Sistema Sanitario Regione Liguria

DIREZIONE SANITARIA

Allegati n. 2

Genova, data del protocollo

Direttori Sanitari Aziende ed Enti del SSR

Ordini dei Medici Regione Liguria

Ordini dei Farmacisti Regione Liguria

Ordini dei Medici Veterinari Regione Liguria

Direttore
Area Centrale Regionale di Acquisto

ASSOFARM

FEDERFARMA Liguria

Distributori Intermedi DPC

p.c. NAS Legione Liguria

Loro sedi

Oggetto: **Trasmissione comunicazione AIFA – RITIRO FARMACO**

Si invia in allegato il provvedimento AIFA di **RITIRO** del medicinale**: CEFIXIMA.**

Si prega di darne massima diffusione presso le strutture ed i soggetti interessati.

Cordiali saluti

Il Sub Commissario
con funzioni di Direttore Sanitario
(Prof. Filippo Ansaldi)

A.Li.Sa. – Azienda Ligure Sanitaria della Regione Liguria
C.F. / P. IVA 02421770997
Sede legale Piazza della Vittoria, n. 15, 16121 Genova (GE) – Tel. 010 548 4162
MAIL: direzione.alisa@regione.liguria.it PEC: protocollo@pec.alisa.liguria.it

PQ-PhCC/SF/DDG

AGENZIA ITALIANA DEL FARMACO

Ufficio Qualità dei Prodotti e Contrasto al Crimine Farmaceutico

PROVVEDIMENTO

A: indirizzi in elenco

A seguito della segnalazione pervenuta dalla ditta Aurobindo concernente problema al confezionamento primario in confezioni del medicinale "**CEFIXIMA AUROBINDO 400 mg compresse rivestite con film**", lotti in allegato, AIC n. **044331015** della ditta Aurobindo Pharma Italia Srl, sita a Saronno (Varese) via San Giuseppe, 102, si comunica, ai sensi dell'art. 70 del D. L.vo219/2006 e per la motivazione sopra evidenziata, il ritiro volontario, a scopo precauzionale, da parte della ditta Aurobindo Pharma Italia Srl.

La ditta Aurobindo Pharma Italia Srl ha comunicato l'avvio della procedura di ritiro che il Comando Carabinieri per la Tutela della Salute è invitato a verificare.

Il Dirigente

Domenico Di Giorgio

Agenzia Italiana del Farmaco Via del Tritone, 181 - 00187 Roma (+39) 06.59.78.401 www.aifa.gov.it

Prodotto	AIC n.	Lotto	Scad.
Cefixima Aurobindo 400 mg compresse rivestite con film - 5 compresse	044331015	EXMTS9035A	06/2021
Cefixima Aurobindo 400 mg compresse rivestite con film - 5 compresse	044331015	EXMTS9035E	06/2021
Cefixima Aurobindo 400 mg compresse rivestite con film - 5 compresse	044331015	EXMTS9048A	09/2021
Cefixima Aurobindo 400 mg compresse rivestite con film - 5 compresse	044331015	EXMTS20023C	08/2022

EudraGMDP

Thu 15 Apr 2021 18:12:37 BST

Swissmedic, Swiss Agency for Therapeutic Products

Report No :***CH20-0566***

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

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and ***Switzerland***

The competent authority of Switzerland confirms the following:

The manufacturer :***Legacy Pharmaceuticals Switzerland GmbH***

Site address : ***Rührbergstrasse 21, Birsfelden, 4127, Switzerland***
DUNS Number :***48-371-8149***

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-08-28*** , it is considered that **it does not comply with the Good Manufacturing Practice** requirements referred to in The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union and ***Switzerland***

Part 2

Human Medicinal Products

Veterinary Medicinal Products

Human Investigational Medicinal Products

1 NON-COMPLIANT MANUFACTURING OPERATIONS
1.1 Sterile products
1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.1 Large volume liquids 1.1.1.3 Semi-solids 1.1.1.4 Small volume liquids 1.1.1.6 Other: Aseptic lyophilisation of sterile bulk and aseptic filling of sterile powder(en) *1.1.2 Terminally Sterilised (processing operations for the following dosage forms)* 1.1.2.1 Large volume liquids 1.1.2.3 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) 1.3.1.6 Human or animal extracted products *1.3.2 Batch Certification (list of product types)* 1.3.2.6 Human or animal extracted products

Manufacture of active substance. Names of substances subject to non-compliant :
[1]SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES(en)

3. NON-COMPLIANT MANUFACTURING OPERATIONS - ACTIVE SUBSTANCES	
Active Substance :SWISSMEDIC LIST OF APIS, SEE 4 ACTIVE SUBSTANCES	
3.2	**Extraction of Active Substance from Natural Sources**
	3.2.6 Purification of extracted substance Animal
3.4	**Manufacture of sterile Active Substance**
	3.4.1 Aseptically prepared

4. Non-Compliant Other Activities - Active Substances :
Sterile dry deproteinized dialysate of calf blood, Sterile Portamin HCL, any other sterile active pharmaceutical ingredient.

Part 3

Nature of non-compliance : Swissmedic is updating the NCR as the situation has changed since the NCR has been issued. Legacy Pharmaceuticals Switzerland GmbH has filed for insolvency early December 2020 and is closed. Swissmedic has withdrawn the manufacturing licence with effect December 31, 2020. Swissmedic has issued a NCR on the 30.09.2020 related to the manufacture of sterile products after during a Swissmedic inspection performed on August 27th - 28th, 2020, 5 critical , 14 major and 6 other deficiencies were identified. the deficiencies included: - insufficient control over the air quality of clean rooms; - incomplete qualification of the air handling system of some of the clean rooms; - incomplete validation of sterile filtration operations of aseptically manufactured products; - inadequate frequency of media fill (less than 2x/year) on some of the production lines; - deviation occurring in the context of media fills were not closed in a timely manner (note, however, that the deviations did not concern turbidity); - inadequate deviation management - quality maintenance and qualification status of equipment is not stat of the art.
Action taken/proposed by the NCA : **Revocation of the marketing authorisation(s)** Marketing authorisation holders of products that have been manufactured by Legacy Pharmaceuticals Switzerland GmbH should check if there is a need to request GMP-relevant documentation on their products from Legacy, and/or retention/reference and stability programme samples should be transferred.

Recall of batches already released Swissmedic will initiate a recall of all batches of sterile products that are on the Swiss market, with the exception of products that are critical due to its therapeutic use and/or availability of alternatives.
Additional comments : The company is not existing anymore and is therefore not in a position to accept or reply to any direct correspondence. There will be no further update to the NCR.

Teleconference Date :	Teleconference Time (CET) :	Dial in no. :

2020-09-30

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

Confidential

Swissmedic, Swiss Agency for Therapeutic Products

Tel :***Confidential***

Fax :***Confidential***