

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Reference: 54T/ 167 – 208		
Date: 23.03.2018	Time: 11:00	Initials: MW
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: Testosteron-Depot 250mg Eifelfango		
Manufacturer: unknown (original MAH EIFELFANGO Chemisch - Pharmazeutische Werke J. Graf Metternich GmbH & Co.KG)		
Supplier: unknown (original supplier in DE: EIFELFANGO Chemisch - Pharmazeutische Werke J. Graf Metternich GmbH & Co.KG 53474 Bad Neuenahr-Ahrweiler)		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: Solution for Injection		
Strength: 250 mg/1.0 ml		
Batch / lot no: 6203 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>		
If yes to the above, advise batch destination country: Germany		
Expiry date: 06/2019		
Language of packaging: German.		
Date of discovery: 03.2018		
Details of discovery: Eifelfango was contacted in the night by a telephone call (emergency number). The caller stated that his son would have used an ampoule of the mentioned batch and that now he shows a mild nausea. Now the caller wanted to know, whether the ampoule might be counterfeit, because it wasn't purchased in a pharmacy. The caller was advised by the company to contact a physician and to stop the use of these ampoules. He was begged in addition to send photos, what he did later on.		
Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>		
If yes, result of analysis: There was no analytical investigation possible. But		

according to a check with the original batch, the photos showed differences concerning labelling and packaging of the product, which leads to the conclusion, that here a counterfeit product is given:

Details revealed: a) labels on the ampoules are too long and not well glued, b) variable data on label shows a different formatting, c) the leaflet shows not the current version (which is Version 6, in counterfeit package Version 5), d) the original cap of the package has 6 contact points (which are broken by first opening)(on foreside), here the cap has 10 contact points, e) The original package shows a different shape of the holes in the internal holder for the ampoules (the original has "teeths" to fix the ampoule)

3. DISTRIBUTION METHOD

Internet: YES <input type="checkbox"/> / NO <input type="checkbox"/> NOT KNOWN	
Internet:	Non internet, advise full details:
URL:	
Website address:	
Other details:	
Currency of payment:	
Has product reached patients/consumers? Yes	

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/>
If yes, please advise details: According to the caller a mild nausea was observed.
Medical assessment details:

5. NEED FOR PUBLICITY

Are you making a public statement? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
Are you issuing a press release? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
Are you recalling product? YES <input type="checkbox"/> / NO <input checked="" type="checkbox"/>
If yes to any of the above, when do you intend to take action?

6. DISSEMINATION

Are you content for this Rapid Alert to be shared outside WGEO membership? YES <input checked="" type="checkbox"/> / NO <input type="checkbox"/> (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 <input checked="" type="checkbox"/> Industry Security <input type="checkbox"/> Trade Associations <input type="checkbox"/>
Traders <input type="checkbox"/> Other <input type="checkbox"/> Please specify _____

7. PHOTOGRAPH

If possible, please attach a photograph of the product. See attachment

HMA WGEO – Rapid Alert Form (Attachement)

Counterfeit or illegal product found in the illegal supply chain
here: Testosteron-Depot 250mg Eifelfango, Batch 6203



Original: labels are shorter and variable date (Batch, Expiry date) is printed fat



Counterfeit Product:

- labels on the ampoules are too long and not well glued,
- variable data on label shows a different formatting



Original: The original package shows a different shape of the holes in the internal holder for the ampoules (the original has "teethes" to fix the ampoule)



Original: the original cap of the package has 6 contact points (which are broken by first opening) (on foreside)



Counterfeit product

The cap (forefront) has 10 contact points

The shape of the holes in the internal holder is round (no "teethes")