Medicines and Healthcare Products Regulatory Agency

Report No : ***UK MIA 17907 Insp GMP 17907/10138-0022 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 : ***BRISTOL LABORATORIES LIMITED***

Site address : ***UNIT 5, TRAYNOR WAY, WHITEHOUSE BUSINESS PARK, PETERLEE, SR8 2RU, United Kingdom***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-04-24*** , 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

1.2 Non-sterile products

1.2.1 Non-sterile products (processing operations for the following dosage forms)
1.2.1.1 Capsules, hard shell
1.2.1.13 Tablets

1.5 Packaging

1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets *1.5.2 Secondary packing*
1.6 Quality control testing
1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*
2 NON-COMPLIANT IMPORTATION OPERATIONS
2.1 Quality control testing of imported medicinal products
2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.3 Other importation activities
2.3.1 Site of physical importation

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, this should be supported by a documented risk assessment containing sufficient information to support activity on a risk management basis.

Part 3

Nature of non-compliance : The inspection in April 2017 identified that recorded analytical results could not be supported by the available records.
Action taken/proposed by the NCA : **Withdrawal, of current valid GMP certificate No. UK MIA 17907 Insp GMP 17907/10138-0021** Withdrawal of previous GMP Certificate No: UK MIA 17907 Insp GMP 17907/10138-0021. Issue of a statement of non-compliance and restricted GMP certificate will be issued to permit continued manufacture and testing of products considered to be medically critical or to ensure continuity of supply, as determined by the national competent authority. Due to the nature of the issues identified batches of any non-critical products not released to market are included in the scope of this SNC. **Prohibition of supply** No batches of non-critical product to be supplied to EU markets whilst this statement of non-compliance remains in force.

Teleconference Date :	**Teleconference Time (CET) :**	**Dial in no. :**

2017-08-24

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

Confidential

Medicines and Healthcare Products Regulatory Agency

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