National Agency for Medicines and Medical Devices

Report No: ***NCF/011/RO***

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 Romania confirms the following:
The manufacturer: ***ZHUHAI UNITED LABORATORIES CO., LTD***
Site address: ***Sanzao Science &Technology Park, National Hi-Tech Zone, Zhuhai, Guangdong, 519040, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-04-02*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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

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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.17 Other

Clarifying remarks (for public users)

a restricted GMP certificate was also issued for Amoxicillin Sodium sterile, Potasium Clavulanate sterile and Amoxicillin Sodium and Potasium Clavulanate sterile mix to be used by marketing authorization holder in Romania, France and UK for critical medicinal products

Part 3

1. Nature of non-compliance:

The company was not operating its aseptic manufacture operations in compliance with EU GMP Annex 1. This was evident from by the high number of observations regarding the aseptic manufacturing facilities design, equipment, operations, environment monitoring and media fill validation. However, the QA system of the company failed to notice these problems and therefore was considered weak and inappropriately implemented. Detailed list of critical and major deficiencies is included in regulatory risk assessment

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. 004/2012/RO
current GMP certificate will be reissued to include only non-sterile products. A restricted GMP Certificate will be issued for sterile critical medicinal products for Romania, France, and UK

Requested Variation of the marketing authorisation(s)
change of API supplier

Prohibition of supply
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Suspension or voiding of CEP (action to be taken by EDQM)
suspension of CEPs

2015-06-15

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

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