

+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: 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: :	
2. PRODUCT DETAILS	
Product name: - GOLD MAX 5 capsules	
Manufacturer: <i>unknown</i>	
Importer: <i>unknown</i>	
Supplier: - GOLD MAX 5 capsules : GLOBAL PRODUCTS EUROPE, S.L. avda. Méjico nº 14, Edificio España, Local a , 29650 Mijas- 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: 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: details not provided	
Language of packaging: Spanish/ English	
Date of discovery: Adulteration detected on:	

- **GOLD MAX 5 capsules**: 23th JUNE, 2014

Details of discovery:

- **GOLD MAX 5 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 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:

- **GOLD MAX 5 capsules**: aminotadalafil

3. DISTRUBUTION METHOD

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

Internet:

URL:

Website address:

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 **aminotadalafil** 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 <input checked="" type="checkbox"/> / NO <input type="checkbox"/>
<p>If yes to any of the above, when do you intend to take action?</p> <p>Action was taken on 24th September, 2014 (recall, note published on 30th September, 2014 AEMPS website¹).</p>
6. DISSEMINATION
<p>Are you content for this Rapid Alert to be shared outside WGEO membership?</p> <p>YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (please see below)</p>
<p>If yes, please specify which of the below you are content for this to be shared with (you may tick more than 1 box)</p> <p>Law Enforcement <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/></p> <p>Traders <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____</p>
7. PHOTOGRAPH
If possible, please attach a photograph of the product.

GOLD MAX 5 CAPSULES

