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	g as much information as possible <u>.</u>	
1. REPORTING PERSON		
Name:	Position:	
Organisation:		
Address:		
Telephone No:	Ext:	
e-mail address: sbentolila@aemps.es		
2. PRODUCT DETAILS		
Product name: ENERGY 48 capsules		
VIRITOTAL capsules		
Manufacturer: unknown		
Supplier: Import/Export Energy Company LTD		
20-22 Wenlock Road, London N1 76 U (United Kingdom)		
Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☒ Stolen ☐		
Dosage form: Capsules		
Strength: NA		
Batch / lot no: Viritotal capsules: B15J116 // Energy 48 capsules: B15J116		
Is batch number genuine: Yes ⊠ No □		
If yes to the above, advise batch destination country: Not applicable		
Expiry date: Viritotal capsules: AUG17 // Energy 48 capsules: AUG17		
Language of packaging: Spanish and English		
Date of discovery:		
Details of discovery:		
After inspections carried out by the Health authorities of Galicia and by		
SEPRONA Guardia Civil, involved in PANGEA IX Operation, the products		
were submitted to our Agency and analysed by the Official Medicines Control		
Laboratory (OMCL) of AEMPS and found to contain tadalafil		

Analysed: YES ⊠ NO □		
If yes, result of analysis: The results of the analysis indicated that this product		
contained the undeclared substance tadalafil.		
a DISTRIBUTION METHOD		
3. DISTRIBUTION METHOD		
Internet: YES ☑ / NO ☐ (not exclusivel		
Internet:	Non internet, advise full details:	
URL:	Possibly sold on herbalist's shops	
Website address:	and health food shops	
Other details:		
Currency of payment:		
Has product reached patients/consumers? Yes		
4. RISK TO PUBLIC HEALTH		
Adverse reactions: YES □/ NO ☒		
If yes, please advise details: No adverse reactions have been notified so far;		
however the presence of the undeclared active substance tadalafil is		
considered to pose a risk to public health, particularly in patients with		
cardiovascular diseases.		
Medical assessment details:		
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 2 <sup>nd</sup> December 2016 (recall, note published on the		
AEMPS website <sup>1</sup> ).		

 $^{1}\,\underline{https://www.aemps.gob.es/informa/notasInformativas/medicamentosUsoHumano/medIlegales/2016/ICM\_MI\_11-2016-Energy.htm}$ 

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.	



Energy 48 capsules (1)



NET WEIGHT: 4500 mg LOT / BEST BEFORE THE END OF: LOTE / CONSUMIR PREFERENTE
ANTES DEL FIN DE: Ver envase.
PRESENTACIÓN: 10 cápsulas de 450 mg
CANTIDAD DIARIA RECOMENDADA: 1 Cápsula
MODO DE EMPLEO: Tomar 1 cápsula al día
ADVERTENCIAS: Los complementos alimenticios
no deben utilizarse como sustitutos de una dieta
variada e equilibrada y un modo de vida sano.
No superar las dosis diaria expresamente recomendada.
Mantener fuera dei alcance de los niños más pequeños.
Almacenar bien cerrado en lugar seco y fresco. PRESENTATION: 10 capsules of 450 mg
RECOMENDED DAILY AMOUNT: 1 capsule
WAY OF USE: Take 1 capsule a day
WARNINGS: Food suplement should not be
used as subsitutes of a varied balanced diet used as submitted as a submitted as and a healthy lifestyle.

Do not exceed the expressly recommend daily dose Keep out of reach of youngest children. Store tightly closed in a cool and dry place. Manufactured outside the U.E. Almacenar bien cerrado en Fabricado fuera de la U.E. DISTRIBUTED BY: Import/Export Energy Company LTD 20-22 Wenlock Road INGREDIENTS PER CAPSULE: INGREDIENTES POR CAPSULA: Tribulus (Tribulus terrestris L.) 120mg, Ashwagandha Ashwagandha (Withania somnifera (L.) Dunal)110mg, (Withania somnifera (L.) Dunal) 110mg, L-Arginina 100mg, Nutmeg (Myristica fragrans Houtt.) L-Arginina 100mg, Nuez moscada (Myristica fragrans 80mg, Black pepper (Piper nigrum L.) 40mg Houtt.) 80mg, Pimienta negra (Piper nigrum L.) 40mg y Agente de recubrimiento (Gelatina). and coating agent (Jely)

## Energy 48 capsules (2)



Viritotal capsules (2)