Irish Medicines Board Safety Notification

Concerning a potentially harmful illegal Medicinal Product:

LiDa Daidaihua Capsules
Manufactured by:
Kunming Dali Industry & Trade Co. Ltd.,
No. 372 West Renmin Road, Kunming, Yuman, China

July 15th, 2008

Dear Sir or Madam,

The Irish Medicines Board (IMB) wishes to advise users of Traditional Chinese Medicinal Products, suppliers and retailers of Traditional Chinese Medicinal Products, practitioners of Traditional Chinese Medicine and Pharmacists that packs of LiDa Daidaihua Capsules, a potentially harmful and illegal medicinal product, have been identified on the Irish market.

The Irish Medicines Board has examined this product and its associated marketing information and considers the product to be an illegal medicinal product, as it is not authorised for marketing in Ireland as a medicinal product and is not being supplied in accordance with applicable regulations. It has also been reported by another EU competent authority that this product has been found to contain a substance called sibutramine hydrochloride and a related degradation product. Sibutramine hydrochloride is regulated as a prescription-only medicine in Ireland. The packaging of LiDa Daidaihua Capsules does not indicate that the capsules contain either of these substances, and it states that the product is made of natural herbs.

The IMB has recently received two complaints relating to possible safety concerns regarding this product on the Irish market.

The IMB is continuing its investigations into this product, but in the meantime, is requesting that the following actions be taken:

- Please make your members aware of this IMB communication.
- If this product is identified by your members as being in their possession, your member(s) should be asked to immediately quarantine the product and notify the IMB at the contact details below. The IMB will arrange for the collection of the product from your members. (The IMB urges any person in possession of this product not to send the product out of the country and not to pass it on to any other person.)
- If any of your members have supplied this product to their customers, patients or other persons, the IMB is requesting that your members immediately try to identify and make contact with those persons, so that any unused product can be quarantined by them. Your members should then immediately contact the IMB to discuss this and further actions.
- Any customers or patients who received this product from your members should be advised to immediately cease taking this product and to consult with their pharmacist or doctor. When

speaking to their doctor or pharmacist, customers/patients 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.

The following information is intended to be helpful in identifying the product of concern:

- This product is packaged in capsule form.
- The capsules are green in colour, and are contained within a blister-strip.
- The blister strip is silver in colour, with blue and purple Chinese markings.
- The blister strip is contained with an aqua-green coloured cardboard box, showing a picture on the front cover of a female behind a newspaper.
- There is both English and Chinese text on the box, and there are several holographic features on the box.
- The name *Li Da Daidaihua Jiao Nang* appears on the front of the box in silver-coloured lettering, along with the name of the manufacturer, Kunming Dali Industry & Trade Co. Ltd.

See the Warning notice posted on the IMB website (www.imb.ie) to view photographs of the product in question.

This communication follows a precautionary alert the IMB issued in April 2006 following receipt of a report from the New Zealand Medicines Agency on the same product. That report indicated that packs of this product were found by the New Zealand Medicines Agency to contain undeclared sibutramine. All batches were reported to be affected. At that time, there was no evidence available to the IMB that the product was on the Irish market.

Any suspected adverse reactions notified in association with the use of this product should be reported to the IMB, via the on-line reporting system accessible from www.imb.ie and by following the link to 'on-line reporting'. A downloadable report form is also available from the website.

The IMB wishes also to advise that vigilance should always be exercised by your members in relation to the purchase, sale and or use of this type of product.

The IMB contact person for this issue is Kevin O'Donnell, whose contact details are stated below. Thank you for you co-operation in this matter.

Yours sincerely,

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