Medicines and Healthcare Products Regulatory Agency

Report No: ***UK GMP 34886 Insp GMP 34886/1148567-0005 NCR***

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 United Kingdom confirms the following:
The manufacturer: ***SAVIOR LIFETEC CORPORATION***
Site address: ***29, KE-JHONG ROAD, CHUNAN CHEN, MIAOLI COUNTY, TW-350, Taiwan***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-03-15*** , 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)
	1.1.1.6 Other: aseptically prepared products <Preparation of sterile Meropenem and meropenem/sodium carbonate blend (Filtration, crystallisation, drying, blending, and packaging)(en)

Clarifying remarks (for public users)

The scope of this statement of non-compliance is limited to medicinal products considered non-critical to public health. Where manufacture and/or testing is continued for critical products, as agreed by the National competent authority, this should be supported by a documented risk assessment containing sufficient information to support activity on a risk management basis.

Part 3

1. Nature of non-compliance:
The inspection identified a critical deficiency relating to the aseptic processing of Meropenem and Meropenem/Sodium Carbonate blend. The deficiency related to a lack of technical knowledge regarding sterile processing and included elements such as, autoclave and dry heat sterilisation of equipment, inadequate VHP load pattern design and application, media fills and environmental monitoring.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. UK GMP 34886 Insp GMP 34886/1148567-0005
Withdrawal of previous GMP Certificate No: UK GMP 34886 Insp GMP 34886/1148567-0005. Issue a statement of non-compliance and restricted GMP certificate to permit continued manufacture and testing of sterile API considered to be medically critical or to ensure continuity of supply, as determined by the national competent authority.

Recall of batches already released
There is no evidence of product having been impacted and therefore the inspectorate does not recommend that products are recalled.

Prohibition of supply
No batches of non-critical product to be supplied to EU markets whilst this statement of non-compliance remains in force.

Additional comments
National Competent Authorities should evaluate the criticality of products using the sterile API supplied by this manufacturing site and enact measures to ensure continued supplies where appropriate. Marketing Authorisation holders are requested to contact the relevant National Competent Authority to verify whether their products are considered medically critical to public health in their territory and therefore outside the scope of this non-compliance statement.

2018-05-15

Name and signature of the authorised person of the Competent Authority of United Kingdom

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