

HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference: No: 20DIS015	
Date: 17.03.2020	Time: 15:00
Initials: KDK	
Please complete sections 1 to 5 providing as much information as possible.	
1. REPORTING PERSON	
Name:	Position:
Organisation:	
Address:	
Telephone No:	
e-mail address:	
2. PRODUCT DETAILS	
Product: Soliris 300 mg	
MAH: Alexion	
Supplier: Türkeli, Tekiner, Eksen	
Legal status: Banned <input type="checkbox"/> Counterfeit <input checked="" type="checkbox"/> Unlicensed <input type="checkbox"/> Stolen <input type="checkbox"/>	
Dosage form: Concentrate for solution for infusion	
Strength: 300 mg (10mg/ml * 30ml vials)	
Batch / lot no: 1000584 Is batch number genuine: Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>	
If yes to the above, advise batch destination country: Turkey	
Expiry date: 03.2021	
Language of packaging: English	
Date of discovery: 12.03.2020	
Details of the discovery:	
On 18 Feb 2020 Alexion was contacted concerning vials of Soliris®, Lot 1000584, expiry 03/2021.	
Soliris Lot 1000584 is a legitimate Alexion Lot number that was distributed in Turkey.	
An examination of photographs of Lot 1000584 showed:	
<ul style="list-style-type: none"> - the absence of Turkish Language labelling, - absence of serialization, 	

- different combination of numbers across the top left and top right of commercial carton,
- a pack with a mismatched carton and vial codes and differing fonts.

Additionally the certificate of analysis accompanying this lot was also confirmed to be falsified.

It was identified that the 305 vials were physically present in the USA at facilities belong to Almac Clinical Services LLC (Souderton, USA), Almac Clinical Technologies (Lansdale, USA).

The falsified vials were purchased from Bionical Emas Inc. (Paulsboro, USA).

The distribution chain was as follows:



Investigation is ongoing, no further information is available to date.

Analysed: YES ☒ NO ☐

If yes, result of analysis: Results not known yet

3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒

Internet: -

L: -

Website address: -

Other details: -

Non internet, advise full details:

-

Currency of payment: -
Has product reached patients/consumers? Unknown
4. RISK TO PUBLIC HEALTH
Adverse reactions: YES <input type="checkbox"/> / NO <input type="checkbox"/>
Unknown
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"/>
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 checked="" type="checkbox"/> Trade Associations <input checked="" type="checkbox"/>
Traders <input checked="" type="checkbox"/> Other <input checked="" type="checkbox"/> Please specify Other relevant parties
7. PHOTOGRAPH
Photos of product packaging:
Not yet available