

EXHIBIT 2

COMPLIANCE PROGRAM AND CERTIFICATIONS

Biocompatibles, Inc., (“Biocompatibles”) is a wholly owned subsidiary of Biocompatibles International Ltd. BTG plc (“BTG”) acquired Biocompatibles and Biocompatibles International Ltd. on January 23, 2011. Since that date, BTG has operated Biocompatibles as a wholly-owned subsidiary of BTG. The Biocompatibles conduct that forms the basis of the criminal charge occurred prior to BTG’s acquisition of Biocompatibles and without BTG’s acquiescence. As the owner of Biocompatibles, BTG agrees to the provisions set forth in this attachment to the Biocompatibles’ Plea Agreement. These provisions shall be in effect for three (3) years following entry of a guilty plea by Biocompatibles in this matter.

I. Compliance and Ethics Program

BTG has in place and will maintain a Compliance and Ethics Program, which applies to BTG’s business operations in the United States. The purpose of the Compliance and Ethics Program is to: (a) prevent, detect, and correct violations of law and company policy and procedures; (b) assure the continuation of compliance-related policies and procedures for business operations; (c) assure the continued development of training and other programs designed to educate employees regarding applicable policies, procedures, and standards; (d) conduct auditing and monitoring of the effectiveness of applicable policies, procedures, and standards; (e) assure that there is a mechanism for internal reporting of questionable or inappropriate activities to enable timely investigation and resolution; and (f) assure that appropriate corrective action is taken to prevent recurrence of misconduct.

The Compliance and Ethics Program consists of a Chief Compliance Officer who reports to the Chief Executive Officer of BTG, a Compliance Committee comprised of senior executives which meets at least quarterly, a comprehensive set of policies and procedures governing the conduct of its employees, a training program focused on the company’s compliance policies and procedures, a hotline to allow employees to report potential violations of law or the company’s compliance policies and procedures, an anti-retaliation policy, and a monitoring and auditing program designed to deter and detect compliance issues. The Chief Compliance Officer is responsible for overseeing the administration and implementation of the Compliance and Ethics Program. The Chief Compliance Officer reports at least quarterly on the Compliance and Ethics Program to the Compliance Committee. The Chief Compliance Officer has direct access to senior executives vested with the authority to direct and implement compliance-related changes in the organization as necessary. The Chief Compliance Officer has the authority to exercise independent judgment in assessing compliance-related matters. The Chief Compliance Officer has authority to seek advice from independent legal counsel or other outside experts when appropriate. The Chief Compliance Officer is authorized to report issues of any kind directly to officers and directors of BTG.

The Compliance and Ethics Program does and will continue to contain policies and procedures designed to (1) prevent, detect, and correct violations of federal healthcare program requirements and the Federal Food, Drug, and Cosmetic Act ("FDCA") regarding the marketing of prescription pharmaceutical products and medical devices and (2) ensure that all information provided to and statements made to the Food and Drug Administration ("FDA") are truthful, accurate, complete, and are in compliance with applicable law, policies, and procedures. In addition to all other policies and procedures necessary to ensure BTG's full compliance with applicable law, policies, and procedures, the Compliance and Ethics Program will include policies and procedures to ensure that BTG employees who are involved in marketing BTG products are trained on the information relevant to their function that BTG has provided to the FDA.

II. Notice to Healthcare Providers and Entities

Within thirty (30) days after the entry of the guilty plea in this matter and for a period of one (1) year thereafter, BTG shall post in a prominent place on the main pages of its LC Bead[®], LC BeadMI[®], and LC Bead LUMI[®] websites a notice, dated and signed by the President of Biocompatibles, containing the language set forth below:

As you may be aware, in January 2011, Biocompatibles was acquired by BTG. As a result of that acquisition, Biocompatibles became an affiliate of BTG plc ("BTG"). Based on Biocompatibles' conduct before the acquisition, Biocompatibles agreed to enter into a criminal and civil settlement with the United States of America in connection with the marketing of LC Bead[®]. This letter provides you with additional information about the settlements, explains our commitments going forward, and tells you how to obtain more information about those commitments.

To resolve these matters, Biocompatibles pled guilty to violating the Federal Food, Drug, & Cosmetic Act and agreed to pay a criminal penalty of \$11 million. In addition, the federal government and several individual states alleged that Biocompatibles' conduct violated the federal False Claims Act and equivalent state statutes. To resolve those allegations, BTG (as Biocompatibles' parent) entered into a separate civil settlement whereby BTG agreed to reimburse federal and state healthcare programs an additional \$25 million. Copies of and more information about these settlements may be found at the following website:

https://www.justice.gov/civil/current-and-recent-cases#_Pharm2

As part of the agreement, we pledged to maintain our existing comprehensive compliance and ethics program, to undertake certain actions designed to advance compliance with federal healthcare program and FDA requirements, and to make periodic compliance certifications to the

Department of Justice. We also agreed to provide this notice to LC Bead[®] users to inform them of the criminal and civil settlements and to remind them that they are encouraged to report any questionable practices by our employees to BTG's North America Compliance Department (1-877-440-7227 or LCbeadConcerns@btgplc.com) or the FDA (1-888-INFO-FDA).

You should direct any medical questions or concerns about our prescription products to our Medical Information Team (1-877-377-3784 or medical.services@btgplc.com).

The Compliance Officer (or a designee) shall maintain a log (the "Log") of all calls and messages received by the Compliance and Ethics Program that report questionable practices by BTG employees, including any such calls or messages made in response to the notice above. The Log shall include a record and summary of each call and message received (whether anonymous or not), the status of the call or message, and any corrective action taken in response to the call or message. BTG shall produce the Log to the United States within ten (10) days of a written request for such production, for a period of three (3) years after the entry of the Biocompatibles guilty plea in this matter.

III. Certifications and Board Resolution

A. Annual Certification of the Log by the President of Biocompatibles

Every year for three (3) years after the entry of the Biocompatibles guilty plea in this matter, the President of Biocompatibles shall conduct a review of the Log. Based on that review, the President shall submit to the United States a certification (the "Log Certification") (1) stating that, to the best of his or her knowledge, during the preceding twelve (12) months, BTG maintained the Log pursuant to this agreement, and (2) stating the total number of calls and messages received, and the number of those calls and messages that related to marketing of Biocompatibles' medical devices in each month in the prior 12-month period.

B. Annual Certification of the Effectiveness of the Compliance and Ethics Program by the President of Biocompatibles

The President of Biocompatibles shall conduct a review of the effectiveness of the Compliance and Ethics Program as it relates to the marketing of LC Bead[®] in the United States during each year subsequent to the date of the entry of the guilty plea in this matter, for a period of three (3) years. The President may, in his or her discretion, rely on an outside consultant/reviewer to perform the review. Based on the review, the President shall submit to the United States a signed certification stating that, to the best of his or her knowledge based on a reasonable inquiry into the operations of the Compliance and Ethics Program, during the preceding twelve (12) months, the Compliance and Ethics Program was effective in identifying and preventing violations of federal healthcare program requirements and the FDCA regarding the

marketing of LC Bead[®]. The certification shall summarize the review described above. If the President is unable to certify that the Compliance and Ethics Program was effective in preventing violations of federal healthcare program requirements and the FDCA regarding the marketing of LC Bead[®], he or she shall provide a detailed explanation of why the Compliance and Ethics Program was not effective, and will state the steps BTG is taking to ensure the effectiveness of the Compliance and Ethics Program.

C. Annual Resolution by BTG's Board of Directors

The Board of Directors of BTG, or a designated Committee thereof (the "Board"), shall conduct a review of the effectiveness of the Compliance and Ethics Program as it relates to Biocompatibles' marketing of LC Bead[®]. This review shall be conducted every year for three (3) years and shall include, but not be limited to, updates and reports by the Chief Compliance Officer and other personnel regarding compliance matters. The Board shall evaluate the effectiveness of the Compliance and Ethics Program, including, among other means, by receiving updates about the activities of the Chief Compliance Officer and Compliance Committee and updates about the adoption and implementation of policies, procedures, and practices to ensure compliance with applicable federal healthcare program requirements and the FDCA. The Board review shall not require the retention of third party experts. Every year for three years after the date of the entry of the guilty plea in this matter, the Board shall, based on its review, submit to the United States a resolution that summarizes its review and oversight of Biocompatibles' compliance with federal healthcare program requirements and the FDCA regarding the marketing of LC Bead[®] and, at a minimum, includes the following language:

The Board of Directors of BTG has made a reasonable inquiry as described in Section III.B of this Attachment (Exhibit __ to the Biocompatibles Plea Agreement) into the operations of the Compliance and Ethics Program for the preceding 12 months, including the performance of the Chief Compliance Officer and the Compliance Committee. Based on its inquiry and review, the Board has concluded that, to the best of its knowledge, Biocompatibles has implemented an effective compliance program, as defined in the United States Sentencing Commission Guidelines Manual, Chapter 8: Sentencing of Organizations, to meet the requirements of federal healthcare programs and the Federal Food, Drug, and Cosmetic Act regarding the marketing of LC Bead[®] and as set forth in this Attachment.

If the Board is unable to provide any part of this statement, it shall include in the resolution a written explanation of the reasons why it is unable to provide such a statement.

D. Filing of the Certifications and Resolution¹

The annual certifications referenced above in paragraphs III.A and III.B shall be sworn to under penalty of perjury and shall set forth that the representations contained therein may be provided to, relied upon, and material to the government of the United States, and that a knowing false statement could result in criminal or civil liability for the signatory. The annual certifications referenced above in sections III.A and III.B and the resolution referenced above in section III.C should be sent to:

Chief, Criminal Division
U.S. Attorney's Office,
District of the District of Columbia
555 Fourth Street, NW
Washington, DC 20530

Director, Consumer Protection Branch
U.S. Department of Justice
P.O. Box 386
Washington, D.C. 20044

IV. Breach of this Attachment

BTG recognizes that each of the terms in this Attachment constitutes a material term of this Attachment. As a contractual remedy, BTG and the United States agree that failure to comply with the obligations set forth in this Attachment may lead to the imposition of the following monetary penalties (hereafter "Stipulated Penalties") in according with the following provisions:

- A. A Stipulated Penalty of \$3,000 per day for each day BTG (1) fails to maintain a Compliance and Ethics Program as set forth in section I above; or (2) fails to timely supply the certifications and board resolution as set forth in section III above. With regard to the certifications and board resolution, the Stipulated Penalty will begin to accrue on the first day after the date the document was due, subject to the provisions for extension of time for compliance and the opportunity to cure set forth below.
- B. BTG may submit a timely written request for an extension of time to provide the certifications or board resolution required above. A written request is timely if it received by the U.S. Attorney's Office for the District of Columbia and the Consumer Protection Branch, U.S. Department of Justice, at least five business days prior to the date by which the certification or board resolution are due. Timely requests for extension will not be unreasonably denied. If an extension of

¹ Consistent with the Department of Justice's Freedom of Information Act ("FOIA") procedures, the government shall make reasonable effort to notify BTG prior to any release by DOJ of information submitted by BTG pursuant to its obligations under this Plea Agreement and identified upon submission by BTG as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, BTG shall have the rights set forth under said procedures.

time is granted in writing, Stipulated Penalties shall not accrue until one day after BTG fails to meet the revised deadline. If not granted, Stipulated Penalties shall not begin to accrue until three business days after BTG receives the United States' written denial of such request or the original deadline, whichever is later.

- C. Upon the United States' reasonable determination that BTG has failed to comply with any of the obligations described herein, the United States shall notify BTG in writing of BTG's failure to comply and the United States' exercise of its contractual right to demand payment of the Stipulated Penalties ("the Demand Letter"). The Demand Letter shall set forth: (1) the provision(s) breached; (2) the date of the breach; (3) a description of the breach sufficient to permit BTG to cure (as described below); and (4) the amount of Stipulated Penalties claimed by the United States as of the date of the Demand Letter. Within fourteen (14) days after receipt of the Demand Letter, or such other period as the United States may agree in writing, BTG shall cure the breach to the United States' reasonable satisfaction ("Cure Period"). If BTG cures the breach within the Cure Period, no Stipulated Penalties shall be due. If BTG fails to cure the breach during the Cure Period, Stipulated Penalties calculated from the date of breach to the date of payment shall be immediately payable to the United States. The Stipulated Penalties shall be paid by electronic fund transfer according to wire instructions that will be provided by the United States. A joint reasonable determination by the United States Attorney for the District of Columbia and the Assistant Attorney General for the Civil Division of the Department of Justice regarding BTG's failure to comply with any of the obligations described herein will be final and non-appealable. BTG agrees that the United States District Court for the District of Columbia shall have jurisdiction over any action to collect such a penalty.

The absence of violation notice from the United States is not, and shall not be construed as, evidence of compliance with this agreement, federal healthcare program requirements, the Federal Food, Drug, and Cosmetic Act ("FDCA"), or other applicable laws, policies or procedures.

□

AGREED:

FOR BTG, plc:



Paul Mussenden
Senior Vice President and
General Counsel

10/5/16

Date

FOR THE UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF COLUMBIA:

CHANNING D. PHILLIPS
United States Attorney



VIRGINIA CHEATHAM
Assistant United States Attorney

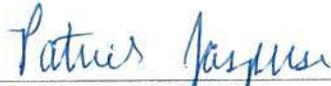
U.S. Attorney's Office for the
District of Columbia
555 Fourth Street, NW
Washington, DC 20530

9-30-16

Date

FOR THE UNITED STATES DEPARTMENT OF JUSTICE,
CONSUMER PROTECTION BRANCH:

MICHAEL S. BLUME
Director



PATRICK JASPERSE
Senior Litigation Counsel

U.S. Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044

9-30-16

Date