1. Statement of Intent

BTG's relationships with healthcare professionals ("HCPs") are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing HCPs about the benefits and risks of our products to help advance appropriate patient use, providing scientific and educational information, and supporting medical research and education.

As such, no financial benefit or benefit-in-kind (including but not limited to grants, sponsorships, scholarships, subsidies, consulting contracts, meals, or educational or practice related items) may be provided or offered to a HCP in exchange for prescribing, recommending, purchasing, supplying or administering our products, for a commitment to do so, or to influence the outcome of a clinical trial. Nothing may be offered or provided in a manner or on conditions that would have an inappropriate influence on a HCP's prescribing practices. This policy defines BTG's commitment to engaging in ethical interactions with HCPs pursuant to these principles.

This policy applies to all BTG employees world-wide and any consultants or vendors acting on behalf of BTG, who are engaged in any, direct or indirect, interactions or activities with HCPs.

2. Responsibility and Authority

Promotional Activities

BTG's promotion encourages the appropriate use of our products by presenting them objectively and without exaggerating their properties or minimizing each product's safety profile. Promotion is defined as any activity undertaken, organized or otherwise directed by BTG which encourages the use, prescription, supply, sale, administration, or recommendation of a BTG medical device or medicinal product. Promotional materials used in those activities must be accurate, substantiated, scientifically rigorous, reflect the balance between risks and benefits, and consistent with applicable legal and regulatory standards. When describing the uses, effectiveness, safety, and other aspects of our products, all BTG employees and others acting on behalf of BTG must take the greatest of care not to promote, or even be perceived as promoting, any unapproved (i.e. "off-label") use.

All BTG promotion and advertising materials must be reviewed and approved through the BTG promotional review process prior to use in the country in which the activity is occuring. Each country or region is required to support a Promotional Review Committee (PRC). The activites of each PRC are described within a local Standard Operating Procedure (SOP) ensuring compliance with global and local requirments (e.g. applicable laws, regulations, industry codes).

BTG staff, including sales representatives, must never change approved promotion or advertising materials or create "home-made" promotional materials. This includes, but is not limited to, marking or highlighting approved materials or writing notes about BTG products to HCPs. Additionally, promotion must not be disguised in the form of clinical assessments, market research, post-marketing surveillance and experience programs, post-authorization studies or advisory boards.

Pre-Approval Communications

Promotion of a product prior to regulatory approval is prohibited, and no pharmaceutical or medical device product may be promoted for use in a specific country until the requisite approval for marketing for such use has been granted in that country. Prior to or outside of the regulatory approval process, activities informing potential regulatory submissions should be limited to investor communications and replying to unsolicited questions/requests for product information.

Medical Information

BTG medical interactions with HCPs are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. In responding to unsolicited inquiries from HCPs about the use of our products, we must endeavour to ensure our communications are accurate, fair and balanced, substantiated, scientifically rigorous and consistent with applicable regulatory and legal requirements. Specific further controls must be followed where the unsolicited request relates to an off-label use of BTG products (as outlined in the country or region specific BTG standard operating procedure related to responding to unsolicted requests for off-label information). In all of these instances, BTG employees or others acting on behalf of BTG must not claim that a product is safe and/or effective for any particular use before being granted regulatory approval for that claim.

HCP Consultants

HCPs provide legitimate and necessary services to BTG, such as assisting in the development of medicines or medical devices, participating in clinical trials, speaking on behalf of BTG, or training BTG employees. In all such arrangements, there must be a documented, legitimate need clearly identified in advance of requesting the services. Additionally, BTG operates in countries where many HCPs are also government employees. Special care should be applied to these interactions, which includes assessment of the services provided against BTG's Anti-Bribery Policy.

In all instances, consultants are selected based on their qualifications to provide the required service (e.g. medical expertise, publication record, clinical trial experience related to the therapeutic area in question). The services provided by the HCP consultant must be those that internal BTG personnel are not the most qualified to provide, cannot reasonably provide or are not reasonably available to provide.

Compensation for HCP consultant services is provided after services are rendered. As such, retainer arrangements (which provide periodic payments irrespective of work completed) with HCP consultants are not permitted. All compensation provided to a HCP consultant must be under a written agreement specifying the services to be provided and be based on fair market value of the services to be provided. Reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing services may be appropriate and must adhere to all applicable BTG requirements.

The process for selection, contracting and documentation of services performed by a HCP consultant must be described in a local SOP.

HCP Speaker Programs

In addition to the above stated consultant requirements which are applicable to external HCP speakers, all materials used in the development or execution of a BTG Promotional Speaker Program, printed or otherwise, must be approved by the applicable BTG Promotional Review Committee (PRC).

The audience attending the speaker program consists of healthcare providers who have a legitimate interest in the program topic. Guests are not permitted to attend programs. See the hospitality section below.

BTG Programs may not be held in conjunction with another pharmaceutical or medical device company unless specific permission has been granted (e.g., BTG has entered into a written agreement with another company that permits such activity).

Accountability for ensuring all activities associated with the execution of a BTG speaker program are compliant, including the accurate capture of all associated expenses, is the responsibility of the coordinating BTG representative and their approving supervisor.

Educational Items

BTG, where allowed by local law and industry codes of conduct (e.g. Eucomed, USA PhRMA, UK ABPI, German FSA), may offer items designed primarily for the education of patients or HCPs, provided the items are not of significant value and do not have a value to the HCP outside of his or her professional responsibilities. Educational items must be pre-approved and not be offered on more than an occasional basis, even if each individual item is appropriate. BTG employees may never offer any item to a HCP, regardless of value, as an inducement to use, prescribe, purchase or recommend a BTG product or to influence the outcome of a clinical trial.

Samples

BTG, where allowed, may provide reasonable quantities of our medical devices to HCPs at no charge for evaluation or demonstration purposes as follows:

- *Single Use Products. The number of single use medical devices provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the medical device under the circumstances.*
- *Demonstration: "Not-For-Human Use" – medical device products. It is permissible to provide non-sterile single-use or mock-up multiple use products for use for Healthcare Professional and patient awareness, education and training. Demonstration products are typically not intended for patient care and are typically marked with language such as "Sample" or "Not For Human Use."*

Additionally, BTG may provide reasonable quantities of our medicines to HCPs at no charge for patient use as defined by local law, regulation, or other government requirement. Questions on permissible practices should be directed to the Legal or Compliance functions. All BTG products provided for demonstration or evaluation should be accompanied by BTG approved documentation clearly stating that the products are for demonstration and/or evaluation purposes only.

Hospitality and Entertainment

BTG interactions with HCPs are professional in nature and are intended to facilitate the exchange of medical or scientific information that will benefit patient care. On occasion, hospitality may be provided in a manner that is secondary to the purpose of the interaction. To ensure the appropriate focus on education and informational exchange, and to avoid even the appearance of impropriety, BTG does not provide any entertainment or recreational items to a HCP who is not a salaried employee. Examples include:

- *Tickets to theatre or sporting events;*
- *Sporting equipment;*
- *Leisure or vacation trips.*

This prohibition on entertainment or recreational activity applies regardless of the value, whether the HCP is a consultant, or whether the entertainment or recreation is secondary to a legitimate BTG business purpose. BTG may provide modest meals or other appropriate hospitality to HCPs in connection with a business meeting so long as the meal or other appropriate hospitality is secondary to the business purpose of the meeting. All such meals shall be provided in accordance with BTG requirements.

The venue selected for any meeting with a HCP, and the manner in which the meeting is conducted, must be suitable for and conducive to a professional exchange of scientific, educational or business information. BTG must be deliberate in selecting the location and venue for such meetings. When attending independent medical conferences, the location of the conference is a suitable location, however, the venue is to be thoughtfully considered to avoid the appearance of impropriety. When BTG is organizing an event independent of a third party (such as a medical conference), five-star hotels, spas, resorts, or venues with "minor hospitality" (e.g., dinner at vineyards, dinner at museums, dinner cruises, etc.) are not acceptable options.

Guests

Inclusion of a HCP's spouse, partner, family member or other guest in a meal or other BTG activity is generally not permitted unless the spouse or guest would independently qualify as a HCP or relevant business guest, invited to attend the event, and thus be an appropriate attendee in their own right. Any attendance by a non-HCP that is not a BTG employee at a business meeting is subject to documented approval by a BTG Leadership Team member.

Providing Unrestricted Support for Third Party Medical Meetings and Conferences

BTG provides unrestricted educational grants to support legitimate independent educational activities and programs that help HCPs enhance the care of their patients. The main purpose of medical symposia, conferences or congresses supported by BTG must be education or the exchange of medical or scientific information and is not a BTG promotional activity. In all instances, BTG does not control or influence the content of these programs, or the selection of the speakers, authors, or faculty planners.

Ethical Research

The safety and wellbeing of study participants is the highest priority for any BTG clinical trial. As such, the following principles and requirements apply:

- *BTG will conduct or support studies only if they are ethically defensible and scientifically valid. They must be conducted in compliance with the FDA's Good Clinical Practices, and with all other applicable international and national regulations, laws and guidelines (e.g. Declaration of Helsinki, ICH guidelines, country specific privacy regulations);*
- *The patient's right to privacy must be respected. Any written or verbal usage of any identifiable patient information such as name, initials, photos or patient testimonials, requires appropriate consent from the patient;*
- *The details of conducting and financing studies must be set out in a written agreement. All remuneration to HCPs provided by BTG relative to clinical study agreements must be appropriate for the study-related activities.*
- *The conduct of clinical studies must not be promotional or otherwise conditioned on the purchasing of product, the prescribing of drugs, or any particular study outcome outside of the the approved study protocol;*
- *For all clinical studies, local or multinational, pre-or post approval, processes must be in place, which ensure full compliance with global pharmacovigilance reporting requirements.*

Results of BTG-sponsored clinical trials will be made available according to applicable regulatory and legal requirements.