*Swedish Medical Products Agency*

Report No: ***6.2.1-2024-045524***

# 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 Sweden confirms the following:
The manufacturer: ***Amara Labs Private Limited***
Site address: ***Plot No 73c/4, Anrich Industrial Estate I D A Bollaram, Sangareddy, Jinnaram, Telangana, 502325***
OMS Organisation Id. / OMS Location Id.: ***ORG-100039458*** / ***LOC-100062151***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-03-14***, 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; | |
| **1.4** | **Other products or manufacturing activity** |
| | *1.4.3 Other: Active substance(en)* |

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

## Part 3

| **1.Nature of non-compliance:** |
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| During this inspection 16 deficiencies were identified, classified as critical (1), major (9) and "other" (6). D1[Critical]: Insufficient knowledge of current EU GMP requirements, ineffective quality risk management measures applied and evident lack of QA oversight, D2[Major]: Failure to report a major production accident, D3[Major]: Evidence of data falsification, D4[Major]: Several GMP critical computerised systems in the QC laboratory lacked validation, D5[Major]: Significant deficiencies identified concerning design, conditions of facilities and equipment across all manufacturing areas, D6[Major]: Inadequate cleaning of manufacturing equipment, D7[Major]: No provisions in place to assess risks associated with manufacturing APIs and intermediates in shared facilities, D8[Major]: Inadequate approach to cleaning validation and not consistently applied to all products. D9[Major]: Insignificant process for handling changes, including procedures for introducing new chemical entities. D10[Major]: Insufficient evaluation of drying process activities carried out during process validation and technology transfer. |
| **Action taken/proposed by the NCA**<br><br>**Prohibition of supply**<br>The non-compliance affects all APIs and intermediates manufactured at the site. Therefore, no new MAs should be approved where APIs or intermediates from this site is used, as long as the non-compliance statement is active. In those cases where APIs or intermediates from this site are included in current MAs, the use of alternative suppliers should be considered. The recommendations are valid for all APIs / intermediates manufactured at the site since the nature of the findings is general and not specific to Irbesartan. Actions on Marketing Authorisations should be assessed by the respective licensing authority covering MAs which include APIs and intermediates manufactured by the inspected firm.<br><br>**Suspension or voiding of CEP (action to be taken by EDQM)**<br>CEP 2020-260 – Irbesartan Process II was suspended by EDQM April 29, 2024, as well as the other impacted CEPs associated with this site. |
| **Additional comments**<br>The inspection was performed in the frame of the EDQM inspection programme. |

***2024-06-26***

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

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