Medicines Evaluation Board

Report No: ***V2059716 2026-3158557***

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 Netherlands confirms the following:
The manufacturer: ***Veyx-Pharma B.V.***
Site address: ***Forellenweg 16, Raamsdonksveer, 4941 SJ, Netherlands***
OMS Organisation Id. / OMS Location Id.: ***ORG-100012404*** / ***LOC-100021420***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2025-12-04***, 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 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other 1.1.1.3 Semi-solids Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other 1.1.1.4 Small volume liquids Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other 1.1.1.6 Other Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.1 Large volume liquids Special Requirements 2 Other highly sensitising materials 7 Other 1.1.2.3 Small volume liquids Special Requirements 2 Other highly sensitising materials 7 Other
	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 Special Requirements 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other 1.2.1.6 Liquids for internal use Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other 1.2.1.11 Semi-solids Special Requirements 1 B-lactam Antibiotics 2 Other highly sensitising materials 6 Ectoparasiticides 7 Other
	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 1.5.1.11 Semi-solids
	1.5.2 Secondary packaging

Part 3

1.Nature of non-compliance:

A GMP re-inspection of the site was performed on 2, 3 and 4 December 2025. Three critical, two majors and sixteen other deficiencies were identified. The three critical deficiencies were regarding the following: 1. In Unit A (building A), the water quality of the purified water (PW) does not meet the specifications for microbial contamination (<100 CFU/ml) for purified water, which poses risks to animal safety and public health. Purified water may contain microbes in accordance with the requirements of the European Pharmacopoeia, but Produlab Pharma has repeatedly measured exceedances both in the installation and at the point of use (before the filter). This purified water has been used in non-sterile veterinary medicinal products specifically produced in unit A, for cleaning product contact materials for all veterinary medicinal products produced in unit A, and as source water for the WFI (water for injection) installation in unit A. 2. Produlab Pharma manufactures aseptically prepared products in Unit B (building B), where environmental and process monitoring (including personal monitoring) data systematically fail to meet the limits set out in Annex 1 of the EU GMP. This means that the risks of product contamination with microorganisms, particles, and endotoxins/pyrogens are not sufficiently minimized. The quality of the veterinary medicines is insufficiently guaranteed and poses a risk to animal safety and public health. Since the previous inspection, where the same issue was identified, the QPs have released four batches in which contamination was found at the most critical locations near the final filling point of the product (three times at the sedimentation plate next to the filling needle and once on the turntable in the A room). The contamination found on the settle plate in close proximity to the filling needle poses a risk that the product may have become contaminated. No sterilization step takes place after filling. The exceedances were not demonstrably taken into account during release, which therefore did not take place in accordance with Annex 16 EU GMP and the company's own procedure. 3. Dismissing abnormal results found during quality control of veterinary medicines during monitoring, release, and stability testing is standard practice at Produlab Pharma. This poses risks to animal welfare and public health. In doing so, Produlab Pharma is not following its own OOS procedure and is not complying with contractual agreements on reporting OOSs to customers. The cause of the abnormal results is not investigated and/or no action is taken.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. NL/V 24/0023

The competent authority is not granting a new GMP certificate because of GMP NC which was determined by the Dutch Inspectorate during the inspection in December 2025. This decision has been sent to the company by means of an official decision on the 14th of April 2026. Following this decision, the NCS is issued by the Dutch NCA in EudraGMDP, whereby the current GMP certificate, based on the previous inspection with a compliant result in December 2023, will be withdrawn from EudraGMDP.

Recall of batches already released

The Dutch Competent Authority (NL) deems not to recall batches of finished products that are produced in Unit A with purified water (PW) and already released and distributed to the market. The risks posed by the non-compliance is deemed to be sufficiently limited by a number of factors, the first of which is the preservatives. Products contain methyl hydroxybenzoate and parahydroxy benzoate, which are bactericidal, or sodium benzoate, which is bacteriostatic. The product containing clindamycin is both bactericidal and bacteriostatic. Furthermore, all concerned products are for oral use, whereby stomach acid acts as an extra chemical barrier. Finally, potential contamination with micro-organisms does not increase during storage of the products concerned, therefore no degradation of the active substance by micro-organisms is expected to occur, making any influence on the efficacy of the veterinary medicinal product highly unlikely. For the batches of aseptic VMPs produced in Unit B, a recall class III on specific batches is issued by the Dutch Competent Authority (NL), based on the provided assessment of PM (process monitoring, including person monitoring) on batch-level. Only batches that are released for the Dutch market and are not deemed critical for the Dutch market are to be recalled. In total, this comes down to 2 batches. For other member states, the recall decision should be made by their respective NCAs, based on criticality of the VMPs and the impact assessment provided by the company. For the batches for which an OOS was reported, the Dutch Competent Authority (NL) issues, at this moment, no recall on the basis of the impact assessments on retested and not-retested batches. The Dutch Competent Authority (NL) agrees with the rationale provided by the company. However, at present, NL is still awaiting the impact assessment for the OOS-results in ongoing stability studies, in which the actions taken or required (market) actions with the relevant MAHs will also be evaluated by Produlab. The company will provide this information to us as soon as possible (deadline April 30th2026 at the latest). Based on this, NL will make a final

decision on possible market actions regarding these batches.

Others

Critical products: At this time, NL has identified a list of products that would most likely be critical for the Dutch market and this list is already shared with the company. This list was compiled based on the following principles: - If the market share of the product is <20%, the product is not critical. - If the market share of the product is >20% and <70%, the product could be critical, depending on other factors, such as: o Is the product prescribed / used daily? o How many acceptable* alternatives are available, that are not produced by Produlab? If there are >3, the product is generally not considered critical. - If the market share of the product is >70%, the product is critical. *In some cases, products of other strengths or for other target species may be acceptable. It should be noted that not all necessary information is known by the Dutch authority at this time and therefore the list is subject to change. Each Member State must determine for its own national market which products are critical, as decisions about recall and limiting product release could lead to potential shortages in the market and prevent animals from being treated in time for a specific condition. As NCA, we emphasize that if a product is considered critical for a member state, they may still be released by the QP for that specific market based on a risk-based analysis, even if the manufacturing process did not meet the GMP requirements and the product may pose a potential risk to animal- and public health. The reason is that having no alternative to critical products available, i.e. not treating animal patients, could entail more risk to public and animal health, animal welfare, and animal survival, compared to allowing products for treatment which were produced under the non-compliance findings. After identifying the critical deficiency listed as number 1 above, the Dutch Food and Consumer Product Safety Authority has, in agreement with the Dutch Health and Youth Care Inspectorate, immediately halted the use of PW in Unit A by means of an administrative measure. The manufacture of veterinary medicinal products using microbially contaminated water does not comply with Article 93(1)(j) of Regulation (EU) 2019/6. An administrative measure has already been taken to avert possible danger to animal and public health. This administrative measure means that the use of water from the water-unit in Unit A has been stopped immediately and must remain stopped until sufficient measures have been taken by the company and approved by the Dutch inspectorate. Discontinuation of the use of PW from Unit A applies to both production and cleaning activities involving this water. This administrative measure remains effective currently. It can only be lifted when Produlab has demonstrated, through planning (CAPA plan) and implementing corrective and preventive actions, that the risk of contamination in the water has been eliminated. This must be assessed by the Dutch Inspectorate (IGJ) before the measure imposed by the Dutch Food and Consumer Product Safety Authority can be lifted.

Additional comments

The Dutch NCA is not intending to take measures on the manufacturer's authorization in order to allow for the production of critical products. For more information about the inspection results and details please see the Supervisory Risk Assessment (SRA).

Teleconference Date	2026-03-02	**Teleconference Time (CET)**	14.00:15.00	**Dial in no.**	

2026-04-21

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

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