Medicines and Healthcare Products Regulatory Agency

Report No: ***UK MIA 20395 Insp GMP 20395/618199-0006 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: ***RELONCHEM LIMITED***
Site address: ***CHESHIRE HOUSE, GORSEY LANE, WIDNES, CHESHIRE, WA8 0RP, United Kingdom***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-02-12*** , 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;	
1.2	**Non-sterile products**
	1.2.2 Batch certification

2 NON-COMPLIANT IMPORTATION OPERATIONS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

Clarifying remarks (for public users)

In order to avoid market shortage of medically essential products, a GMP certificate will be conditioned to permit continued importation of 'critical' products in situations where it has been agreed by the national competent authority or EMA (as appropriate) that there is no feasible alternative in the market concerned. The scope of batch certification and importation activities covered by the GMP certificate will be limited to medicinal products critical to public health and with a valid marketing authorisation naming the site address approved before 30 Apr 2015. Critical medicinal products are those where there is no feasible alternative in the market concerned and have been agreed by the national competent authority or EMA as appropriate. The certificate may not be used to support marketing authorisation applications made to a competent authority after the date of issuance. This Statement of serious non-compliance is in force for all other certification and importation activities.

Part 3

1. Nature of non-compliance:
The company systems for investigating product that was potentially out of specification and not in compliance with the Market Authorisation were not robust and had allowed certification of potentially non-compliant product without appropriate investigation and product impact assessment. The Quality Management System had a number of issues including lack of robust product review, and lack of appropriate root cause investigation into deviations. The company had transported a large number of batches of product from the Manufacturing sites in India that were subject to temperature excursions during transport. These had not been adequately investigated, recorded or the impact of these excursions assessed.
Action taken/proposed by the NCA **Withdrawal, of current valid GMP certificate No. UK MIA 20395 Insp GMP 20395/618199-0002** UK MIA 20395 Insp GMP 20395/618199-0002 **Recall of batches already released** No recall actions are proposed at present. The situation remains under review.

2015-04-30

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

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