

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: 19/12/2016 | 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: GREEN SYNERGY capsules | | |
| Manufacturer: unknown | | |
| Supplier: Anastore Bio S.L. 88 ter avenue Général Leclerc, 92100 Boulogne-Billancourt (France) c/Juan Negrín 17 Parque empresarial Elche- Torrellano, Alicante (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: D09115 | | |
| 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: 09/2017 | | |
| Language of packaging: French | | |
| Date of discovery: | | |
| Details of discovery: The product was submitted to our Agency by SEPRONA Guardia Civil, analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain yohimbine. | | |

| |
|---|
| 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 substance yohimbine. |

| 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 the undeclared active substance yohimbine 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 <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 13 rd December 2016 (recall, note published on the AEMPS website ¹). | | |

¹ https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM_MI_15-2016_green_synergy.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.

