

Report No.: OKDLaL/2384/2018 (4914/2018/1310)

## **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 Slovak Republic confirms the following:

The wholesale distributor: NETPHARMA, s.r.o., Priekopa 1915/55A, 060 01 Kežmarok, Slovak Republic

Authorisation number: FV-591/13

Site address: 094 01 Štefanovce 18, Slovak Republic

From the knowledge gained during an inspection of this wholesale distributor, the latest of which was conducted on May 21, 2018, 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:

Temperature monitoring is not performed by calibrated measuring instruments, their location is not sufficient to meet the required purpose.

The qualification of warehouse storage area, including temperature monitoring during the transport of the medicinal products were found non-compliant with current GDP requirements.

The acquisition documents (delivery notes, invoices, analytical certificates) of the drugs stored during the inspection at the time of inspection were missing.

A product recall simulation has never been tested.

The obligations of the QP can't be fulfilled: recall of products from the market, keeping of stock records and the power of inventory performance due to the absence of a computerized storage system.

The suppliers and customer's qualifications were not performed.