

## +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.		
<b>1. REPORTING PERSON</b>		
Name:	Position:	
Organisation: Pharmaceutical Inspection and Enforcement Department; Spanish Agency for Medicines and Medical Devices (AEMPS)		
Address: Campezo 1, edificio 8, 28022 Madrid (Spain)		
Telephone No: +	Ext:	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
Product name: - <b>HAVOC</b>		
Manufacturer: - <i>RECOMP PERFORMANCE NUTRITION (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: - <b>Capsules</b>		
Strength: as per the labelling. <b>2<math>\alpha</math>,3<math>\alpha</math>-epithio-17<math>\alpha</math>-methyl-5<math>\alpha</math>-androstan-17<math>\beta</math>-ol, 10 mg</b>		
Batch / lot no: 4500614 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: ¿?		
Expiry date: Not provided		
Language of packaging: English		
Date of discovery: <del>Adulteration (undeclared ingredients) detected on:</del> - <b>HAVOC: 8<sup>th</sup> September, 2014</b>		

Details of discovery: - <b>HAVOC:</b> Adverse reactions have been notified to Regional Health Authorities. After that, a sample of the product was taken by Regional Inspection Services from a retailer and submitted to our Agency and analyzed by the Official Medicines Control Laboratory (OMCL) of AEMPS and found to contain the declared pharmacologically active substance.
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 declared actives substance: - <b>HAVOC: 2<math>\alpha</math>,3<math>\alpha</math>-epithio-17<math>\alpha</math>-methyl-5<math>\alpha</math>-androstan-17<math>\beta</math>-ol</b>

<b>3. DISTRIBUTION METHOD</b>	
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? Yes	
<b>4. RISK TO PUBLIC HEALTH</b>	
Adverse reactions: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>	
If yes, please advise details: Adverse reactions have been notified such as hepatic cholestasis; the presence of the declared active substance methylepithiostanol (prohormone) that is metabolized in desoxymethyltestosterone (17 $\alpha$ -methyl-5 $\alpha$ -androst-2-en-17 $\beta$ -ol) <sup>1</sup> , is considered to pose a risk to public health. Also there are risks of adverse reactions such as hepatic injury and increased risk of fatal cardiovascular events. <sup>2</sup> .	
Medical assessment details: hospital admission caused for hepatic cholestasis	
<b>5. NEED FOR PUBLICITY</b>	

<sup>1</sup> Okano M, Sato M, Ikekita A, Kageyama S. "Analysis of non-ketotic steroids 17 $\alpha$ -methylepithiostanol and desoxymethyl- testosterone in dietary supplements". Drug Test Analysis. 2009 Nov;1(11-12):518-25. doi: 10.1002/dta.72.

<sup>2</sup> <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm174833.htm>

**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 09<sup>th</sup> October, 2014 (recall, note published on AEMPS website<sup>3</sup>).

**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.

# HAVOC

