

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: 18/09/2019	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Organisation: Pharmaceutical Inspection and Enforcement Department; Spanish Agency for Medicines and Medical Devices (AEMPS)		
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: VOLFORT capsules		
Manufacturer: Unknown		
Supplier: EUGENIO RODRIGO TRUJILLO-SPAIN, Avd. José Miguel Galván Bello, 6, Edf. Magallanes 1-30, 38612 El Médano (Santa Cruz de Tenerife)		
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: AF151219		
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: 15/12/2019		
Language of packaging: Spanish, German, French, Italian, English		
Date of discovery:		
Details of discovery: After initial investigations carried out by SECOMA (Guardia Civil), the product was submitted to our Agency and analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain sildenafil and 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 sildenafil and 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: Adverse reactions have not been notified. In any case, the presence of the undeclared active substance sildenafil and 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 13rd September 2019 (recall, note published on the AEMPS website¹).

¹ <https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2019/NI-ICM-MI-14-2019-Volfort.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.

