Bezirksregierung Duesseldorf

Report No: ***24.05.05.01-Neuraxpharm***

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 Germany confirms the following:
The manufacturer: ***Zim Laboratories Limited***
Site address: ***B 21/22 M.I.D.C. Area, Kalmeshwar, Nagpur, 441501, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100024947*** / ***LOC-100034137***

Other
(Human) (EG) 726/2004 Art. 19 (3)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-07-04***, 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 1.2.1.8 Other solid dosage forms: Orodispersible films, powder for oral suspension (bulk, finished product), sublingual films(en) 1.2.1.13 Tablets 1.2.1.17 Other: intermediate product(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Orodispersible films, powder for oral suspension (bulk, finished product), sublingual films(en) 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:
1. Nature of non-compliance: The inspection was carried out as EMA centralised GMP inspection by the Local Government of Düsseldorf as lead authority and INFRAMED I.P: as supporting authority between 28th June and 4th July 2025. The company applied for a GMP certificate with an scope of: Tablets, capsules, powder for oral suspension, oro-dispersible firlms ,sublingual films, primary packaging, secondary packaging quality control, storage and distribution. During the inspection two critical and seven major findings were observed so that the inspection team decided that a statement of non-compliance with the principles and guidelines of GMP laid down in Commission Delegated Regulation (EU) No. 1252/2014 and Commission Directive 2003/94/EC of 8th October 2003 is to be issued about the site. The GMP inspection report will contain more details about the origin of the non-compliance and will be available at EMA shortly. The critical findings are related to critical deficiencies in data integrity throughout relevant documents such as log books, CoAs and maintenance reports as well as fraud on one logbook of the HVAC in building No. 1. The major findings are related to inacceptable conditions during the production of pellets within the manufacturing room (sticky and dirty ground floor), no quality assurance control performed on specifications, sampling booth in building No. 6 with unlocked and uncontrolled backdoor and unlockable doors, unvalidated use of excel for QC calculations, non-functional differential pressure throughout several corridors, non-investigated temperature deviations in stability study room in building No. 1, no environmental monitoring in all GMP areas and unclean cleaning-equipment in LAFs.
Action taken/proposed by the NCA

Others
Market actions should be determinated by each Member State based on QRM principles in order to avoid shortages of medical products in the market. Additionally, no marketing authorisation applications, line extensions or variations to existing marketing authorisation applications should be authorised for the time being. No GMP certificate should be issued unless a further inspection finds this site to be fully compliance. Finally, member states are recommended to on contact the corresponding MAHs for NAPs/MRPs/DCPs for product specific impact assessments.

2025-07-11

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

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Confidential
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