



## **Mayne Pharma Comprehensive US Compliance Program**

Mayne Pharma (“Mayne”) has established a Comprehensive Compliance Program that is consistent with applicable state and federal regulations and with the “Compliance Program Guidance for Pharmaceutical Manufacturers” developed by the United States Department of Health and Human Services, Office of Inspector General (“OIG Guidance”). The Comprehensive Compliance Program also incorporates policies that comply with the Pharmaceutical Research and Manufacturers of America “Code on Interactions with Healthcare Professionals” (“PhRMA Code”).

Mayne is committed to ensuring compliance with its Company policies and with applicable laws and regulations. The Comprehensive Compliance Program represents Mayne’s commitment to the highest standards of corporate conduct. The OIG Guidance acknowledges that the implementation of an effective compliance program cannot itself ensure that improper employee conduct will not occur. Nevertheless, Mayne expects and requires its employees to be aware of and abide by its Business Code of Conduct and all other applicable policies and supporting procedures.

Mayne will assess its Comprehensive Compliance Program annually. The Program includes the following key elements:

- Written policies and supporting procedures
- A Compliance Officer that reports directly to the Chair of the Audit & Risk Committee of the Board of Directors
- Effective training and education
- Effective lines of communication
- Internal monitoring programs
- Employee and third-party vendor screening procedures
- Disciplinary guidelines
- Investigatory procedures
- Corrective and preventive actions following investigations



### **Written Policies and Supporting Procedures**

Mayne maintains guidance throughout the organization that outlines standards and expectations for our commercial pharmaceutical businesses. Those standards include, but are not limited to:

- Business Code of Conduct
- Anti-Bribery/Anti-Corruption Policy
- Antitrust/Anti-Competition Policy
- Misconduct & Whistleblower Policy
- Insider Trading Policy
- Prescription Drug Promotion Policy
- Advisory Board Policy
- Speaker Program Policy

Each of the aforementioned policies are supported by standard operating procedures that guide our employees in performing the specific tasks that will lead to compliance with applicable laws and regulations as well as lead to sound business performance.

### **Compliance Officer that Reports to the Audit & Risk Committee of the Board of Directors**

Mayne appointed a Vice President of Governance, Risk & Compliance (VP, GRC) whose responsibilities include oversight of the US Healthcare Compliance Program. The VP, GRC reports directly to the Chair of the Audit & Risk Committee of Mayne's Board of Directors and provides the Committee a monthly summary of activities. The VP, GRC meets with the Audit & Risk Committee four to six times a year. Additionally, the VP, GRC provides regular reports to the Corporate Executive Committee which consists of members of Mayne's senior management team.

### **Effective Training & Education**

All Mayne employees are required to be trained annually on the Business Code of Conduct, the Misconduct & Whistleblower Policy, and the Insider Trader Policy. Employees with applicable responsibilities must also complete periodic training on the Anti-Bribery/Anti-Corruption Policy, and the Antitrust/Anti-Competition Policy. All other policies and supporting procedures are assigned to employees based upon roles and responsibilities. Sales teams within the commercial business hold periodic regional meetings and an annual national sales meeting. At each of these meetings, compliance training is provided to support the ongoing understanding of regulatory requirements and industry standards.



### **Effective Lines of Communication**

To support effective communication, Mayne trains employees on the Misconduct & Whistleblower Policy annually. That training and policy highlights our internal Employee Hotline system which provides 24 hour access seven days of each week, every day of the year through both telephone communication and internet connectivity. The VP, GRC also engages in quarterly awareness campaigns to ensure that employees know about the Employee Hotline system and how to access it.

### **Internal Monitoring Programs**

The VP, GRC oversees several monitoring programs designed to confirm compliance with Company policies and procedures as well as detect when employees fail to comply with that guidance. The monitoring programs include:

- The US Healthcare Compliance Monitoring Program (Specialty Brand Division focused)
  - Email review
  - Travel & expense submission review
  - Call note review
  - Sampling review
  - Sales Representative compliance field assessment
  - Speaker program documentation assessment
  - Advisory Board documentation assessment
  - Medical Information Request Form review
- The Antitrust/Anti-Competition Compliance Monitoring Program (Generic Product Division focused)
  - Email review
  - Travel & expense submission review
  - Call note review

### **Employee and Vendor Screening Procedures**

Mayne has developed and implemented procedures whereby all employee applicants are screened to ensure that they are not excluded or debarred by any US federal agency. Further, applicants must certify that they are neither excluded nor debarred and that they are not involved in a review process that may result in their exclusion or debarment. All third-party vendors are screened to ensure that they are not excluded, debarred, or on the Office of Foreign Assets Control (OFAC) exclusion list.



### **Disciplinary Guidelines**

Mayne's Business Code of Conduct includes guidance that outlines the Company's approach to disciplinary guidelines. Additionally, Mayne communicates to all commercial employees who are eligible to participate in variable compensation programs that a pre-condition for eligibility is full compliance with all applicable Company healthcare compliance policies and procedures.

### **Investigatory Procedures**

Mayne's Misconduct & Whistleblower Policy is supported by a procedure entitled "Misconduct & Whistleblower Investigations" standard operating procedure. This guidance outlines the steps that must occur following the receipt of an allegation of wrongdoing and the employees who are responsible to carry out the procedure.

### **Corrective and Preventive Actions Following Investigations**

The VP, GRC is responsible to report all material allegations of misconduct in the monthly report to the Audit & Risk Committee of the Board of Directors. The matrix that is provided includes a column where the VP, GRC must describe the root cause of the issue. An additional column also requires an explanation of how the root cause will be prevented going forward. This information is reviewed and evaluated by the Audit & Risk Committee of Mayne's Board of Directors.