

# California Annual Declaration of Compliance



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Effective Date: **August 2024**

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BTG International Inc. (a SERB Pharmaceutical company)

As part of SERB Pharmaceuticals and BTG International Inc.'s ("SERB") commitment to operating ethically and in compliance with applicable laws and regulations, a comprehensive Healthcare Compliance Program has been established. The program also supports SERB in meeting the compliance standards in accordance with the requirements set forth by California Health and Safety Code §119400-119402.

Therefore, to the best of our knowledge and understanding of the legal requirements, as of 21 August 2024, SERB is in compliance with its good faith understanding of the statutory requirements of California Health and Safety Code §119400-119402.

- The SERB Healthcare Compliance Program includes the following:
- The appointment of a dedicated Compliance Officer
- Oversight by SERB Executive Leadership through a Compliance Committee
- Documented compliance policies and procedures
- Regular and effective compliance education and training
- Open lines of communication, including a toll-free number for reporting
- Monitoring and auditing activities to continually evaluate and reassess compliance with the SERB Corporate Compliance Program
- Procedures for responding to identified problems and implementing corrective action

In Accordance with California Health and Safety Code, SERB has established a specific annual dollar limit of \$2,000.00 per healthcare professional (HCP) for promotional materials, items or activities that SERB may give or otherwise provide to an individual HCP located in the State of California, subject to permitted exclusions.

The description of the SERB Healthcare Compliance Program is outlined below. The SERB Code of Conduct can be found online at the following link: [Code of Conduct](#). Additional information regarding Anti-bribery and corruption, the Compliance Program, and other important governance information may be found on the [SERB website here](#).

A copy of this declaration of compliance and Code of Conduct may also be obtained by visiting the "Contact Us" page on our website, and choosing Ethics / Compliance as the Message Subject.

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## I. Introduction

### A. Who we are

SERB is a global specialty pharmaceutical company with a growing portfolio of medicines for emergency care and rare diseases. For over 30 years we have made treating these complex and life-threatening conditions possible, supporting clinicians, healthcare systems and governments while offering hope to patients and their families. SERB is a leading provider of essential acute care medicines, addressing unmet medical needs and supplying antidotes and medical countermeasures for chemical, biological, radiological and nuclear (CBRN) risks. As a fully integrated company, we have the experience and capabilities to acquire, develop, and manufacture our medicines to the highest standards, and make them available worldwide through our secure supply chain.

### B. General

SERB has established an effective Healthcare Compliance Program in accordance with "Compliance Program Guidance for Pharmaceutical Manufacturers," published by the Office of Inspector General, U.S. Department of Health and Human Services (the "HHS-OIG Guidance"). SERB's Corporate Compliance Program is a component of SERB's Core Values, which encourage openness, accountability, and integrity by SERB employees.

### C. Purpose

The goal of the SERB Healthcare Compliance program is to promote an ethical culture within the Company, to prevent and to detect violations of law, regulations or company policies, and to take corrective actions. As the HHS-OIG Guidance recognizes, however, the implementation of such a program cannot guarantee that improper employee conduct will be entirely eliminated. In the event that SERB becomes aware of violations of external requirements or Company policy, SERB will investigate the matter and where appropriate, take disciplinary action and implement corrective measures to prevent future violations.

Described below are the fundamental elements of SERB's Healthcare Compliance program that govern the business activities of SERB. As HHS-OIG calls for in its Guidance, SERB regularly reviews and evaluates its program to meet evolving compliance needs and expectations.

## II. Overview of the Healthcare Compliance Program

### A. Leadership and Structure

SERB has appointed a senior-level official who serves as SERB's Global Healthcare Compliance Officer with daily responsibility for overseeing the development, implementation and monitoring of the SERB Healthcare Compliance Program. The Healthcare Compliance Officer has direct access to the Audit

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Committee and Board of Directors. The Compliance Officer is charged with developing company policies issued as part of the SERB Healthcare Compliance Program, directing auditing and monitoring activities, investigating alleged compliance violations, and implementing corrective measures, as necessary. SERB's Compliance Officer can be reached at [compliance@serb.com](mailto:compliance@serb.com).

## B. Compliance Committee

- SERB has established a Compliance Committee to assist the Compliance Officer in identifying and managing risk areas of critical focus for SERB.

## C. Written Standards

- SERB has adopted a Code of Conduct which reflects SERB values and serves as a statement of ethical principles that guide SERB's business decisions and interactions. The Code applies to all SERB employees and establishes expectations that every employee will act in accordance with applicable laws and Company policies. SERB has also established written global and local healthcare policies and procedures to support adherence to applicable laws, regulations, and industry codes of conduct.

## D. Education and Training

- SERB is committed to providing comprehensive and effective training for all employees on their legal and ethical obligations under applicable health care program requirements. SERB reviews and updates SERB's training programs regularly and identifies additional areas of training on an "as needed" basis.

## E. Internal Lines of Communication

- SERB is committed to encouraging dialogues between management and employees. SERB's goal is that employees should always be able to report any suspected policy violations or potential instances of misconduct, fraud or abuse.
- Employees should know to whom to turn for a meaningful response and should be able to do so without fear of retaliation. To that end, SERB has adopted principles regarding confidentiality and policies prohibiting retaliation, as well as a helpline number to report any issues. Employees can report suspected violations of company policy by speaking with their supervisor, contacting Compliance or by any of the other reporting methods available via the Compliance & Risk page on the SERB Intranet.

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## F. Auditing and Monitoring

- SERB's Healthcare Compliance Program includes efforts to monitor, audit and evaluate adherence to SERB compliance policies, procedures and applicable laws. Results of these auditing and evaluation activities are shared with senior management to improve SERB's business practices and maintain connectivity between the Healthcare Compliance Program efforts and business decisions.

## G. Responding to Potential Violations and Corrective Actions

- The SERB Healthcare Compliance Program strives to ensure that the consequences of violating the law and or SERB policy are clearly understood, and that appropriate, consistent disciplinary action is taken. SERB's Healthcare Compliance Program requires 1) evaluation and prompt response to all reported incidents, 2) where applicable, clear and appropriate disciplinary action, 3) conducting a post-reporting assessment to identify whether the violations were a result of gaps in SERB's policies, practices or internal controls, and 4) appropriate action is taken to prevent future violations.

## III. Contact Information

For questions or comments regarding the SERB Healthcare Compliance Program, or to request a printed copy of the program, please email [compliance@serb.com](mailto:compliance@serb.com).