Finnish Medicines Agency

Report No: ***FIMEA/2023/006158***

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 Finland confirms the following:
The manufacturer: ***Liaoyuan City Baikang Pharmaceutical Co. Ltd.***
Site address: ***No 2858 Wealth Road, Economic Development Zone, Liaoyuan, 136200, China***
OMS Organisation Id. / OMS Location Id.: ***ORG-100039187*** / ***LOC-100061677***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-11-10***, it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/EC.

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;	
1.4	**Other products or manufacturing activity**
	1.4.3 Other: Manufcature of API(en)

Manufacture of active substance. Names of substances subject to non-compliant:
PARACETAMOL PH. EUR.(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance:PARACETAMOL PH. EUR.	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps: crystallisation
3.5	**General Finishing Steps**
	3.5.1 Physical processing steps: milling, blending etc. 3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Part 3

1.Nature of non-compliance:
The inspection team identified 25 deficiencies against EU GMP. Of these, one was classified as critical and found in the area of data integrity controls in the QC laboratory. In addition, five deficiencies were classified as major and related to controls regarding product release from the site, contamination risks arising from inadequate maintenance and cleaning of equipment, buildings and facilities, records of GMP activities, out-of-specification investigations in the QC laboratory, and cleaning validation. The remaining 19 deficiencies were classified as other.

Action taken/proposed by the NCA

Prohibition of supply
After issuance of the non-compliance report and as long as it remains active, the site should not be authorized to distribute active ingredients for pharmaceutical use.

Suspension or voiding of CEP (action to be taken by EDQM)
EDQM withdrawal of CEP 2007-054 – Paracetamol

Additional comments
This manufacturer should not be authorised in any new marketing authorisation or variation application. The inspection was performed in the frame of the EDQM inspection programme.

2024-03-06

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

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