

## HMA WGEO – Rapid Alert Form

Falsified product (source unknown)

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:		
Address:		
Telephone	Ext: --	
e-mail address:		
<b>2. PRODUCT DETAILS</b>		
Product name:		
Somatropin (HGH) Jenapharm		
Manufacturer: unknown (declared Jenapharm GmbH & Co. KG)		
Supplier: unknown		
Legal status: Banned <input type="checkbox"/> <b>Counterfeit x</b> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: solution for injection (vials)		
Strength: 100 IU		
Batch / lot no: unknown		
Is batch number genuine: Yes <input type="checkbox"/> No <input type="checkbox"/> unknown		
If yes to the above, advise batch destination country:		
Expiry date: unknown		
Language of packaging: German and English		
Date of discovery: 08.05.2020		
Details of discovery:		
On 08-May-2020 the authorisation holder Jenapharm GmbH & Co. KG informed the TLV of a falsified product. Somatropin (HGH) Jenapharm is a full falsification, because it is not a product of the Jenapharm GmbH & Co. KG.		

The authorisation holder got knowledge about this by a concerned user by email.

Further information is not available.

Analysed: YES ☐ NO ☒

If yes, result of analysis: --

### 3. DISTRIBUTION METHOD

Illegal distribution

### 4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO ☐ unknown

If yes, please advise details: --

Medical assessment details: --

### 5. NEED FOR PUBLICITY

Are you making a public statement? YES ☐ / NO X

Are you issuing a press release? YES ☐ / NO X

Are you recalling product? YES ☐ / NO X

### 6. DISSEMINATION

No information available

### 7. PHOTOGRAPH

