National Centre For Public Health And Pharmacy

Report No: ***NNGYK/11120-1/2026***

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. 111(7) of Directive 2001/83/EC as amended

The competent authority of Hungary confirms the following:
The manufacturer: ***Panacea Biotec Pharma Limited***
Site address: ***Malpur, Baddi, Solan, 173205, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100038848*** / ***LOC-100060994***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2026-01-31***, 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 (EU) 2017/1572

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

Human 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) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.2 Capsules, soft shell 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.6 Liquids for internal use 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	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*

Part 3

1.Nature of non-compliance:

Critical observations: 1. The Site Master File did not indicate the outcome of the listed inspections and audits. The failed inspection, leading to OAI status, conducted by the US FDA in 2023 was not reported. 2. Deficiencies of IT systems and CSs management were identified as: - the ERP system was not indicated on the lists of computerized systems, and it was not validated, the validation had not yet started at the time of the inspection. The system was commissioned on 05.04.2025. - backup restoration check was not performed in 2025, although it was SOP requirement. Planner and performed restoration checks in 2026 were presented. - there was no clear requirement to verify the validity of data stored in a system before its decommissioning. 3. The gowning qualification monitoring points did not include the backplane of the body and the lower legs for operators who entered the Grade A with their whole body (back of the head, back, bottom). For operators in Grade A and B, only the five finger dabs were monitored, not the whole fingers. The personal monitoring did not take into consideration the non-routine interventions where – occasionally – an operator or engineer had to enter into Grade A with body parts which were not part of the routine monitoring plan. This is a recurring observation from the US FDA report from 2023. Major observations: 1. The dryer used for the drying of pre/fine filters of AHUs in OSD, was dirty. Recurring observation. 2. • Weaknesses identified in the CCS were the followings: - The opening/closing mechanism of the automatic door leading to the Grade B filling room (type DORMA ED 100/ED 250 and the risks and necessary controls related to its mechanism were not captured. - No Contamination Control Strategy (microbial) was developed for the OSD block (especially for oral liquids and ointments/cremes). - The CCS failed to capture risks specific to certain materials and items, transferred through DPBs with wet mopping and with or without removal of wrapping. As a consequence, CAPA and monitoring programme were not established for those items. - Joints of the robotic arm used in C-RABS were not identified as hard to disinfect locations, the VHP cycle validation therefore did not address these joints. 3. The conditions triggering anaerobic aseptic process simulation and the pre-requisites necessary to perform such a simulation were not defined in the APS procedure. Non-inherent (corrective) interventions were required to be performed only annually. Durations and number (count) of corrective interventions were not defined in the APS protocol. Corrective interventions performed with open C-RABS door were defined, however only one of the six types was required to be performed per APS and the duration and count of these interventions was not defined. Visual inspection findings (other than intactness issues) were not reported for the APS batches (e.g. particles, fibers and other contaminations).

Action taken/proposed by the NCA

Withdrawal, of current valid GMP certificate No. OGYÉI/496-7/2022, NNGYK/07707-2/2026
All certificates revoked.

Recall of batches already released
The inspectors did not observe any behaviour or manufacturing process that would pose risk to the quality of products already released.

Prohibition of supply
The NCPHP proposes halting of supplies, except those supplying patients being on treatment with the oncology products. Non-vital supplies are proposed to be halted.

Suspension of clinical trials
The NCPHP has no information about clinical trials with IMPs from the site

2026-02-03

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

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