Spanish Agency Of Medicines And Medical Devices

Report No: ***PE010-4529***

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. 94(2) of Regulation (EU) 2019/6 as amended

The competent authority of Spain confirms the following:
The manufacturer: ***Super's Diana S.L.***
Site address: ***Carretera C-17 Km 17, Parets Del Valles, 08150, Spain***
OMS Organisation Id. / OMS Location Id.: ***ORG-100013280*** / ***LOC-100059616***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-12-12***, 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 91/412/EEC. Article 93(2) of Regulation (EU) 2019/6

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

Veterinary 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 Special Requirements 1 B-lactam Antibiotics 7 Other: Hormones or substances with hormonal activity(en) 1.1.1.4 Small volume liquids Special Requirements 1 B-lactam Antibiotics 7 Other: Hormones or substances with hormonal activity(en)
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification

Part 3

1.Nature of non-compliance:

- Pharmaceutical quality system implemented in the company does not allow for adequate identification of risks and the adoption of the necessary measures to avoid them and ensure the quality of the medicinal products manufactured in the facility. Deviations, OOS, OOT management is very poor and no appropriate corrective and preventive actions are taken in response to the investigations. - The Company has not enough qualified personnel to be able to manage the Pharmaceutical Quality System to assure an adequate level of quality and safety for the veterinary medicines manufactured. - There is a lack of sterility assurance, including mayor deficiencies involving the aseptic process simulation (APS), as well as several deficiencies with Annex 1 of the EU GMP Guidelines in relation with non-viable and viable particle monitoring, sterility of primary packaging, qualification of sterile manufacturing rooms, sterilizing filters, among others. - Facilities are not adequately designed to provide assurance for the activities carried out and a poor state of maintenance was observed.

Action taken/proposed by the NCA

Suspensionof the manufacturing authorisation No. 0728in Part

Recall of batches already released

No specific quality defects on concrete batches present in the market were detected, and thus no action/recall is deemed necessary against concrete batches released and placed on the market. Recall of medicinal product is not suggested or it should be evaluated by the involved NCAs' following assessment conducted in conjunction with MAHs, if there are alternative suppliers and there is no risk of shortage.

Additional comments

The activity of manufacturing and batch certification of sterile medicinal products (corresponding to points 1.1.1.1, 1.1.1.4, 1.1.2.3 and 1.1.3 in the MIA authorisation) has already been suspended as a precautionary measure. This measure has been adopted due to the possible risk to animal/public health that may occur as a result of the criticality of the deficiencies identified during the inspection in relation to the activity of the aseptic processing of sterile medicinal products. This measure will be maintained until all the deficiencies observed in the inspection have been corrected and it has been verified, through a new inspection. This measure includes, in addition, the quarantine and prohibition of placing on the market any batch of sterile medicinal products manufactured by SUPER´S DIANA, S.L. located in its facilities.

2025-02-06

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

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