

HMA WGEO – Rapid Alert Form

Unlicensed falsified product found in Colombia

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		
Case 1: Product name: Vitamin C Injektapas Strength: 50 g ascorbic acid / 100 mL Dosage form: 100 mL injection bottle, solution for Injection		
Case 2: Product name: Vitamin C Injektapas Strength: 50 g ascorbic acid / 100 mL Dosage form: 100 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: 50 g/ 100 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 Colombian 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 Colombia (Case 1). 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 "Pharmazeutishche Praparate GmbH, D-85877 GieBen" or "Pharmazeutische Praparate GmbH, D-85877 GieBen"The strength is indicated to be 50 g of ascorbic acid in 100 mL, the genuine product's strength is 7,5 g/ 50 mLThe MAH does not distribute the medicinal product in 100 mL vialsThe design of the packaging differs strongly from the original design
Secondly, the physician informed the MAH about a website where falsified "Vitamin C Inyectopas" is sold (Case 2).

It is not known if the falsified product on the photographs provided by the physician was supplied from the mentioned website.

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 ☐ NO ☒

If yes, result of analysis: n.a.

3. DISTRIBUTION METHOD

Internet: YES ☒ (case 1) / NO ☐ unknown (case 2)

Internet: Mercado libre	Non internet, advise full details: Distribution method not known (Case 1)
URL: https://articulo.mercadolibre.com.co/MCO-615503597-vitamina-c-inyectable-JM#reco_item_pos=2&reco_backend=machinalis-seller-items&reco_backend_type=low_level&reco_client=vip-seller_items-above&reco_id=d7b54b11-6e08-42e9-892b-48d6ff4e601c	
Website address: Carrera 17 Numero 93 - 09 Piso 3, Bogotá D.C., Colombia	
Other details: n.a.	

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?
n.a.

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





