

## 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: 28/04/2021	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: <b>+ ACTIVO capsules</b>		
Manufacturer: Parapharm SRL		
Supplier: Bestdeal 2014 S.L (C/ Colonia de San Lamberto, 10A 50011 Zaragoza, 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: 012019		
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: 04/2022		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: After initial investigations carried out by Guardia Civil and Health authorities in Castilla-La Mancha, as part of PANGEA XIII Operation, the product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain nortadalafil.		
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 nortadalafil.

### 3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒ (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 ☒ / NO ☐

If yes, please advise details: Adverse reactions have not been notified. In any case, the presence of the undeclared active substance nortadalafil 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 14<sup>th</sup> April 2021 (recall, note published on the AEMPS website<sup>1</sup>).

<sup>1</sup> <https://www.aemps.gob.es/informa/notasinformativas/medicamentosusohumano-3/medIlegales/2021-8/la-aemps-retira-el-producto-activo-capsulas/>

## 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.

