Medicines Authority

Report No: ***MT/001NCR/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 Malta confirms the following:
The manufacturer: ***Theon Pharmaceuticals Ltd***
Site address: ***Village Saini Majra, Tehsil Nalagarh, District Solan, Himachal Pradesh, 174101, India***
DUNS Number: ***65-060-3637***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-03-11*** , 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

[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

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) 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms: Oral powder(en) 1.2.1.11 Semi-solids 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: Oral powder in sachets and bottles for oral suspension(en) 1.5.1.11 Semi-solids 1.5.1.13 Tablets
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

The beta lactam manufacturing blocks were not included in the scope of this inspection

Part 3

1. Nature of non-compliance:
A total of 1 (one) 'Critical', 6 (six) 'Major' and 11 (eleven) 'Other' deficiencies were reported during this inspection. The 'Critical' deficiency concerned evidence of falsification of documents whilst 'Major' deficiencies were cited for an inadequate pharmaceutical quality system and documentation management, and deficient control of cross-contamination, manufacturing activities, qualification and validation activities and approval of suppliers.

Action taken/proposed by the NCA

Others
The Medicines Authority recommends that, marketing authorisation applications or variation applications to current marketing authorisations to include the above manufacturing site, should not be considered.

Additional comments
There are no current EU GMP Certificates for this site since it was the first inspection by an EU/EEA authority of the site. The site is currently not supporting any application for and/or Marketing Authorisation for human medicinal products on any EU/EEA market. Thus there should not be any impact on any product on the EU/EEA market.

2018-04-23

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

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