Follow-up and non-urgent Information for Quality Defects

Regierungspräsidium Darmstadt, 64278 Darmstadt

	Meldende Stelle **Regierungspräsidium Darmstadt, D-64278 Darmstadt**		
1	To: (see list attached, if more than one) Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) Hessisches Ministerium für Soziales und Integration, Referat V3		
2	Recall Number Assigned: DE-HE_2022-337	2a	National reference number (when applicable) NL/I/38/02
4	Product: Xeplion 150 mg Depot-Injektionssuspension SynCo pharma (PZN 16613785) Trevicta 525 mg Depot-Injektionssuspension SynCo pharma (PZN 16613845)	5	Marketing Authorisation number: Xeplion: EU/1/11/672/005 Trevicta: EU/1/14/971/010
6	Brand/Trade name: Xeplion, Trevicta	7	INN or Generic Name: Xeplion: Paliperidone Trevicta: Paliperidone
8	Dosage form: Xeplion: Prolonged-release suspension for injection Trevicta: Prolonged-release suspension for injection	9	Strength: Xeplion: 150 mg Trevicta: 525 mg
10	Batch number (and bulk, if different) Xeplion: LCB0800/BD, LCB0800/BE, LEB4A01/BA, LEB4A01/BB, LEB4A01/BC, LIB1700/BA, LIB1700/BB, LIB1700/BC, LIB1M00/BA, LIB1M00/BB, LIB1M00/BC, LIB1M00/BD, LIB1M00/BE, LKB0U00/BB, LKB0U00/BD, LKB0U00/BF Trevicta: LHB0A01/BA		
14	Marketing Authorisation holder: Janssen-Cilag International NV		

15	Manufacturer[1]/ Parallel Distributor: SynCo Pharma B.V.	16	Contact Person: Josta de Jong Minervaweg 2 8239DL Lelystad Tel.: +31 320 216 387 E-Mail: j.dejong@bmodesto.com

17 Details of Defect/Reason for Recall:

Previous Notifications: The EMA has sent out a Defective Product Report on July 4th 2022 (QD2022-132/H/Keytruda/Defective Product Report) regarding the falsification of Keytruda, based on a report of Bmodesto to EMA on July 1st 2022. The Health and youth Inspectorate (The Netherlands) has sent out a Rapid Alert Notification on the 11th of August (Rapid Alert; falsification; class I; Keytruda and Enbrel; recall; NL/I/38/01) and on the 30th of August (Rapid Alert Update; falsification; Simponi, Cosentyx, Humira, Roactemra, Trevicta, Xeplion, Xtandi; NL/I/38/02). Please see this alert for original information. On the 1st of september a recall of the products Enbrel, Humira, Simponi, Trevicta and Xtandi was already carried out by Axicorp GmbH and Axicorp B.v. in germany, which was covered by a follow-up notification by the Regierungspräsidium Darmstadt (DE).

Xeplion:
Following the recommendation of german authorities, SynCo Pharma recalls batches of the product Xeplion 150 mg as listed above, which are suspected to be falsified medicinal products due to the distribution chain Bmodesto – Pharmagen (BG).
Pharmacies are asked to contact customers that received the respective batches to carry out the recall on a patient-level.

Trevicta:
A single package of the product Trevicta originating from Pharmagen in BG is also beeing recalled from a specific pharmacy in Germany which was already informed of the possible falsification before. Now the pharmacy is asked to recall the product from the patient which received the package.
A recall notification via the AMK is not published, since the pharmacy is contacted directly.

22	From (issuing Authority):	23	Contact Person:		
24	Signed:	25	Date: 13.09.2022	26	Time: 12:00