State Institute For Drug Control

Report No: ***sukls397498/2025***

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. 63 of Regulation (EU) 536/2014 as amended

The competent authority of Czechia confirms the following:
The manufacturer: ***Fagofarma s.r.o.***
Site address: ***Vltavska 53, Roztoky, Stredocesky, 252 63, Czechia***
OMS Organisation Id. / OMS Location Id.: ***ORG-100050191*** / ***LOC-100087938***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-11-12***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- Commission Delegated Regulation (EU) 2017/1569

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 Investigational 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;

1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.17 Other: lyophilized tablets(en)
	1.2.2 Batch certification
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.8 Other: biotherapeutic products based on microorganisms and bacterial lyzates(en)
	1.3.2 Batch Certification (list of product types) 1.3.2.8 Other: biotherapeutic products based on microorganisms and bacterial lyzates(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.17 Other non-sterile medicinal products: lyophilized tablets(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical *1.6.4 Biological*

Part 3

1.Nature of non-compliance:
The inspection team identified a total of 25 deficiencies: three classified as critical, 17 as major and 5 as minor. Two critical deficiencies concerned the implementation of the pharmaceutical quality system and the knowledge, experience, and number of qualified personnel. The third critical deficiency related to the certification of manufactured preparations and the maintenance of a register of manufactured and certified batches. The principal deficiencies across most areas of GMP involved missing or inadequate records of deviation investigations, change management, training, validation and qualification, documentation management, risk assessment, and stability studies. Critical deficiencies: 1: The pharmaceutical quality system, including good manufacturing practice, is not functional. The system has not been implemented and properly documented, and the monitoring of its effectiveness is not based on real data and quality risk management. Records were either missing or incorrect. 2: The company employs six staff workers. Since the last inspection, three personal changes have occurred in the area of plant management and quality assurance. New employees, in some areas, do not have sufficient knowledge and experience to perform and supervise the relevant activities. 3: The register of manufactured batches is maintained only in an Excel spreadsheet. The inspected entity failed to provide evidence of certification of several batches by a Qualified Person.
Action taken/proposed by the NCA **Withdrawal, of current valid GMP certificate No. sukls218594/2023** NCR **Suspension of clinical trials** Suspension of clinical trials (if any) is recommended

2025-12-16

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

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