Agency For Medicinal Products And Medical Devices Of Croatia

Report No: ***530-10/26-06/03; 381-13-08/366-26-06***

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 Croatia confirms the following:
The manufacturer: ***Swiss Parenterals Limited***
Site address: ***808 809 And 810 Kerala Industrial Estate, GIDC Near Bavla, Ahmedabad, Gujarat, 382220, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100033193*** / ***LOC-100051804***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-03-13***, 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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Powder for solution for injection or infusion(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
1.5	**Packaging**
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

1.6.4. Refers to bacterial endotoxin testing.

Part 3

1.Nature of non-compliance:

Onsite inspection identified 7 critical and 9 major deficiencies. Critical deficiencies relate to: 1. The pharmaceutical quality system does not effectively encompass the specific requirements for sterile product manufacturing, as evidenced by inadequate deviation management and the lack of effective implementation of risk management and risk-based decision-making. 2. During the observation of production activities and review of selected smoke studies it was noticed that interventions were often poorly designed, and aseptic techniques, operators qualification, training, behaviour, and practices in many cases did not comply with the requirements of EU GMP Annex 1. 3. The manufacturer failed to supply the requested documentation promptly and transparently during the inspection. There are concern about authenticity and control of documentation, and there is insufficient assurance that records are attributable and contemporaneously generated. 4. Deficiencies were identified in the design of premises and equipment (including lack of appropriate barrier systems), handling of disinfectants, garment washing procedures, coverage of all processes during APS, omission of products from cleaning validation matrices, inadequate design of airflow visualisation studies, and absence of a validated procedure for CCIT of ampoules. 5. Inadequate equipment and process design for dispensing, sampling and blending, as well as inadequate design of manual interventions manual interventions related to handling of sterile powders. 6. Inadequate material transfer pathways and processes. 7. Inadequate OOS investigations. The major deficiencies are related to: pharmaceutical quality system, sanitary/hygienic practices, premises and equipment, production, quality control, qualification and validation, aseptic process simulation (media-fill), cleaning validation and cleaning practices, computerized systems.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. 530-10/24-06/07, 381-13-08/284-25-13
Current certificate 530-10/24-06/07; 381-13-08/284-25-13 will be withdrawn.

Suspensionof the marketing authorisation(s)
Member States should consider not authorising marketing authorisation applications/variations to marketing authorisations with this site listed as a finished product manufacturing site until the non-compliance statement remains in place.

Recall of batches already released
Recall of medicinal products should be considered where potential quality defect has greater impact to public health than supply restriction in affected Member State(s).

Prohibition of supply
Following issuance of the final Statement of non-compliance with the principles and guidelines of GMP and as long as it remains in place, the prohibition of importation and/or supply from the site should be considered.

2026-04-17

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

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Agency For Medicinal Products And Medical Devices Of Croatia
Tel:***Confidential***
Fax:***Confidential***