*State Institute For Drug Control*

Report No: ***sukls159106/2024***

# 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 CZECHIA confirms the following:
The manufacturer: ***Elkoplast Slusovice s.r.o.***
Site address: ***Ostrata 13/13, Ostrata, 763 11, CZECHIA***
OMS Organisation Id. / OMS Location Id.: ***ORG-100015467*** / ***LOC-100024186***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-08-13***, 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.

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

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| 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;

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|---|---|
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.1 Manufacture of*<br>1.4.1.3 Other: API(en) |

Manufacture of active substance. Names of substances subject to non-compliant:
***CANNABISFORMEDICINALUSE(en)***

## Part 3

**1.Nature of non-compliance:**

In total 21 deficiencies were identified by the inspection team, two as critical and 16 as major. The critical deficiencies were identified in batch production documentation and personnel responsibilities, the major deficiencies in most of the GMP areas with regards to change control, suppliers´ qualification, training, validation and qualification, documentation management, risk assessment and stability studies. The company had been subjected to 4 previous inspections, these inspections had defined similar issues as were observed during the current inspection indicating a lack of QA oversight and inadequate approach with regard to addressing the issues identified during GMP inspections. Based on the number and severity of the major observations and also two critical deficiencies, the inspector team concluded that the inspected company cannot be considered as in compliance with EU GMP Part II and that the combination of deficiencies identified constitutes a critical risk of production which could be harmful to patients. Here below the Critical deviations: [Critical 1] No records are kept on the production of active substances. Records of the primary and secondary packaging of batches EP 23 25092023 and EP00.08012024 were not kept. Eudralex Vol. 4 Part II, paragraphs 2.4 and 6.5 [Critical 2] The organizational structure of the company described in the SMF is not in accordance with the submitted documents (job descriptions, staff contracts and other documents). Responsibilities of managers are not defined. Eudralex Vol. 4 Part II, paragraphs 3.10 and 3.11

**Action taken/proposed by the NCA**

**Withdrawal, of current valid GMP certificate No. sukls83218/2023**
Withdrawal of current GMP certificate

**Prohibition of supply**
Prohibition of supply

*2024-12-02*

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

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