Spanish Agency of Medicines and Medical Devices

Report No: ***DICM/INSP/MBP-SLA-PAL***

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
Art. 15 of Directive 2001/20/EC

The competent authority of Spain confirms the following:
The manufacturer: ***INMUNOTEK, S.L.***
Site address: ***Avda. de Somosierra 22, nave 14 A, San Sebastián de los Reyes, Madrid, 28700, Spain***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2016-03-16*** , 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
Human Investigational 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;

1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.3 Batch certification
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
	1.3.2 Batch Certification (list of product types) 1.3.2.2 Immunological products
1.5	**Packaging**
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.3 Chemical/Physical* *1.6.4 Biological*

Clarifying remarks (for public users)

1.3.1.2 Immunological products: allergens, vaccines for individual use and allergenic extracts. All the sterile products manufactured are biological products.

Part 3

1. Nature of non-compliance:
The deficiencies detected on the last inspection carried out on 15-16/03/2016 impact on the Quality system of the site and the manufacturing process of sterile immunological products (aseptic process). The quality, and especially the sterility of the products manufactured cannot be assured. As a consequence of this and to prevent risk for the patients, AEMPS has decided to suspend the site´s manufacturer authorization for finished products until the implementation of necessary corrective/preventive actions.

Action taken/proposed by the NCA

Suspension of the manufacturing authorisation No. 0660 in Part
Temporarilly suspension of the site in San Sebastian de los Reyes, Madrid. (INMUNOTEK, S.L. has another site authorised in Alcala de Henares, Madrid, with a current GMP certificate that has not been affected).

Recall of batches already released
Recall of batches of parenteral immunological products (vaccines for individual use) manufactured in this site.

2016-04-07

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

---

Confidential
Spanish Agency of Medicines and Medical Devices
Tel: ***Confidential***
Fax: ***Confidential***