

Organon & Co. Comprehensive Compliance Program (U.S.)

I. Introduction

Organon has established and maintains a Compliance Program that reflects its commitment to compliance with the laws and regulations that govern pharmaceutical and medical device marketing and selling activities in the United States. Organon's Compliance Program also is consistent with the recommendations set forth in "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"), the provisions of the Code on Interactions with Healthcare Professionals created by the Pharmaceutical Research and Manufacturers of America ("PhRMA Code"), and the provision of the Advanced Medical Technology Association (AdvaMed) Code of Ethics on ethical interactions and relationships with Health Care Professionals. The goal of Organon's Compliance Program is to maintain a culture that promotes the prevention, detection, and resolution of potential violations of law or Company policies.

The fundamental elements of Organon's Compliance Program as it relates to sales and marketing activities in the United States are described below. Organon's Compliance Program is dynamic involving regular assessment and adjustment to ensure the Program is responsive to the Company's evolving business and associated compliance risks.

II. Overview of Compliance Program

1. Leadership and Structure

Organon has the appropriate resources in place to support our commitment to compliance.

- The Organon functional group that engages in pharmaceutical sales and marketing activities in the United States has dedicated Compliance Business Counseling and Support Professionals to support Organon's culture of compliance. The Chief Ethics and Compliance Officer (Compliance Officer) has responsibility for corporate-wide activities including in the United States. The Compliance Officer reports to the General Counsel and periodically to the Audit Committee of the Company's Board of Directors.
- The Compliance Officer manages a department of compliance professionals who provide guidance and oversight for the processes, training, and implementation needed to ensure full compliance with the laws, regulations, and policies that include but are not limited to direct interactions with physicians and other customers in the U.S. marketing and sales units.
- Organon is committed to ensuring that its Compliance Officer has the ability to effectuate change within the organization as necessary and to exercise independent judgment. The compliance function has unrestricted access to information, executives and meetings related to business operations.

2. Written Standards

The development and publication of written standards of conduct, as well as written policies, procedures and guidelines are a key element of Organon's Compliance Program.

- Organon's Code of Conduct sets forth ethical principles that guide our daily activities and decisions. The Code of Conduct is available to all employees on the Company's intranet and applies to everyone conducting business on behalf of Organon. All employees must read and acknowledge Organon's Code of Conduct on an annual basis to remain in compliance with our standards of conduct.

[Declaration of Compliance](#)

To the best of its knowledge, information and belief, Organon LLC. was in compliance, in all material respects, with its Comprehensive Compliance Program and its good faith understanding of the requirements of California health and Safety Code §§ 119400-119402 during the period between June 2, 2021 to December 31, 2021.

A copy of this document can be obtained by calling the Organon Service Center at 1-844-674-3200.

[Organon's Code of Conduct](#)

[Download Code of Conduct](#) (PDF*)

- In addition to the Code of Conduct, Organon has corporate policies, procedures and guidelines that outline the specific behaviors required for day-to-day operations and outline how Organon employees are expected to conduct their activities. Among other things, these policies, procedures, and guidelines address potential risk areas such as those identified in the HHS-OIG Guidance. For example, Organon has policies regulating: prescription drug sampling; Organon-led promotional and educational programs; financial support of independent continuing medical education; scientific research grants; consulting arrangements with medical or healthcare professionals; service agreements with customers; and the provision of grants or other funding in support of healthcare-related initiatives sponsored by professional societies, patient advocacy groups, trade associations, charitable entities and other organizations.
- Organon's policies relating to Field Based Employees' interactions with medical or healthcare professionals provides that such interactions must focus on: (1) providing honest, fair, non-misleading, accurate, and balanced information about Organon products consistent with the product label or approved promotional materials, (2) providing approved product, disease, or other legitimate business information or technical instruction to appropriate customers in a professional and proper manner. As a matter of policy, Organon Field Based and Headquarters employees are prohibited from offering healthcare professionals recreational or entertainment items of, such as tickets to sporting events, support for office social events, gift certificates to stores or golf outings.
- Under Organon's policies, Organon Field Based Employees occasionally may provide medical or healthcare professionals with approved educational items that are not of substantial value. These materials are intended primarily for the education of healthcare professionals or for healthcare professionals to use for the education of patients and may include items such as medical textbooks, medical journals, or anatomical models. Items, even of minimal value, may not be provided for healthcare professionals' use that do not advance disease or treatment education. For example, pens, notepads and similar "reminder items" with company logos may not be distributed. Organon's policies have been developed to be consistent with the PhRMA Code, Advamed Code of Ethics, and the HHS-OIG Guidance.
- Organon's policies HCPs attending should have an independent, bona fide educational need to receive information about the risks, benefits, and appropriate uses of Organon products and disease states. These events provide high-quality clinical, disease and drug therapy information, are in accordance with FDA regulations, and are specifically designed to provide the type of information practicing medical and healthcare professionals have indicated to Organon that they need and find most useful in the treatment of their patients. In connection with such presentations or discussions, occasional modest meals may be provided to medical or healthcare professionals provided the meals occur in a venue and manner conducive to informational communication, and provided that there is a reasonable expectation, and reasonable steps are taken to confirm, that each attendee has a substantive interaction or discussion with Organon's representatives. Guests of permitted attendees, including spouses and significant others, are prohibited, even if they show up uninvited. Repeat attendance at a speaker program on the same or substantially the same topic is generally not appropriate unless the attendee has a bona fide educational need to receive the information presented and as specifically approved by Organon Headquarters. Organon's policies are designed to ensure that these meals are provided in accordance with the PhRMA Code, Advamed Code of Ethics and the HHS-OIG Guidance.
- As required by California Health & Safety Code §§ 119400-119402, Organon has established an annual dollar limit on educational or practice-related items, items of minimal value and meals which Organon Field Based Employees are permitted to provide to medical or healthcare professionals in California under Organon's policies. The annual limit of \$2,000 applies to educational or practice-related items, items of minimal value, and meals associated with informational presentations or discussions provided to medical or healthcare professionals in California; and incorporates the limitations and definitions contained in the statute.
- Consistent with California Law, Organon's annual dollar limit does not include drug samples given to medical and healthcare professionals intended for free distribution to patients, financial support for continuing medical education forums, financial support for health educational scholarships or fair market value payments for legitimate professional services provided by healthcare or medical professionals. In addition, the annual dollar limit does not include reprints of medical journal articles, printed advertising or promotional materials, and items provided for distribution to patients (e.g., patient-oriented health and disease management information). The annual limit is not intended to serve as a spending objective or goal by Organon for healthcare professionals in California; rather, it is intended to establish an annual upper limit for those healthcare professionals with whom Organon employees interact across multiple therapeutic areas and reflects that Organon may interact with medical or healthcare professionals through multiple channels, as discussed below.

- Some of the medical and healthcare professionals Organon calls on may have practices spanning multiple therapeutic categories in which Organon has medicines or other health products. Organon's pharmaceutical portfolio of products currently includes seven products and one medical device that are actively promoted by Organon Field Based Employees and contracted sales teams. There may be multiple discussions and informational presentations that occur between these individuals and Organon Field Based Employees. It is in recognition of these instances that Organon's annual upper limit on expenditures for medical and healthcare professionals is currently set at \$2,000. These expenditures included modest meals associated with informational presentations and discussion and include the fair market value of educational and practice-related items provided to medical and health care professionals as set forth above.

3. Education and Training

Another critical element of our Compliance Program is the education and annual training of our Field Based and Headquarters employees on their legal and ethical obligations under Organon's policies and the laws, regulations and guidelines that govern pharmaceutical and device marketing and selling activities in the United States.

- Organon is committed to taking all necessary steps to effectively communicate our standards and procedures to all affected field based and headquarters personnel. Organon's Code of Conduct and policies are always available to employees through the Organon intranet.
- All Organon Field Based and Marketing Headquarters employees are required to participate in annual training as a condition of their employment. In addition, these employees may be required to undergo periodic re-training and remedial training programs as necessary.
- The following training plan applies to all Field Based Employees: New hires receive testing and certification on Organon's Field Policy Letters, Awareness Training, and general sales and product training. This includes training to ensure compliance with federal laws and regulations that relate to pharmaceutical and device sales and marketing such as the Medicaid Anti-Kickback Statute, the Prescription Drug Marketing Act, and FDA drug and medical device promotion regulations. After this initial training, there is periodic training aimed at recertifying Field Based Employees on relevant policies. Field Based Employees in geographies with state or other region-specific legal or regulatory requirements also receive training specific to the local requirements.
- The following training plan applies to all U.S. Headquarters employees engaged in marketing and sales activities: employees receive annual training designed to ensure compliance with Organon's policies and Awareness Training and federal laws such as: the Medicaid Anti-Kickback Statute, antitrust laws, and FDA drug and medical device promotion regulations. In addition, more specific training and testing is provided as needed to HQ employees consistent with their roles and responsibilities within the company.
- The content for all training is evaluated and updated annually to ensure it remains relevant and current.

4. Internal Lines of Communication

As a matter of policy, employees are required to bring workplace issues of any type to the attention of management. Organon strives to provide a work environment that encourages employees to communicate openly with management about all types of workplace issues without fear of retaliation or recrimination. To support this concept, Organon has established the following resources:

- Organon encourages employees, as a first step, to seek out an immediate supervisor or manager to discuss workplace issues. If the matter is not successfully resolved, an employee is encouraged to pursue the issue with his/her next level of management or Human Resources.
- The Speak Up tool at organon.com/integrity, managed by the Office of Ethics & Compliance, complements Organon's primary reporting mechanisms described above by providing an alternative channel for employees to report work-related concerns, including conduct inconsistent with Organon's policies, practices, values, and standards. The tool is available to all employees and allows employees and colleagues to raise concerns or ask questions confidentially and anonymously in their preferred language via phone or internet. The Office of Ethics & Compliance is accountable for ensuring appropriate review and follow-up with respect to issues raised via the Speak Up tool.

5. Auditing and Monitoring

Organon's Compliance Program includes monitoring, auditing, and ongoing evaluation regarding compliance with the company's policies and procedures. In accordance with the HHS-OIG Guidance, the nature of our reviews as well as the extent and frequency of our compliance monitoring and auditing will vary according to a variety of factors, including new regulatory requirements and changes in business practices. Results of auditing, monitoring and evaluation will be, as appropriate, followed up on specifically, incorporated in training and communications strategies and considered when making choices in connection with ongoing general management of the business.

The primary responsibility for oversight is with line management. To assist managers with this responsibility, Organon provides them with reports from tracking and oversight systems that capture key compliance indicators to aid them in monitoring compliance with company policy and investigating any potential violations of policy. Management oversight is supplemented by audits.

Organon will utilize a combination of up-front planning, and monthly tracking and monitoring to comply with the annual dollar limit established pursuant to California Health & Safety Code §§ 119400-119402.

6. Hiring

Organon is committed to hiring a workforce whose actions will reflect a high degree of integrity and ethics, recognizing that Organon's ability to excel depends on the integrity, knowledge, and skills of our people. Accordingly, the Company invests significant resources in identifying and hiring highly qualified and skilled individuals. In addition, prior to allowing the individual to commence employment with the Company, Organon performs a drug screening and background investigation of the individual. The background investigation includes verification of employment history, and education. Organon also performs a criminal background investigation that searches for any felony or misdemeanor on both a county and federal level and reviews all candidates against the Federal exclusions list. If deemed appropriate to the position, checks also will be conducted of professional certifications and licenses, motor vehicle records and credit history.

7. Responding to Potential Violations

Our Compliance Program increases the likelihood of preventing, or at least identifying, unlawful and unethical behavior. However, HHS-OIG recognizes that even an effective compliance program may not prevent all violations. As such, our Compliance Program requires employees to report and Organon to respond promptly to potential violations of law or Organon's policies and take appropriate disciplinary action. Specifically, Organon's Compliance Program includes a clearly defined violations process that sets out the potential consequences of violating the law or company policy. Although each situation is considered on a case-by-case basis, Organon's policies requires that consistent and appropriate disciplinary action be taken to address inappropriate conduct and deter future violations. Organon also assesses whether identified violations are in part due to gaps in our policies, practices, or internal controls, and if so, takes appropriate action to prevent future violations.

8. Conclusion

In summation, a copy of this document can be obtained by calling 844-674-3200.