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**U.S. CORPORATE ETHICS AND COMPLIANCE POLICY**

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**1. LETTER FROM THE GENERAL MANAGER**



**Michael Waters  
General Manager, Recordati Rare Diseases Inc. (RRD)**

Dear Colleague,

As General Manager of Recordati Rare Diseases Inc., I enthusiastically endorse the company's Corporate Compliance Program and our commitment to ethical and legal standards of conduct. Our goal is to accomplish our mission and to conduct our business with excellence, integrity, and responsibility. Compliance with governmental laws and regulations has never been more important than it is today. All of us are expected to follow the laws and policies for our jobs, to be honest, and to respect others.

To that end, this U.S. Corporate Ethics and Compliance Policy has been prepared to provide an overview of the policies and procedures governing our business conduct. The company has identified a Healthcare Compliance Officer and has created a Healthcare Compliance Committee to implement and monitor our Corporate Compliance Program and promote responsible decision-making by all employees. I am confident that this Policy will help you resolve any ethical or compliance issue that may arise.

I am relying on each of you to make every effort to conduct yourself in accordance with the Recordati Rare Diseases Inc.'s ethical and legal standards of conduct in your dealings with colleagues, customers, business partners, regulators, and other members of society. I encourage each of you to embrace these standards as evidence of your personal commitment to uphold Recordati Rare Diseases' reputation as a well-respected pharmaceutical company.

Sincerely,

*Mike Waters*

General Manager  
Recordati Rare Diseases Inc.

## **2. INTRODUCTION**

Recordati Rare Diseases Inc. (hereinafter “RRD”) is committed to compliance with all applicable international, federal, state and local laws, rules and regulations as well as industry standards and ethical standards of business conduct. Furthermore, RRD is committed to avoiding any distraction from its vital mission of developing, manufacturing, and supplying quality pharmaceutical products to patients. To meet these goals, RRD has developed a Corporate Compliance Program.

The Program exhibits RRD’s commitment to ethical and legal standards of conduct and sets forth guidelines to prevent and detect any violation of the law, as well as the values RRD intends to foster. The Program also establishes a process for education, monitoring, and documentation of RRD’s efforts to comply with the law. All RRD, officers, employees, contractors, business associates and agents are expected to comply with the Program.

This U.S. Corporate Ethics and Compliance Policy is intended to explain RRD’s policies to you and reinforce our commitment to the highest ethical and legal standards. Many, but not all, of RRD’s policies regarding compliance are described herein. Every employee, contractor and business associate must understand these policies and must report any and all violations to the Healthcare Compliance Committee or the Healthcare Compliance Officer (see Section 4.3.1). Please refer to Section 3 of this Manual entitled “How to Handle and Report Ethical and/or Compliance Issues” for a description of what an employee should do if an ethics or compliance issue occurs on the job.

It is critical to RRD’s continued success that ethics and compliance be an integral part of every employee’s decision-making process. Inappropriate business ethics and/or poor compliance actions cannot and will not be tolerated and will be grounds for disciplinary action, up to and including termination of employment. Every employee has a responsibility to know applicable laws, rules and regulations and RRD policies and procedures that apply to him or her in the course of their jobs. If there are procedures that apply to you or your job that you do not understand, you should ask to have them explained to you by your supervisor.

### **3. HOW TO HANDLE AND REPORT ETHICAL AND/OR COMPLIANCE ISSUES**

#### **3.1 Violations of Law or the RRD Integrity Policy**

Officers, employees, contractors, business associates and agents of RRD who know of or suspect violations of law or the RRD Integrity Policy (Section 4.1) should immediately contact their supervisor, or if they are uncomfortable sharing a concern with their supervisor or not satisfied by the response, they may contact the Healthcare Compliance Officer or any member of the Healthcare Compliance Committee. Reports can be made in person or in writing. Employees can choose to remain anonymous if preferred by, for example, sending an unsigned letter in a confidential envelope to the Healthcare Compliance Officer. Employees should not attempt to investigate known or suspected violations on their own. Reporting fabricated violation or reporting in bad faith with ill-intent will not be tolerated. Absolutely no retribution is permitted or will be tolerated for reporting possible violations in good faith.

To report a violation, in addition to the above, please follow the directions given on the Company's website at: <http://recordatirarediseases.com/compliance>

#### **3.2 Other Violations**

If an ethical or compliance issue that does not involve a breach of law or of the RRD Integrity Policy arises in connection with your job, your supervisor is often the best person to approach for assistance in resolving the issue. If your supervisor is not available, or you do not feel comfortable addressing the issue with your supervisor, you may discuss the issue with another manager in your department or with your manager's manager. If your issue involves a particular area of expertise, such as Regulatory or Quality, you may wish to contact a Manager within that department. If you are not sure who to contact for an ethical or compliance issue, the Healthcare Compliance Officer or a member of the Healthcare Compliance Committee is always available to help you.

### **4. CORPORATE COMPLIANCE PROGRAM**

#### **4.1 RRD Integrity Policy**

## **INTEGRITY POLICY**

### *Corporate Integrity and Ethics*

RRD is committed to the highest standards of ethics, honesty, and integrity in pursuit of its mission. All officers, employees, contractors, business associates and agents are expected to adhere to these Standards of Conduct in the discharge of their duties.

*Compliance with Laws and Regulations*

RRD is committed to obeying all applicable international, federal, state, and local laws, regulations and industry standards. It is the responsibility of each individual officer, employee, contractor, business associate and agent, to obey all applicable laws and regulations in the course and scope of his or her work for or on behalf of RRD.

*Work Environment*

RRD is committed to providing a work environment that is physically safe and free from discrimination and harassment. All officers, employees, contractors, business associates and agents are expected to uphold RRD's commitment to ensuring quality working conditions.

*Accounting Principles*

RRD is committed to ensuring that all of the RRD's assets, profits, losses, and financial transactions are properly documented, fully accounted for, and promptly recorded in the appropriate books and records in conformity with applicable general accounting principles.

*Fees to Consultants, Agents and Government Employees*

RRD is committed to legal remuneration in all of the RRD's contractual arrangements. Payment of fees to health care practitioners, consultants, contractors, or other third party agents on behalf of RRD are only allowed in those instances where the services required are legitimate and necessary and if the payments represent fair market value and reasonable consideration for the services rendered. In addition, neither RRD nor its employees or agents will make improper payments or payments with a corrupt intent to government officials in order to influence substantive decisions of a judgmental nature by such government official.

*Confidentiality*

RRD is committed to respecting and maintaining the confidentiality of personal and medical information. RRD is committed to safeguarding confidential information and prohibiting its disclosure inconsistent with applicable law.

*Conflict of Interest*

RRD is committed to avoiding any conflict of interest that offends the highest standards of corporate ethics, honesty, and integrity. All officers, employees, contractors, business associates and agents are expected to not only disclose but also affirmatively identify potential or perceived conflicts of interest in their work on behalf of RRD.

*Recordati S.p.A.*

RRD acknowledges its obligations to comply with the Ethics Code of the Recordati Group and the role of this Policy in facilitating and fulfilling its obligations thereunder as a member of the Recordati Group of companies. The Ethics Code of the Recordati Group can be accessed at <http://www.recordati.com>.

## **4.2 Healthcare Compliance Officer**

### **4.2.1 Appointment**

The Company has appointed a Healthcare Compliance Officer. This individual also serves as the Chair of the Healthcare Compliance Committee.

### **4.2.2 Responsibilities**

With the active assistance, counsel and guidance of the Healthcare Compliance Committee, the Healthcare Compliance Officer shall have final authority and be responsible for the overall implementation and maintenance of the RRD Compliance Program. Specifically, the Healthcare Compliance Officer shall:

- Regularly review statutory and regulatory compliance matters and developments;
- Periodically monitor and audit departments of RRD to assess their adherence with the Compliance Program and all applicable laws, rules regulations and industry standards;
- Train, educate, and update officers, employees, contractors, business associates and agents about the Compliance Program, as appropriate;
- Develop effective lines of communication;
- Assist departments of RRD in implementing any corrective action plan, including enforcing standards through well-publicized disciplinary guidelines;
- Initiate and lead the activities and responsibilities of the Healthcare Compliance Committee;
- Report and apprise the Recordati S.p.A. Group Internal Audit Department, the Recordati Group Legal Department, and obtain U.S. legal counsel on significant issues impacting the compliance status of the Company;

### **4.2.3 Authority**

The Healthcare Compliance Officer shall have the authority to coordinate with all departments of RRD on any compliance activity or matter. The Healthcare Compliance Officer shall report directly to the General Manager.

## **4.3 Healthcare Compliance Committee**

### **4.3.1 Membership**

The Board of Directors has the authority to appoint the Healthcare Compliance Committee and has elected the following functions to serve as active advisory members on this Healthcare Compliance Committee:

#### Committee Membership

General Manager (ad-hoc)  
Healthcare Compliance Officer  
Commercial Operations  
Finance and Administration  
Technical Operations  
Regulatory Affairs  
Medical Affairs  
Legal

### **4.3.2 Responsibilities**

The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, will develop and implement internal controls and procedures that promote RRD's adherence to all laws, rules, regulations, industry standards and requirements that apply to any aspect of the business. The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, will also monitor RRD's commitment to compliance and the highest standards of ethical and just conduct. The goal of the Healthcare Compliance Committee is to prevent, identify and correct unlawful and/or unethical behavior.

The Healthcare Compliance Officer, with the active involvement and advisement of the Healthcare Compliance Committee, will have final authority to develop, implement, and maintain a Compliance Program for RRD that will consist of:

- Written standards of conduct and policies/procedures that codify the Company's commitment to compliance;
- Regular education and training programs for all affected employees;
- An effective line of communication between the Healthcare Compliance Officer and all employees and a confidential system/process by which

compliance issues can be reported while protecting the anonymity of the complainant;

- An audit process to help monitor compliance and to identify problem areas;
- A mechanism to perform independent investigations of potential compliance or ethical breaches;
- Policies to ensure that appropriate disciplinary actions are taken for any employee who is found to be guilty of non-compliance or misconduct; and
- A mechanism to report any self-discovered violations to appropriate federal, state, and local agencies within 60 days after a determination is made that there is credible evidence of a reportable violation.

### **4.3.3 Meetings**

The Healthcare Compliance Committee should meet quarterly. The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, shall have the authority to schedule additional meetings or to cancel scheduled meetings as necessary.

## **4.4 Education and Training**

### **4.4.1 Mandatory Education and Training**

RRD is committed to educating and training its employees about the Compliance Program. All employees shall be educated and trained about relevant standard operating policies and procedures related to the Compliance Program. In addition to the Compliance Program, each respective department shall be trained on their particular applicable policies and procedures.

### **4.4.2 Schedule**

All employees shall be educated and trained about the Compliance Program on an annual basis. New employees shall be educated and trained about the Compliance Program within 60 days of their date of hire. Additional or specific education and training sessions may be held as necessary to comply with any corrective action plan, to address new statutory or regulatory developments or as supplemental and reinforcement training as determined by the Healthcare Compliance Officer or Healthcare Compliance Committee.

### **4.4.3 Documentation**

Each employee shall certify in writing (either electronically or in writing) his or her completion of or attendance at the education and training sessions. RRD shall maintain a training file for each employee and shall monitor/audit these files

periodically to ensure that each employee has obtained the required education and training in a timely manner.

## **4.5 Reporting and Remediation**

### **4.5.1 Duty to Report**

It is the duty of every employee to report, in good faith, at the first opportunity his or her belief that a violation of RRD's Integrity Policy has occurred. Employees may report suspected violations to their supervisor, the Healthcare Compliance Officer, or any member of the Healthcare Compliance Committee in writing or in person. If a report is made in writing, then the report may be made anonymously, in which case the employee should give as much detail as possible in order to assist in the investigation of the suspected violation.

### **4.5.2 Response to Reporting**

The Healthcare Compliance Officer with the assistance and input from the Healthcare Compliance Committee shall investigate all suspected violations of the Compliance Program. RRD shall not take adverse action against any employee who in good faith reports a suspected violation of the Compliance Program in accordance with the standard operating policies and procedures and who was not involved in the suspected violation.

### **4.5.3 Corrective Action**

With the assistance of the Healthcare Compliance Committee, the Healthcare Compliance Officer shall establish a corrective action plan in response to an actual violation. Suspected violations of the RRD Integrity Policy will be investigated, and violators will be disciplined, all in a fair manner regardless of the suspected violator's position within RRD.

### **4.5.4 Disciplinary Action**

RRD may discipline all violators of the RRD Integrity Policy, dependent upon the nature of the violation. If the investigation by the Healthcare Compliance Officer or the Healthcare Compliance Committee determines that an actual violation has occurred, then the corrective action plan established by the Healthcare Compliance Committee, with specific input and guidance from the available legal and human resources advisors as necessary, shall be put into effect, which may include disciplinary action, up to and including termination of employment as necessary for any violators identified.

### **4.5.5 Documentation**

The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, shall document its investigation of any report of a suspected

violation of the Compliance Program. If its investigation results in the conclusion that an actual violation has occurred, then the Healthcare Compliance Committee shall establish a corrective action plan. The Healthcare Compliance Committee shall retain its records and documents for a period of seven (7) years from the date of creation.

## **4.6 Monitoring and Auditing**

### **4.6.1 Mandatory Internal Monitoring and Auditing**

The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, shall periodically audit various departments of RRD to ensure compliance with applicable laws, regulations, and internal operating procedures. The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, shall have the authority and financial resources to retain outside auditors as needed.

### **4.6.2 Schedule**

The Healthcare Compliance Committee shall audit an element of at least one department of RRD per year. The Committee may conduct additional audits as necessary. Each department may be subject to additional audits per year.

### **4.6.3 Response to Internal Monitoring and Auditing**

The Healthcare Compliance Committee, under the direction of the Healthcare Compliance Officer, shall establish a corrective action plan as necessary in response to an internal audit.

### **4.6.4 Response to External Monitoring and Auditing**

RRD is committed to cooperating with government investigators as required by law. If an employee receives a subpoena, search warrant, or other similar document, before taking any action, the employee must immediately contact the Healthcare Compliance Officer. The Healthcare Compliance Officer is responsible for authorizing the release or copying of documents. If a government investigator, agent, or auditor comes to a RRD facility, the Director of Regulatory Affairs or Healthcare Compliance Officer must be contacted before an employee discusses any matter with such investigator, agent, or auditor.

With the assistance of the Healthcare Compliance Committee the Healthcare Compliance Officer shall establish a corrective action plan as necessary in response to an internal or external audit.

### **4.6.5 Documentation**

The Healthcare Compliance Officer shall document every audit. The Healthcare

Compliance Officer shall retain his or her records and documents for a period of seven (7) years from the date of creation.

## **5. PERSONAL ETHICS AND INTEGRITY**

### **5.1 Conflict of Interest**

Employees and officers of RRD are required to avoid any situation in which their personal interest or that of a family member, friend, or associate might affect or restrain their actions, restraint from actions, or decisions in the course of normal business activities. Employees and officers must not accept any gift or entertainment that is intended to, may appear to, or in fact does improperly influence the way RRD conducts business. Employees also must not offer any gift or entertainment that is intended to, may appear to, or in fact does improperly influence those with whom RRD conducts business. If there is any question regarding this matter, please contact the Healthcare Compliance Officer.

### **5.2 Disclosure of Confidential and Proprietary Information**

RRD owns intellectual property that is of great economic value to RRD, and all employees must safeguard and not disclose RRD's proprietary information to unauthorized parties.

## **6. WORK ENVIRONMENT**

### **6.1 Health and Safety**

RRD is committed to complying with all applicable federal and state laws, regulations, and policies governing working conditions and the health and safety of workers, including those established by the US Occupational Safety and Health Administration ("OSHA") and the US Department of Labor.

### **6.2 Nondiscrimination/Harassment**

RRD is committed to the principles of equal opportunity and affirmative action. RRD does not discriminate on the basis of race, color, religion, sex, national or ethnic origin, age, disability, sexual orientation, or military service in its employment policies.

Any employee who experiences harassment or discrimination on the basis of race, color, religion, sex, national or ethnic origin, age, disability, sexual orientation, or military service should immediately seek assistance by contacting their manager or the Healthcare Compliance Officer. RRD prohibits retaliation against any employee who utilizes such resources in good faith to make complaints of harassing or discriminatory conduct.

### **6.3 Debarment and Exclusion**

RRD shall not hire or enter into contracts with individuals or entities who have been convicted of health care related violations or who are or have been listed on the FDA debarment list, excluded, or otherwise ineligible to participate in federal health care programs. RRD shall conduct due diligence as part of the decision-making process in hiring and retaining individuals and entities and in engaging in business relationships with individuals and entities.

### **6.4 Privacy**

RRD is committed to safeguarding the privacy of the personal and health information of its employees. RRD shall comply with all applicable international, federal, state or local laws, regulations, and policies governing the protection of privacy, including when applicable the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”).

## **7. MANUFACTURING, DISTRIBUTION AND MARKETING AUTHORIZATION**

### **7.1 Good Manufacturing Practices**

RRD is committed to complying with current Good Manufacturing Practices during the manufacture, testing, packing, and storing of its products. RRD shall oversee contract manufacturing and analytical testing facilities to ensure that all products distributed under the RRD name have the identity and strength and meet the quality and purity characteristics that they are represented to possess.

### **7.2 Intellectual Property**

RRD is committed to complying with all applicable intellectual property laws of the countries in which the Company operates. RRD shall not infringe on patents, trademarks, or copyrights of third parties and shall not seek to obtain trade secrets from third parties.

### **7.3 Customs and Export Controls**

RRD is committed to complying with all applicable import and export controls of the countries in which the Company operates. As a corporation with headquarters in the United States, RRD shall respect all embargoes and international boycotts imposed by the U.S. federal government. Employees must not enter into business dealings with restricted countries, individuals, or entities.

### **7.4 Product Recall**

RRD shall remove any of its drug products from the domestic and foreign markets in the event of the discovery of an unacceptable health hazard or risk associated with its use. RRD shall submit applicable reports to regulatory authorities for any

product that fails to meet established specifications during ongoing analytical testing, and RRD shall discuss with these authorities the disposition of such product.

## **7.5 Marketing Authorizations**

All data submitted by RRD to support to support its marketing authorizations will be reviewed and will be certified to be true and accurate to the best of the Company's knowledge. All marketing authorizations will be maintained according to applicable laws and regulations.

## **8. SALES AND MARKETING**

### **8.1 Fair Trade Practices**

RRD is committed to complying with all applicable federal and state laws, regulations, and policies governing antitrust, deceptive trade practices, and consumer protection. RRD shall not set charges in collusion with competitors, enter into unlawful exclusive arrangements with vendors, or share confidential information with competitors. RRD shall not furnish misleading or false information about its products to its consumers.

### **8.2 Prescription Drug Marketing**

RRD shall implement practices to ensure that none of its products are diverted from appropriate channels of distribution. RRD shall administer its prescription drug sampling program in full compliance with all applicable State and Federal laws including the Prescription Drug Marketing Act ("PDMA"), and RRD shall monitor and report to appropriate authorities any potential or actual diversion of drug samples.

RRD shall not engage in promotional programs regarding the use of any of its products for indications or uses not approved by the appropriate regulatory authorities, including the U.S. Food and Drug Administration ("FDA"). Any dissemination of off-label information regarding a RRD product to a health care practitioner, a pharmacy benefit manager, a health insurance issuer, a group health plan, or a federal or state government agency shall fully comply with RRD procedures. Off-label promotion is strictly prohibited.

### **8.3 Fraud and Abuse**

RRD is committed to complying with all federal and state laws, regulations, and policies governing fraud and abuse, including applicable Anti-Bribery laws, the Anti-Kickback Law, the Civil Monetary Penalty Statute, the Office of Inspector General ("OIG") Compliance Guidance for Pharmaceutical Industry, and the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with

Health Care Professionals.<sup>1</sup> No officer, employee, contractor, business associate or agent may solicit, accept, offer, or give gifts, gratuities, or favors of any kind in the performance of RRD's business, if it will appear to obligate, or will actually obligate, the person who receives it, or if solicited or offered for the purpose of influencing the business decision of the person who receives it. Receiving or giving inappropriate gifts or cash is never allowed. The meaning and perception of the solicitation, acceptance, offer or giving of non-monetary gifts, gratuities or personal benefits or favors may be interpreted in a variety of ways by different people depending on the situation.

#### **8.4 Pricing Calculations**

RRD is committed to ensuring that all data used in calculations performed for purposes of determining pricing under government programs shall be determined in good faith and in accordance with applicable law.

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<sup>1</sup> Note that RRD has adopted the PhRMA Code in all states requiring adoption of the Code (cf. State Laws Policy). In states not requiring adoption of the PhRMA Code, RRD has adopted the Code with one exception. Section 2 of the PhRMA Code limits meals offered to HCPs in connection with informational presentations made by field sales representatives or their immediate managers to in-office or in-hospital settings. The RRD VP-Commercial Operations currently serves as the immediate manager of certain field sales representatives. The RRD Meals, Hospitality and Gifts Policy permits the RRD VP, Commercial Operations to provide an occasional meal incidental to a substantive interaction with an HCP outside of his office or hospital, even though he is an immediate supervisor of field sales representatives, provided that the other requirements of the PhRMA Code and RRD Meals, Hospitality and Gifts Policy are met. The Compliance Committee reviewed this issue and made the determination that this exception to the PhRMA Code is appropriate based on the size, organizational structure and business needs of RRD.