檔　　號：
保存年限：

正本

衛生福利部食品藥物管理署　函

機關地址：11561 臺北市南港區昆陽街161-2號
傳　　真：0227877178
聯絡人及電話：蘇子婷0227877148
電子郵件信箱：daisyhaha@fda.gov.tw

10668
106台北市大安區敦化南路二段128號15樓

受文者：中華民國藥品行銷暨管理協會

發文日期：中華民國106年8月1日
發文字號：FDA風字第1061104713號
速別：
密等及解密條件或保密期限：
附件：原料藥廠違反GMP警訊乙份

主旨：有關中國原料藥廠「Chongqing Succeway Pharmaceutical Co. Ltd.」（廠址：531 Tonghe Avenue, Tongliang County, Jinlong Industrial District, Chongqing, Sichuan, 402566, China）經國際通報違反GMP乙案，詳如說明段，請轉知所屬會員知照。

說明：

一、法國衛生主管機關ANSM於106年6月24日查核旨揭原料藥廠，判定違反GMP，並於106年7月20日發布旨揭藥廠「STATEMENT OF NON COMPLIANCE WITH GMP」警訊（詳附件）。

二、承上，法國ANSM已啟動相關後續處置，包括：

(一)基於品質風險管理（Quality Risk Management，以下簡稱QRM）原則評估是否啟動回收。

(二)原料藥暫停出貨，GMP狀態尚未改善完畢前，不應使用於製劑產品之生產。

(三)建議使用旨揭原料藥廠原料藥之製劑產品，應基於QRM評估是否變更原料來源。

三、鑑於旨揭原料藥之製造品質恐無法符合GMP之要求，可能導致對藥品製造品質帶來影響與危害，請轉知所屬會員釐清相關輸台製劑產品是否使用旨揭原料藥廠所生產原料藥「Rilmenidine Dihydrogen Phosphate」，並應依說明段二所述辦理。

正本：中華民國西藥商業同業公會全國聯合會、中華民國西藥代理商業同業公會、台北市西藥代理商業同業公會、中華民國開發性製藥研究協會、中華民國藥品行銷暨管理協會

副本：

署長吳秀梅

台灣藥品行銷暨管理協會
收文日期：106年8月4日
本文件保留：□1M.□3M.□6M
□1Y.□3Y.□5Y
□未定.☑永久

□最急件
□急　件
☑普通件

French National Agency for Medicines and Health Products Safety

Report No: *17MPP048NCR*

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: ***CHONGQING SUCCEWAY PHARMACEUTICAL CO LTD***
Site address: ***531 Tonghe Avenue, Tongliang County, Jinlong Industrial District, CHONGQING, SICHUAN, 402566, China***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2017-06-24*** , 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 :
RILMENIDINE DIHYDROGEN PHOSPHATE(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES Active Substance : RILMENIDINE DIHYDROGEN PHOSPHATE	
3.1	**Manufacture of Active Substance by Chemical Synthesis**
	3.1.1 Manufacture of active substance intermediates 3.1.2 Manufacture of crude active substance 3.1.3 Salt formation / Purification steps : -
3.5	**General Finishing Steps**
	3.5.2 Primary Packaging (enclosing / sealing the active substance within a packaging material which is in direct contact with the substance) 3.5.3 Secondary Packaging (placing the sealed primary package within an outer packaging material or container. This also includes any labelling of the material which could be used for identification or traceability (lot numbering) of the active substance)
3.6	**Quality Control Testing**
	3.6.1 Physical / Chemical testing

Part 3

1. Nature of non-compliance:
Overall around 22 deficiencies were observed, out of which one was classified as critical and three as major // Critical: manipulation, backdating and falsification of GMP documents such as batch manufacturing record, report of starting material manufacturer audit, GC and HPLC chromatograms. // Major 1: undeclared workshop without any traceability of the activities underaken. // Major 2: undeclared storage of unidentified product without any traceability. // Major 3: poor standards for issuance of batch manufacturing records.

Action taken/proposed by the NCA **Recall of batches already released** A recall of products should be considered using QRM principles. **Prohibition of supply** After issuance of the non-compliance report and as long as it remains active, the site should not be named in any new MAs or used in drug compounding activities.
Additional comments The existence of MAs or MA variations referencing an active substance manufactured by this site has to be verified. In these circumstances, the removal of the site from the MA should be considered using QRM principles.

2017-07-20

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

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Confidential
French National Agency for Medicines and Health Products Safety
Tel: *Confidential*
Fax: *Confidential*