+HMA WGEO – Rapid Alert Form

Counterfeit or illegal product found in the illegal supply chain

Shaded area to be completed by the secretariat

Reference: French Customs case J3072020		
Date: 06/10/2020	Time: 15h19	Initials: ODM

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: Juvéderm ULTRA 3 et ULTRA 4, CE 0459

Manufacturer: ALLERGAN, Route de Promery, Zone Artisanale de Pré-Mairy, 74 370 PRINGY-FRANCE

Supplier: ALLERGAN

Distributor: Rhenus Logistics

Legal status: Banned ☐ Counterfeit ☒ Unlicensed ☐ Stolen ☐

Dosage form: Vials

Strength: 1ml

Batch / lot no: X30LA 70025

Is batch number genuine: Yes ☒ No ☐

If yes to the above, advise batch destination country: Europe

Expiry date: 2022-12

Language of packaging: French

Date of discovery: 31/07/2020

Details of discovery:

Product discovered in postal freight coming from China.

Analysed: YES ☒ NO ☐

If yes, result of analysis:

Both pack images and certificate of analysis have been analysed by Allergan, who indicated the product was a counterfeit.

The batch number and the product code are assigned to a Juvéderm ULTRA 3 lot manufactured by Allergan, however the date of manufacture, expiration date and shelf life do not match. The manufacturing date (2019-11) and expiry date (2022-12) of the Juvéderm ULTRA 3 showed that they provide 25 months shelf-life, while the genuine products have a 24 months shelf-life.

Other counterfeited products of the same batch (X30LA 70025) were discovered in Ireland with a 12 months shelf-life (manufactured in January 2017 and expiry December 2018).

In order to determine whether a Juvéderm product is counterfeited, it is preferable to refer to the origin of the packages (China versus Pringy-France).

3. DISTRIBUTION METHOD

Internet: YES ☐ / NO ☒

Internet:	
URL:	
Website address:	
Other details:	

Currency of payment: Details not provided

Has product reached patients/consumers? Yes

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☒ / NO ☐

If yes, please advise details

Medical assessment details: N/A

5. NEED FOR PUBLICITY

Details as per original form

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

If possible, please attach a photograph of the product.


Juvéderm®
ULTRA
LOT X30LA70025
2019.11
2022.12
0459 J. ULTRA 3
ALLERGAN
44503JR10B


Juvéderm
ULTRA 3
2 X 1mL