



**Alexza Pharmaceuticals, Inc.**

A Ferrer Company  
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## **Summary of the Alexza Pharmaceuticals, Inc. Comprehensive Compliance Program Pursuant to California Health and Safety Code §§ 119400-119402**

### **1. INTRODUCTION**

Alexza Pharmaceuticals, Inc. (the "Company" or "Alexza"), a wholly owned subsidiary of Grupo Ferrer Internacional S.A. ("Ferrer"), is committed to establishing and maintaining an effective compliance program that promotes ethical conduct in accordance with the April 2003 "Compliance Program Guidance for Pharmaceutical Manufacturers," developed by the United States Department of Health and Human Services Office of the Inspector General ("OIG Guidance") and the Code on Interactions with Healthcare Professionals, mostly recently updated as of January 2022, issued by Pharmaceutical Research and Manufacturers of America (the "PhRMA Code").

To help achieve this objective, the Company has established a Comprehensive Compliance Program (the "Compliance Program") that is founded on the seven elements described in the OIG Guidance as well as the principles set forth in the PhRMA Code.

Alexza's Compliance Program is based on Ferrer's Ethics & Compliance Program, risk prevention and management, and the promotion of ethical culture in the organization. Ferrer ethical fundamental principles are available at Ferrer website (click [here](#) to visit our website) and Alexza adheres to the Ferrer Code of Ethics (click [here](#) to access).

The purpose of Alexza's Compliance Program is to prevent and detect violations of law or Company regulations. But, as acknowledged by the OIG Guidance, implementing a Compliance Program may not eliminate improper employee conduct in its entirety. Nevertheless, Alexza expects all employees, executive officers and directors to comply with applicable laws and regulations, the Ferrer Code of Ethics (available here [https://www.ferrer.com/sites/default/files/2022-11/Codi%20%C3%88tic\\_101122\\_EN\\_sin.pdf](https://www.ferrer.com/sites/default/files/2022-11/Codi%20%C3%88tic_101122_EN_sin.pdf))

applicable for Employees, Executive Officers, and Directors (the "Code"), and Ferrer policies and procedures established in support of the Code to which Alexza expressly adheres as being a subsidiary of Ferrer.

In case of violations of law or Company policy, the matter will be investigated and, if appropriate, Alexza will take disciplinary action and implement corrective measures to prevent future violations.

The following is an overview of the fundamental elements of our Compliance Program. As encouraged by the OIG Guidance, we have tailored these elements to address our Company's unique compliance needs. Moreover, Alexza regularly reviews the effectiveness of its Compliance Program and refines it to meet the Company and Ferrer's evolving compliance needs.



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## 2. OVERVIEW OF COMPLIANCE PROGRAM

### 2.1. Leadership and Structure

Alexza has designated an Ethics & Compliance Manager who is responsible for developing, maintaining, operating, and monitoring Alexza's Compliance Program. The Ethics & Compliance Manager also has the authority to effectuate changes within the Company as needed and the ability to exercise independent judgment. The Ethics & Compliance Manager has the authority to report directly to the corporate officers and/or board of directors.

### 2.2. Written Policies and Procedures

Alexza's parent company, Ferrer has an Ethical Code that contains the principles by which the Company and all its affiliates and subsidiaries conduct business.

The Code establishes the Company's expectation that each employee of the Company act in accordance with the highest ethical and legal principles. These measures reflect our commitment to compliance with federal and state laws, OIG Guidance and PhRMA Code. We review our policies and procedures on a routine basis and revise them as necessary to meet the changing requirements imposed by law.

### 2.3. Training and Education

Training and education are essential elements of Alexza's Compliance Program.

Compliance education is mandatory for Alexza employees and consists of both initial and refresher training on appropriate policies. Alexza regularly reviews and updates its training program to ensure the most current and meaningful education on Company policies and procedures and compliance with federal and state laws.

### 2.4. Effective Lines of Communication

Alexza is committed to fostering dialogue between management and employees. Our goal is that all employees, when seeking answers to questions, will know who to turn to for a meaningful response. Alexza's Ethics & Compliance Manager is available for the whole team. Additionally corporate consultation channel [compliance@ferrer.com](mailto:compliance@ferrer.com) is also available for Alexza's employees.

### 2.5. Monitoring and Auditing

Alexza's Compliance Program provides for monitoring and evaluation of its internal regulations and practices to evaluate whether they adequately address risk areas and to assess the level of employee compliance with internal regulations and federal laws. In accordance with the OIG Guidance, we note that the nature of our reviews as well as the scope and frequency of our compliance monitoring varies according to a number of factors, such as new regulatory requirements and changes in business practices.



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## 2.6. Responding to Potential Violations

Alexza's Compliance Program supports prompt response and corrective action for any detected problems or violations. In keeping with the goals of our Compliance Program, Alexza adheres to Ferrer corporate Ethical channel, which can be reached by corporate website, by internal intranet or by emailing [ethicalchannel@ferrer.com](mailto:ethicalchannel@ferrer.com) to allow employees, and also third parties, to confidentially submit concerns.

An investigation unit will be assigned by the Corporate Ethics and Compliance Committee to investigate the potential violation. The Committee will direct appropriate corrective actions and preventive measures to ensure the integrity of the Compliance Program. When appropriate, a compliance report may be provided to the relevant authorities.

Employees who violate company policies and procedures and/or applicable state and federal laws may be subject to disciplinary action, up to and including termination, as determined on a case-by-case basis.

Ferrer Whistleblowing management system protects all rights and guarantees of all involved parties including the principle of no retaliation.

## 2.7. Corrective Action Procedures

The goal of our Compliance Program is to prevent, or at least detect, unlawful and unethical behaviour. As the OIG Guidance recognized, however, even an effective compliance program may not prevent all violations. Therefore, Alexza is committed to continuously assessing the effectiveness of our Compliance Program, in alignment with corporate standards and Ferrer's Ethics & Compliance Program, to enable us to make the necessary adjustments or refinements to the Program.

## 3. STATEMENT OF ANNUAL AGGREGATE LIMIT

California Health and Safety Code §§ 119400, 119402 requires pharmaceutical companies to adopt a Comprehensive Compliance Program that imposes an annual aggregate dollar limit on gifts and expenditures provided to medical and healthcare professionals ("HCPs"). In accordance with the requirements of California's law, Alexza has determined that, effective January 1, 2022, the annual aggregate limit on gifts, promotional materials, and items or activities that may be provided to HCPs within California is \$1,500 per covered HCP per year.

In setting this aggregate annual limit, Alexza has considered the size of the Company and the size of the Company's product portfolio. As the size of the Company and product portfolio changes, Alexza may revise its annual aggregate limit.

It is important to note that Alexza's annual aggregate limit represents a maximum limit and is not a spending goal. In tracking expenditures, the Company excludes from its annual aggregate limit the following items that are exempt under California law: (1) drug samples given to HCPs for the free distribution to patients; (2) financial support for continuing medical education forums; (3) financial support for health educational



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scholarships; and (4) payments made at fair market value for legitimate professional services provided by HCPs.

For purposes of making its declarations under California law, Alexza applies its annual aggregate limit to expenses incurred during the calendar year (January 1st through December 31st of each year).

#### 4. DECLARATION OF COMPLIANCE

This Declaration is based upon an analysis of information available for the period of January 1 through December 31, 2022. Alexza Pharmaceuticals, Inc., based on a good faith understanding of the California requirements, as of the date of this Declaration, declares that to the best of its knowledge and belief it is in compliance with its Comprehensive Compliance Program as required by California Health and Safety Code §§ 119400 to 119402.

We also declare that the structure of our Comprehensive Compliance Program, and the guidelines enunciated in our Policies incorporate the principles articulated in the OIG Guidance and the PhRMA Code.

In addition, Alexza declares that upon the date of this declaration it has not exceeded the annual aggregate limit, set at \$1500 per HCP per year, on gifts, promotional materials, and items or activities that may be provided to HCPs within California.

While we cannot eliminate the possibility that an individual employee will violate these standards, our Compliance Program is designed to prevent, detect, and address violations of state and federal laws as well as our own internal policies and procedures.

As appropriate and in accordance with the law, Alexza will amend and update its internal regulations and this Declaration as necessary to assure compliance.

This Declaration is effective as of December 15, 2023.

Copies of this Summary Comprehensive Compliance Program and the Declaration of Compliance may be obtained upon request by contacting Alexza Pharmaceuticals, Inc. at [info@alexza.com](mailto:info@alexza.com).

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