



## California Declaration of Compliance Program

California Health & Safety Code, Sections 119400 – 119402 (“California Compliance Law”) requires pharmaceutical companies to adopt a compliance program in accordance with the April 2003 publication “Compliance Program Guidance for Pharmaceutical Manufacturers” (“OIG Compliance Guidance”) developed by the United States Department of Health and Human Services Office of Inspector General (“OIG”) and policies for compliance with the Pharmaceutical Research and Manufacturers of America (“PhRMA”) “Code on Interactions with Health Care Professionals” (“PhRMA Code”) within six months of any update or revision of the PhRMA Code. The most current revisions to the July 1, 2002 PhRMA Code were effective January 2022.

The Celltrion USA Compliance Program includes numerous policies and procedures and is continually assessed and evaluated to ensure consistency with additional laws and guidance. It is designed to prevent, detect, and remediate violations of law, regulations, and company policies, as well as to promote an ethical culture that will, among other things, guide our interactions with healthcare professionals and healthcare entities. In the event that Celltrion USA becomes aware of any potential or actual violations of policy or law, an investigation may be triggered and, if substantiated and necessary, followed by appropriate remedial or corrective actions in accordance with the Celltrion USA Compliance Program.

Celltrion USA has adopted the applicable principles set forth in the PhRMA Code. Celltrion USA commits to making relevant conforming changes to its Comprehensive Compliance Program, within six months of any update or revision of the PhRMA Code.

As part of the Compliance Program, Celltrion USA has established a specific annual aggregate dollar limit of \$3,000 on gifts, items or activities Celltrion USA may give or otherwise provide to an individual medical or healthcare professional in California on an annual basis. This limit may be revised from time to time by Celltrion USA in its sole discretion, in which case the revised limit will be published in this section of the Celltrion USA website within a reasonable period of time following revision. This limit represents an expenditure cap and not a goal or an average expenditure amount. Celltrion USA has established an internal monitoring system designed to help ensure compliance with the annual spending limits in California. The annual limits do not include the following:

- Drug samples given to physicians and healthcare professionals;
- Financial support for Continuing Medical Education forums;
- Financial support for health education scholarships;

- Fair market value compensation for bona fide and legitimate professional services such as consulting or speaking agreements, and any meals or expenses associated with the provision of such services;
- De minimus items of nominal value with a retail value of less than \$13 (examples include: visual aids, reprints, and medical journal articles);
- Patient education materials provided to patients by their physician for the purpose of educating the patient or enhancing the patient's understanding or management of the condition;
- Evaluation, replacement products, or demonstration product packs or equipment;
- Receptions at third party educational or professional meetings; and
- Items used to provide charity care.

Celltrion USA is committed to conducting its business ethically and in compliance with all applicable laws. To the best of its knowledge and based on a good faith understanding of the statutory requirements, the Company has established a Compliance Program that meets the requirements set forth in California Health & Safety Code, Sections 119400-119402. Celltrion USA has tailored its Compliance Program to meet the company's specific needs and continuously assesses its effectiveness. Celltrion USA has established an internal monitoring system designed to help ensure compliance with its respective annual spending limits in California and is working to establish additional corporate tracking and monitoring processes. Thus, subject to the limitations described above, Celltrion USA declares that, based upon current tracking and monitoring systems, the Company is in material compliance with its Compliance Program, its good faith understanding of the requirements of the California Compliance Law, and its established annual spending limits for the current time period. Celltrion USA will assess its Compliance Program at least annually and the Compliance Program was last assessed in June 1, 2024.

As recognized by the OIG Compliance Guidance, even an effective compliance program cannot eliminate the possibility that one or more individual employees engage in conduct that would be considered improper. Accordingly, this declaration is not intended and should not be construed to imply that the Celltrion USA has not identified any individual instances in which an employee has or may have violated one or more provisions of its Compliance Program. In such situations, Celltrion USA takes reasonable and appropriate remedial or corrective action in a manner consistent with its Compliance Program.

A written copy of the Celltrion Compliance Program overview is available by emailing: [ethicscompliance\\_usa@celltrionhc.com](mailto:ethicscompliance_usa@celltrionhc.com).