

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.		
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: NATHERB capsules		
Manufacturer: unknown		
Supplier: BODY BASICS S.L. Ronda Guinardo 57-59, 08024 Barcelona		
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: 0617, 0117, 1127, 12_17, 10_17, 11_17 and 01_18		
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: 06/19, 01/19, 12/19, 12/19, 10/19, 11/19 and 01/20 respectively		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: 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: 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 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 19th January 2018 (recall, note published on the AEMPS website¹).

¹ https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medillegales/2018/ICM_MI_03-2018-Natherb-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.

