National Institute of Pharmacy and Nutrition

Report No: ***OGYÉI/28807-5/2018***

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 Hungary confirms the following:
The manufacturer: ***JIANGSU YEW Pharmaceutical Co. Ltd.***
Site address: ***Fangqiao Town Industrial Park, Fangquiao Town, Yixing City, Jiangsu province, China 214 264, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-06-20*** , 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;	
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.4 Other: Manufacturing of APIs(en)

Manufacture of active substance. Names of substances subject to non-compliant :
TEMOZOLOMIDE(en) / TEMOZOLOMIDUM(cs)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance : TEMOZOLOMIDE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates

Part 3

1. Nature of non-compliance:
Refusal of the EDQM inspection supported Hungarian Inspectorate on 20th June 2018.
Action taken/proposed by the NCA **Suspension of the marketing authorisation(s)** Suspension of marketing authorization shall be assessed by the NCAs. **Recall of batches already released** The recall shall be defined based on the risk assessment by the NCAs. **Suspension or voiding of CEP (action to be taken by EDQM)** EDQM is going to refuse approval of CEP.
Additional comments Jiangsu Yew Pharmaceutical Co., Ltd. is an API / Intermediate manufacturer according to the company's website and other sources. Other products: 10-Deacetylbaccatin III, Demehylcantharidin, Ramosetron Hydrochloride, Paclitaxel, Docetaxel, Cabazitaxel, Oxaliplatin, Irinotecan, Decitabine, Allopurinol, Granisetron, Praziquantel, Cisplatin, Gemcitabine Hydrochloride, Camptothecin, Vinorelbine Tartarate, Palonosetron Hydrochloride, Bleomycin Sulphate, Lentinan, Dolasetron Mesylate, Capecitabine, Pemetrexed Disodium, Fludarabine Monophosphate, Eptalatin, Cephalomannine.

2018-09-11

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

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