

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: 02/11/2016	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation: Pharmaceutical Inspection and Enforcement Department; Spanish Agency for Medicines and Medical Devices (AEMPS)		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: VITALPLANT SPORT capsules		
Manufacturer: unknown		
Supplier: Antonio Pérez Guardia, Avda. de Madrid 39, Chipiona, Cádiz (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: 151120		
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: 11/19/2018		
Language of packaging: ES		
Date of discovery:		
Details of discovery: After inspections carried out by the Health authorities of Galicia, as part of PANGEA IX Operation, the product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain thiosildenafil and homosildenafil.		

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 following undeclared substances: thiosildenafil and homosildenafil.

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 type="checkbox"/> / NO <input checked="" type="checkbox"/>
If yes, please advise details: No adverse reactions have been notified so far; however the presence of these undeclared substances is considered to pose a risk to public health.
Medical assessment details:

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 18th October 2016 (recall, note published on the AEMPS website ¹).

¹ https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM_MI_07-2016-Vitalplant.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

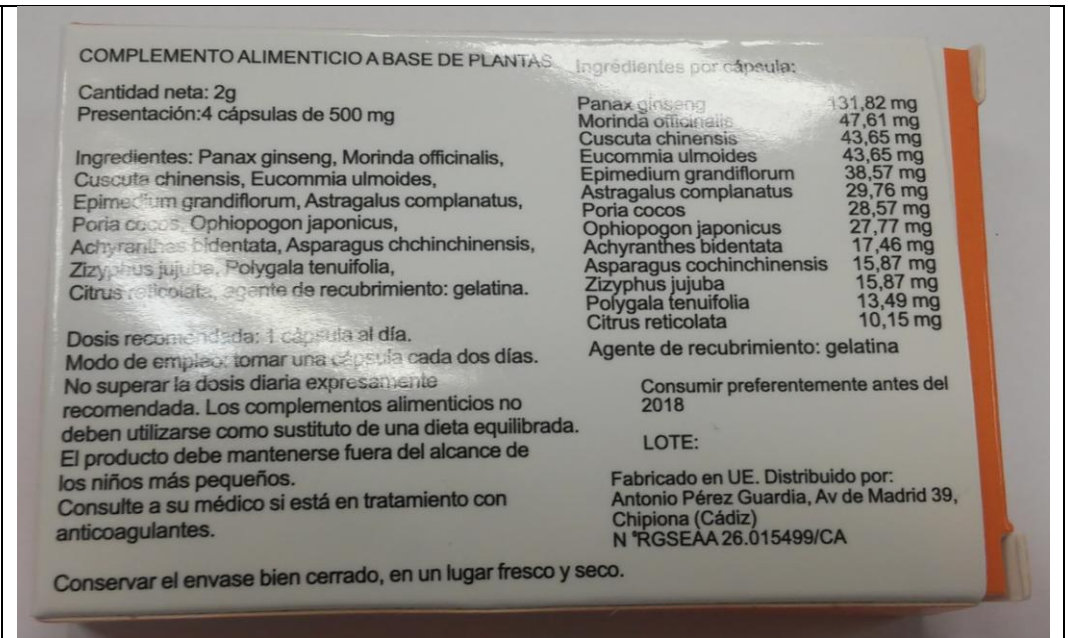
Traders Other Please specify _____

7. PHOTOGRAPH

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



VITALPLANT SPORT capsules (1)



VITALPLANT SPORT capsules (2)