Health And Youth Care Inspectorate

Report No: ***NL/H 25/2058195***

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 Netherlands confirms the following:
The manufacturer: ***Sun Pharmaceutical Industries Limited***
Site address: ***District Sirmour, Paonta Sahib, Village Ganguwala, 173025, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100008538*** / ***LOC-100018019***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-12-31***, 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;

1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.13 Tablets
	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 non-compliance is limited to the following list of products directly involved in one of the critical findings (see Part 3): Atorvastatin tablets, Isotretinoin capsules, Olanzapine tablets, Candesartan tablets, Levetiracetam tablets, Esomeprazole capsules, Esomeprazole tablets, Gliclazide tablets, Pantoprazole tablets, Perindopril tablets, Ramipril tablets, Rosuvastatin tablets and Valsartan tablets.

Part 3

1.Nature of non-compliance:

Critical finding #1: Impact assessments of major deviations, which have impact on the validated status of the process, are not performed sufficiently, and in a timely manner. Impact on batches in the market is insufficiently assessed. This was observed in 13 out of 57 assessed products marketed in the EU, namely: Atorvastatin tablets, Isotretinoin capsules, Olanzapine tablets, Candesartan tablets, Levetiracetam tablets, Esomeprazole capsules, Esomeprazole tablets, Gliclazide tablets, Pantoprazole tablets, Perindopril tablets, Ramipril tablets, Rosuvastatin tablets and Valsartan tablets.
Critical finding #2: The extent to which SPL communicates significant product quality-related issues with the EU batch release site and EU authorities is not sufficient. The involvement of the EU QP in any ongoing investigations, rejections, OOS/OOT results and other notifications, which could affect the quality of EU products is insufficient. Involvement of the EU-QP in the product assessment reports could not be demonstrated. EU-QP involvement was only demonstrated during recalls.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. NL/H 24/2049272
IGJ has the intention not to grant a new GMP certificate and to issue a Non-Compliance Statement upon finalization of the inspection report. This proposed decision was communicated with the company upon receival of the draft inspection report from IGJ. Following this decision the current GMP certificate (NL/H 24/2049272) previously granted based on the previous inspection in October 2023 will be withdrawn from EudraGMDP. Because of the second critical finding, IGJ has decided to not follow the option of issuing a partial GMP certificate. A re-inspection will be performed on the basis of the company plan of action to address the deficiencies (currently not scheduled yet). After a positive result following the re-inspection a new GMP certificate will be issued and this Non-Compliance Statement withdrawn.

Recall of batches already released
At present, IGJ is awaiting an assessment which products are considered critical for the Dutch market. At the same time, IGJ is awaiting an impact assessment from the MAH for continued batch certification. Therefore, currently not all information is available to determine whether a recall is deemed necessary based on the critical findings. IGJ is only considering market actions for the 13 products that are in scope of the first critical finding (see restrictions in Part 2). Each Member State is asked to determine, based on the provided product list of this Sun-site, which medicinal products are considered critical for the national market. In case IGJ decides on market actions required, a rapid alert will be initiated separately.

Additional comments
Not applicable

Teleconference Date	2026-03-23	**Teleconference Time (CET)**	15:30	**Dial in no.**	Teams invitation

Products manufactured at site, if known	Products	Dosage Form	Reference Member State, National or EMA
Human Medicinal Products	Atorvastatin	tablets	National, NL amongst others
	Isotretinoin	capsules	National, NL amongst others
	Olanzapine	tablets	National, NL amongst others
	Candesartan	tablets	National, NL amongst others
	Levetiracetam	tablets	National, NL amongst others
	Esomeprazole	tablets and capsules	National, NL amongst others
	Gliclazide	tablets	National, NL amongst others
	Pantoprazole	tablets	National, NL amongst others
	Perindopril	tablets	National, NL amongst others
	Ramipril	tablets	National, NL amongst others
	Rosuvastatin	tablets	National, NL amongst others
	Valsartan	tablets	National, NL amongst others

2026-03-30

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

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