Chief Pharmaceutical Inspectorate

Report No: ***IPN.41.10.2024.AWL***

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 Poland confirms the following:
The manufacturer: ***Przedsiebiorstwo Farmaceutyczne Okoniewscy Vetos Farma Sp. z o.o.***
Site address: ***Ul. Pocztowa 6, Bielawa, 58-260, Poland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100008386*** / ***LOC-100012701***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-02-21***, 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.

---

[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 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.16 Veterinary premixes
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.16 Veterinary premixes
	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*

Part 3

1.Nature of non-compliance:

An unannounced inspection was carried out in connection with the suspicion of conducting activities in the scope not covered by the registration in the National Register of Manufacturers, Importers and Distributors of Active Substances. The main assumptions during this inspection were to check the distribution chains of the active substance streptomycin sulphate and to verify the activities covered by the MIA. During the inspection 2 critical, 3 major and 1 finding classified as other were identified. The critical deficiencies concerned: - unauthorised sale of the active substance: Streptomycin sulphate, previously purchased for veterinary manufacture product Strepto 37.5; powder for solution for pigs. - unauthorised sale of 17 barrels of the active substance: Streptomycin sulphate s: L6A-220413-5 to retail customers, of which 5 were previously released for the manufacture of the medicinal product Strepto 37.5; powder for solution for pigs. - Sales of APIs as chemical substances to retail customers. - Lack of consistency and reliability of the entry in the “Batch Processing Records” for the calculation of the quantities of starting materials (including active substance) used in the manufacture of a batch of the veterinary medicinal product Strepto 37.5; powder for solution for pigs. There is no clearly defined link between the record and the production operation. - storage of APIs for sale under uncontrolled conditions, in a room not included in the Site Master File. - performing of inter-warehouse operations between the plant's warehouse and the chemical substances warehouse and waste warehouse that were not included in the SMF. The evidence gathered during the inspection shows that Vetos-Farma as the MIA holder purchases from APIs importers streptomycin sulphate, which should be used in the manufacture of the veterinary medicinal product Strepto 37.5; powder for solution for pigs. However, part of the purchased active substance is subject to further distribution to unknown customers by the Vetos-Farma without being authorised, i.e. not being entered in the National Register of Manufacturers, Importers and Distributors of Active Substances as distributors of active substances. Additionally, the manufacturer does not keep sales records enabling customers identification.

Action taken/proposed by the NCA

Revocationof the marketing authorisation(s)
Revocation of Manufacturing Authorisation No. 011/0233/15 of 4.10.2022 decision under case number NPA.402.2.2024.KWO.4

Additional comments
Based on the available data, all the medicinal products manufactured by Vetos-Farma have substitutes on the Polish market. No decision has been made to recall the products from the market

2024-09-23

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

---

Confidential
Chief Pharmaceutical Inspectorate
Tel:***Confidential***
Fax:***Confidential***