HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference: No:	•			
	Time:		Initials:	
Please complete sections 1	to 5 providin	g as much	information as possible.	
1. REPORTING PERSON				
Name:	Position:			
Address:				
Telephone No:			Ext:	
e-mail address:				
2. PRODUCT DETAILS				
Product name: Genotropin PS.INJ.SOL12MG/CARTRIDGE				
Manufacturer:				
Supplier:				
Legal status: Banned ☐ Counterfeit ☒ Unlicensed ☐ Stolen ☐				
Dosage form: PS.INJ.SOL				
Strength: 12MG/CARTRIDGE				
Batch / lot no:ZP3380 Is batch number genuine: Yes \(\subseteq \text{No } \text{X} \)				
If yes to the above, advise batch destination country:				
Expiry date: 06/2019				
Language of packaging: Greek				
Date of discovery:				
Details of discovery: Following a police operation, a criminal gang engaging in				
the illegal manufacturing and distribution of anabolic preparations was broken				
up. The gang had set up two laboratories for the manufacturing of steroids. It				
also ran a storage site and a printing site for packaging artwork of the				
products.				
Analysed: YESX NO				
If yes, result of analysis: Samples were handed to MAH for expert evaluation.				
According to the MAH's report, the individual folding carton and cartridge label				
of greek market format as well as the two chamber cartridge plastic tray				

packaging are counterfeit. The enclosed PIL and the two chamber cartridge were found to be authentic; the latter was relabelled with non-valid lot/expiry and contains counterfeit drug product. Based on FTIR, the content was characterized as unknown formulation, that is chemically different to authentic Genotropin 12mg (38.5% match to the authentic powder). It should be noted that the outer packaging bears a matrix for the attachment of an authentication sticker, as is required by national legislation for products intended for the greek market. The authentication sticker itself had been removed and the remaining barcode was determined to be invalid.

3. DISTRUBUTION METHOD				
Internet: YES / NO /				
Internet:	Non internet, advise full details:			
URL:	Apart from Greece, the products			
Website address:	were shipped abroad via courier			
Other details:	or transport operators.			
Currency of payment:				
Has product reached patients/consumers?				
4. RISK TO PUBLIC HEALTH				
Adverse reactions: YES ☑/ NO □				
If yes, please advise details: Products were manufactured in non-authorised				
laboratories and stored in a non-authorised site. Since GMP and GDP				
requirements are not met, the products are dangerous for public health.				
All the products and raw materials found were seized.				
Medical assessment details:				
5. NEED FOR PUBLICITY				
Are you making a public statement? YES \(\subseteq \) / NO \(\overline{\mathbb{X}} \)				
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?				
A press release was made in cooperation with the police. All the products and				
raw materials were seized. No recall was justified due to the kind of				

distribution (wholesalers were not involved).		
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.		



Figure 2: Representative subject sample 20917-21234-D10142190 contents.



FIGURE 3: Photograph detailing the representative subject sample 20917-21234-D10142190 IFC.

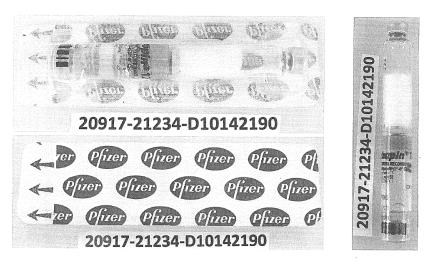


FIGURE 5: Photographs detailing the sample 20917-21234-D10142190 - plastic tray and dual cartridge.



FIGURE 6: Photographs detailing the sample 20917-21234-D10142190. Top Left: Plastic tray paper logo region. Top Right: Cartridge label. Bottom: sample 20917-21234-D10142190 powder.