

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: 02/04/2020	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
1. REPORTING PERSON		
Name:	Position:	
Address:		
Telephone No:	Ext:	
e-mail address:		
2. PRODUCT DETAILS		
Product name: MIRACLE SLEEP PILLS		
Manufacturer: Unknown		
NICHE BEAUTY LAB S.L. sita en Ctra. GI 600 PK 3.250, 8490 Tordera, Barcelona (SPAIN)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: PILLS		
Strength: NA		
Batch / lot no: Unknown		
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: Unknown		
Language of packaging: Spanish		
Date of discovery:		
Details of discovery: After initial investigations carried out by Health authorities, the product was submitted to our Agency for containing 3 mg of melatonin.		
Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
If yes, result of analysis:		

3. DISTRIBUTION METHOD

Internet: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/> (not exclusively through the internet)	
Internet:	Internet, advise full details: www.primor.eu
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 3 mg of melatonin 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 02 rd April 2020 (recall, note published on the AEMPS website ¹).	

¹ <https://www.aemps.gob.es/informa/la-aemps-retira-el-complemento-alimenticio-man-sinfin-sobres-por-contener-un-principio-activo-no-declarado-en-su-etiquetado/>

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.

