

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference:		
Date: 03/12/2020	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No: +	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: Li Da Daidaihua/Capsules		
Manufacturer: Dali		
Importer: -		
Address: -		
Supplier: -		
Address: -		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Capsules		
Strength: as per the labelling.		
Batch / lot no: PA518ET		
Is batch number genuine: Yes <input type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: -		
Expiry date: 03/2022		
Language of packaging: English		
Date of discovery: Adulteration detected on: 02/12/2020		
Details of discovery: A severe adverse reaction has been notified by Hospital la Fe Valencia (Spain) linked to this product that led to death of the patient . Local and Regional Authorities sent samples of the product to the AEMPS.		

These samples were analyzed by the Official Medicines Control Laboratory (OMCL) of the AEMPS and found to contain undeclared pharmacologically active substance.

Analysed: YES ☒ NO ☐

If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared active substance: **Sibutramine**

3. DISTRIBUTION METHOD

Internet: YES ☒ / NO ☐ (not exclusively through the internet)

Internet:

URL: <https://www.alfamed24.es/>

Website address: -

Other details:

Non internet, advise full details:

Currency of payment:

Has product reached patients/consumers? Yes

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☒ / NO ☒

If yes, please advise details:

The OMCL of AEMPS analysis found the presence of undeclared sibutramine.

The presence of sibutramine in this product is considered to pose a serious risk to public health, particularly in patients with cardiovascular diseases.

Sibutramine is an appetite suppressant that was withdrawn from the EU market due to safety concerns.

Medical assessment details:

5. NEED FOR PUBLICITY

Details as per original form

Are you making a public statement? YES ☒ / NO ☒

Are you issuing a press release? YES ☒ / NO ☐

Are you recalling product? YES ☒ / NO ☐

If yes to any of the above, when do you intend to take action?

Action was taken on ***note published on AEMPS website¹⁾ and withdrawal requirement of illegal website: <https://www.alfamed24.es>.***

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership?

YES ☒ / NO ☐ (please see below)

If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)

Law Enforcement ☒ Industry Security ☐ Trade Associations ☐

Traders ☐ Other ☐ Please specify _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product.

Li Da Daidaihua

