



RedHill Biopharma Inc. Compliance Program – U.S. Operations

Comprehensive Compliance Program and California Law

RedHill Biopharma Inc. (RedHill) is committed to compliance with applicable federal state, and local laws. RedHill has developed policies and procedures that are created to meet the requirements of the regulated healthcare industry.

California 2021 Compliance Policy and Declaration

NOTICE: this information is provided pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765), which requires certain pharmaceutical and medical device companies doing business in California to make available their program for compliance with applicable federal and state laws and industry standards regulating the marketing and promotion of their products.

I. INTRODUCTION

RedHill has established a program designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of its products. Additionally, RedHill recognizes that adherence to these standards can be furthered through a compliance program that is informed by the Compliance Program Guidance for Pharmaceutical Manufacturers, published by the Office of Inspector General of the U.S. Department of Health and Human Services (the “OIG Guide”). The OIG Guide advises that effective compliance programs are comprised of seven elements. As described below, these elements form the basis of RedHill’s program for compliance with the standards regulating the marketing and promotion of its products. In addition, RedHill has implemented and maintains a website (www.redhillbio.com) and the number (1.984.444.7010) to facilitate communication and requests for information related to California State requirements.

II. OVERVIEW OF COMPLIANCE PROGRAM

1. Written Policies and Procedures

RedHill has written policies to assure substantial compliance with the applicable laws, regulations and standards governing the marketing and promotion of our products. RedHill follows the spirit of the Pharmaceutical Research and Manufacturers of America (“PhRMA”) “Code on Interactions with Healthcare Professionals.” RedHill has established written policies that govern activities involving communicating with healthcare professionals and patients about the appropriate use of our products, including appropriate instruction and education required for the safe and effective use of our products. RedHill also has policies governing activities involving the advancement of scientific and educational activities supporting medical research and education.

These policies include:

Policy on Educational Grants and Research Grants

Upon appropriate request, RedHill may consider and provide grants for specific educational purposes. These may include, but are not limited to, continuing medical and paraprofessional education programs and programs operated by organizations that provide high-quality, nationally recognized patient education. Funding of educational programs will generally only be considered for organizations and institutions and not to individual practitioners. Research grants to support physician-initiated research may be considered and provided for programs involving research in areas of legitimate interest to the company. All requests are subject to scientific review and contract requirements prior to funding approval.

Policy on Charitable Contributions

RedHill will consider charitable contributions pursuant to its established policies and procedures and appropriate approvals.

Policy on Travel Expense Reimbursement for Healthcare Professionals

Consistent with applicable laws and regulations, RedHill may reimburse healthcare professionals for their reasonable travel and lodging expenses associated with attendance at professional meetings (e.g., trainings for performing services) conducted by RedHill. Any such meetings will be conducted either virtually or in locations conducive to the exchange of information such as educational or conference settings. Where face-to-face training is reasonably necessary, RedHill may provide training at company facilities, at independent teaching centers such as medical institutions, or in other appropriate clinical settings.

Policy on Business Meals

RedHill may occasionally offer a modest meal as part of an educational presentation or a business discussion. Venues that feature entertainment or recreation are not permitted.

Policy on the Provision of Educational and Practice-Related Items

On occasion, RedHill may consider providing items that benefit patients or serve a genuine educational function for healthcare professionals.

Total Annual Dollar Limit for Meals, Educational or Practice-Related Items Training Expenses and Expense Reimbursement for Training Meetings

RedHill has established an annual limit of \$3,000 for meals and educational items as the aggregate value of the items or activities that may be provided to California healthcare professionals pursuant to the requirements of Cal. Health & Safety Code § 119402 (S.B. 1765). Consistent with the California statute, certain items are excluded from the annual limit, such as financial support for CME, health educational scholarships, fair market value payments for legitimate professional services, product samples, and research sponsorship and related activities.

Policy Prohibiting Entertainment

It is the policy of RedHill not to provide entertainment (e.g., sporting events, golf outings, concerts, etc.) to healthcare professionals.

Other

In addition to those mentioned above, RedHill also maintains policies and procedures to account for a variety of other requirements, such as reporting adverse events relating to RedHill products, provision of samples of RedHill products, and selection and retention of healthcare professionals for consultation.

2. Assigned U.S. Compliance Officer

RedHill has a U.S. Compliance Officer. Our U.S. Compliance Officer is empowered with appropriate authority to exercise independent judgment and has free and unencumbered access to senior management and board of directors.

RedHill has a U.S. Compliance Committee. The committee is comprised of the company's U.S. Compliance Officer and members of the company's management team.

3. Training

RedHill has an annual Compliance Training process. New employees receive training at the time of hire and annually thereafter. The training covers applicable guidelines governing our compliance program. Employees are trained on the consequences of failure to comply with the requirements of the company's compliance program.

4. Communication

RedHill encourages open and candid discussion between management and employees regarding any compliance concern. RedHill employees are encouraged to report their concerns to their manager, Legal Affairs, or the U.S. Compliance Officer. Employees also have the option to report potential violations using the Company's confidential Compliance and Ethics Hotline: 1-855-581-5187.

5. Auditing and Monitoring

RedHill self-assesses and periodically audits its compliance with its policies and procedures. Monitoring for compliance with policies and laws is first conducted by managers and supplemented by independent monitoring in certain areas.

6. Enforcement and Disciplinary Guidelines

RedHill may/will take disciplinary action, up to and including termination, in response to violation of the company's compliance policies or procedures. RedHill will investigate matters that are brought to the company's attention in order to ensure the consistent application of the company's standards.

7. Responses to Detected Problems and Actions to Correct Issues

RedHill requires a prompt and diligent response to potential violations of the company's compliance program, including its standards regulating the marketing and promotion of our products. Actions in response to detected problems may include improving policies and/or procedures, retraining, communication, and increased monitoring or may require disciplinary action, including termination of employment, to prevent future violations.

III. DECLARATION FOR CALIFORNIA COMPLIANCE LAW

As part of RedHill's ongoing efforts in the area of compliance, we have developed a Comprehensive Compliance Program that is designed to comply with applicable federal and state laws and industry standards relating to the marketing and promotion of our products. To our knowledge as of the date of October 26, 2021, RedHill is in compliance with our Comprehensive Compliance program, as described here, and with California Health & Safety Code sections 119400-119402.

Last updated: October 26, 2021

Annual Declaration of Compliance

RedHill Biopharma Inc, Comprehensive Compliance Program & California Law

RedHill is committed to compliance with applicable federal and state laws and regulations. RedHill has developed policies and procedures which are intended to meet the requirements of the regulated healthcare industry. These policies and procedures are a part of the Company's Comprehensive Compliance Program, which is required by

California law SB 1765 (California Business & Professions Code 119400, 119402). The Company has modified certain policies and procedures that regulate interactions with covered medical and healthcare professionals in the State of California. California requires that we set an annual aggregate limit on certain promotional expenditures provided to healthcare professionals. The Company has set the annual aggregate dollar limit on gifts and promotional materials and activities provided to healthcare professionals at \$3,000.00 per covered healthcare professional. Not included in this limit are drug samples given to healthcare professionals intended for free distribution to patients, financial support for continuing medical education forums, financial support for health educational scholarships, or payments made at fair market value for legitimate professional services provided by healthcare professionals. This limit, which is an annual aggregate limit, is based on an estimate of the maximum value of gifts and promotional materials that a recipient may receive in a year, may be revised by RedHill from time to time. As of October 26, 2021 to the best of our knowledge and based upon our good faith interpretation of the requirements of various statutory provisions of California law, Cal. Health & Safety Code §§ 119400 – 119402, we are in substantial compliance with the requirements of these provisions and with our Comprehensive Compliance Program. Copies of the CCP and our Annual Declaration of Compliance can be obtained from our website at www.redhillbio.com.