Chief Pharmaceutical Inspectorate

Report No: ***ISC.41.28.2024.DO***

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 Poland confirms the following:
The manufacturer: ***World Markets Sp. z o.o.***
Site address: ***Ul. Hutnicza 10, Lublin, 20-218, Poland***
OMS Organisation Id. / OMS Location Id.: ***ORG-100013333*** / ***LOC-100020482***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2024-06-05***, 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

2 NON-COMPLIANT IMPORTATION OPERATIONS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.1 Site of physical importation

Part 3

1.Nature of non-compliance:

During the inspection, despite the fact that, by decision of the President of the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products No. UR/DZL/UD/0002/22 of 23 August 2022, authorisation No. 4617 for the medicinal product Liv.52 was suspended, it was confirmed that the medicinal product in question was being imported, certified and released. The above actions show signs of a violation of the provisions of the Polish Criminal Code, who states that whoever endangers the life or health of many people or property of significant value by producing or placing on the market medicinal products that do not meet the applicable quality standards shall be subject to imprisonment for up to 8 years. In addition it wasfound that the importer broke the Polish Pharmaceutical Law by failing to apply GMP requirements and failing to comply with the obligations of the holder of a manufacturing or importing authorisation for medicinal products. During the inspection 3 critical, 4 major and 2 others deficiencies were identified. The critical deficiencies concerned: the certification and release for market (batches release) of 16 batches of the medicinal product Liv.52, composite product, tablets despite the suspension of the marketing authorisation number 4617; lack of certification by a Qualified Person of the distributed batch number 112302613 of the medicinal product Liv.52 composite product; there was no confirmation at the place of import, for the distributed batch number 112302613 of the medicinal product Liv.52, composite product, tablets, the Qualified Person had ensured that the batch was subjected to quality analysisin the territory of the Republic of Poland for the following parameters: product appearance, product form, TLC identity, active substances/markers (sum of flavonoids, mustard index,iron), average tablet weight, mass uniformity, pH, tablet disintegration time, drying weight loss, heavy metals (lead, cadmium, mercury, arsenic), compliance of packaging testing with the registry; 6 batches of the medicinal product Liv.52, composite product, tablets were marketed, despite the suspended marketing authorisation number 4617; the organisation, location and size of the ‘Import warehouse’ room were not suitable for carrying out the operations for which it was intended, as they did not minimise the risk of mixing and any adverse impact on the quality of the product, owing to the lack of storage space, in an orderly manner, for the batch of the product, in quarantine status in the areas dedicated to: released products and products in preparation for shipment to wholesalers.

Action taken/proposed by the NCA

Revocationof the manufacturing authorisation No. 231/0315/15in Full

Withdrawal, of current valid GMP certificate No. IWSF.405.112.2022.IP.1 WTC/0315_01_01/252
Withdrawal of Good Manufacturing Practice Certificate IWSF.405.112.2022.IP.1 expiry date passed on 22.07.2025

Recall of batches already released
Recall of batches: 112302614, 112302613, 112301842, 112302503, 112300609, 112301841, 112302502, 112302504, 1123,01843, 112300610, 112203813, 112203288, 112202216, 112202215, 112203815, 112203814, 112203289, 112201909. Recall of next batches have been initiated: 112201908, 112203108, 112401596, 112401836, 112401837, 112402091, 112402090, 112401595, 112400913, 112400914, 112402269, 112402270, 112402271, 112402272

Additional comments
Based on the available data no batechs were placed on the EU/EEA market.

2025-12-05

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

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