

## 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: 18/09/2017	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: <b>SENSAMAX capsules</b>		
Manufacturer: unknown		
Supplier: <b>Sensamax Limited</b> ( <i>Unit 5611. 13 Freeland Park. Wareham Road, Lytchett Matravers, Poole, Dorset, UK, BH16 6FH</i> )		
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: 160103		
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: 02/01/2019		
Language of packaging: English		
Date of discovery:		
Details of discovery: The product was discovered and analysed by the Medicines and Healthcare Products Regulatory Agency, (MHRA) and found to contain 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 sildenafil.

### 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: <a href="http://www.sensamax.es">www.sensamax.es</a>	
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: No adverse reactions have been notified so far; however the presence of the undeclared active substance sildenafil is considered to pose a risk to public health, particularly in hypertensive patients.

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 28<sup>th</sup> July 2017 (recall, note published on the AEMPS website on 14<sup>th</sup> September 2017<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)

<sup>1</sup>[https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2017/ICM\\_MI\\_05-2017-sensamax.htm](https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2017/ICM_MI_05-2017-sensamax.htm)

Law Enforcement  Industry Security  Trade Associations   
Traders  Other  Please specify \_\_\_\_\_

## 7. PHOTOGRAPH

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



**SENSAMAX** is a food supplement made from extracts of plants traditionally used for its properties on energy and male vitality.

**Ingredients per capsule:** Capsule: gelatin, maca root extract ( Lepidium meyeri Walp ) extract, oat (Avena sativa ) 80 mg extract, green tea leaf (Camellia sinensis L. ) 20 mg, herbapids, mum 50 mg, grape extract ( Vitis vinifera L. ) 80 mg extract, ginseng root (Panax ginseng CA Meyer ) 50 mg, astragalus root extract (Astragalus membranaceus Moench ) 45 mg.

**Recommended use:** Take 1 capsule every two days.

Do not exceed the recommended daily amounts.  
Food supplements should not replace a varied and balanced diet and a healthy lifestyle.  
Store in cool, dry place.  
Keep out of reach of children.