Malta Medicines Authority

Report No: ***MT/001/NCR/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: ***Karoo Bioscience (Pty) Ltd.***
Site address: ***Portion 13 Of 211, Farm Opzoek, Van Wyksdorp, Western Cape, 6690, South Africa***
OMS Organisation Id. / OMS Location Id.: ***ORG-100054569*** / ***LOC-100096733***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-04-07***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC and an appropriate level of GMP as referred to in Article 46(f) of Directive 2001/83/EC.

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;

1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.17 Other non-sterile medicinal products: inflorescence in 10g patient pouches(en)

Clarifying remarks (for public users)

The site was inspected against EU GMP Part 1 for finished products (inflorescence in patient pouches)

Part 3

1.Nature of non-compliance:

Following an on-site inspection at Karoo Bioscience (Pty) Ltd. in South Africa (4–7th April 2025) for non-sterile cannabis-based medicinal products, 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. Three critical and five major deficiencies were identified, including inadequate facility and equipment qualification, insufficient process validation, and limited GMP expertise within Quality Assurance. Major issues also involved poor risk assessments, weak documentation and data integrity controls, and deficiencies in line clearance, deviation management, and sampling practices. The company currently has no 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

Others

Member States should consider refraining from initiating or authorizing marketing authorization applications that list this site as a finished product manufacturing site until the recommended non-compliance statement is issued and remains in place.

Additional comments

Draft supervisory risk assessment is being circulated through the rapid alert network for any comments by NCAs with deadline for responses set to the 7th of May 2025 (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.

2025-05-12

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

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Confidential
Malta Medicines Authority
Tel:***Confidential***
Fax:***Confidential***