

## California Declaration of Compliance

*PTC Therapeutics*

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California: PTC Declaration of Compliance

Expiration: June 30, 2021

PTC Therapeutics (PTC) is committed to bringing hope to patients with rare and genetic diseases through the development and commercialization of treatments of neglected diseases. PTC conducts activities in accordance with all applicable laws and regulations and is committed to acting honestly, ethically, and fairly.

We also declare that the structure of our Comprehensive Compliance Program (CCP) incorporates the principles articulated in the *Compliance Program Guidance for Pharmaceutical Manufacturers* published by the Office of the Inspector General of the United States Department of Health and Human Services (OIG-HHS) in April 2003, and the *Code on Interactions with Healthcare Professionals* originally dated July 1, 2002 and updated January 1, 2009 adopted by the Pharmaceutical Research and Manufacturers of America (PhRMA), commonly referred to as the PhRMA Code.

PTC's CCP is designed to prevent non-compliance with company policies and the laws and regulations applicable to the pharmaceutical industry as well as effectively detect and correct non-compliance.

PTC's compliance program includes the following:

1. **Implementing Written Policies and Procedures** – As part of PTC's compliance program, PTC has established a *Code of Business Conduct and Ethics*. All employees interacting with healthcare professionals (HCPs) and other customers are required to follow additional policies and procedures governing appropriate and inappropriate actions. These policies and procedures are available and provided to all employees and relevant third parties.
2. **Designating a Compliance Officer and Compliance Committee** – PTC has designated a Compliance Officer and a Compliance Committee charged with operating and monitoring PTC's CCP. Additionally, the Compliance Officer has the authority to report directly to PTC's Chief Executive Officer (CEO) and has access to the Board of Directors.
3. **Conducting Effective Training and Education** – PTC requires regular compliance training for all applicable employees on the policies and procedures established as part of the CCP.
4. **Developing Effective Lines of Communication** – PTC has established an open line of communication for employees to contact the Compliance Officer and report compliance questions and concerns to management and the Board of Directors. Employees are provided a mechanism to report questions and concerns anonymously.
5. **Conducting Internal Monitoring and Auditing** – PTC reviews and assesses business activities for compliance with applicable laws, regulations, guidelines, and company policies and procedures. Additionally, PTC employees at all levels are responsible for reporting potential compliance issues of which they become aware.
6. **Enforcing Standards Through Well-Publicized Disciplinary Guidelines** – PTC's Code of Business Conduct and Ethics includes a clear description of disciplinary action for non-compliance.

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Disciplinary action may include warnings, suspension, termination and other sanctions, as appropriate.

- 7. Responding Promptly to Detected Problems and Undertaking Corrective Action** – PTC develops corrective action plans to address identified concerns in a timely fashion. Appropriate corrective action may include disciplinary action, enhanced training, improvement of policies and procedures, or reporting obligations to governmental authorities.

It is PTC's expectation that all employees and applicable contractors comply with its CCP and all policies that support this program. As part of PTC's continuing commitment to compliance, PTC continually reviews and revises the elements of its CCP.

As required by California Health & Safety Code section 119402, with specific reference to the provision of "gifts, promotional material, or items or activities" a pharmaceutical company may provide to an individual healthcare professional (HCP), PTC has established an aggregate, annual dollar limit of \$2,000 on promotional items and/or meals directed to an individual HCP who resides or practices in California.

To obtain a written copy of PTC's CCP and written Declaration of Compliance, contact us at [Compliance@PTCbio.com](mailto:Compliance@PTCbio.com) or toll-free at: +1 (888) 985-0646.

### **Declaration of Compliance**

PTC declares that, to the best of our knowledge, and based on our good faith understanding of the statutory requirements of the California Health & Safety Code sections 119400-119402, we are in compliance with our Comprehensive Compliance Program (CCP) for the prior calendar year.

Dated: May 2020