

## 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: 03/01/2018	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: ULTIM8 capsules		
Manufacturer: unknown		
Supplier: HERBAL SOLUTIONS S.L. Carretera de Cádiz 199, Hotel Océano, Miujas (Málaga) Spain		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: capsules		
Strength: NA		
Batch / lot no: ULTIM8 capsules: AMD-0001135 and AMD-0001014		
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: ULTIM8 capsules 10/19 and 11/18		
Language of packaging: ULTIM8 capsules: Spanish/English		
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 product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain tadalafil and		

sildenafil
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 substances tadalafil and sildenafil

### 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 checked="" type="checkbox"/> / NO <input type="checkbox"/>
If yes, please advise details: Adverse reactions have not been notified. In any case, the presence of the undeclared actives substances tadalafil and sildenafil 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 03rd January 2018 (recall, note published on the AEMPS website <sup>1</sup> ).

<sup>1</sup> <https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medllegales/home.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.

