French National Agency for Medicines and Health Products Safety

Report No: ***15MPP074HFR01NCS***

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 France confirms the following:
The manufacturer: ***SAS JARMAT « LABORATOIRE ADP »***
Site address: ***ZA DU SALUANT, REVENTIN VAUGRIS, 38121, France***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2015-11-20*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in

- The principles of GMP for active substances referred to in Article 47 of Directive 2001/83/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

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) 1.2.1.17 Other: active substance(en)

Manufacture of active substance. Names of substances subject to non-compliant :
REPACKED ACTIVE SUBSTANCES(en)

Part 3

1. Nature of non-compliance:

As a preliminary note, the starting materials repacked by the site were intended for pharmaceutical compounding activity in community pharmacies. The site did not distribute to the industry. Overall, 21 deficiencies were found, including 3 critical deficiencies and 5 major deficiencies: [Critical 1] Important risks of confusion in the repacking operations were identified. [Critical 2] Important risks of cross contamination in the repacking operations by substances of high pharmacological activity or toxicity were identified. [Critical 3] The active substances and excipients batches were not analysed as per the pharmacopoeial specifications. [Major 1] The release of active substances batches was deficient, notably in the absence of batch production records. [Major 2] Several risks of contamination in the sampling operations, notably cross contamination, were identified. [Major 3] The management of active substance suppliers was deficient, notably in the absence of written confirmation. [Major 4] Several risks of contamination in the repacking operations, notably cross contamination, were identified. [Major 5] The transmission of information to pharmacies was incomplete and confusing, notably regarding the analyses actually performed by the site. The inspection's observations also apply to excipients, which are repacked and distributed under the same conditions as the active substances.

Action taken/proposed by the NCA

Recall of batches already released
The site has decided to inform their customers and to recall the remaining batches on the market. The recalls from all clients were performed under the responsability of the site and were initated on 10 December 2015. Identified customers were located in France, Belgium, Luxembourg and Switzerland.

Prohibition of supply
The site has decided to end its activities related to starting materials on 03 December 2015. See additional comments section.

Additional comments
The withdrawal of the starting materials manufacturing and distribution licence has been published on the ANSM website on 06 January 2016.
(http://ansm.sante.fr/Decisions/Autorisations-pour-les-operateurs-Demandes-d-autorisations-pour-les-operateurs)

2016-01-19

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

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