Landesamt Fuer Gesundheit Und Soziales

Report No: ***DE_BE_01_NC_2025/01***

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: ***Mera Cannabis Corp.***
Site address: ***27 Sparling Road, St Thomas, N5P 4A4, Canada***
OMS Organisation Id. / OMS Location Id.: ***ORG-100050193*** / ***LOC-100087634***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-07-30***, 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
	1.4.1.3 Other: dried cannabis flowers as bulk and cannabis extracts as bulk(en)
1.5	**Packaging**
	1.5.1 Primary Packaging
	1.5.1.17 Other non-sterile medicinal products: dried cannabis flowers as bulk and cannabis extracts as bulk(en)

4. Non-Compliant Other Activities - Active Substances:
Raw cannabis extract, Dronabinol, Live Resin, Live Rosin

Part 3

1.Nature of non-compliance:

The inspection was conducted between 24th and 30th of July 2025. During the inspection ten major findings were observed, whereas one major finding was related to an external warehouse, which was not finalized yet and has no impact on the current production, and one was related to the process validation of planned products. The other major findings were related to the purchase of dried cannabis flowers from non-GMP facilities, to a missing calibrated and validated monitoring system for environmental conditions, to stability studies, to a non-functional management system for documents, samples, equipment and products, to data integrity and to qualification of facilities. Partially, it was conducted that not all corrective actions of observations from the initial inspection were taken although these were confirmed by the company. Therefore, a follow-up inspection is necessary.

Action taken/proposed by the NCA

Recall of batches already released
Since the certificate was issued, several batches have been imported into the EU. The decision on a recall is at the discretion of the respective competent authorities. The competent authority of Berlin decided to recall the only batch from the market that was imported so far from the Berlin importer. Since only one pharmacy was affected, no Rapid Alert Notification was issued.

Prohibition of supply
No further batches should be imported and supplied to the market until GMP compliance was confirmed through an inspection.

Additional comments
It is not necessary to restrict or revocate the GMP certificate No. DE_BE_01_GMP_2023_0085. The GMP certificate was issued with the inspection date of 8th of september 2022 and is not valid anymore. No GMP certificate should be issued unless a further inspection founds this site to be fully compliant. The responsible authorities were given the opportunity to comment on the draft.

2025-09-11

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

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