

Bezirksregierung Düsseldorf

Report Number : 1

STATEMENT OF NON-COMPLIANCE WITH GDP MEDICINAL PRODUCTS FOR HUMAN USE

**Exchange of information between National Competent Authorities (NCAs) of the EEA
following the discovery of serious GDP non-compliance at a wholesale distributor**

Part 1

Issued following an inspection in accordance with Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Germany confirms the following:

The wholesale distributor: PexMed GmbH

Authorisation number : DE_NW_03_WDA_2018_0026/24.05.05.01-Pexmed

Site address: Timmerhellstr. 31, Mülheim an der Ruhr, 45478, Germany

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on 2021-03-05, it is considered that **it does not comply with the Good Distribution Practice** requirements referred to in Article 84 of Directive 2001/83/EC.

Part 2

Wholesale distribution activity affected : Distribution of Human Medicinal Products

Part 3

1. Nature of non-compliance: Critical and mayor violations of the GDP-guideline regarding:

- Trading of falsified medicinal products
- Trading of medicinal products with unclear trade chain
- Storage of expired medicinal products in between those ready for trading
- Storage of expired medicinal products in regular stock
- Storage of medicinal products for consumers in regular stock
- Missing connection to the securepharm-system
- Doubtful reliability of the responsible person due to an ongoing criminal procedure
- Doubtful reliability of the CEO due to an ongoing criminal procedure

2. Action taken/proposed by the NCA: Suspension of Wholesale Distributor Authorisation

2021-03-05

Name and signature of the authorised person of the
Competent Authority of Germany

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EudraGMDP