

## 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: 25/05/2018  | Time:     | Initials: |
| Please complete sections 1 to 5 providing as much information as possible.  |           |           |
| <b>1. REPORTING PERSON</b>  |           |           |
| Name:   | Position: |           |
| Organisation:   |           |           |
| Address:  |           |           |
| Telephone No:   | Ext:      |           |
| e-mail address:   |           |           |
| <b>2. PRODUCT DETAILS</b>   |           |           |
| Product name: TR-500 capsules   |           |           |
| Manufacturer: unknown   |           |           |
| Supplier: Natural Innova S.L., c/ Principado de Asturias 4, 23009, Jaen   |           |           |
| 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: 16125   |           |           |
| 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: 10/2019  |           |           |
| Language of packaging: Spanish  |           |           |
| Date of discovery:  |           |           |
| Details of discovery:<br>After inspections carried out by SEPRONA Guardia Civil and Health authorities in Galicia, as part of PANGEA X Operation, the product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain tadalafil and sildenafil |           |           |
| 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 substances tadalafil and sildenafil

### 3. DISTRIBUTION METHOD

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

|                  |   |
|------------------|---|
| Internet:        | Non internet, advise full details:<br>Possibly sold on herbalist's shops<br>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  / NO

If yes, please advise details: Adverse reactions have not been notified. In any case, the presence of the undeclared actives substances tadalafil and sildenafil 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 25<sup>th</sup> January 2018 (recall, note published on the AEMPS website<sup>1</sup>).

<sup>1</sup> [https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medillegales/2018/ICM\\_MI\\_04-2018-TR-500-Capsulas.htm](https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medillegales/2018/ICM_MI_04-2018-TR-500-Capsulas.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.

