Medicines and Healthcare Products Regulatory Agency

Report No: ***UK MIA 17907 Insp GMP 17907/13988-0029 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: ***LAPORTE WAY, LUTON, LU4 8WL, United Kingdom***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-11-15*** , 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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Powders for sachets(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility*

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*

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

1. Nature of non-compliance:

The inspection in July 2017 identified two critical deficiencies relating to the integrity and recording of GMP critical data and with the ongoing stability monitoring programme. A further GMP inspection for importation and batch certification of imported products on 13 - 15th November 2018 indicated that the site was now in compliance with EU GMP for these activity only. This SNC is therefore updated to approve importation and batch certification of importation following the most recent inspection. Please note that Microbiological and Physical testing for Importation at this site is not approved but can be performed at contract laboratories.

Action taken/proposed by the NCA

Recall of batches already released

There is no evidence of risk to product and therefore the inspectorate does not recommend that products are recalled

Prohibition of supply

No manufactured batches of non-critical products from this site should be supplied to EU markets whilst this statement of non-compliance remains in force. Imported batches may now be supplied to the EU following the November 2018 inspection.

Others

Withdrawal of previous GMP Certificate No: UK MIA 17907 Insp GMP 17907/13988-0024. 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. The GMP certificate is now updated to include importation and batch certification of imported products following the November 2018 inspection. Due to the nature of the issues identified manufactured batches only of any non-critical products not released to market are included in the scope of this SNC.

Additional comments

National Competent Authorities should evaluate the criticality of manufactured products only being supplied by this manufacturing site and enact measures to ensure continued supplies where appropriate. Marketing authorisation holders are requested to contact the relevant National 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. Imported and certified batches are not now affected by this SNC.

2019-01-08

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

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