

Celltrion USA, Inc. Compliance Program Overview

Celltrion USA, Inc.'s Compliance Program may be referred to as our "Compliance Program".

Celltrion USA, Inc. (the "Company" or "we") aspires to the highest standards of corporate conduct and is committed to establishing and maintaining an effective and comprehensive corporate compliance program.

As a part of this effort, the Company implemented a compliance program that addresses the matters covered by the May 2003 publication "Compliance Program Guidance for Pharmaceutical Manufacturers" ("OIG Guidance"), which was developed by the United States Department of Health and Human Services Office of Inspector General ("OIG"). As stated in the OIG, the Company developed its compliance program in consideration of and proportional to Company's business scope and size of its workforce. The Company's Compliance Program aims to address the three major potential risk areas of pharmaceutical manufacturers such as (1) integrity of data used by state and federal governments to establish payment; (2) kickbacks and other illegal remuneration; and (3) compliance with laws regulating drug samples.

Our goal is to maintain compliance with the laws, regulations and company directives and guidance that apply to our products, to train our employees on these matters and to prevent, detect, and correct instances of non-compliance. The Company expects that our directors, management, employees (including those employees dispatched and/or seconded from affiliates of the Company), and agents (collectively "Company Personnel") will comply with all applicable directives and guidance, as well as the related laws, regulations, and health plan program requirements. In the event that the Company becomes aware of non-compliance, we will investigate the matter and, where appropriate, take disciplinary action, up to and including employee termination, and implement corrective measures to prevent future non-compliance.

The Compliance Program is detailed below, however please be advised that due to the constantly evolving nature of compliance related regulations, our Compliance Program may be modified and updated from time to time to reflect appropriate changes.

1. Leadership and Structure

The Compliance Team at the Company (hereinafter the "Compliance Team") has overall responsibility for oversight and management of the Compliance Program. This includes oversight of the development and operation of the Compliance Program. The Compliance Team has been vested with the authority relating to oversight and management of the Compliance Program and shall exercise independent judgment concerning these matters. In this role, the Compliance Team reports directly to the **CEO** of the Company and makes reports, on need basis, concerning operation of the Compliance Program.

2. Written standards

The Company has designed, drafted, and implemented the various compliance codes, standard operating procedures, and policies (which include, but are not necessarily limited to (i) the Code of Business Ethics and Conduct, (ii) the Interactions with Healthcare Professionals (USA) Policy, (iii) the Anti-Bribery & Anti-Corruption Policy, (iv) the False Claims Act Policy, (v)

the Anti-Kickback Statute Policy, and (vi) the Whistleblower Policy, along with this document, collectively, the “Compliance Program Documents” to ensure that our business conduct is in compliance with industry standards, including the Pharmaceutical Research and Manufacturers of America (PhRMA) Code, the OIG Guidance, and all applicable federal and state regulations.

The Compliance Program Documents contain our statement of ethical and compliance principles that guide our daily operations. The Compliance Program Documents establish key ethical principles that we expect all Company Personnel of Celltrion USA to follow, as well as standards to help ensure compliance with applicable laws and company policies. To emphasize the importance of the principles and guidelines contained in the Compliance Program Documents, we require each of our employees to certify that he or she has read and agrees to abide by all the rules and procedures listed in the applicable Compliance Program Document.

- **Annual Spending Limit**

The Company also has established guidance regarding appropriate interactions with health care professionals, which is contained in greater detail in the “Interactions with Healthcare Professionals Policy”. It is the policy of the Company to comply with the PhRMA “Code on Interactions with Health Care Professionals” dated January 1, 2022¹, which includes limits on gifts, meals and other activities with health care professionals to a value of up to \$100, but solely for educational items, which are defined as items designed primarily for the education of patients or healthcare professionals. Items (such as, but not necessarily limited to, promotional items that have no educational value like cosmetics or health vitamins/supplements, etc.) that are not educational items cannot be provided as gifts. For clarity, please refer to (i) the gifts section in the Interactions with Healthcare Professionals Policy, and (ii) Anti-Bribery & Anti-Corruption Policy, which specifically prohibits any and all gifts “Government Officials” as such term is defined in the said policy.

For purposes of complying with the California Health and Safety Code 119402, the Company has established a maximum annual aggregate dollar limit of \$1,000 for gifts, promotional materials or activities provided to California healthcare 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 the limit would require the approval of the Compliance Team.

To attempt to assure that health care professionals (“HCP”) fully understand our products, our representatives may take time to explain the benefits and risks associated with them, as well as the relevant clinical efficacy studies and mechanisms of action, where appropriate. Some of these informational and educational presentations may take place over the course of a modest meal to avoid taking HCPs away from important time with their patients.

3. Education and Training

A critical element of our Compliance Program is education and training. The Company is committed to implementing programs to effectively and timely communicate our directives and guidance to our employees. New personnel will receive such training as part of their initial training and existing personnel are expected to receive compliance training. The Compliance

Team will allocate sufficient resources to review and update its training programs periodically, as well as identify additional areas of training on an ongoing basis.

4. Internal Communication and Reporting

We expect all Company Personnel to promptly report suspected, planned or actual violations of our directives and guidelines and/or laws which govern our commercialization activities. We encourage reports to be made to the Compliance Team. If these individuals are not available or if the reporter prefers, reports of violations, including those from outside the company, may be made on an anonymous basis via the Celltrion USA Compliance hotline: hotline_usa@celltrionhc.com.

We also encourage Company Personnel to ask questions about any activity where they are unclear about a potential violation or application of the Compliance Program. Questions may be posed through any of the established channels, such as a direct inquiry to the Compliance Team via telephone or email.

Acts of retaliation or retribution against an employee who in good faith reports a potential, suspected, planned or actual violation or application of our directives and guidelines and/or laws which govern our activities are not permitted and will be dealt with appropriately. For more details regarding reporting of violations, please refer to the Whistleblower Policy of the Company.

5. Auditing and Monitoring

It is the role of the Compliance Team to

develop a plan for auditing and monitoring compliance with the Compliance Program and the implementation of related directives and guidelines. These audits are intended to identify potential or existing problem areas and to take corrective measures in an effort to prevent the recurrence of non-compliance. The nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing varies according to a variety of factors, including new regulatory requirements, changes in business practices and other considerations.

6. Responding to Potential Violations

An additional role of the Compliance Team is to follow up with the review of non-compliance reports and determine whether further investigation is necessary. When deemed necessary, the Compliance Team will conduct an investigation into potentially non-compliant activity to determine whether a violation of Celltrion's directives and guidelines has occurred. As necessary to evaluate a report, audit findings, or to undertake further investigation, the Compliance Team may request the assistance of outside experts or legal counsel.

7. Corrective Action Procedures

On an as needed basis, the Compliance Team will provide corrective measures to take into account the findings of reviews of non-compliance, which may include appropriate and consistent disciplinary action regardless of the individual's position within the organization (up to and including termination). Corrective measures also include assessing whether enhancements should be made to policies, practices, training, or internal controls, and taking action to prevent future non-compliance.

8. Risk Assessment

The Company regularly conducts a compliance risk assessment to ensure that its Compliance Program continues to address appropriate compliance risks.

The Company is committed to conducting all activities in compliance with applicable laws and ethical standards. We believe we have developed and implemented an effective Compliance Program, and we will continue to work to improve our Compliance Program and all of our compliance-related activities

Modification

The Company expressly reserves the right to change, modify, or delete the provisions of this Compliance Program without notice.

Administration

The Compliance Team is responsible for the administration of this Compliance Program. All employees are responsible for consulting and complying with the most current version of this Compliance Program. If you have any questions regarding this Compliance Program or concerning the scope or delegation of authority, please contact the Compliance Team.