

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: 07/12/2016	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: EL BONER GOLD capsules		
Manufacturer: unknown		
Supplier: El Boner Vending S.L. c/ Méndez Núñez 23, 07470 Puerto de Pollensa (Islas Baleares)		
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: BN02		
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: 01-19		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: After inspections carried out by the Health authorities of Madrid, as part of PANGEA IX Operation, the product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain tadalafil.		
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 tadalafil.

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: No adverse reactions have been notified so far; however the presence of the undeclared substance tadalafil 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 25th November 2016 (recall, note published on the AEMPS website¹).

¹ https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM_MI_10-2016-Boner-Gold.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.



EL BONER GOLD capsules (1)



EL BONER GOLD capsules (2)