

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference:		
Date:	Time:	Initials:
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: Gerovital H ³		
Manufacturer: Zentiva S.A. Romania		
Supplier:		
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>		
Dosage form: tablets		
Strength: 100 mg		
Batches / lot no 7ZP4925A	Is batch number genuine: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
If yes to the above, advise batch destination country:		
Expiry date: 03.2020		
Language of packaging: Romanian		
Date of discovery: 23.08.2019		
<p>Details of discovery: A non-healthcare professional from Philippines sent to the MAH messages and photos asking about the authenticity of two boxes of Gerovital H³ that he bought "from a clinic". After comparing the photos received from this patient with reference samples kept at the manufacturer, the MAH informed the National Agency for Medicines and Medical Devices of Romania about:</p> <ul style="list-style-type: none">- the counterfeit of the box from batch 7ZP4925A; this batch was not released by the manufacturer;		

- for the box from batch 8 ZR1153A (which is a batch released by the manufacturer), there are differences in package comparing with the reference samples.

Analysed: YES ☐ NO ☒

If yes, result of analysis:

3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒

Internet:

URL:

Website address:

Other details: export in Philippines was not approved by the National Agency for Medicines and Medical Devices of Romania

Non internet, advise full details:

Currency of payment:

Has product reached patients/consumers?

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO ☒

If yes, please advise details:

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?

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: authorities from Philippines

7. PHOTOGRAPH

If possible, please attach a photograph of the product.

Attachment





Serie:
EXP:

87R1153A
01.2020

2

Serie:
EXP:

87R1153A
01.2020

99

Serie:
EXP:

87R1153A
01.2020

200







Gerovital®

clorhidrat de procaină

Produs original Prod. Dr. A. Mănuș

Prof. Dr. A. Mănuș

comprimat filmat

comprimat filmat conține

Fiecare comprimat filmat conține

100 mg clorhidrat de procaină

Conține metabisulfita de sodiu

A se citi prospectul însoțitor de utilizare

Administrare orală

ATC N02BA01 - 500 mg - 30 comprimate

Serie:
EXP:

VZT038A
03/2020

