Federal Agency for Medicines and Health Products

Report No: ***BE/NC/2022/01***

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 Belgium confirms the following:
The manufacturer: ***Emergent Manufacturing Operations Baltimore LLC***
Site address: ***5901 East Lombard Street, Baltimore, MD, 21224-6824, United States***
OMS Organisation Id. / OMS Location Id.: ***ORG-100038966*** / ***LOC-100061324***

Other
Distant Assessment

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-10-29***, 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 2003/94/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;	
1.3	**Biological medicinal products (list of product types)**
	1.3.1 Biological medicinal products (list of product types) 1.3.1.2 Immunological products
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: Manufacture of non-sterile biological drug substance(en)
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.4 Biological*

Part 3

1.Nature of non-compliance:
The site fails to demonstrate full control of the manufacturing process of Janssen's viral vector drug substance with repeated contamination issues as well as a history of cross contamination with another viral vector vaccine drug substance. After 14 batches manufactured (7 of which were terminated), the site has failed to provide 3 successful consecutive PPQ batches. In light of the recent contamination issues (notified on the 7th of February and updated on the 18th of March 2022) and the unsuccessful PPQ runs, it is concluded that the site has failed to demonstrate consistent production of viral vector vaccine drug substance in accordance to the EU GMP requirements and that contamination issues are still present and are not under control which presents a risk to the quality of the vaccines and public health.
Action taken/proposed by the NCA **Recall of batches already released** Consideration for recall of vaccines produced with drug substance originating from the Emergent facility **Prohibition of supply** No further supplies of Janssen's COVID vaccine's drug substance should be allowed in the Union

2022-04-01

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

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Federal Agency for Medicines and Health Products
Tel:***Confidential***
Fax:***Confidential***