Malta Medicines Authority

Report No: ***MT/002NCR/2024***

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: ***Emil Pharmaceutical Industries Private Limited***
Site address: ***Plot No J 76, M.I.D.C. Tarapur, Dist Palghar, Boisar, 401506***
OMS Organisation Id. / OMS Location Id.: ***ORG-100052208*** / ***LOC-100091903***

Other
Directive (EU) 2017/1572

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-05-15***, 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 (EU) 2017/1572 and/or Commission Delegated Regulation (EU) 2017/1569, as reflected by the product categories stated in Part 2.

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
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Part 3

1.Nature of non-compliance:
An initial onsite GMP inspection was conducted, to assess compliance with EU GMP guidelines. During the onsite inspection, the inspectors observed 4 Critical, 11 Major and a total of 14 Other issues. Inadequate cross contamination measures, lack of good documentation practices leading to data integrity and traceability issues and inadequate packaging operations which were leading to mix ups were of critical concern. Major issues were related to ineffective training, lack of validation studies and control in production, deficiencies in sampling areas as well as in dispensing areas and storage areas, inadequate batch review and release processes, lack of sample and microbiology control and inadequate complaint handling. As a result of this outcome, the Inspection Review Group (IRG) 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 (EU) 2017/1572 is to be issued for the site.
Action taken/proposed by the NCA **Suspensionof the marketing authorisation(s)** Member states should consider whether the status of any ongoing marketing authorisation applications should be reviewed until the statement of non-compliance remains in place.
Additional comments Draft supervisory risk assessment has been circulated through the rapid alert network for any comments by NCAs with deadline for responses set to the 18th June 2024 (1 week from date of issue). No replies were received, confirming that there are no medicinal products on the EU/EEA market and no critical medicinal products on MRA partner markets.

2024-07-02

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

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Confidential
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