Läkemedelsverket

Report No: ***6.2.1-2015-043292***

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 Sweden confirms the following:
The manufacturer: ***Svenska Bioforce AB***
Site address: ***Borrsvängen 5, Södra Sandby, 24732, Sweden***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-08-11*** , 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

[1] *The statement of non-compliance referred to in paragraph 111(7) of Directive 2001/83/EC and 80(7) of Directive 2001/82/EC, as amended, shall also be required for imports coming from third countries into a Member State.*

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;	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.2 Secondary packing
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.6 Liquids for internal use 1.5.1.13 Tablets
1.6	**Quality control testing**
	1.6.3 Chemical/Physical

2 NON-COMPLIANT IMPORTATION OPERATIONS	
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

Part 3

1. Nature of non-compliance:

During the inspection, 42 deficiencies were found. None of the deficiencies was critical but 17 were major. The 17 major deficiencies related to batch certification, Product Quality Review, change management system, deviation handling system, management responsibility, training, premises and equipment, documentation, line clearance, quality control, complaint handling, and cleaning validation. Re-inspection after implementation of CAPA is required in order to verify that the Pharmaceutical Quality System meets the requirements according to EU-GMP.

Action taken/proposed by the NCA

Recall of batches already released

The concerned manufacturing steps are packaging, quality control and batch certification. The Products are only intended for the Swedish market, no recall of batches already released was necessary. It is recommended that the site is not approved in any new or ongoing applications before a re-inspection has confirmed GMP compliance.

Prohibition of supply

The site does not possess a valid GMP certificate and can therefore not supply the market with Product.

Teleconference Date		**Teleconference Time (CET)**	N/A	**Dial in no.**	N/A

2016-02-07

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

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Confidential
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