

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:		
e-mail address:		
2. PRODUCT DETAILS		
Product name: DOSEX capsules		
Manufacturer/Supplier: Mareva4 – Servicios Integrales S.L. - Preciados, 29, Planta 3, 28013 Madrid (Spain) - Paseo de los Parques 6 – Portal 11, Bajo B, 28109 Alcobendas, Madrid (Spain)		
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: 001-2015		
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: 09-2017		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: A sample of the product was taken during an inspection carried out by SEPRONA Guardia Civil in a retail store and was submitted to our Agency. The active substance sildenafil (100 mg) was declared in its label, which confer to it the status of illegal medicinal product. It was analysed by the Official Medicines Control Laboratory (OMCL) of AEMPS and the declared composition in sildenafil was confirmed.		

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 declared substance sildenafil.

3. DISTRIBUTION METHOD

Internet: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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?	

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
If yes, please advise details: No adverse reactions have been notified so far; however the presence of sildenafil in an illegal medicinal product is considered to pose a risk to public health.
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 25th November 2016 (recall, note published on the AEMPS website ¹).

¹ https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/NI-ICM_MI_09-2016-dosex.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.



DOSEX capsules (1)



DOSEX capsules (2)