

Report No.: 3485/2015/900
15/4797**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: D-Pharm Slovakia, s.r.o., Malé námestie 2873/18, 901 01 Malacky,
Slovak Republic

Authorisation number: FV-609/14

Site/s address/es: Kysucká cesta 3, 010 01 Žilina, Slovak Republic

From the knowledge gained during inspection of this wholesale distributor, the latest of which was conducted on July 28, 2015, 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:

- Wholesale distributor does not have authorized storage facilities.
- Wholesale distributor does not have a qualified person for distribution activities.

Part 3

1. Nature of non-compliance: The company has seriously violated the conditions on which is the permission for activities linked and fell short of the obligations set out in § 17 part 1 of the Act no. 362/2011 Coll. on Drugs and Medical Devices and on Amendment and Supplementing of Certain Acts, as amended later.

2. Action taken/proposed by SIDC: SIDC sent to the Ministry of Health of the Slovak Republic with legal competency the proposal for suspension of the wholesale distribution authorization no. FV-609/14, issued by Ministry of health.

3. Additional comments:



PharmDr. Ján Mazag
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