HMA WGEO – Rapid Alert Form
Deficit Bocouture Vial 100 Unit GB / 2021-393

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: Dr. Frank Sielaff	Position:
Organisation: Regierungspraesidium Darmstadt, GMP-Inspectorate	
Address: Luisenplatz 2, 64283 Darmstadt, Germany	
Telephone No: +49 6151 12 5070	Ext: –
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2. PRODUCT DETAILS

Product name: BOCOUTURE 100 Units
Manufacturer: Merz Pharma GmbH & Co. KGaA, Dessau, Germany
Supplier: Merz Pharmaceuticals GmbH, Frankfurt, Germany
Legal status: Banned ☐ Counterfeit ☐ Unlicensed ☐ **Stolen X**
Dosage form: powder for solution for injection
Strength: 100 units
Batch / lot no: 034162 Is batch number genuine: Yes X No ☐
If yes to the above, advise batch destination country: Japan
Expiry date: 31.03.2023
Language of packaging: Great Britain presentation; English
Date of discovery: 08th September 2021
Details of discovery: On 06th Oct 2021, the Head of Logistics informed that the location of 1158 packs Bocouture Vial 1st 100 Unit GB is unclear. The difference was identified in the warehouse Merz Logistics Center in Darmstadt on September 8th, 2021. The concerned batch is serialized but Merz cannot track the serial numbers of deficit packs.
Analysed: YES ☒ NO ☐
If yes, result of analysis:
Intensive internal investigation did not reveal any results on the whereabouts of the deficit vials.

3. DISTRUBUTION METHOD

Bocouture® is distributed in Japan via private doctor´s license. Therefore, Bocouture is ordered by the Merz Affiliate Merz Asia Pacific Pte. Ltd, Singapore. The goods are directly shipped to three distribution partners located in Singapore and Hong Kong. These foreign sellers deliver Bocouture® directly to doctors in Japan. The latter personally import them through the Japanese physician import system and based on a private doctor´s license. The import support agent (located in Japan) assist the doctors in placing their orders.

4. RISK TO PUBLIC HEALTH

Adverse reactions: YES ☐ / NO X
If yes, please advise details: –
Medical assessment details: –

5. NEED FOR PUBLICITY

Are you making a public statement? YES ☐ / NO X
Are you issuing a press release? YES ☐ / NO X
Are you recalling product? YES ☐ / NO X
Incident will be reported to the local police; official complaint will be filed.

6. DISSEMINATION

Currently no information available

7. PHOTOGRAPH

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