

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: 08/03/2021	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position: Head of Service/Technical Advisor	
Organisation:		
Address:		
Telephone No:	Ext:	
2. PRODUCT DETAILS		
Product name: ZENELEY capsules		
Manufacturer: Unknown		
Supplier: Momentarimentar Unipessoal LDA		
Address: Rúa do Ecuador 14 bajos, 36203Vigo (La Coruña)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: capsules		
Strength: as per the labelling.		
Batch / lot no: 08JR21122024		
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: 30/11/2023		
Language of packaging: Spanish/French		
Date of discovery: Adulteration detected on: 14/02/2022		
Details of discovery:		
These samples were analyzed by the Official Medicines Control Laboratory (OMCL) of the AEMPS and found to contain undeclared pharmacologically		

active substance **tadalafil**.

Analysed: YES ☒ NO ☐

If yes, result of analysis: The results of the analysis indicated that this product contained the following undeclared active substance: **tadalafil**

3. DISTRIBUTION METHOD

Internet: YES ☒ / NO ☐ (not exclusively through the internet)

Internet:

URL:

Website address:

Other details:

Non internet, advise full details:

Possibly sold on herbalist's shops and health food shops

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; however 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 ☐ / 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 25/02/2022

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.

