Danish Medicines Agency

Report No: ***2019090306***

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
Art. 80(7) of Directive 2001/82/EC as amended

The competent authority of Denmark confirms the following:
The manufacturer: ***Scanpharm A/S***
Site address: ***Topstykket 12, Birkerød, 3460, Denmark***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-09-26*** , 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
- The principles and guidelines of Good Manufacturing Practice laid down in Directive 91/412/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
Veterinary 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**
	1.2.2 Batch certification
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility
	1.6.3 Chemical/Physical

2 NON-COMPLIANT IMPORTATION OPERATIONS

2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products

Part 3

1. Nature of non-compliance:

The Inspection performed in the period 24.-26. Sep 2019 at Scanpharm, Topstykket 12, Birkerød, showed lack of ability to adhere to the principles of Good Manufacturing Practice, according to the following subjects: Lack of knowledge regarding the company's Qualified Person's responsibility, reporting of OOS results, OOS and missing data for stability studies, inconsistencies between registration files and specifications, use of non-validated analytical methods and not EU reference standards, insufficient performance of self inspection. As a results of this, the quality of the products manufactured at the site is not ensured.

Action taken/proposed by the NCA

Suspension of the manufacturing authorisation No. 37632 in Part

The company's manufacturing authorisation for the manufacture of medicines in accordance with section 39 (1) of the Danish Medicines Act. 1 and 2 with authorization number 37632 are hereby partly suspended The Company must no longer perform batch certification and quality control testing of its own products and external companies' products.

Withdrawal, of current valid GMP certificate No. DK H 00110218

DKH0110218 DKV011218

Recall of batches already released

Recall of batches from wholesalers are recommended depending on each NCAs assessment on criticality of the product.

Others

Each NCA is asked to inform the Danish Medicines Agency on rapidalert@dkma.dk of their final decision on recall

2019-10-16

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

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