

<b>DOCUMENT</b>	<b>Legacy Ranbaxy Disclosure Policy</b>
<b>DATE</b>	<b>22 May 2024</b>

## 1. PURPOSE

To provide means by way of a structured program for Disclosing Individuals (defined below) who wish to disclose to the Chief Data Reliability Officer (CDRO) any issues or questions related to policies, conduct, practices or procedures believed to be a potential violation of requirements of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities.

## 2. SCOPE

- 2.1 This policy applies to any Disclosing Individuals (defined below) who wish to disclose to the CDRO any issues or questions associated with policies, conduct, practices, or procedures believed to be a potential violation of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities. Legacy Ranbaxy Facilities include the following:
- (1) Ohm Laboratories, 14 Terminal Road, New Brunswick, NJ.
  - (2) Ohm Laboratories, 1385 Livingston Ave. North Brunswick, NJ.
  - (3) Sun Pharmaceutical Industries Limited, , Plot No. A-41, Industrial Area, SAS Nagar, Phase VIIIA, Mohali, Punjab, India.
  - (4) Sun Pharmaceutical Industries Limited, Research & Development Centre, and Clinical Pharmacology & Pharmacokinetics, Sarhaul, Sector 18 Udyog Vihar Industrial Area, Gurugram, Haryana, India.
  - (5) Sun Pharmaceutical Industries Limited, Ghirongi Industrial Area, Malanpur, Madhya Pradesh, India
  - (6) Sun Pharmaceutical Industries Limited, Clinical Pharmacology Unit, Hamdard Nagar, New Delhi, India.
  - (7) Terapia S.A, Clinical Pharmacology & Pharmacokinetics Department, 124 Fabricii Street, 400632 Cluj-Napoca Romania.
  - (8) Any other Legacy Ranbaxy Facility as defined in Section 3.6.
- 2.2 The disclosures described in Paragraph 2.1 may refer to, but are not limited to, the following:
- 2.2.1 Data irregularities related to Legacy Ranbaxy Facilities
  - 2.2.2 Untrue statements related to Legacy Ranbaxy Facilities
  - 2.2.3 Adulteration of drugs related to Legacy Ranbaxy Facilities
  - 2.2.4 Methods, facilities, controls etc. being used to manufacture drugs not complying with cGMP requirements related to Legacy Ranbaxy Facilities
  - 2.2.5 Irregularities observed in any of the processes pertaining to manufacturing, processing, packing, re- packing or labeling holding and/ or distribution of drugs related to Legacy Ranbaxy Facilities
  - 2.2.6 Standard Operating Procedures (SOPs) not being updated periodically to remain in continuous compliance with the applicable law, rule or regulation related to Legacy Ranbaxy Facilities
  - 2.2.7 Non existence of comprehensive, adequate and effective Stability program, Quality Assurance/ Quality Control management related to Legacy Ranbaxy Facilities.

- 2.3 Queries related to the Consent Decree, but not covered under this Disclosure Policy, shall be investigated separately by Sun.

### **3. DEFINITIONS**

- 3.1 Chief Data Reliability Officer- See Section 4.5.
- 3.2 Consent Decree- The Consent Decree of Permanent Injunction entered by the United States District Court for the District of Maryland on January 25, 2012 (Civil Action No. JFM12CV0250), specifying conditions and specific actions related to Ranbaxy and FDA.
- 3.3 Designee- Is a person appointed by CDRO, required for assistance to investigate the Disclosure in confidence and provide his/ her unbiased findings to CDRO.
- 3.4 Disclosing Individual- Any person notifying to third party or CDRO or his/ her designee of any potential violation of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities..
- 3.5 Disclosure- is any communication made in good faith by the Disclosing Individual that discloses or demonstrates information that may indicate evidence of a potential violation of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities.
- 3.6 Legacy Ranbaxy – Ranbaxy Laboratories, Ltd., Ranbaxy Inc., and any subsidiaries of those companies as they existed at the time Ranbaxy was acquired by Sun Pharmaceuticals on March 24, 2015. See Section 2.1 under Scope for the list of some Legacy Ranbaxy Facilities.
- 3.7 Subject Matter - Is a person, condition or practice for which a Disclosure has been made or evidence gathered during the course of an investigation. It could be a group or individual.

### **4. GUIDELINES**

#### **4.1 Disclosure/ Disclosing Individual**

- 4.1.1 All individuals are encouraged to notify the CDRO, as soon as possible, once the individual (hereby, being called as The Disclosing Individual) becomes aware of a condition or practice that they believe to be a potential violation of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities. To enable timely commencement of review of the allegation, the Disclosing Individual is requested to notify the CDRO, as soon as practically possible.
- 4.1.2 The authenticity of the Disclosing Individual's identity, if possible, will be established by the CDRO's Office before considering the case for the purpose of a diligent, good faith investigation into the allegations set forth in every Disclosure.
- 4.1.3 The Disclosing Individual can request that their identity need not to be disclosed. Anonymous complaints (complaints that do not bear the identity of the Disclosing Individual) shall be inquired and appropriate confidentiality shall be maintained for all complaints, to the extent permitted by law.

4.1.4 The Disclosing Individual must provide all factual corroborating information, as is available and to the extent possible.

## **4.2 Confidentiality**

4.2.1 Disclosing Individuals are encouraged to disclose their identity so as to allow a thorough investigation.

4.2.2 All communications, concerns and issues reported under this policy shall be treated in a confidential manner except to the extent necessary to conduct a complete, fair, and effective investigation.

4.2.3 Similarly, the identities of the Disclosing Individual and subject matter of the investigation or complaint shall be treated with confidentiality at all times, to the extent permitted by law.

## **4.3 Non- Retribution and Non-Retaliation**

4.3.1 No unfair treatment shall be exhibited towards the Disclosing Individual by virtue of his/ her having reported a Disclosure under this policy and the Company shall ensure that full protection has been granted to him/ her against:

4.3.1(a) Unfair employment practices like retaliation, threat or intimidation of termination/ suspension of services, etc.

4.3.1(b) Direct or indirect abuse of authority to obstruct the Disclosing Individual's right to continue performance of his/ her duties/ functions during routine daily operations, including making further Disclosures under this policy.

4.3.2 The Disclosing Individual may also report any violation of clause 4.3.1 to CDRO or his/ her designee, who may direct an investigation into the same. The CDRO may recommend appropriate disciplinary action against any person(s) who is found to be responsible for any unfair practice of retribution, retaliation or obstruction towards the Disclosing Individual.

4.3.3 Although the fact that an individual "self-reported" may be taken into account when determining appropriate disciplinary action, the reporting individual remains subject to disciplinary actions for his or her improper and unlawful acts as determined by CDRO investigation.

## **4.4 Subject Matter of the Complaint**

4.4.1 For any disclosure that is sufficiently specific to: (a) permit a determination of the appropriateness of the alleged improper practice; and (b) provide an opportunity for taking corrective action, the CDRO shall conduct a review of the allegations set forth in the disclosure and ensure that proper follow-up is conducted.

4.4.2 The individuals, groups or subject shall have a duty to co-operate with the CDRO until the investigation process is completed.

4.4.3 Senior Management of Sun shall have a right to be informed about the results of the investigation process in writing by the CDRO after the completion of the investigation. They will be given an opportunity to respond to the investigation results, as contained in the investigation report.

#### **4.5 Chief Data Reliability Officer**

4.5.1 The CDRO oversees this Disclosure Program, functioning as an independent and objective body that reviews and evaluates compliance issues/ concerns regarding any potential violation of the U.S. Federal Food, Drug, and Cosmetic Act related to Legacy Ranbaxy Facilities.

4.5.2 Pursuant to the terms of the Consent Decree, the CDRO has direct access and authority to communicate promptly and personally with senior management regarding any complaint or potential violation.

4.5.2 The CDRO is authorized to receive any Disclosures reported under this policy. He/ she is responsible for obtaining all necessary information and ensuring appropriate action.

4.5.3 The CDRO is also authorized to appoint a representative/ designee to represent his Office to receive any Disclosures under the policy.

4.5.4 Upon receipt of a disclosure by third party, the CDRO or his/ her designee shall gather all relevant information from the Disclosing Individual.

4.5.5 The CDRO or his/ her designee shall make a diligent, good faith investigation into the allegations set forth in every disclosure to ensure that he/she has obtained all of the information necessary to determine whether a further review should be conducted.

### **5. DISCLOSING PROCEDURE**

#### **5.1 What to Disclose:**

5.1.1 Any issues or questions associated with policies, procedures, conduct, or practices related to Legacy Ranbaxy Facilities and believed by the Disclosing Individual to be a potential violation of the U.S. Federal Food, Drug, and Cosmetic Act.

#### **5.2 Whom to Disclose to:**

5.2.1 Written communication should be forwarded to the following mailing address  
Sun Pharmaceuticals Industries Ltd  
C/o CDRO  
14 Terminal Road  
New Brunswick, NJ 08901

All India based communications may be addressed to:  
Head-ODR India  
Office of Data Reliability  
Sun Pharmaceutical Industries Limited  
Sector – 18 Udyog Vihar Ind Area,

Gurugram 122015 (Haryana) India

5.2.2 Complaints/ issues can be made by following website

[www.ranbaxydisclosure.ethicspoint.com](http://www.ranbaxydisclosure.ethicspoint.com)

5.2.3 Additionally, a worldwide toll-free complaint/issues reporting telephone line has been established to receive Disclosures from the Disclosing Individuals.

Toll free Hotline#1-855-382-2640

5.2.3 Complaints/ Issues/ Questions can be reported directly to ODR office

[ODR@sunpharma.com](mailto:ODR@sunpharma.com)

Note: The Hotline is operated by an independent third party service provider and is available to callers at all times. Callers / complainants can request not to disclose their identity. Identities of all callers will be kept strictly confidential. For the calls received in any language other than English, Ethics Point will connect the call to interpreter, who will speak to the disclosure individual in their local language. The interpreter will translate the content of the issue/allegation and provide/submit to the Ethics Point.

In case any issues / allegations are received directly by the CDRO, the same will be entered in to the Disclosure Program Database by the CDRO or his/her Designee to assign a system generated unique case number for each Disclosure (Disclosure Case Number) before further investigation is carried out by Office of Data Reliability.

### **5.3 When to Disclose:**

5.3.1 Disclosing Individuals are encouraged to express their concern at the earliest possible and/or preferably within 5 working days so that timely action can be taken.

### **5.4 Publicizing the Disclosure Program**

5.4.1 Sun shall publicize the existence of the 'Disclosure Program' by sending, semi- annually, e-mails to employees, posting the information prominently on the Sun corporate website as well as posting in employee common areas of all Legacy Ranbaxy Facilities.

## **6 Investigation**

6.1 The type of investigation will depend on the nature of Disclosure made and is to be treated as a neutral and fact finding process.

6.2 The CDRO or Designee is responsible for ensuring that a diligent, good faith and unbiased investigation is conducted.

6.3 The CDRO or his/ her designee shall report the findings of the investigation to appropriate authority.

6.4 The investigation shall be launched after the review of the Disclosure/ allegations confirming that it is sufficiently specific but not limited to the following:

- (a) Permit a determination of the appropriateness of the alleged improper practice; and
- (b) Provide an opportunity for taking corrective action

6.5 The outcome of the investigation may or may not support the Disclosure made.

6.6 The investigation process shall be completed within a timely manner to ensure a thorough investigation of the disclosure is performed.

**7 DOCUMENTATION & RETENTION**

7.1 The CDRO's Office establishes a system to receive and maintain written submissions from Disclosing Individuals.

7.2 Upon receipt of a disclosure, the CDRO or his/ her designee shall gather all relevant information from the Disclosing Individual.

7.3 The Office of Data Reliability shall maintain a disclosure log, which shall include a record and an accurate and complete summary of each disclosure received (whether anonymous or not), the status of the respective reviews, and any corrective action taken based on the investigation conclusion.

7.4 All information gathered under this policy shall

- (a) Be maintained for at least four years following closure of the review and corrective action, and
- (b) Be provided to FDA, upon request.

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**Prevention of Misuse of the Disclosure Program**

Employees are not to make frivolous, mala fide or malicious or untrue allegations of violation of the applicable law, rule or regulation.

**Reference**

Consent Decree of Permanent Injunction with USFDA filed with the United States District Court for the District of Maryland on January 25, 2012 (Civil Action No. JFM12CV0250).