

HMA WGEO – Rapid Alert Form

Unlicensed falsified product found in Venezuela

Reference:		
Date: 2021-09-30	Time:	Initials: Br
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: Vitamin C Injektapas		
Strength: 12,5 g ascorbic acid / 50 mL		
Dosage form: 50 mL injection bottle, solution for Injection		
Note: the strength of the genuine product is 7,5 g/ 50 mL		
Manufacturer (site of batch certification): Pascoe Pharmazeutische Präparate GmbH Europastraße 2 35394 Giessen, Germany		
Marketing authorisation holder (MAH): Pascoe Pharmazeutische Präparate GmbH Schiffenbergerweg 55 35394 Giessen, Germany		
Supplier: unknown		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input checked="" type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: solution for injection		
Strength: 12,5 g/ 50 mL ascorbic acid		

Batch / lot no: unknown	
Is batch number genuine: Yes <input type="checkbox"/> No <input type="checkbox"/> n.a.	
If yes to the above, advise batch destination country: n.a.	
Expiry date: n.a.	
Language of packaging: German	
Date of discovery: 2021-09-29	
Details of discovery: A Venezuelan physician informed the MAH about the falsified product and provided photographs. It is not known where the medicinal product was supplied from. The MAH does not hold a marketing authorisation in Venezuela.	
The falsified product can easily be identified: <ul style="list-style-type: none">on the secondary packaging the name of the MAH is misspelled and incomplete, it is stated "Pharmazeutische Präparate GmbH, D-85887 GieBen"The strength is indicated to be 12,5 g of ascorbic acid in 50 mL, the genuine product's strength is 7,5 g/ 50 mLThe design of the packaging differs strongly from the original design	
The MAH was informed on 2021-09-24 and forwarded the information to RP Darmstadt on 2021-09-29.	
Law enforcement agencies were not informed by the MAH.	
Analysed: YES <input type="checkbox"/> NO <input checked="" type="checkbox"/>	
If yes, result of analysis: n.a.	

3. DISTRIBUTION METHOD	
Internet: YES <input type="checkbox"/> / NO <input type="checkbox"/> unknown	
Internet:	Non internet, advise full details: Distribution method not known
URL:	
Website address:	
Other details:	
Currency of payment:	

Has product reached patients/consumers? unknown

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO ☐ unknown

If yes, please advise details: unknown

Medical assessment details: unknown

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?

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



Zusammensetzung:

1 Injektionsflasche mit 50 ml

Injektionslösung enthält:

Ascorbinsäure 12,5 g

(1 ml Injektionslösung enthält
250 mg Ascorbinsäure)

Sonstige bestandteile:

Natriumhydrogencarbonat,

Wasser für Injektionszwecke.

Enthält Natriumhydrogencarbonat.

Packungsbeilage beachten.

Für Kinder unzugänglich
aufbewahren.

Pharmazeutische Präparate
GmbH, D-85877 Gießen