

## +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:	Time: Initials:
Please complete sections 1 to 5 providing as much information as possible.	
<b>1. REPORTING PERSON</b>	
Name:	Position:
Organisation: Pharmaceutical Inspection and Enforcement Department; Spanish Agency for Medicines and Medical Devices (AEMPS)	
Address: Campezo 1, edificio 8, 28022 Madrid (Spain)	
Telephone No:	Ext:
e-mail address: :	
<b>2. PRODUCT DETAILS</b>	
Product name: - <b>XSTRONG-UP for him capsules</b>	
Manufacturer: <i>unknown</i>	
Supplier: Jasmimgália, Lda (Portugal)	
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>	
Dosage form: - <b>Capsules</b>	
Strength: as per the labelling.	
Batch / lot no: 14/03/14	
Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
If yes to the above, advise batch destination country: Spain	
Expiry date: 13/03/17	
Language of packaging: Spanish	
Date of discovery: Adulteration detected on: - <b>XSTRONG-UP for him capsules: 10<sup>th</sup> JULY, 2014</b>	

Details of discovery:

- **XSTRONG-UP for him capsules:** After inspections carried out by SEPRONA Guardia Civil in PANGAEA VII operation, a sample of the product was taken from a retailer and submitted to our Agency and analyzed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain undeclared pharmacologically active substances.

Analysed: YES ☒ NO ☐

If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared actives substances:

- **XSTRONG-UP for him capsules: tadalafil**

### 3. DISTRIBUTION METHOD

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

Internet:

URL:

Website address

Other details:

Currency of payment: Details not provided

Has product reached patients/consumers? Yes

### 4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO ☒ (Not notified)

If yes, please advise details: No adverse reactions have been notified so far for this product; however the presence of the undeclared active substance **tadalafil** is considered to pose a risk to public health, particularly in patients with pre-existing cardiovascular diseases.

Medical assessment details: N/A

### 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 24<sup>th</sup> September, 2014 (recall, note published on 29<sup>th</sup> September, 2014 on 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.

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<sup>1</sup>[http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIIegales/2014/ICM\\_MI\\_11-14-xstrong.htm](http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIIegales/2014/ICM_MI_11-14-xstrong.htm)

# XSTRONG -UP for him capsules

