Danish Medicines Agency

Report No: ***2017090955***

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: ***EuroPharma.DK ApS***
Site address: ***Oddesundvej 39, Esbjerg N, 6715, Denmark***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-09-21*** , 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;

1.5	**Packaging**
	1.5.2 Secondary packing

Part 3

1. Nature of non-compliance:

A general lack of will and ability to adhere to the principles of good manufacturing and good distribution practices. Examples of non-adherence are: QP not present in company for supervision and competent interaction with staff and management as agreed with our Agency, QA department understaffed, Inadequate follow-up and implementation of corrective and preventive actions from previous inspection, Insufficient handling of deviations and complaints, Inadequate control for falsifications and temperature excursions during transportation upon receipt of medicinal products, Deficient procedures for qualification of transporters/forwarders.

Action taken/proposed by the NCA

Suspension of the manufacturing authorisation No. 34525 in Part
EuroPharma DK must no longer perform manufacturing activities including purchase of medicinal products from other EU markets. Medicinal products including retention samples may, however, be stored under quarantine, and EuroPharma DK may still have activities related to handling of complaints and recall of medicinal products from the market.

Recall of batches already released
Based on a risk assessment and due to the general nature of the non-adherence issues observed we do not recommend recall of medicinal products already in the market at this point.

Prohibition of supply
Medicinal products purchased by EuroPharma DK must not be re-packed by EuroPharma DK or any of their contract manufacturers. Medicinal products already re-packed by EuroPharma DK must not be released and distributed.

Others
The GMP certificate no. DK H 00089917 issued after our inspection 8 March 2017 has been withdrawn

2017-11-08

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

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Confidential
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