Pharmaceutical Services Ministry Of Health

Report No: ***NCALG/2024/001***

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 Cyprus confirms the following:
The manufacturer: ***Algorithm s.a.l.***
Site address: ***Sea Road Zouk Mosbeh, P. O. Box 11-962, Beirut, 1107 2060, LEBANON***
OMS Organisation Id. / OMS Location Id.: ***ORG-100034180*** / ***LOC-100054078***

Other
(Human) Directive (EU) 2017/1572
Distant Assessment

From the knowledge gained during Distant Assessment of this manufacturer, the latest of which was conducted on ***2023-10-05***, it is considered that**it does not comply with the Good Manufacturing Practice** requirements referred to in

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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;

1.2	**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
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The inspection was limited to non-sterile liquid dosage forms

Part 3

1.Nature of non-compliance:

Following the inspection, the team of the inspectors recorded 6 major deficiencies and 10 others all of which concerned failures in maintaining controlled environment such as pressure cascade, ineffective measures for cross-contamination such as improper handling of frequent power cuts, quality control issues, absence of toxicological evaluation of the multi production facility, inadequate presentation of the process validation, use of materials which may elevate the risk of contamination, warehouse issues such as limited space and lighting, improper gowning procedures and other document system failures. Since 2023 the company has managed to address some of the findings (major and other) however, failed to provide adequate rectifications within timeframe agreed on maintaining pressure cascade in liquid production line.

Action taken/proposed by the NCA

Recall of batches already released

No.

Prohibition of supply

Prohibition of supply from the date of issue and until this statement remains in place. No recall of any products will be enforced.

Others
The GMP certificates No. ALG01/20 & ALG01/2017 are suspended.

Additional comments
A draft supervisory risk assessment was circulated through the rapid alert network for comments by NCAs with a deadline for responses until 12th of November 2024 (1 week from the date of issue). No replies were received as of 13th November 2024 and therefore all the recommendations will be implemented.

2024-11-20

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

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Confidential
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