



## **KV Pharmaceutical Company**

### **Compliance Program Description**

***Posted as Required by Cal. Health & Safety Code §§ 119400-119402***

KV Pharmaceutical Company and each of its subsidiaries, including Ther-Rx Corporation and ETHEX Corporation (collectively, the “Company”) are firmly committed to compliance with federal, state, and local laws and regulations in all facets of their corporate activities. Accordingly, the Company has instituted a corporate compliance program (the “Compliance Program”) covering all of its operations and applicable to (1) all permanent and temporary employees and directors<sup>1</sup> of the Company and each of its subsidiaries, and (2) independent contractors, agents, and representatives (collectively, “contractors”) of the Company who are engaged in sales and marketing activities and who have notice of the provisions of the Compliance Program.

The Company’s Compliance Program is structured around the seven elements identified in the April 2003 Department of Health and Human Services, Office of Inspector General “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Guidance”). This Compliance Program Description provides an overview of the Company’s Compliance Program. As discussed in the OIG Guidance, the Company has tailored its Compliance Program to the characteristics of the Company. A compliance program is not a static set of rules, but a combination of policies, procedures, and programmatic elements that may be adapted to effectively address changing needs.

The KV Board of Directors has reviewed and approved the Company’s Compliance Program and will review on an annual basis any changes to the Compliance Program, as well as review relevant compliance metrics for the previous year. The Board of Directors has delegated authority to KV’s Corporate Compliance Officer to implement and administer the Compliance Program for all KV entities. Every employee is responsible for reviewing the

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<sup>1</sup> The term “Director” as used throughout this Program Description refers to any member of the Company’s Board of Directors.

Employee Handbook, the Corporate Compliance Policy (as defined below), applicable Policies and Procedures (as defined below), and other compliance-related documents distributed to Company employees. The Corporate Compliance Officer will ensure that applicable compliance-related documents are accessible to all personnel. Every director, officer, manager and employee is subject to, and is responsible for adhering to, the standards set forth in the Company's Compliance Plan and other Company compliance-related directives.

## **PURPOSES OF THE COMPANY'S COMPLIANCE PROGRAM**

The Company's Compliance Program is an integrated, enterprise-wide set of policies, practices, and internal controls designed to prevent, detect, and correct illegal or other improper activity, and to promote compliance with federal, state, and local laws and company policies. A primary goal of the Compliance Program is to promote within the Company a culture of commitment to the prevention, detection, and resolution of situations that may not conform to applicable standards of conduct or business ethics.

We are committed to producing high quality products and providing high quality services in full compliance with all applicable requirements and authorities, and an effective Compliance Program will help achieve these goals. While the OIG Guidance recognizes that even an effective compliance program cannot entirely eliminate all improper conduct by individuals, an effective Compliance Program can help prevent misconduct from occurring, and can identify and resolve potential problems before they become more serious. A commitment to compliance is also good business: customers and suppliers not only expect companies to have effective compliance programs, but frequently take a company's commitment to compliance into account when deciding whether to do business with that firm. Employees, shareholders, contractors, and other stakeholders also benefit from an effective compliance program, because morale and productivity are higher when all involved are aware of the Company's commitment to high ethical standards.

## **ELEMENTS OF THE COMPANY'S COMPLIANCE PROGRAM**

### **1. WRITTEN STANDARDS**

The Company's Compliance Program includes multiple written standards, including: (1) KV's Compliance Plan, (2) KV's Employee Handbook, (3) the KV "Standards of Business Ethics Policy" (the "Corporate Compliance Policy"), (4) official written policies and procedures governing the duties, activities, and responsibilities of KV employees ("Policies and Procedures"), and (5) Company compliance-related memoranda, publications, and training materials. These Compliance documents support the Company's Compliance Program. The Employee Handbook sets forth policies, principles, and rules

governing ethical conduct of employees, and provides an overview of the Company's philosophy, culture, mission statement, and general corporate statements of ethical and compliance principles (i.e., code of conduct). In addition, the Corporate Compliance Policy sets forth a detailed statement of the Company's compliance philosophy and commitment to compliance, as well as practical guidance on how to handle compliance issues arising in specific areas.

The OIG Guidance identifies several potential risk areas of particular relevance to pharmaceutical manufacturers: (1) data integrity pertaining to government reimbursement policies, (2) kickbacks and other illegal remuneration, and (3) compliance with laws regulating drug samples. The Company has written standards addressing these areas. The Policies and Procedures are official written requirements detailing duties, responsibilities, and activities involved in an individual's daily work. Many Policies and Procedures incorporate specific regulatory requirements, e.g., compliance with Medicaid rebate regulations or federal procurement laws. Other examples of Policies and Procedures include a policy on compliance with federal health care program rules and requirements, policies relating to various pricing-related topics, sales and marketing compliance standards (including drug sample management, where applicable), PhRMA Code guidelines, and a senior executive code of ethics.

Also, compliance-related memoranda, publications, and training materials provide timely and targeted guidance to personnel on discrete compliance-related topics and supplement the Corporate Compliance Policy, this Compliance Plan, the Policies and Procedures, and the Employee Handbook.

KV Pharmaceutical Company, Ther-Rx Corporation, and ETHEX Corporation have each established a specific annual dollar limit on gifts, promotional materials, or items or activities that it may give or otherwise provide to an individual California-based medical or health care professional: for each entity, the annual limit is \$2,500.00.

## **2. LEADERSHIP AND STRUCTURE**

The Director, Employee and Labor Relations has been appointed as the Company's Corporate Compliance Officer ("CCO"). The CCO has direct access

to the Chief Executive Officers (“CEOs”) and Presidents, boards of directors and board committees (including but not limited to the Audit Committee), all senior management, and in-house legal counsel as well as subject matter expert external legal counsel, and is the focal point for the Company’s compliance activities. The CCO has the authority, subject to any restrictions of law, to review all documents and records created or controlled by any department or business unit. The CCO will demonstrate high integrity, good judgment, assertiveness, and an approachable demeanor, while eliciting the respect and trust of employees.

The Director of Human Resources, Vice President of Staffing, and Vice President of Corporate Quality Assurance/Quality Control have each been designated to assist the CCO in implementing the Company’s Compliance Program.

The CCO’s efforts are also supported by the CEOs and Presidents. The CEO of KV Pharmaceutical Company and the CEOs/Presidents of each subsidiary are ultimately responsible for their respective entities and for their employees’ compliance with law, regulation, and Company policy. Assisted by the CCO and other members of management, the CEOs and Presidents develop corporate policy, oversee the Compliance Program, and have overall responsibility for their entities’ adherence to legal and contractual obligations.

In addition, the CCO will consult with subject matter expert legal counsel for guidance on matters requiring legal advice or analysis. Both external and internal counsel will provide legal direction and guidance on the legal framework governing compliance matters, and will assist the CCO in formulating appropriate corrective action and reporting misconduct to the CEOs/Presidents as appropriate, to the Audit Committee if reasonable responsiveness is not demonstrated by the CEO/President, or subsequently to proper authorities in the event reasonable responsiveness is not demonstrated by the previously listed channels. They may also assist the CCO if requested to participate in internal investigations of suspected wrongdoing.

Company managers and supervisors will assist the CCO by implementing the Compliance Program, enforcing standards, reporting misconduct, and ensuring that personnel under their control are aware of and comply with all applicable laws, regulations, and corporate policies.

### **3. EDUCATION AND TRAINING**

In addition to the requirement that all new employees read (and acknowledge reading) KV’s Corporate Compliance Policy, the Company has developed and implemented compliance education and training for affected employees. The CCO will, in consultation with the CEOs and Presidents, the

KV Law Department, Company Training personnel, and appropriate subject matter experts, oversee the Company's compliance training and education program. This compliance training program includes broad compliance training for all sales and marketing employees of Ther-Rx and ETHEX, targeted training on selected compliance-related topics for affected employees (e.g., Government Contract Compliance training, Medicaid Drug Pricing Compliance training, etc.), and periodic compliance training to other key functional areas on an ad hoc basis. Training records are maintained in the Company's Professional Development Learning Management System (LMS). In addition, the Employee Handbook and Human Resources Policies and Procedures are available to all employees on the Company's intranet, and the CCO, the Company's Law Department, and all supervisors/managers will be available or will provide appropriate approved resources on a continuing basis to answer questions from employees who seek clarification of compliance issues. Additional training may be provided based on issues identified during internal reviews.

In partnership with external and internal legal counsel and appropriate functional area managers, the CCO will ensure that relevant publications issued by or on behalf of the government or other regulatory bodies are appropriately distributed to CEOs/Presidents, supervisors and managers, and affected employees. In conjunction with counsel, the CCO will also periodically disseminate compliance-related memoranda announcing new Policies and Procedures or changes to Compliance Program documents as necessary to respond to new federal or state laws, rules, regulations, industry standards, and incorporate these additions into training and compliance program materials, where appropriate.

#### **4. LINES OF COMMUNICATION**

All functional area heads and management personnel have an "open door policy" allowing employees to discuss any possible compliance problems. The CCO or one of the three principal designees will be reasonably available to respond to individuals who seek clarification with respect to the Compliance Program or any related policy or procedure.

Employees and contractors are required to report any significant compliance problem of which they become aware. The failure to report a problem of which an employee or contractor is aware may itself represent a potential violation of the Company personal conduct policies and the Compliance Program. Individuals who wish to remain anonymous may report suspected violations via the Compliance Hotline (see below). Where an individual making a report identifies him- or herself in the report but requests that his or her identity remain confidential, the Company will endeavor to maintain the requested anonymity to the extent consistent with the best

interests of the Company. In some instances, however, the Company may need to reveal the person's identity, if known, in order to comply with legal requirements and/or to facilitate an investigation.

Generally, reports of possible compliance-related violations are made to the employee's supervisor or next level manager/executive, and/or directly to the CCO or one of the other three principal Compliance Officer designees, either in person, by telephone, in writing or email, or through the Compliance Hotline. Supervisory personnel who receive compliance-related reports should promptly report the information to the CCO, who will then review the report and take appropriate action, including, where appropriate, coordination regarding an internal investigation.

The Company has established and publicized a Compliance Hotline to report any suspicion of wrongdoing or suspected violations of legal or ethical standards and also for posing questions regarding the requirements of the Compliance Program or related Policies and Procedures. The Compliance Hotline is operated by an independent third party service provider, and is available to callers 24 hours a day, 7 days a week. Callers can request that their identity not be disclosed, providing for complete anonymity, if desired. The CCO will maintain a log of Hotline calls, including the nature and result of any investigation. The phone number for the Company's Compliance Hotline is 1-800-679-0187 (toll free).

The successful implementation of this Compliance Program depends in part on the willingness of employees and contractors to ask questions and raise concerns about compliance issues. Accordingly, no form of retaliation may be taken against (1) directors, employees, or contractors who make good faith claims or complaints to the company or to any agency charged with jurisdiction over the complaint or claims, or (2) witnesses to any such complaints or claims.

## **5. COMPLIANCE AUDITING AND MONITORING**

The Company's auditing and monitoring activities may take several forms.

For example, the CCO will ensure the proper processing and maintenance of records of compliance-related reports and communications. These activities will include recording and maintaining reports of possible violations of the Compliance Program as well as all inquiries or complaints relating to the Compliance Program; recording the appropriate disposition of compliance-related reports; requesting assistance from legal counsel when appropriate, monitoring compliance files, and incorporating corrective actions and lessons learned into the Company Policies and Procedures or other Compliance Program documents or activities as appropriate.

The Company will also conduct periodic internal reviews (self-audits) of systems, processes, and procedures to ensure that the Company complies with legal and policy requirements applicable to its operations. The frequency and comprehensiveness of such internal reviews will be based on such factors as the pervasiveness and complexity of relevant legal requirements, the risks and potential consequences of noncompliance, the importance of the system or process to the entity's operations, and the length of time that has passed since the system or process was reviewed previously.

If the CCO determines that there is reasonable cause to believe that a compliance issue may exist, an inquiry into the matter will be undertaken with appropriate assistance as requested from inside or outside counsel.

## **6. RESPONDING TO POTENTIAL VIOLATIONS**

As part of its commitment to compliance, the Company will not knowingly (a) hire, retain, or do business with any person or organization that has been excluded from participation in federal health care programs<sup>2</sup>; or (b) hire, retain, or offer any type of appointment to any person as an officer, director, or senior manager (plant managers/functional area heads and above) who (1) has been debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any federal agency<sup>3</sup>; (2) has been convicted of, or pleaded *nolo contendere* to, a criminal offense involving fraud in government programs; or (3) has been convicted of, or pleaded *nolo contendere* to, any felony within the past seven years. If a current employee or contractor becomes ineligible for continued employment, affiliation, or retention by virtue of any of the foregoing, the Company will, unless exceptional circumstances exist, terminate the employment or other contract, subject to any union or contract rights.

The CCO will work with the Company's Staffing Department to ensure that an appropriate background check – in accordance with applicable law – is part of every employment application and agreement. All applicants as well as current employees and contractors have a continuing obligation to inform management as soon as possible if they become the subject of any action, charge, or investigation which could lead to their ineligibility from participation in federal procurement or health care programs.

The Company will implement corrective action and discipline in response to compliance problems on a fair and equitable basis. All violations of

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<sup>2</sup> A listing of parties excluded from participation in federal health care programs is available on the internet at <http://www.oig.hhs.gov/fraud/exclusions.html>.

<sup>3</sup> A listing of parties excluded from procurement and nonprocurement programs is available on the internet at <http://www.epls.gov/epls/search.do>.

Compliance Program requirements by directors, officers, managers, and employees are subject to appropriate discipline. Violations subject to discipline include, without limitation, the failure to detect and report a problem of which the individual is aware or reasonably should have been aware. Intentional or reckless actions will subject individuals to more significant discipline than problems resulting from negligence.

The determination of appropriate discipline will take into account all relevant factors, to include existing contractual or other legal obligations affecting the individual.<sup>4</sup> Personnel reviews for employees should include an assessment of adherence to the Compliance Program. A record of any discipline imposed under the Compliance Program will be maintained in the individual's personnel record.

## **7. RESPONSES TO SUSPECTED COMPLIANCE PROBLEMS: INVESTIGATION AND CORRECTIVE ACTION**

In the event that an employee or contractor suspects that a violation of the Compliance Program may have occurred, he or she should immediately report the matter as discussed above (e.g., notify his or her supervisor or next level manager/executive, and/or the Compliance Officer or one of the other three principal Compliance Officer designees). Personnel receiving such reports should forward them to the CCO. The CCO or his/her designee will, in coordination with and under any direction from legal counsel as appropriate, promptly conduct an internal investigation of credible allegations of violations.

The OIG recognizes that even an effective compliance program may not completely eliminate misconduct. Nonetheless, a compliance program increases the likelihood of preventing – or at least identifying – unlawful or unethical behavior. Upon verifying the factual basis of a problem or suspected violation, the CCO, in consultation, as needed, with the affected management executive and appropriate external and/or internal legal counsel, will formulate and coordinate an appropriate response as soon as practicable. Corrective action may include preparing recommendations for a corrective action plan, notifying the Company's Audit Committee or board of directors of the matter and the planned response, addressing the practices within the functional area which led to the problem and incorporating measurements to confirm the problems are corrected, instituting disciplinary action against the employee

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<sup>4</sup> Although no element of the Compliance Program or any document pertaining to the Compliance Program will create or affect any contract rights that may exist between a KV entity and a person or entity employed or retained by KV, all KV directors and employees are nonetheless bound by the provisions of this Compliance Plan and Compliance Program documents.

who is involved in the problem (or exercising contractual remedies against a contractor who is involved in the problem), and implementing educational programs to prevent similar situations in the future.

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A primary goal of the Compliance Program is to promote within the Company a culture of commitment to the prevention, detection, and resolution of situations that may not conform to applicable standards of conduct or business ethics. In order to effectively address these issues, the CCO will periodically review the Compliance Program, and may adapt this program to address evolving needs.