

# 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:		
Date:	Time:	Initials:
Please complete sections 1 to 5 providing as much information as possible.		
<b>1. REPORTING PERSON</b>		
Name:	Position:	
Address:		
Telephone No:	Ext:	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
Product name: Genotropin PS.INJ.SOL12MG/CARTRIDGE		
Manufacturer:		
Supplier:		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: PS.INJ.SOL		
Strength: 12MG/CARTRIDGE		
Batch / lot no: ZP3380 Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>		
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: YES <input checked="" type="checkbox"/> NO <input type="checkbox"/>		
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. DISTRIBUTION 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-authorized laboratories and stored in a non-authorized 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  / 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?

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.