HMA WGEO - Rapid Alert Form

Stolen products from a warehouse in Darmstadt, Germany

Shaded area to be completed by the secretariat Reference: Time: Date: Initials: Please complete sections 1 to 5 providing as much information as possible. 1. REPORTING PERSON Position: Name: Organisation: Address: Telephone No:+ Ext: -e-mail address: f 2. PRODUCT DETAILS Product name: Medicinal Product: Xeomin 100 units, powder for solution for injection Medical Device: Belotero Soft Lido FSYR 1ML Manufacturer: Xeomin: Merz Pharma GmbH & Co. KGaA, Dessau, Germany Legal Manufacturer Belotero Anteis S.A., 18 Chemin des Aulx, CH-1228 Plan-les-Ouates, Geneva, Switzerland Supplier: Merz Pharmaceuticals GmbH, Frankfurt, Germany Legal status: Banned Counterfeit Unlicensed Stolen X Dosage form: Xeomin: powder for solution for injection Belotero: 1 ml syringe Strength: Xeomin: 100 units Belotero: Cross-linked sodium hyaluronate: 20 mg/ml

Lidocaine hydrochloride: 3 mg/ml
Phosphate buffer pH 7 q.s.: 1ml
Batch / lot no:
Xeomin: 031052
Belotero: 256009/1
Is batch number genuine: Yes X No
If yes to the above, advise batch destination country:
Xeomin: United States of America
Belotero: worldwide, excluding US
Expiry date:
Xeomin:12/2022
Belotero: 09/2022
Language of packaging:
Xeomin: English
Belotero: as applicable
Date of discovery: approximately 19. Nov 2020
Details of discovery:
On 24-Nov-2020, the Commissioner of the Graduated Plan and
QPPV of the Merz Group was informed by the Head of Logistics of
Merz that a thievery occurred and was in the meantime confirmed
by the Merz warehouse held by Logosys, Logistik GmbH in
Darmstadt, Hessen, Germany. According to the information the
thievery took place in the night between 18. and 19. Nov 2020.
In total, 10 cartons including 840 single vial packs of 100 Units
Xeomin, powder for solution for injection were stolen. Additionally,
2 further cartons were supposed to be stolen but found in front of
the warehouse.
In addition, 6 cartons including 558 packs Belotero were stolen.
Additionally, 2 further cartons were supposed to be stolen but
found in front of the warehouse.

Xeomin was packed to be delivered to the Merz Affiliate in the
United States of America. So far, no delivery of this batch took place
to customer or Affiliate.
Belotero was packed to be delivered to world wide recipients,
excluding USA.
Remaining stock was put in quarantine. The police was informed
accordingly.
Serialization codes are currently identified and respective
serializations codes will be changed to status "stolen".
Analysed: YES ☐ NO ☒
If yes, result of analysis:
3. DISTRUBUTION METHOD
Xeomin: Distribution via Merz Affiliate in he USA.
Belotero: as applicable
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
Police was informed by Head of Logistics of Merz Pharma GmbH & Co.
KGaA, Germany
6. DISSEMINATION
7. PHOTOGRAPH
-