State Institute for Drug Control

Report No: ***SK/001NC/2018***

STATEMENT OF NON-COMPLIANCE WITH GMP

Exchange of information between National Competent Authorities (NCAs) of the EEA following the discovery of serious GMP non-compliance at a manufacturer [1]

Part 1

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

The competent authority of Slovakia confirms the following:
The manufacturer: ***UNIMED PHARMA, spol. s r.o.***
Site address: ***Oriešková 11, Bratislava, Slovakia, 821 05, Slovakia***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-12-13*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

Part 2

Human Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS	
Include total and partial manufacturing (including various processes of dividing up, packaging or presentation), batch release and certification, storage and distribution of specified dosage forms unless informed to the contrary;	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification

Part 3

1. Nature of non-compliance:
A total of 2 (two) 'Critical' and 21 (twenty-one) 'Major' deficiencies were observed during this inspection. The 'Critical' deficiencies are related to pharmaceutical quality management, cross-contamination management and quality assurance management which were found to be inadequate and not capable of putting in place proper design, planning, implementation, maintenance and continuous improvement of system implemented at the site to ensure the consistent delivery of products with appropriate quality attributes, whilst the 'Major' deficiencies were cited for inadequate documentation management, validation activities and lack of trained personnel.
Action taken/proposed by the NCA **Withdrawal, of current valid GMP certificate No. SK/023V/2018** Restriction of current valid GMP certificate no. SK/023V/2018. **Recall of batches already released** If there are alternative suppliers and there is no risk of shortage, recall of medicinal products should be evaluated by involved NCA's following assessment conducted in conjunction with MAHs. Given the nature of non-compliances, assessment should include a complete retest of all imported batches of medicinal products. **Prohibition of supply** Due to the nature of the non-compliance prohibition of supply is recommended, unless there are no alternative suppliers and there is a risk of shortage.

2019-01-15

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

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