Spanish Agency Of Medicines And Medical Devices

Report No: ***PE010-5017***

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: ***Laboratorios Eurisko S.L.***
Site address: ***Nave 3, Poligono Industrial El Moli, Sant Iscle De Vallalta, 08359, Spain***
OMS Organisation Id. / OMS Location Id.: ***ORG-100019229*** / ***LOC-100037468***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-06-17***, 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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.6 Liquids for internal use
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.6 Liquids for internal use
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

Part 3

1.Nature of non-compliance:

During the inspection conducted on June 15-17th, 2026, critical and major deficiencies in compliance with EU Good Manufacturing Practices (GMP) were observed in the authorised facilities in building 3. In general, these deficiencies were related to an non-existent Pharmaceutical Quality System and, consequently, affecting all the site's authorised activities: poor or non-existent supplier approval, control and release of raw materials, facility maintenance and cleaning, access control, management of planned changes and deviations, personnel qualification and training, qualification/calibration control and equipment management, manufacturing operations, prevention of cross-contamination, comply with procedures, management of documentation and data integrity, among others. Furthermore, the inspection revealed an insufficient and ineffective monitoring of the company's review quality system activities, as deficiencies identified in previous inspections have not been addressed. These deficiencies pose a risk to the quality and safety of the veterinary medicinal products manufactured. It should be noted that the company has a history of non-compliance with EU GMP Guidelines according to previous inspection reports. The manufacturing authorisation (MIA) had been suspended in September 2022, following the inspection on November 2021, but suspension was lifted after the inspection on July 2023. In addition, the last day of inspection (June 17th) an adjacent building belonging to the company LABORATORIOS EURISKO, S.L. (located in the "El Molí" Industrial Park, building 1B) was inspected. This building was not declared in the Site Master File, and it is not authorised for the manufacture and/or storage of medicinal products and active substances. In building 1B inspectors found a large quantity of veterinary medicinal products in their final packaging (liquids for internal use and powders for oral solution), intermediates (bulk solution), active substances, starting materials, samples, and other non-medicinal products, such as supplements, as well as production equipment and manufacturing documentation (including delivery notes, invoices, and production records) related to veterinary medicines and active substances. All these materials, documents, and equipment were outside the control of the quality system, poorly identified, and managed in a manner that did not ensure their proper traceability, integrity, or preservation. It was demonstrated that unauthorised manufacturing activities of veterinary medicinal products were being carried out in building 1B without meeting any of the applicable quality requirements and controls and necessary guarantees, in compliance with Good Manufacturing Practices (GMP). It was also detected that distribution activities of active substances were being performed without registration in the applicable API Register. The unauthorised manufacturing activity performed in building 1B had not been detected in previous inspections, although it has been ongoing for several years, as evidenced by the documentation reviewed. Furthermore, based on the labelling of medicinal products and available customer invoices, it is evident that most part of the products are intended for export, for which the company lacks the required authorisations.

Action taken/proposed by the NCA

Suspensionof the manufacturing authorisation No. 6558in Full

Recall of batches already released

Recall of any medicinal product manufactured at LABORATORIOS EURISKO, S.L. is proposed.

Prohibition of supply

Taking into account the deficiencies identified during the inspection it is concluded that all the products manufactured by LABORATORIOS EURISKO, S.L. are affected by the GMP non-compliance. During the inspection, veterinary medicinal products containing the following actives substances with the pharmaceutical form liquids for internal use, powders for oral solution, solution for injection and intramammary suspension were found: Norfloxacin, Ciprofloxacin, Enrofloxacin, Kanamycin, Cephalexin, Tylosin tartrate, Doxycycline, Neomycin sulfate, Gentamicin, Erythromycin, Amoxicillin, Ivermectin, Amprolium, Albendazole, Sulfachloropyridazine, Acetylsalicylic acid, Florfenicol, Ampicillin trihydrate, Piperazine, Oxytetracycline, Chlortetracycline, Lincomycin, Trimethoprim, Metamizole, Diclazuril, Sulfadiazine, Spectinomycin, Tiamulin, Colistin sulfate, Tilmicosin sulfate. (non-exhaustive list). In building 3 one pilot batch STI15012025 and the three validation batches STI18122025A, STI18122025B and STI18122025C of Norfloxacin were legally manufactured since 2023. The pilot batch was released on 03/11/2025 destined for Bangladesh and the three validation batches were released on 01/03/2026 destined for Bangladesh, too. Veterinary medicinal products manufactured in the unauthorised facility were intended for distribution and export to Greece, Lebanon, Bangladesh, Siria, Oman, Yemen, Iraq and Lybia. The reviewed documentation indicates that exports of medicinal products to these countries have been carried out. Other destinations countries cannot be ruled

out. The reviewed documentation during the inspection indicates that the company has distributed and export active substances (Kanamycin, Cephalexin, Tylosin, Amoxicillin and Piperazine) to the following countries: Greece, Lebanon, Oman and Yemen. Other destination countries cannot be ruled out.

Additional comments

The activity of manufacturing and distribution of medicinal products and active substances was immediately suspended onsite 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 and findings identified during the inspection. 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 medicinal products and active substances located in its facilities. The current GMP certificate ES/152HV/23 has been withdrawn from EudraGMDP. A new inspection was performed in July 21-22nd, 2026, to follow up the precautionary measures adopted in June and to collect additional information (documentary evidence such as invoices and customs documentation) regarding the unauthorised manufacturing activities performed in building 1B, which was confirmed to have been carried out at least since 2023. It was demonstrated that exportation of veterinary medicinal products was not declared, since it was performed as supplements, avoiding the applicable mandatory inspection controls in customs. Veterinary medicinal products were found in addition to liquids for internal use and powders for oral solution, including sterile products (injectable and intramammary suspension). Among the documents, there are certificates issued by a registered veterinarian that have been falsified by the qualified person of LABORATORIOS EURISKO, S.L.

2026-07-13

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

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Confidential
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