

## +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.		
<b>1. REPORTING PERSON</b>		
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: :		
<b>2. PRODUCT DETAILS</b>		
Product name: - <b>VIFORT VIGOR capsules</b>		
Manufacturer: - <i>unkonwn</i>		
Supplier: <i>DESMAR SANA FOOD, S.L., Polígono Industrial Valmor, Avda las Canteras nº 87, nave 812, 28340-Madrid (SPAIN)</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: as per the labelling.		
Batch / lot no: 27		
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: end of 2014		
Language of packaging: Spanish		
Date of discovery: Adulteration detected on:		

- **VIFORT VIGOR capsules**: 14<sup>th</sup> JULY, 2014

Details of discovery:

- **VIFORT VIGOR 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 actives substances.

Analysed: YES ☒ NO ☐

If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared actives substances:

- **VIFORT VIGOR capsules sildenafil and yohimbine**

### 3. DISTRUBUTION 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 **sildenafil** is considered to pose a risk to public health, particularly in patients with pre-existing cardiovascular diseases. Also the presence of the undeclared active substance **yohimbine** can caused cardiovascular and intestinal adverse effects.

Medical assessment details: N/A

### 5. NEED FOR PUBLICITY

Details as per original form

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 29 <sup>th</sup> September, 2014 (recall, note published on 7 <sup>th</sup> October, 2014 on AEMPS website <sup>1</sup> ).
<b>6. DISSEMINATION</b>
Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/> Traders <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____
<b>7. PHOTOGRAPH</b>
If possible, please attach a photograph of the product.

# VIFORT VIGOR CAPSULES

