Medicines Evaluation Board

Report No: ***V2059716 2026-3152394***

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: ***Belgica De Weerd B.V.***
Site address: ***Van De Reijtstraat 21, Breda, 4814 NE, Netherlands***
OMS Organisation Id. / OMS Location Id.: ***ORG-100021844*** / ***LOC-100030547***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-02-26***, 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**
	1.2.2 Batch certification

Part 3

1.Nature of non-compliance:
Routine GMP inspection was performed on 29 January and 26 February 2026 . Two critical, four major and three other deficiencies were defined. The two critical deficiencies were regarding the following: 1. The quality of the certified veterinary medicines cannot be assured concerning the results of the ongoing stability studies. A high number of out of specifications on ongoing stability were reported of which at least four exceed the internal specifications of Belgica de Weerd, the rationale to not recall these batches and inform the authorities was insufficient. The rationale for accepting the out-of-specification results on the ongoing stability batches does not account for the spectrum of action of the antibiotic, the safety, therapeutic window, the synergistic effect of the different active ingredients and the development of antimicrobial resistance. This poses a risk to animal safety and public health. Also, Belgica de Weerd uses specifications for the amount of active ingredient during on-going stability of 90%-110% of the label claim. In the rationale for these limits the spectrum of action of the antibiotic, the safety, therapeutic window, the synergistic effect and the development of antimicrobial resistance of these limits are not accounted for. These limits are set for all products without a rationale to account for the different product composition of these products. In the risk assessment for an OOS on ongoing stability it is stated that it does not apply to the batches on the market, while a stability batch is representative for batches on the market. This poses a risk to animal safety and public health in the market. 2. Belgica de Weerd does not comply to GMP annex 16 and can not sufficiently assure the quality of the certified products on the market. The QP could not make clear against which specifications in the registration dossier the batches were certified since the QP had no access to the registration dossiers. This poses a critical compliance risk. The batch documentation does not comply to the release specifications in the registration dossier for several products and a variation for the change in contract manufacturing organization was not submitted to the competent authorities, while the batches produced by the new CMO were released to the market. After withdrawal of the GMP certificate of the contract manufacturer the QP continued to release the produced batches.

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. NL/V 23/0006
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 February 2026. This decision has been sent to the company by means of an official decision on the 29th of July 2026. Following this decision, a NCS will be issued by the Dutch NCA in EudraGMDP, whereby the current GMP certificate,will be withdrawn from EudraGMDP.

Recall of batches already released
The concerned products are only National registrated in The Netherlands (NL) and Romania (RO). If the concerned medicinal products are potentially critical, the marketing authorization holder (MAH) must report this to the competent authorities. The competent authority may determine whether a particular VMP is critical for the market and, based on a risk assessment, can be released to the market if shortages occur. This information is not yet available for the Dutch market. If the concerned VMP's are assessed as critical, a recall will not be initiated.

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

2026-08-11

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

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