

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: 19/10/2021	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: HARD MAN capsules	
Manufacturer: Unknown	
Supplier: ¿R-Vitality? (as indicated in the label)	
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: RX170	
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: 01/2024	
Language of packaging: English	
Date of discovery:	
Details of discovery: After inspections carried out by SEPRONA Guardia Civil, as part of PANGAEA XIV 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 <input type="checkbox"/> / NO <input checked="" type="checkbox"/> (not exclusively through the internet)	
Internet:	Non internet, advise full details: 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 <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
If yes, please advise details: Adverse reactions have not been notified. In any case, the presence of the undeclared active 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 <input type="checkbox"/> / NO <input checked="" type="checkbox"/>	
Are you issuing a press release? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
Are you recalling product? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
If yes to any of the above, when do you intend to take action? Action was taken on 7 th October 2021 (recall, note published on the AEMPS website ¹).	

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.

