of one of these products during a recent visit to Singapore. The adulterants were glibenclamide, which is a potent medicine used for the treatment of diabetes, sildenafil, which is a medicine used for the treatment of erectile dysfunction, and sibutramine, a medicine used for the treatment of obesity. These medicines are prescription-only medicines and should not be present in these products. Note that consuming a high amount of glibenclamide can cause serious harm as it may reduce a person's blood sugar to a dangerously low level, and this can result in seizures, stroke, coma or death. The Health Sciences Authority (HSA) in Singapore has recently detected numerous cases of drug-induced hypoglycaemia (low blood sugar) associated with the consumption of the adulterated products numbered 1 through 3 above. The symptoms have included drowsiness, seizures, loss of consciousness and coma. The IMB understands that these products are being marketed in some countries for sexual enhancement as well as for erectile dysfunction problems. Some of the product labelling is in English, and some is in Chinese. [Click here for photographs of the four products in question.](#) The IMB, as a precautionary measure, is alerting the general public, users of Traditional Chinese Medicinal Products, Suppliers and Retailers of Traditional Chinese Medicinal Products, Practitioners of Traditional Chinese Medicine, and Pharmacists of this issue, so that the actions stated below can be taken.

Part 4. Background Information

a) Background Information:

The following information is intended to be helpful in identifying the products of concern: Product 1: Power 1 Walnut Tablets These packs contain blue or green or pink tablets, and the tablets are marketed with the code P1S-100. There are four 500mg tablets per blister pack, or ten 100mg per tablet per bottle. There is only one colour of tablet per pack. Product 2: Cialis Tablets (Suspected Counterfeit Product) These packs contain yellow tablets, marked with the code C50. This is a suspected counterfeit version of an authentic medicinal product. Important Note: This is a suspected counterfeit version of an authentic medicinal product marketed by Eli Lilly Nederland B.V. The authentic product is called Cialis Film-Coated Tablets, and is not the subject of this IMB Warning statement. Product 3: Santi Bovine Penis Erecting Capsules These packs contain blue & white capsules. The product name appearing on the bottle is . The product name Santi Bovine Penis Erecting Capsules is the name provided on the product leaflet only, it does not appear on the bottle. The product is manufactured by the Santi Medical and Health Products Company, located in Anhui Province, China. Product 4: Zhong Hua Niu Bian capsules These packs contain orange & grey capsules. The product name is in Chinese, . In English this reads Zhong Hua Niu Bian. The English product name does not appear on the packaging. [Click here](#) for photographs of the four products in question.

Part 5. Action to be taken

a) Action to be taken:

Any patients or members of the public who are using, or have used, any of the above products, are advised to immediately cease taking that product and to consult with their pharmacist or doctor, even if they have stopped using the product. When speaking to their doctor or pharmacist, patients or members of the public may find it helpful to take a copy of this IMB notification with them. This can be downloaded from the IMB website at www.imb.ie. Patients should continue to take any medication prescribed by their doctor.

Any persons holding stock of any of the above products, or who have supplied any of these products to others, or who may have packs of any of these products in their possession, should put the packs in a safe place immediately and notify the IMB at the contact details below.

The IMB is also alerting trade and other relevant organisations representing companies or individuals supplying, selling or using Traditional Chinese Medicinal Products today to advise them of this issue, so that their members can be made aware of this information as soon as possible. In this regard, the IMB requests trade and other relevant organisations to bring the information in this Warning notice to the attention of their members, so that their members may cease supplying/selling/using these products, and contact the IMB. Any packs of these products should be immediately quarantined.

The Irish Medicines Board is also requesting any retailers and suppliers of these products to contact their customers, where possible, so that they can be advised of the above. The IMB wishes to advise that vigilance should always be exercised in relation to the purchase, sale and/or use of any medicinal product, including Traditional Chinese Medicinal Products. Medicinal products such as the above four products are not authorised for use in Ireland, and cannot be regarded as safe. These types of products are illegal medicines and should not be purchased for use over the internet. The IMB contact person for this issue is: Kevin O' Donnell, Ph.D. Senior Inspector & Market Compliance Manager, Irish Medicines Board, Earlsfort Terrace, Dublin 2, Ireland Tel: +353-1-6764971 (office) Fax: +353-1-6764061

Part 6. Enquiries

a) All enquiries should be made to:

* Important Note: This is a suspected counterfeit version of an authentic medicinal product marketed by Eli Lilly Nederland B.V. The authentic product is called Cialis Film-Coated Tablets, and is not the subject of this IMB Warning statement.

Part 7. Keywords

a) Keywords:

Power 1 Walnut Tablets, Cialis Tablets (Suspected counterfeit Product)*, Santi Bovine Penis Erecting Capsules, Zhong Hua Niu Bian Capsules