

+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.		
1. REPORTING PERSON		
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: :		
2. PRODUCT DETAILS		
Product name: - XSTRONG-UP for him capsules		
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: - Capsules		
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: - XSTRONG-UP for him capsules: 10th JULY, 2014		

Details of discovery:

- **XSTRONG-UP for him capsules:** After inspections carried out by SEPRONA Guardia Civil in PANGEA 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 24th September, 2014 (recall, note published on 29th September, 2014 on AEMPS website¹).

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.

¹http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIIegales/2014/ICM_MI_11-14-xstrong.htm

XSTRONG -UP for him capsules

