Italian Medicines Agency

Report No: ***IT/NCR/01/H/2026***

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 Italy confirms the following:
The manufacturer: ***Avlab S.r.l.***
Site address: ***Via Emilio Morosini 22, Milan, MI, 20135, Italy***
OMS Organisation Id. / OMS Location Id.: ***ORG-100050435*** / ***LOC-100088037***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-06-24***, 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 (EU) 2017/1572

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;	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.4 Biological

Clarifying remarks (for public users)

Production based on article 5 Decree nb. 219/2006; 1.1.3 Batch certification: products aseptically prepared; 1.6.4 Biological: LAL test. This NCR refers to the manufacturer AVLAB S.R.L. Legal address VIA EMILIO MOROSINI, 22 - 20135 MILAN (MI) Site address VIA TETTI GAY, 59 - 10091 ALPIGNANO (TO)

Part 3

1.Nature of non-compliance:
An inspection performed by AIFA between 22 and 24 June 2026 identified serious and systemic deficiencies affecting the Pharmaceutical Quality System and the implementation of EU GMP requirements applicable to aseptic preparation of parenteral nutrition products. Twelve major deficiencies were identified. • Pharmaceutical Quality System deficiencies. • Inadequate documentation and data integrity controls. • Deficiencies in computerized systems validation and electronic data management. • Inadequate Contamination Control Strategy. • Deficiencies in aseptic process simulation (APS/media fill). • Deficiencies in environmental and microbiological monitoring. • Inadequate qualification and validation activities. • Deficiencies in personnel training, supplier qualification and quality control oversight.
Action taken/proposed by the NCA **Withdrawal, of current valid GMP certificate No. IT/265/H/2024** Regulatory Action Taken A Statement of Non-Compliance with GMP has been issued. Suspension of the manufacturing authorization No. aM-194/2024. While a state of non-compliance with GMP requirements was identified, the Inspection Team also took into account the nature of the medicinal products manufactured at the site, which are intended for patients receiving parenteral nutrition and therefore constitute essential and potentially life-sustaining therapies. Based on the inspection findings, no evidence emerged indicating an immediate and concrete

risk to patient health associated with batches already manufactured and distributed. Consequently, following a risk-benefit assessment, which was considered favourable to the continued use of the medicinal products already supplied, the Inspection Team does not consider it necessary, based on the information currently available, to recommend the recall of batches already manufactured and distributed.

Others

The site manufactures sterile parenteral nutrition preparations exclusively on a medical prescription basis pursuant to Article 5 of Directive 2001/83/EC, as transposed into Italian legislation by Legislative Decree No. 219/2006. Parenteral nutrition preparations are supplied exclusively to the Italian market on a medical prescription basis (Article 5 of Directive 2001/83/EC). No actions for other countries are needed.

Additional comments

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2026-07-23

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

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Confidential
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