

## 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: 07/12/2016	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: <a href="mailto:sbentolila@aemps.es">sbentolila@aemps.es</a>		
<b>2. PRODUCT DETAILS</b>		
Product name: <b>ENERGY 48 capsules</b> <b>VIRITOTAL capsules</b>		
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: <b>Capsules</b>		
Strength: NA		
Batch / lot no: Viritotal capsules: B15J116 // Energy 48 capsules: B15J116		
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: Viritotal capsules: AUG17 // Energy 48 capsules: AUG17		
Language of packaging: Spanish and English		
Date of discovery:		
Details of discovery: After inspections carried out by the Health authorities of Galicia and by SEPRONA Guardia Civil, involved in PANGEA IX 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 <input checked="" type="checkbox"/> NO <input type="checkbox"/>
If yes, result of analysis: The results of the analysis indicated that this product contained the undeclared substance tadalafil.

3. DISTRIBUTION METHOD	
Internet: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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 <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
If yes, please advise details: No adverse reactions have been notified so far; however 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	
<b>Details as per original form</b>	
Are you making a public statement? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
Are you issuing a press release? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
Are you recalling product? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
If yes to any of the above, when do you intend to take action? Action was taken on 2 <sup>nd</sup> December 2016 (recall, note published on the AEMPS website <sup>1</sup> ).	

<sup>1</sup> [https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM\\_MI\\_11-2016-Energy.htm](https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM_MI_11-2016-Energy.htm)

## 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 \_\_\_\_\_

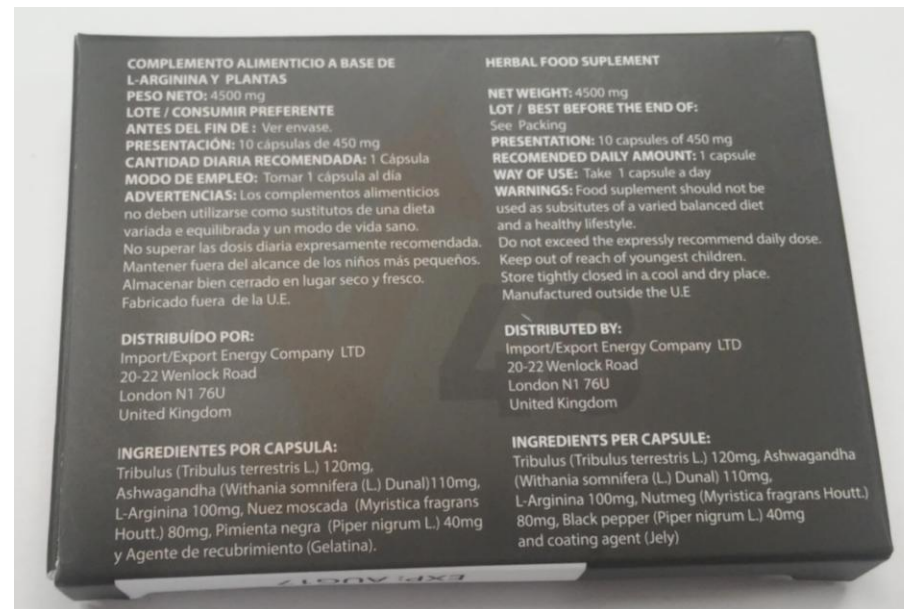
## 7. PHOTOGRAPH

If possible, please attach a photograph of the product. See below.

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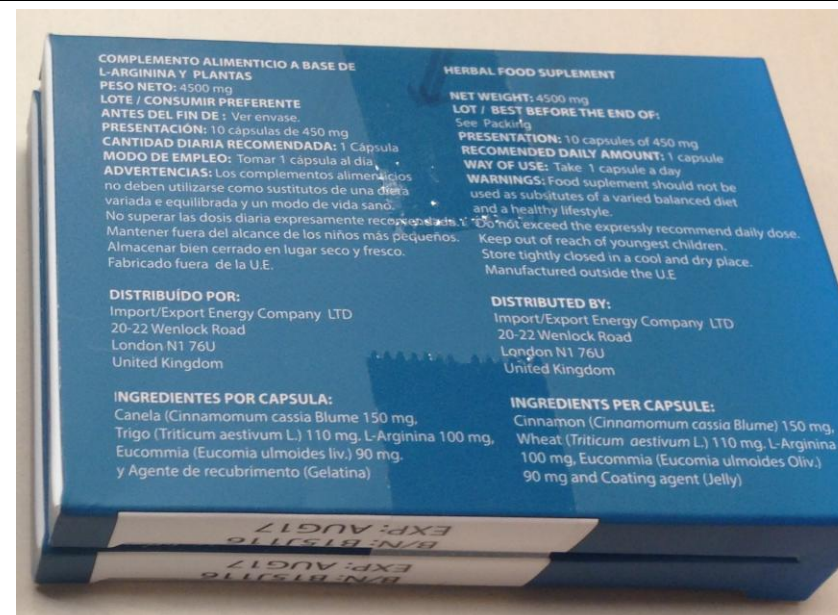
Energy 48 capsules (1)



Energy 48 capsules (2)



Viritotal capsules (1)



Viritotal capsules (2)