+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: - HALO-PLEX XTREME				
Manufacturer: - HardRock Supplement Co. (USA), as declared on the label				
(not verified)				
Importer: -Unknown				
Supplier: -Unknown				
Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☒ Stolen ☐				
Dosage form: - Capsules				
Strength: as per the labelling. <i>4-chloro-17α-methyl-androst-1,4-diene-</i>				
3β,17β -diol 50 mg				
Batch / lot no: 78343 Is batch number genuine: Yes No				
If yes to the above, advise batch destination country: Information not available				
Expiry date: 12/17				
Language of packaging: English				
Date of discovery:				
- HALO-PLEX XTREME: 28 th January, 2015				

Details of discovery: - HALO-PLEX XTREME: 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 the undeclared pharmacologically active substance chlorodehydromethyltestosterone in addition to the declared one. Analysed: YES ⊠ NO □ If yes, result of analysis: The results of the analysis indicated that this product contained the declared active substance: 4-chloro-17α-methyl-androst-1,4*diene-3β,17β –diol,* besides the following undeclared active substance: Chlorodehydromethyltestosterone 3. DISTRIBUTION METHOD Internet: YES / NO (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 □/ NO ☒ 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 ☐ / 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 04 th February, 2015 (recall, note published on AEMPS website ¹).		
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.		

-

 $^{^{1}\,\}underline{http://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2015/ICM\ MI\ 01-15-haloplex.htm}$

HALO-PLEX XTREME



