Malta Medicines Authority

Report No: ***MT/002NCR/2025***

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: ***Vinlab Pharma (Pty) Ltd.***
Site address: ***Bosmans Crossing, Vinlab Building Distillery Road, Stellenbosch, 7600, South Africa***
OMS Organisation Id. / OMS Location Id.: ***ORG-100053643*** / ***LOC-100094861***

Other
(Human) Directive (EU) 2017/1572

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-04-13***, 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;	
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

Part 3

1.Nature of non-compliance:
Following an on-site inspection at Vinlab Pharma (Pty) Ltd. in South Africa (10–13th April 2025) for the analytical testing (chemical and microbiological) of non-sterile dosage forms, specifically for Cannabis medical products (inflorescence), the draft post-inspection letter's critical and major deficiencies were reviewed by the Inspectors' Review Group (IRG). The inspection aimed to evaluate the company's eligibility for EU GMP certification. The inspection resulted in the identification of four critical and three major deficiencies. The critical findings were concerned with Validation and Qualification activities and QC Chemistry and Micro analytical operations, whilst the major deficiencies were concerned with risk considerations and risk assessments, deviation management and IT systems and their back-ups with serious data integrity implications, amongst others. During the inspection it was confirmed that the company does not currently perform any analytical testing for products on the EU/EEA market. Based on these findings, the IRG concluded that EU GMP certification could not be granted, and a statement of non-compliance with GMP will be issued as per the Compilation of Union Procedures.
Action taken/proposed by the NCA **Revocationof the marketing authorisation(s)** Member States should consider refraining from initiating or authorizing marketing authorization applications that list this site as a finished product analysis site whilst the recommended non-compliance statement is issued and remains in place.
Additional comments A draft supervisory risk assessment and non-compliance statement was circulated through the rapid alert network for any comments by NCAs with a deadline for responses set to the 14th of May 2025 (1 week from date of issue). No replies were received as of 15th May 2025, thus confirming that there are no medicinal products on the EU market and no critical medicinal products on MRA partner markets using this site for analytical services. Therefore, the draft supervisory risk assessment and non-compliance statement along with their recommendations will be implemented. The company shall be notified accordingly.

2025-05-15

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

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