Medicines Authority

Report No: ***MT/001NCR/2023***

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 Malta confirms the following:
The manufacturer: ***Bda Health Care Private Limited***
Site address: ***B 1 B 2 B 3 Midc Parseoni, Near Government Iti, Nagpur, 441105***
OMS Organisation Id. / OMS Location Id.: ***ORG-100046381*** / ***LOC-100076523***
DUNS Number: ***87-368-2036***

Other
(Human) First GMP Inspection - New Application

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2022-12-08***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

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Note to receiving authorities: Please contact the issuing authority within 20 working days in case there are critical(2) medicinal products potentially affected by this statement.
Manufacturing Authorisation Holders directly affected by this statement have failed to comply with their obligations under Art. 46 of Directive 2001/83/EC or Art. 93(1)(j) to (l) of Regulation (EU) 2019/6 and as a consequence the Qualified Person referred to in Art. 48 of Directive 2001/83/EC and Art. 97(1) of Regulation (EU) 2019/6 is unable to perform the batch certification referred to in Art. 51 of Directive 2001/83/EC and Art. 97 (6) and (7) of Regulation (EU) 2019/6.
In exceptional circumstances there may be no objection to the Qualified Person certifying affected batches thereby allowing their release provided all of the following conditions are fulfilled:

1. Batch certification is performed in order to maintain supply of critical medicinal products only.
2. A documented risk assessment has been performed by, or on behalf of, the Qualified Person and additional actions have been implemented by the manufacturing and/or batch release site to mitigate the risks posed by the non-compliance. Note: Repeated testing alone is not normally sufficient risk mitigation but, together with other actions, can form part of a strategy commensurate with the nature and the level of risk.
3. A thorough risk-benefit evaluation has been performed for the acceptance of risk and a report prepared that takes full account of the nature of the non-compliance with the involvement of:
    - The Manufacturing Authorisation Holder and the Qualified Person of the site responsible for

batch certification.

- The manufacturing site subject to this Statement of Non-Compliance, if different from the above.
- The relevant Marketing Authorisation Holder(s).

The report has been shared with the National Competent Authorities of the countries in which distribution of the affected batches is anticipated and that any comments from those authorities have been taken into account.

4. Written confirmation has been obtained from the National Competent Authorities in whose territories the affected batches are intended to be distributed that the product is considered critical on its territory, and that there is no objection to distribution.
5. The Supervisory Authority has been informed, if different from the above, and it has not suspended or revoked the relevant Manufacturing Authorisation.
6. The affected Marketing Authorisations have not been revoked or suspended.
7. Any further conditions imposed by the Supervisory Authority and other involved National Competent Authorities are met.

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[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and Art. 94(2) of Regulation (EU) 2019/6, as amended, is also applicable to importers.*

[2] *See Appendix 3 of the relevant procedure in the Compilation of Union Procedures.*

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 1.2.1.13 Tablets 1.2.1.17 Other: Sachets and Pellets(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: Sachets and Pellets(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

Please note that the site details are: BDA Healthcare Pvt. Ltd., B-1, B-2, B-3, MIDC, Near Govt. ITI, Parseoni, Nagpur, Maharashtra, 441105, INDIA

Part 3

1.Nature of non-compliance:
First GMP inspection performed at the above-mentioned site by an EU Competent Authority on the 3rd – 8th December 2022. The company applied for a GMP certificate with the scope of non-sterile medicinal products, including capsules, hard shell; tablets (coated and uncoated); sachets and pellets. Microbiological non sterility and chemical/physical QC control are also carried out at this site. The inspectors found four critical, five major and seven other deficiencies. The Inspection Review Group (IRG) meeting at the Malta Medicines Authority has met and decided that a Statement of Non-Compliance with the principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC is to be issued about the site. Main inspection findings: Four critical and five major deficiencies were found during the course of this inspection. The critical findings are related to -data integrity issues -issues found in the quality control laboratory -qualification and validation activities -manufacturing activities, Good Manufacturing Practice and relevant manufacturing areas Major deficiencies were found in the areas of: -archival of GMP documentations -supplier qualification and approval -sampling of starting materials -Technical Agreements -Quality Management System, including Quality Risk Management For further details the post-inspection letter (dated: 28th December 2022) that lists all findings is available by request. Since this site does not have a valid EU GMP certification no medicinal products should be on the European market.
Action taken/proposed by the NCA

Others
No marketing authorisation applications, line extensions or variations to existing marketing authorisations, applications should be authorised with this site as a new site of manufacture.

Additional comments
-Draft supervisory Risk Assessment was circulated through the rapid alert network on the 9th of January 2023 and no comments or objections were received, the Malta Medicines Authority issued a statement of GMP non-compliance on the 17th of January 2023. -The 3rd country finished product manufacturer was informed with this decision accordingly.

2023-01-17

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

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Confidential
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