

## 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: 02/04/2019	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: VOCATIV sachets		
Manufacturer: Unknown		
Supplier: IMPORT/EXPORT ENERGY COMPANY LTD, 20/22 Wenlock Road- London N1 76U-UK.		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: sachets		
Strength: NA		
Batch / lot no: 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: 12/2018		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: After initial investigations carried out by Health authorities in Galicia, as part of PANGEA XI Operation, the product was 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 ☐ / 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 have not been notified. 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 29<sup>th</sup> March 2019 (recall, note published on the AEMPS website<sup>1</sup>).

<sup>1</sup> <https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2019/NI-ICM-MI-02-2019-Vocativ.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.

