

**TERCICA COMPREHENSIVE COMPLIANCE PROGRAM**  
(Approved August 2, 2005)

**I. Key Goals of the Comprehensive Compliance Program**

The key goals of Tercica's Comprehensive Compliance Program (the "Compliance Program") are to establish, implement and enforce effective:

- compliance with Tercica's policies and applicable laws and regulations, including without limitation, California Health and Safety Code Section 119402 *et seq* ("CHSC 119402"); the 2003 Guidance of the Office of the Inspector General of Health and Human Services, Compliance Program Guidance for Pharmaceutical Manufacturers (the "OIG Guidelines"); and the 2002 PhRMA Code on Interactions with Health Care Professionals (the "PhRMA Code"); and Tercica's Code of Business Conduct and Ethics.
- clear and uniform written standards of conduct, policies and procedures;
- education and training programs for Tercica employees regarding their responsibilities for maintaining a high level of compliance and ethical and legal behavior;
- procedures for auditing compliance;
- procedures for receiving employee concerns and questions and encouraging employees to report allegations of non-compliance; and
- fair processes for taking disciplinary actions for non-compliance.

**II. Compliance Committee**

The Compliance Committee is responsible for oversight of the Compliance Program and is comprised of the members of the Management Committee, **the Vice President of Regulatory Affairs, the Vice President of Quality, and the Senior Director of Technical Operations**. The Compliance Committee meets at least twice annually. The responsibilities of the Compliance Committee include the following:

- Setting goals and monitoring the progress of the implementation of the Compliance Program;
- Monitoring compliance review, implementation, training and auditing activities;
- Approving major non-GXP companywide or cross-departmental compliance policies (e.g., Code of Business Conduct and Ethics, Signature Authorization Policy, etc.);

- Recommending periodic updates to the Compliance Program; and
- Reporting to the appropriate committee of the Board of Directors (i.e., Audit and/or Corporate Governance and Nominating Committee) on all significant compliance matters, including providing periodic reports of any anonymous tips received by the Compliance Committee.

The Compliance Committee will be responsible for monitoring compliance with this Compliance Program. The Company's General Counsel will be responsible for scheduling and setting agendas for Compliance Committee meetings.

### **III. Operation of the Compliance Program**

The Compliance Program consists of five components: (A) establishing compliance policies, (B) education and training, (C) reviewing and assessing compliance, (D) reporting of non-compliance and (E) monitoring and responding to compliance issues.

#### *A. Compliance Policies and Specific Limitations*

Each department is responsible for establishing, implementing and enforcing compliance policies in the department's respective area. For example: the head of Commercial Operations is responsible for establishing policies governing marketing and sales and interactions with healthcare professionals that are in compliance with the OIG Guidelines and PhRMA Code; the CFO is responsible for establishing policies governing accounting, internal controls, investments, etc.; the Chief Medical Officer is responsible for establishing policies governing good clinical practices (GCP); the head of Quality is responsible for establishing policies governing good manufacturing practices (GMP), etc.

The Compliance Committee approves non-GXP Company-wide or cross-departmental compliance policies (e.g., this Compliance Program, Code of Business Conduct and Ethics, etc.). In addition to the foregoing, this Compliance Program explicitly includes the following:

#### **Limits on gifts and incentives to medical or health care professionals;**

Tercica has also established guidance regarding appropriate interactions with medical or health care professionals. It is Tercica's policy to comply with the PhRMA Code, which includes limits on incentives, gifts, meals and other activities with medical or health care professionals.

#### **Annual Spending Limit**

For purposes of complying with the California Health and Safety Code §119402, Tercica has established, commencing August 31, 2005, a maximum annual aggregate dollar limit of \$2000 for gifts, promotional materials or activities provided to California health care professionals. This dollar limit represents a spending cap, not a goal or average, and typically the amount spent per physician is anticipated to be substantially less than this

maximum amount. Waiver of limit would require the approval of the Compliance Committee.

*B. Education and Training*

Each department will create and administer an appropriate compliance training program to cover the department's policies, and collaborate with other departments for cross-departmental training, as appropriate. Human Resources will be responsible for training employees on non-GXP company-wide or cross-departmental compliance policies (e.g., this Compliance Program, Code of Business Conduct and Ethics, etc.). Training will be conducted by qualified individuals on a continuing basis and with sufficient frequency to ensure that employees remain familiar with the Tercica's policies and the requirements applicable to them. Each department will review its training program annually, and update it as necessary. Tercica employees must be familiar with Tercica's policies and SOPs and the applicable laws and regulations that apply to their activities at Tercica. All Tercica employees are required to participate in Tercica's training programs.

*C. Reviewing and Assessing Compliance*

Each department head is responsible for periodically reviewing and assessing their department's compliance with the Compliance Program and for ensuring that all members of the department attend appropriate training programs. Department heads will report any significant non-compliance to the Compliance Committee. Monitoring, including cross-departmental and outside audits, will be conducted as described in Section III.E. below.

*D. Reporting of Non-Compliance*

Tercica's Compliance Program relies on the identification and reporting by employees of actual and potential non-compliant activities. Tercica has established various communication mechanisms (e.g., anonymous tip line) that permit employees to report, ask questions, raise concerns about or report actual or suspected violations without fear of retaliation.

1. Reporting Procedures

When an employee becomes aware of any actual or potential violation of Tercica's policies or applicable laws or regulations, they should report the violation to the persons and in the manner provided in the "Reporting Procedures" section of Tercica's Code of Business Conduct and Ethics (**Appendix I**). Investigations into suspected violations will be conducted in accordance with the "Investigative Procedures" section of Tercica's Code of Business Conduct and Ethics (**Appendix I**).

2. "Open Door" Policy

3.

Tercica employees may discuss any compliance concerns, whether or not of a material nature, with supervisory personnel at any time. All supervisory and management personnel, including all officers, the heads of Human Resources and Legal Affairs, and the Chief Executive Officer, have an "open door policy" that permits employees to present any concerns, problems or complaints directly to, and ask questions directly of, senior personnel of Tercica. ***Tercica believes that working together in an atmosphere of genuineness and partnership provides the most productive work environment. Whatever the issue may be, employees are encouraged to discuss these matters with their supervisors.***

### 3. Policy on Retaliation

As provided in Tercica's Code of Business Conduct and Ethics, Tercica will take no adverse action against persons making good faith reports of actual or potential compliance issues. If any Tercica employee believes that they are being retaliated against for reporting a suspected violation, they should immediately contact a member of the Compliance Committee or report the violation in the manner provided in the "Reporting Procedures" section of Tercica's Code of Business Conduct and Ethics (**Appendix I**).

### 4. Response to Government Investigations or Litigation

*(Note: This section does not apply to regulatory inspections and audits; however, this section does specifically apply to, among other activities, those regulatory inspections and audits that concern marketing and/or sales activities..)*

State and federal agencies have broad legal authority to investigate Tercica and inspect and review its records. Tercica complies with subpoenas and cooperates with governmental inspections, reviews, and investigations to the full extent required by law. The General Counsel, in consultation with the CEO, is responsible for coordinating Tercica's response to inspections, reviews, investigations, litigation and the release of any related information. If a Tercica employee receives an investigative or litigation demand, subpoena, or search warrant involving Tercica, it should be brought immediately to the General Counsel. The employee should not release or copy any documents without authorization from the General Counsel. If an investigator, agent, or government auditor comes to Tercica, the General Counsel should be contacted immediately. Employees should ensure that the investigator waits until the General Counsel arrives before permitting any review of documents, interviews or signing anything. Legal Affairs is responsible for assisting with such reviews of documents and interviews, and Tercica will provide counsel to employees, where appropriate, to counsel employees regarding the signing

of documents. If a Tercica employee is approached by government investigators or agents, the employee has the right to insist on being interviewed only at Tercica, during business hours and with Tercica counsel present. Tercica employees are not permitted to alter, remove, or destroy documents or records of Tercica, except in compliance with Tercica's document retention and data integrity policies.

E. *Prevention and Monitoring and Responding to Compliance Issues*

The Compliance Program seeks not only to respond to issues reported by employees, but also to prevent potential compliance issues, and to identify and resolve any existing compliance issues. The key activities are described below:

1. Employee Qualifications

Tercica will not knowingly employ, engage, contract with or delegate authority to individuals or entities that are either: (a) listed by a federal agency as debarred, suspended or otherwise ineligible to participate in federal programs; or (b) excluded from federal health care programs under the Officer of the Inspector General (OIG) of the Department of Health and Human Services List of Excluded Individuals. In connection with the above, Human Resources will make reasonable and appropriate inquiries into the status of potential employees, consultants and contractors.

2. Compliance Audits and Reviews

**No department will audit or manage the audit of its compliance activities.** Legal Affairs will periodically audit, or arrange for the audit of, Human Resource's employment practices and compliance training and the press release practices of Investor Relations. Regulatory Affairs will periodically audit, or arrange for the audit of, Sales and Marketing's commercial practices and compliance training. The Company's outside financial auditors will audit the activities of the Finance Department. Tercica's external regulatory auditors will periodically audit, or arrange for the audit of, GXP, Promotional Review Committee and Medical Review Committee policies and practices. The departments with auditing responsibility may designate Tercica personnel to conduct audits or may retain independent consultants. Only those persons reasonably qualified may act as auditors. Tercica personnel must comply with their departmental audit policies. The results of all audits will be reported to the Compliance Committee, which will take appropriate action to address any material issues identified by the audits.

3. Response to Non-Compliance

Any Tercica employee who violates the Compliance Program will be subject to disciplinary actions, which will be assessed on a case-by-case

basis. Disciplinary actions may include oral or written warning, disciplinary probation, suspension, reduction in salary, demotion or dismissal from employment. These disciplinary actions also apply to a supervisor who directs or approves an employee's improper actions, or is aware of those actions but does not act appropriately to correct them, or who otherwise fails to exercise appropriate supervision.

#### **IV. Review and Updating of Compliance Program**

The Compliance Committee will review the Compliance Program from time-to-time and consider any proposed amendments to the Compliance Program.

The Compliance Committee will update the Compliance Program to comply with any applicable laws or regulations and within six months of any amendments to either the OIG Guidelines or the PhRMA Code.

#### **V. Public Disclosure of Compliance Program**

A copy of each of the following will be posted on Tercica's website:

- This Compliance Program, including the appendix:
- An annual written declaration in conformance with CHSC 119402 confirming Tercica's compliance with this Compliance Program and CHSC 119402; and
- Tercica's Code of Business Conduct and Ethics.

## APPENDIX I

### REPORTING PROCEDURES

One of Tercica's values is Genuineness. Accordingly, we strongly encourage you to freely discuss any complaint or conduct that you believe is improper with your supervisor, or with any of the following Reporting Designee (as you deem appropriate):

- ranking vice president of your group
- Associate Director of Human Resources
- General Counsel
- CEO
- Chairperson of the Corporate Governance and Nominating Committee of the Board of Directors
- Chairperson of the Audit Committee of the Board of Directors (for violations regarding accounting, internal accounting controls, disclosure controls or auditing matters)

Examples of improper conduct are: discrimination; harassment; other violations regarding Tercica's policies, accounting, internal accounting controls, disclosure controls or auditing matters; fraud; abuse of Tercica's assets or violations of laws, regulations or the policies or standards in this Code.

If you want to anonymously report a complaint or conduct that you believe is improper, you may send a letter or use our anonymous compliance webpage, which is operated by an outside vendor. Please see our intranet for instructions on how to use Tercica's anonymous reporting procedures. ***No retaliatory action will be taken against employees making good faith reports.***

### INVESTIGATIVE PROCEDURES

All good faith reports of misconduct will be taken seriously and will be subject to investigation and appropriate corrective actions. Upon learning of an allegation of misconduct, the Reporting Designee will inform the General Counsel and the CEO (unless the allegation concerns the General Counsel or CEO). As appropriate, the General Counsel, with CEO review, will conduct a timely, full and fair fact-finding to determine whether a violation has occurred. The General Counsel and CEO will timely inform the Chairperson of the Audit Committee of any misconduct allegations regarding accounting, internal accounting controls, disclosure controls or auditing matters; or the Chairperson of the Corporate Governance and Nominating Committee of any other allegations of material misconduct. The Chairpersons of the Audit Committee and Corporate Governance and Nominating Committee will timely inform the other members of their respective committees and the Board of Directors of any allegations of misconduct; provided that the Chairpersons will expedite such communications when it concerns allegations of material misconduct or allegations of misconduct pertaining to any officer (i.e., vice president or above) or any director.

If an allegation of misconduct concerns the CEO, the Reporting Designee will inform the General Counsel, who will inform the Chairman of the Board of Directors and either the Chairperson of the Corporate Governance and Nominating Committee or Audit Committee (for violations regarding accounting, internal accounting controls, disclosure controls or auditing matters).

If an allegation of misconduct concerns the General Counsel, the Reporting Designee will inform the CEO, who will inform the Chairman of the Board of Directors and either the Chairperson of the Corporate Governance and Nominating Committee or Chairperson of the Audit Committee (for violations regarding accounting, internal accounting controls, disclosure controls or auditing matters).

If an allegation of misconduct concerns a Director, the Reporting Designee will inform the General Counsel and the CEO, who will inform the Chairman of the Board of Directors and either the Chairperson of the Corporate Governance and Nominating Committee or Chairperson of the Audit Committee (for violations regarding accounting, internal accounting controls, disclosure controls or auditing matters).

If an allegation of misconduct concerns the Chairman of the Board of Directors, the Reporting Designee will inform the General Counsel and CEO, who will inform either the Chairperson of the Corporate Governance and Nominating Committee or Chairperson of the Audit Committee (for violations regarding accounting, internal accounting controls, disclosure controls or auditing matters). The Legal Department will ensure the confidentiality (i.e., on a need-to-know basis) and retention of all anonymous reports and investigative records.

#### **DISCIPLINARY ACTIONS**

The matters covered in this Code are of the utmost importance to Tercica, its stockholders and its business partners, and are essential to our ability to conduct our business in accordance with our stated values. We expect all of our employees, directors, agents, contractors and consultants to adhere to these rules in carrying out their duties for Tercica.

Tercica will take appropriate action against any employee, director, agent, contractor or consultant whose actions are found to violate any laws or regulations, these policies or any other company policies. Disciplinary actions may include immediate termination of employment or business relationship at Tercica's sole discretion. Where Tercica has suffered a loss, it may pursue its remedies against the individuals or entities responsible. Where laws have been violated, Tercica will cooperate fully with the appropriate authorities.