

+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:	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: - ULTRA-STEN capsules	
Manufacturer: - <i>IronFlex Supplements (USA), as declared on the label (not verified)</i>	
Importer: - <i>Unknown</i>	
Supplier:	
- <i>Unknown</i>	
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. 2,17α-dimethyl-5α-androsta-1-en-17β-ol-3one 10 mg	
Batch / lot no: Not provided Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
If yes to the above, advise batch destination country: <i>Not known</i>	
Expiry date: <i>Not provided</i>	
Language of packaging: English	
Date of discovery: <i>Adulteration (undeclared ingredients) detected on:</i>	
- ULTRA-STEN : 28 th January, 2015	

Details of discovery:
- ULTRA-STEN : During an inspection, a sample of the product was taken by Regional Inspection Services from a retailer and submitted to our Agency. The product was analyzed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain another undeclared pharmacologically active substance instead of the declared one.
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 following undeclared active substance:
- ULTRA-STEN : 2α,17α-dimetil-4-androst-3-one azine,17β-ol (dymethazine)

3. DISTRIBUTION METHOD	
Internet: YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/> (also, not exclusively through the internet)	
Internet:	
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"/> (not reported, but cannot be ruled out)	
If yes, please advise details:	
Medical assessment details: N/A	
5. NEED FOR PUBLICITY	
Details as per original form	
Are you making a public statement? YES <input checked="" type="checkbox"/> / NO <input 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 04 th February, 2015 (recall, note published on AEMPS	

Comment [MIL1]: ¿No viene en la caja?

Comment [MIL2]: No entiendo porqué esta esto tachado...

website ¹).
6. DISSEMINATION
Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/> Traders <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____
7. PHOTOGRAPH
If possible, please attach a photograph of the product.

¹ http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2015/ICM_MI_02-2015-ultra-sten.htm

ULTRA-STEN

