Austrian Medicines and Medical Devices Agency

Report No: ***INS-482723-12976686***

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. 80(7) of Directive 2001/82/EC as amended
Art. 111(7) of Directive 2001/83/EC as amended

The competent authority of Austria confirms the following:
The manufacturer: ***Lupuca Pharma GmbH***
Site address: ***Gewerbering 4, Grafenwörth, 3484, Austria***

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-05-14***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC and Directive 91/412/EEC.
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/EEC.
- 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.

---

[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
Veterinary 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;

1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: bath additive(en) 1.2.1.11 Semi-solids 1.2.1.12 Suppositories 1.2.1.13 Tablets
	1.2.2 Batch certification
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.1 Herbal products 1.4.1.2 Homoeopathic products
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: bath additive(en) 1.5.1.11 Semi-solids 1.5.1.12 Suppositories 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

4. Non-Compliant Other Activities - Active Substances:

The authorisation for Distribution of Active Substances is revoked. No active substance has ever been distributed by the Company.

Clarifying remarks (for public users)

Restricted to the manufacturing, quality control and distribution of Labisan Fieberblasensalbe, Osanit Zahnungszäpfchen, Darmol Dragees, AMO Varroxal 85% Ameisensäure-Lösung zum Verdunsten im Bienenstock für Honigbienen, Lactat-oral "Wabo" flüssig, Salhumin Rheuma Bad and Hydrosan Tabletten; The following manufacturing operations are not limited to a certain product: primary packaging of non-sterile products, secondary packaging of non-sterile products and labeling of medical samples. valid until 06/2020

Part 3

1.Nature of non-compliance:
The company held a restricted manufacturing authorisation until 30 June 2020. Based on the evaluation of the company's CAPA plan the manufacturing authorisation cannot be prolonged. Major systemic deficiencies in the areas of supplier qualification, change management, deviation management, qualification of equipment, validation of computerised systems and good documentation practice could not be resolved.
Action taken/proposed by the NCA **Revocationof the manufacturing authorisation No. 482723in Full** **Withdrawal, of current valid GMP certificate No. 482723-0003** The company held a restricted GMP certificate valid until 30 June 2020. A new certificate will not be issued.

Products manufactured at site, if known	**Products**	**Dosage Form**	**Reference Member State, National or EMA**
Human Medicinal Products	Labisan Fieberblasensalbe	Ointment	National (AT)
	Osanit Zahnungszäpfchen	Suppositories	National (AT)
	Darmol Dragees	Sugar-coated tablets	National (AT)
	Lactat-oral "Wabo" flüssig	Liquid for internal use	National (AT)
	Salhumin Rheuma Bad	Bath additive	National (AT)
	Hydrosan Tabletten	Tablets	National (AT)
Veterinary Medicinal Products	AMO Varroxal 85% Ameisensäure-Lösung	Liquid for external use	National (AT)

2020-06-30

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

---

Confidential
Austrian Medicines and Medical Devices Agency
Tel:***Confidential***
Fax:***Confidential***