

California Annual Declaration of Compliance



Effective Date: July 2023

BTG International Inc. (a SERB pharmaceutical company)

As part of BTG International Inc.'s and its US affiliates' ("BTG") commitment to operating ethically and in compliance with applicable laws and regulations, a comprehensive Healthcare Compliance Program has been established. The program also supports BTG 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 17 July 2023, BTG is in compliance with its good faith understanding of the statutory requirements of California Health and Safety Code §119400-119402.

- The BTG Healthcare Compliance Program includes the following:
- The appointment of a dedicated Compliance Officer
- Oversight by BTG 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 BTG Corporate Compliance Program
- Procedures for responding to identified problems and implementing corrective action

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

The description of the BTG Healthcare Compliance Program is outlined below. The BTG 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 Pharmaceuticals represents the combination of SERB, BTG Specialty Pharmaceuticals and Veriton Pharma to form a new, growing specialty pharmaceutical company focused on critical care and rare diseases. We make treating complex and life-threatening conditions possible; supporting clinicians, healthcare systems and governments while offering hope to patients and their families.
- Inspired by a deep understanding of our customers' needs, we're working to meaningfully improve the lives of patients and their healthcare experience. Our competitive advantage is our dedication to finding smart, often unconventional solutions to complex medical problems.

B. General

BTG 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"). BTG's Corporate Compliance Program is a component of BTG's Core Values, which encourage openness, accountability, and integrity by BTG employees.

C. Purpose

The goal of the BTG 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 BTG becomes aware of violations of external requirements or Company policy, BTG 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 BTG's Healthcare Compliance program that govern the business activities of BTG. As HHS-OIG calls for in its Guidance, BTG regularly reviews and evaluates its program to meet evolving compliance needs and expectations.

II. Overview of the Healthcare Compliance Program

A. Leadership and Structure

BTG has appointed a senior-level official who serves as BTG's Global Healthcare Compliance Officer with daily responsibility for overseeing the development, implementation and monitoring of the BTG 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 BTG Healthcare Compliance Program, directing auditing and monitoring activities, investigating alleged compliance violations, and implementing corrective measures, as necessary. BTG's Compliance Officer can be reached at compliance@btgsp.com.

B. Compliance Committee

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

C. Written Standards

- BTG has adopted a Code of Conduct which reflects BTG values and serves as a statement of ethical principles that guide BTG's business decisions and interactions. The Code applies to all BTG employees and establishes expectations that every employee will act in accordance with applicable laws and Company policies. BTG 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

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

E. Internal Lines of Communication

- BTG is committed to encouraging dialogues between management and employees. BTG'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, BTG 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 telling their supervisor, calling Compliance or any of the other methods available. These can be found on this resource link (BTG employees only): [How to get advice and questions answered, Ethics, Compliance, Code of Conduct, or report a concern.](#)

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F. Auditing and Monitoring

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

G. Responding to Potential Violations and Corrective Actions

- The BTG Healthcare Compliance Program strives to ensure that the consequences of violating the law and or BTG policy are clearly understood and that appropriate, consistent disciplinary action is taken. BTG'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 BTG'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 BTG Healthcare Compliance Program, or to request a printed copy of the program, please email compliance@btgsp.com.