

## 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: 18/10/2017	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
<b>1. REPORTING PERSON</b>		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
Product name: VITALMAN capsules DAME MAX capsules CATUABA sachets		
Manufacturer: unknown		
Supplier: Import/Export Energy Company LTD 20-22 Wenlock Road, London N1 76 U (United Kingdom)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: capsules/capsules/sachets		
Strength: NA		
Batch / lot no: VITALMAN capsules: A17Y117 // DAME MAX capsules: B15J116 // CATUABA sachets A17Y117		
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Not applicable		
Expiry date: VITALMAN capsules: DEC18 // DAME MAX capsules: AUG17 // CATUABA sachets DEC 2018		
Language of packaging: VITALMAN capsules: Spanish and French // DAME MAX capsules: Spanish and French // CATUABA sachets: Spanish and Portuguese		
Date of discovery:		

Details of discovery:

After inspections carried out by SEPRONA Guardia Civil and Health authorities in different Spanish regions, as part of PANGEA X Operation, the products were submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain tadalafil

Analysed: YES  NO

If yes, result of analysis: The results of the analysis indicated that this product contained the undeclared substance tadalafil.

### 3. DISTRIBUTION METHOD

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

Internet:	Non internet, advise full details: Possibly sold on herbalist's shops and health food shops
URL:	
Website address:	
Other details:	

Currency of payment:

Has product reached patients/consumers? Yes

### 4. RISK TO PUBLIC HEALTH

Adverse reactions: YES  / NO

If yes, please advise details: Adverse reactions, possibly due to the product DAME MAX, have been notified by the Official College of Pharmacists. In any case, the presence of the undeclared active substance tadalafil is considered to pose a risk to public health, particularly in patients with cardiovascular diseases.

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 18<sup>th</sup> October 2017 (recall, note published on the AEMPS

website<sup>1</sup>).

## 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. See below.

VITALMAN capsules - DAME MAX capsules - CATUABA sachets

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<sup>1</sup> [https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2017/ICM\\_MI\\_06-2017-Vitalman.htm](https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2017/ICM_MI_06-2017-Vitalman.htm)



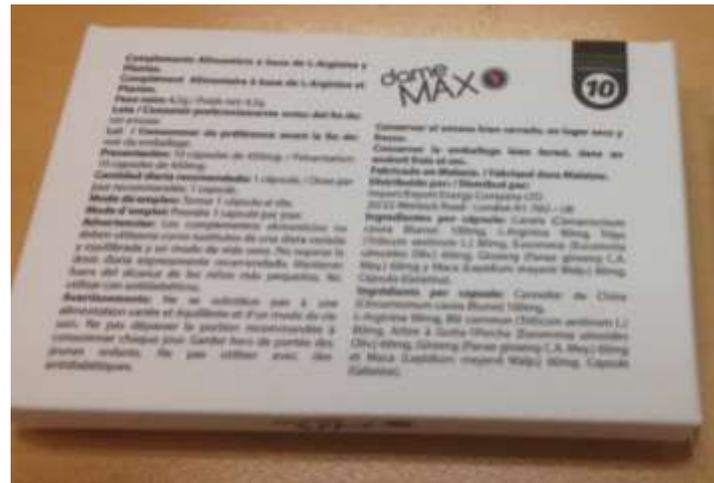
VITALMAN capsules (1)



VITALMAN capsules (2)



DAME MAX capsules (1)



DAME MAX capsules (2)



CATUABA sachets (1)



CATUABA sachets (2)