

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: 03/01/2018	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: GOBILOR CAPSULES and BAMBOO-X CAPSULES		
Manufacturer: unknown		
Supplier: BEPHARMA SUPPLIES S.L. General Yagüe 13, street, 45510 (Toledo) 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: GOBILOR capsules: 02-2016 BAMBOO-X capsules 20170301-002		
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: ULTIM8 capsules 06-2018 BAMBOO-X capsules 2019-03		
Language of packaging: ULTIM8 capsules: Spanish/English /French		
Date of discovery:		
Details of discovery: After inspections carried out by SEPRONA Guardia Civil and Health		

authorities in different Spanish regions, 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 sildenafil

Analysed: YES NO

If yes, result of analysis: The results of the analysis indicated that this product contained the undeclared substance 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 active substance 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 03rd January 2018 (recall, note published on the AEMPS website¹).

¹ <https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medllegales/home.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.

