

+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.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: - VIGORAXIA capsules		
Manufacturer: <i>ARGENFARMA (Argentina)</i>		
Importer: <i>Miguel Ángel Tripicchio, Sicilia Street nº 226 5º 08013 Barcelona (Spain)</i>		
Supplier: - VIGORAXIA capsules: <i>Miguel Ángel Tripicchio, Sicilia Street nº 226 5º 08013 Barcelona (Spain)</i>		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: - Capsules		
Strength: as per the labelling.		
Batch / lot no: details not provided Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country:		
Expiry date: 12/18		
Language of packaging: Spanish		
Date of discovery: Adulteration detected on: - VIGORAXIA capsules: <i>04th FEBRUARY, 2015</i>		

Details of discovery:

- **VIGORAXIA capsules:** After inspections carried out by Health authorities of Cataluña Region, 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 active substance.

Analysed: YES ☒ NO ☐

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

- **VIGORAXIA capsules: thiosildenafil**

3. DISTRIBUTION METHOD

Internet: YES ☒ / NO ☒ (also, not exclusively through the internet)

Internet:

URL:

Website address: www.vigoraxia.es

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; however the presence of the undeclared active substance **thiosildenafil** 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 2th March, 2015 (recall, note published on 9th March, 2015 AEMPS website¹).

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.

VIGORAXIA CAPSULES

