

# CODE OF CONDUCT



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## INTRODUCTION

### COMMITMENT TO INTEGRITY

EMD Serono is dedicated to delivering innovative products that fight debilitating diseases and improve the lives of patients. Our commitment to integrity in everything we do is fundamental to achieving this vision. To achieve our objectives, we will apply the highest legal and ethical standards to all of our business activities. EMD Serono will comply with all applicable laws and expects all employees to do the same. No employee may violate the law on EMD Serono's behalf, or direct anyone else to do so. Even more basically, EMD Serono expects employees to perform their jobs with honesty and integrity. It is our pledge to always do what is right.

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We have a shared commitment to act with integrity and to do what is right. To make it happen, "It's Up to You."



By acting with integrity and following the Code, we can uphold the EMD Serono vision together.

### THE EMD SERONO CODE OF CONDUCT

To demonstrate our commitment to integrity and to explain some of the most important laws and policies that apply to our business, EMD Serono has prepared this Code of Conduct. The Code summarizes certain critical laws and policies that affect how we work at EMD Serono and explains how to get help when we need it. The Code supplements the Merck KGaA, Darmstadt, Germany Code of Conduct, as well as their Pharmaceutical Marketing Best Practices.

Of course no Code can describe all laws that apply to our business or address every company policy, but we can highlight resources available to help with situations that may arise. If you suspect that a violation of law, company policy, or this Code may have occurred, you are obligated to report it. Every EMD Serono employee is responsible for following this Code of Conduct. Employees of affiliated companies must follow this Code while assigned to work for EMD Serono, even if formally an employee of another company. Contract and temporary employees must also follow the principles in this Code during their assignment on behalf of EMD Serono.

If you have a question about any part of this Code, or about any other compliance matter, you should ask:

- Your manager
- Your Human Resources Business Partner
- An attorney in the Legal Department
- A member of the Compliance Department

We also have established a 24-hour, toll-free, confidential Compliance Helpline (877-846-8839).

## POLICIES AND PRACTICES

THIS SECTION HIGHLIGHTS SOME OF THE MOST IMPORTANT LAWS AND POLICIES THAT GOVERN OUR WORK. MORE INFORMATION ABOUT THESE TOPICS IS AVAILABLE ON THE EMD SERONO INTRANET OR FROM THE COMPLIANCE DEPARTMENT.

### EMPLOYMENT PRACTICES

EMD Serono's strength is its people. To confirm its status as an employer of choice; to abide by applicable laws; and to emphasize the importance of respect, integrity, and teamwork, EMD Serono has developed a number of policies governing how we work with one another.

A few of these policies are mentioned here briefly and are described in greater detail in the EMD Serono Employee Handbook, which includes additional important policies. If you have questions or concerns about any of these matters, you should contact your manager, Human Resources or the Legal or Compliance Departments.

### EQUAL EMPLOYMENT OPPORTUNITY

EMD Serono is an equal opportunity employer. EMD Serono prohibits discrimination on the basis of race, color, religion, age, sex, sexual orientation, national origin, ancestry, disability, military or veteran status, genetic information, gender identity, or any other classification protected by applicable federal, state, or local law. This policy applies to all aspects of the employment relationship, such as hiring, promotion and compensation.

EMD Serono strives to do business with customers and suppliers of sound business character and reputation. EMD Serono does not knowingly support any public or private organizations that espouse discriminatory policies or practices.

### UNLAWFUL HARASSMENT

Our work environment should be free from harassment on the basis of race, color, religion, age, sex, sexual orientation, national origin, ancestry, disability, military or veteran status, genetic information, gender identity, or any other classification protected by applicable federal, state or local law. Prohibited harassment is verbal, physical or written conduct that interferes with work performance or that creates an intimidating, offensive or hostile work environment.

Violence, intimidation and threats of any kind are prohibited. Employees may not possess firearms, other weapons, or dangerous materials on EMD Serono premises.

Prohibited sexual harassment includes unsolicited or unwelcome sexual overtures or comments.

### DRUGS AND ALCOHOL

To ensure the unimpaired judgment of our employees and the decorum of our workplace, employees may not work under the influence of drugs or alcohol. Employees may not operate a vehicle owned or leased by EMD Serono while under the influence of drugs or alcohol.

The unlawful possession, use or distribution of a controlled substance in the workplace or during working hours is prohibited. The consumption of alcohol in the workplace or during working hours is similarly prohibited, except at events approved by a member of senior management.

FOR MORE INFORMATION:  
[EMPLOYEE HANDBOOK](#)



Although we respect one another's privacy, there are certain limits to what is private at work. Employees should be aware that voice mail, email, and information created, stored or retrieved on any EMD Serono provided or supported equipment may be monitored or reviewed by the company at any time.

#### ENVIRONMENT, HEALTH AND SAFETY IN THE WORKPLACE

EMD Serono is committed to maintaining a healthy and safe workplace and to complying with all applicable environmental and safety laws. The Health and Safety Office develops procedures and conducts training to protect employees and the environment. If you are aware of any condition that may be unsafe, unhealthy or hazardous to the environment, contact your manager or the Health and Safety Office immediately.

#### SOLICITATION

Employees may not sell products such as cosmetics or solicit any non-EMD Serono business during working hours. Unrestricted solicitation and distribution of literature can be disruptive to business. Unless employees have advance permission from Human Resources, they may not solicit, canvass or distribute materials at work or during working hours. Permission is typically granted for company-sponsored community activities such as health-related walk-a-thons.

Solicitation by non-employees is prohibited unless invited by Human Resources in connection with a company-sponsored project.

#### PRIVACY

In the course of our work, we may be entrusted with confidential medical information about patients. We should treat that information, and other personal information, with the care we would expect to be given to information about ourselves. We should also protect private information about fellow employees.

Personally identifiable health information should be shared internally only with those employees who have a need to know. To the extent possible, remove personal identifiers from this sort of information so that the individual's identity cannot be determined. Other rules may forbid or limit the disclosure of personal information outside the company.



### USE OF EMD SERONO PROPERTY AND INFORMATION

Use EMD Serono's resources and property solely for the benefit of the company. Do not misappropriate or misuse company assets, whether through theft, fraud or other means, for personal benefit.

This includes physical resources, intellectual property, intangible assets and proprietary information. Information concerning pricing, products and services being developed; a prospective acquisition or sale; and any other information not generally available to the public must be held in the strictest confidence.

Exercise care to prevent inadvertent disclosure and do not use proprietary or confidential information in any way other than as required to perform your job. These obligations to protect the confidentiality of EMD Serono's nonpublic information continue even after separation of employment.

All files, records and other information acquired or created in the course of employment are the property of EMD Serono and, like EMD Serono's physical property, must be returned upon separation from EMD Serono. (See the Section on Intellectual Property as well.)

Do not discuss confidential information in public places where you can be overheard. Take special care to make sure your use of electronic devices and paper records cannot be observed by others.

### INTELLECTUAL PROPERTY

Protection of EMD Serono's intellectual property, including patents, trade secrets, trademarks and copyrights, is critical to EMD Serono's ability to compete. Employees should take care to preserve EMD Serono's rights and to honor the rights of others.

As a condition of employment, all employees are required to enter into an Employee Obligations Agreement which confirms that the product of all work for EMD Serono is owned by the company.

Unauthorized use of the intellectual property of others can give rise to personal liability. Do not make copies of copyrighted materials without permission, and honor license agreements under which EMD Serono is permitted to use computer software.

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The newspaper test—how would I feel if my actions were reported on the front page of the business section?—is a good method for evaluating questions of business ethics. Be proud of your work for EMD Serono, and be proud of the decisions you make.

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FOR MORE INFORMATION:  
[CONFIDENTIALITY POLICY](#)  
[EMPLOYEE OBLIGATIONS AGREEMENT](#)



EMD Serono captures the value of meals, educational items, speaking and consulting fees, and all other transfers of value to healthcare professionals and healthcare organizations to comply with federal, state, and internal reporting requirements. The company relies on its employees to accurately record information in the company's systems, which are used to help prepare these reports. In addition, employees must certify to the accuracy of their expense reports.

### ACCURATE BOOKS AND RECORDS

The integrity of EMD Serono's books, records and reports is essential. Established accounting procedures must be followed to ensure the complete and accurate recording of all transactions. False or misleading entries or statements of any kind are prohibited. This includes, but is not limited to, the accuracy of records that will be relied on to prepare the company's financial, price, expense, physician aggregate spend, and safety reporting, as well as other drug study data.

Our obligation goes beyond merely avoiding intentional deceit. If you are not sure of the accuracy of information, take the steps necessary to verify it. If you become aware of any mistaken record, transaction, report or accounting practice, report the matter immediately to either your manager, your Human Resources Business Partner, an attorney in the Legal Department, or a member of the Compliance Department.

Special attention to accurate books and records is also addressed under the section titled "Key Laws and Regulations" in connection with healthcare fraud and abuse laws.

### RECORD RETENTION

EMD Serono will retain all paper and electronic records required by law or that are necessary for employees to do their jobs. Records that we are not required to retain and that are not needed for our business should be discarded in accordance with the company's retention schedules.

Some types of documents, such as financial reports, government filings, contracts and personnel records, must be retained for lengths of time specified by law. Other types of records are retained for periods determined by EMD Serono to enable efficient business operation. Before disposing of documents, employees should make sure they carefully follow the record retention policy.

Whenever it becomes apparent that records will be required in connection with a lawsuit, audit or investigation, or a potential lawsuit, audit or investigation, disposal of documents pertaining to the subjects of the litigation or investigation should be suspended immediately and all possibly relevant records should be preserved. Employees will be notified if such a situation exists. If you are unsure whether documents under your control relate to a lawsuit, audit or investigation, contact the Legal or Compliance Departments.



**CORPORATE COMMUNICATIONS**

EMD Serono’s aim in all communications is to convey the truth, completely and accurately, to all of our audiences, including employees, patients, physicians, government authorities, business partners, the securities market and the media. Whether in internal or external communications, use good judgment in what you write, especially in email messages. Avoid language that could be taken out of context—assume that someone without full knowledge of the situation may read your communication at a later date.

To ensure that public statements are accurate and consistent, external communications must be prepared and approved by the assigned business units. For example, press releases may only be issued by the Communications Department and product marketing materials must be approved in accordance with the Promotional and Scientific Materials Review Process. Only individuals designated by the Communications Department may serve as spokespersons for EMD Serono. Immediately refer external inquiries to the area responsible for exclusive handling:

From the Media	Communications
From investors or analysts	Communications
From the FDA or other product regulators	Regulatory Affairs
From elected or appointed government officials	Government Affairs
From other government agencies or officials	Legal

It is EMD Serono policy to cooperate fully with authorized government investigations. In the event that you are contacted by a law enforcement official concerning an EMD Serono matter, you should immediately seek assistance from the Legal Department, which will provide guidance to make sure that accurate information is supplied, consistent with the law. Employees should be aware that Legal Department attorneys are obligated to act in the best interests of EMD Serono and do not serve as personal lawyers or representatives for employees.

FOR MORE INFORMATION:  
[PROMOTIONAL AND SCIENTIFIC MATERIAL REVIEW POLICY](#)



### INSIDER TRADING

Do not trade in shares of Merck KGaA, Darmstadt, Germany or other companies based on inside information. Prohibited "insider trading" is the purchase or sale of a publicly traded security while in possession of material nonpublic information about the company. You should assume that most information obtained as an employee of EMD Serono is material and is not public.

Do not share inside information with—or give advice about buying or selling stock to—anyone, even close family members. "Tipping," the communication of inside information to anyone who might use it to purchase or sell securities, is illegal. Criminal and civil penalties for violating securities laws are severe.

Trading on or disclosing inside information about other companies is prohibited. For example, it is against the law to purchase the stock of a company to which EMD Serono is about to award a major contract.

Examples of material non-public information include information not yet broadly disclosed to the public about findings in clinical trials, revenues or losses, and business deals.

If you have a question about whether the sale or purchase of a security is permissible, contact the Legal or Compliance Departments.

### FAIR COMPETITION

EMD Serono embraces the competitive marketplace in which it operates and is committed to compliance with antitrust and fair competition laws. These laws are designed so that customers enjoy the benefit of open competition among suppliers and sellers benefit from open competition among purchasers. Violation of antitrust laws can lead to civil or criminal liability for corporations and individuals.

Given the risks facing companies like EMD Serono, take particular care to guard against actions that could be construed as price-fixing or a restraint on trade.

To avoid prohibited price-fixing, do not propose, consider, or enter into any agreement or understanding with any competitor concerning prices, price policies, sales, or resales terms or conditions. To avoid the appearance of improper collusion, EMD Serono employees should not even discuss these topics with a competitor.

To avoid prohibited restraints on trade, consult the Legal Department before considering any type of agreement or understanding that might appear to limit any party's freedom to trade with others or to trade in a particular territory.

There are lawful ways to enter into certain types of exclusive or limited arrangements, but expert guidance is required. There is no substitute for Legal Department review before action is taken in any matter that may implicate antitrust laws.

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Do not post messages with confidential information about EMD Serono or its competitors or business partners on an Internet "chat room" or message board.



## CONFLICTS OF INTEREST

All employees have an obligation to act in EMD Serono's best interest and to protect its assets. All employees should avoid conflicts between personal interests and the interests of EMD Serono.

A conflict of interest may arise if outside activities or personal interests jeopardize your ability to make objective decisions in the course of doing your job. Moreover, the mere appearance of a conflict of interest can be as damaging as an actual conflict. Some conflicts may be unavoidable, but they can usually be managed by disclosing the situation in advance and taking steps to prevent the conflict from compromising EMD Serono's interests. When in doubt, tell your manager, Human Resources or the Compliance Department about the situation that may give rise to a conflict, and document any permission received.

Here are a few specific guidelines:

- **Avoid the Appearance of a Conflict of Interest and Disclose Potential Conflicts.**

Anytime you face a situation that might prompt others to question whether your judgment for EMD Serono may be affected by outside personal interests, you should disclose the potential conflict to your manager, Human Resources or the Compliance Department. If you are not sure whether a situation presents a conflict, ask.

- **Do Not Profit from an EMD Serono Transaction.**

Do not participate, directly or indirectly, in any EMD Serono decision that might benefit you personally. Do not take advantage of EMD Serono activities for personal gain.

- **Avoid Conflicts with Interests of Family Members.**

Avoid situations in which the interests of a close relative may be at odds with the interests of EMD Serono. Take steps to avoid a conflict just as if the family member's interest were your own.

Conflicts may also arise in non-financial situations. Avoid secondary employment or outside activities that could have a negative impact on job performance, conflict with EMD Serono job obligations or diminish EMD Serono's reputation. Affiliations with competitors, customers, suppliers or business partners are not permitted without prior written approval from the Compliance Officer.

In considering whether a situation poses a conflict of interest, ask yourself:

- *"Would I be concerned if other people found out about this situation?"*
- *"How would it look if this situation was reported in the newspaper?"*
- *"What is the right thing to do?"*

Please also review the section on Political Activities for additional information on conflicts of interest.

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Do not participate in a decision to hire a company in which you or an immediate family member has a financial interest. Disclose your interest in advance and ask your manager and the Compliance Department whether you can continue your relationship with the firm during your employment by EMD Serono.

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FOR MORE INFORMATION:  
[SUPPLIER AND VENDOR RELATIONS POLICY](#)



Tickets to sporting events are a frequent means of business hospitality. You may accept a colleague's invitation to a local sporting event for an opportunity to further your business relationship. But you should not accept an invitation to a lavish event (such as a trip to the Super Bowl) or a gift of tickets if the host will not be present.

### GIFTS AND ENTERTAINMENT

To deter others from seeking improper influence over EMD Serono and to discourage others from believing that EMD Serono makes decisions based on improper influence, use caution in accepting gifts or entertainment from vendors and customers.

To avoid the appearance of improper influence:

- Never ask for a gift;
- Never accept a gift if it could reasonably appear that the giver is seeking to influence an action or decision by EMD Serono;
- Never accept a gift of cash or its equivalent, such as gift certificates.

Only accept entertainment, such as joining a business associate for dinner or a sporting event, if it is a routine social amenity that could not reasonably be construed as an attempt to gain improper influence. Outright gifts should be declined if they exceed nominal value (typically \$100). These same rules apply to gifts and entertainment offered to your immediate family members.

Bribery or kickbacks by EMD Serono are, of course, prohibited. Avoid giving gifts, favors or entertainment of any kind that might appear to be a bribe or a kickback. More rules on gifts and entertainment given by EMD Serono employees are discussed in the Travel and Expense Policy. (See the sections on Political Activities and Key Laws and Regulations as well.)

FOR MORE INFORMATION:  
[SUPPLIER AND VENDOR RELATIONS POLICY](#)  
[TRAVEL AND EXPENSE POLICY](#)



### POLITICAL ACTIVITIES

EMD Serono is committed to full compliance with both the letter and the spirit of all federal, state, and local political laws in the United States. EMD Serono and its employees must avoid even the appearance of impropriety and adhere to the highest standards of ethical behavior and transparency when engaging in political activities.

Recognizing that the laws of politics constantly change and evolve, EMD Serono has looked to best practices to create guidelines to make compliance as easy and accessible as possible. EMD Serono's policies, such as the Policy on Political Activities, have been designed to help you navigate the law well within its limits.

Employees interacting with government agencies, government employees, or a candidate for office, should ask themselves if they are doing one of these three things:

Supporting or opposing a candidate for office in an election	This can be limited by campaign finance laws.
Attempting to influence a decision of a government official or employee	This can require lobbying disclosure.
Acting in a way that can create a conflict of interest between personal and governmental interests, such as providing a "gift" or other payment	This can implicate government ethics laws.

### CAMPAIGN FINANCE

Although EMD Serono encourages employees to participate in the political process, employees must take care that personal support for a candidate or issue cannot be mistaken for the position of the company. Employees must also avoid actions that could put EMD Serono at risk of violating campaign finance and election laws.

Employees may not act on behalf of EMD Serono to contribute money or resources to candidates, elected officials or political organizations, nor may employees use EMD Serono assets to support a candidate or issue. These restrictions also apply to services and facilities, such as office space, photocopying, administrative assistance and telephone use. Employees may not work for a candidate or political party on company time. This prohibition does not apply to participation in the EMD Serono Political Action Committee (PAC) by eligible employees.

On occasion, the fact that EMD Serono does business with a government entity can impact the personal campaign finance activities of employees. In such instances, impacted employees will be notified.

Under no circumstances may EMD Serono, its sponsored PAC, or any employee on behalf of EMD Serono, make a campaign contribution or expenditure in exchange for, or to reward, an official action. Please see related information under the Foreign Corrupt Practices Act section for additional guidance surrounding interactions with foreign government officials and government entities.

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EMD Serono sponsors a federal separate segregated fund, or PAC, to accept personal employee contributions and make contributions to federal candidates and committees. Federal Law restricts membership in the PAC and participation in any PAC activity by eligible employees is entirely voluntary.



A gift includes any direct or indirect payment for food, beverages, travel, promotional items, or other things of value that could personally benefit a government official. Neither EMD Serono, nor any employee or consultant on behalf of the company, may provide a gift to a federal, state, or local government official without prior written approval from the Vice President of Government Affairs.

### LOBBYING

Lobbying activities are heavily regulated and are coordinated through the Government Affairs Department. Employees must provide prior notification before engaging in lobbying or hiring a consultant to engage in lobbying for the company. Also no EMD Serono employee may register as a lobbyist, or approve a consultant's registration as a lobbyist, without prior approval from the Vice President of Government Affairs.

EMD Serono must track employee activity related to lobbying. In addition, employees and consultants engaged in lobbying must certify to the accuracy of, and may be required to sign, lobby disclosure reports required by various federal, state, and local governments. Information that requires tracking may include: hours spent lobbying and supporting lobbying of others, including planning, preparation and research; identification of the specific government matters lobbied; government officials contacted; and expenses related to lobbying such as personal travel.

### GOVERNMENT ETHICS

Employees who do business with federal, state, or local government employees must conduct themselves in a manner that cannot reasonably give rise to a perception that EMD Serono is attempting to improperly influence public officials in the performance of their duties. Rules concerning the providing of government employees with gifts, meals or entertainment are very restrictive.

Furthermore, employees who were formerly or are currently government officials must notify the Vice President of Government Affairs. The company's Revolving Door and Conflict of Interest guidelines prohibit employees from contacting their government employer on behalf of EMD Serono or making or participating in any governmental decisions that may result in a conflict of interest between their public and professional duties.

Payments relating to a meeting, conference, retreat, event sponsorship, grant, or other event relating to a government entity or official may potentially violate ethics laws or require political disclosure. Employees should notify the Vice President of Government Affairs before making a payment.

Employees should know the guidelines before engaging in any of these activities, directly or indirectly. However, if there is one overriding rule, it is to ask first. Employees will find that your colleagues in Government Affairs, Compliance, Legal, and Human Resources are ready to work with you.

FOR MORE INFORMATION:  
[POLICY ON POLITICAL ACTIVITIES](#)

## KEY LAWS AND REGULATIONS

EMD SERONO EMPLOYEES MUST COMPLY WITH ALL LAWS RELATING TO THE CONDUCT OF BUSINESS IN THE PHARMACEUTICAL AND BIOTECHNOLOGY INDUSTRIES. THERE ARE A FEW LAWS AND REGULATIONS DESERVING SPECIAL ATTENTION.

Criminal and civil penalties for noncompliance with healthcare laws are severe and may apply to both companies and individuals. Compliance with these laws is critical to EMD Serono's mission.

These laws can be complex and can be changed by new regulations, legislation or judicial interpretation. Fundamentally, however, EMD Serono employees should conduct their business affairs so that EMD Serono's reputation for integrity will not be damaged should their actions become public. If you do not understand how—or if—a law or policy applies to a particular situation, seek assistance from your manager, the Legal or the Compliance Departments.

### PREVENTING BRIBERY, KICKBACKS AND FRAUD THE ANTI-KICKBACK STATUTE

The anti-kickback law makes it a crime to pay or receive anything of value to induce the prescribing or purchasing of items or services paid for by a federal healthcare program. As applied to pharmaceutical companies, the law prohibits payments intended to induce someone to purchase or prescribe a drug reimbursable under a federal healthcare program or to reward someone for purchasing or prescribing a drug. Put simply, do not "buy business." Under the anti-kickback law, questions about underlying intent might be raised concerning almost any type of payment, including direct compensation, educational and research grants, speaker fees, and reimbursement for participation in clinical trials.

A principal purpose of the anti-kickback law is to protect the independence and objectivity of decisions affecting federal healthcare programs and their patients. A physician's treatment decision should be free from considerations of personal gain.

Many states have laws similar to the federal anti-kickback statute making it a violation to pay anything of value to influence prescriptions paid for by state healthcare programs, private health plans and even individuals. Accordingly, EMD Serono prohibits improper inducements to prescribe or purchase EMD Serono products, regardless of whether a federal healthcare program is involved.

To maintain the integrity of our relationships with providers and to help EMD Serono employees abide by the anti-kickback law, EMD Serono has adopted the *PhRMA Code on Interactions with Healthcare Professionals*, a set of industry guidelines governing relationships between pharmaceutical firms and physicians. EMD Serono employees should follow the *PhRMA Code* as if it were an internal company policy.

A number of EMD Serono policies and procedures, consistent with the *PhRMA Code*, address appropriate conduct in connection with product promotion, consulting arrangements and educational programming. For example:

- Only items designed primarily for the education of patients or healthcare professionals that are less than \$100 in value and do not have value to the healthcare professionals outside of their professional responsibilities may, on an occasional basis, be offered to healthcare professionals. No other materials, including materials for the personal benefit of healthcare professionals, can be offered.

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Among other things, the *PhRMA Code* aims to prevent conduct that could be perceived as a bribe or kickback to healthcare professionals. Employees should not act in a way that could lead others to think they are offering or proposing a bribe or kickback.

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FOR MORE INFORMATION:  
[PHRMA CODE ON INTERACTIONS WITH HEALTHCARE PROFESSIONALS](#)



Certain states, such as Massachusetts and Vermont, impose additional limitations governing our interactions with healthcare providers. Employees should read the Policy on Annual Limits on Compensation for Healthcare Professionals for more information regarding state-specific limits.

- Informational presentations may be accompanied by modest meals in a setting conducive to professional communication. Meals offered to healthcare professionals in connection with informational presentations made by field sales representatives or their immediate managers are limited to in-office or in-hospital settings only. Such meals must not be offered in a restaurant or similar setting. In addition, providing physicians or their staff with meals to be eaten on their own would be considered a personal gift, and is, therefore, prohibited.
- Entertainment and recreational items (such as tickets to the theater or sporting events) must not be offered to any healthcare professional under any circumstances.
- Healthcare professionals may be engaged by the company to serve as speakers or consultants, but speaker and consulting agreements must meet a bona fide need for the services at fair market rate financial terms, as documented in an approved written contract.

The *PhRMA Code* and EMD Serono policies, such as the Policy on Compensation and Expenses for HCPs, The Annual Limits on Compensation for Healthcare Professionals, the Consultant and Speaker Policy, and the Travel and Expense Policy, address several related topics, and employees who interact with providers, healthcare professionals, and healthcare organizations must be familiar with their provisions.

An employee violating this Code or any company policy will be subject to discipline, up to and including termination of employment and criminal proceedings may result. All employees have a responsibility to report any actual or attempted bribery, kickback or fraud to their manager, the Legal or Compliance Departments, or the Helpline.

#### THE FOREIGN CORRUPT PRACTICES ACT (FCPA) AND OTHER LAWS

The Foreign Corrupt Practices Act (or FCPA) and other laws prohibit bribery, kickbacks and fraud.

The FCPA is a U.S. law that covers U.S. companies and their representatives, as well as anyone located in the U.S. It prohibits the payment or offering of anything of value directly or indirectly to a foreign government official, political party, party official or candidate for the purpose of influencing an official act of the person or the government in order to obtain such an advantage. It is important to recognize that physicians and other employees of foreign government-owned clinics or hospitals could be considered foreign officials under the FCPA.

Other federal and state laws prohibit bribery of U.S. officials and private individuals. All EMD Serono employees must comply with the FCPA and other anti-bribery laws.

Please contact a member of the Legal or Compliance Departments if you have any questions regarding the FCPA, other anti-bribery laws or their potential application to your work at EMD Serono.

FOR MORE INFORMATION:  
[POLICY ON COMPENSATION AND EXPENSES FOR HCPS](#)  
[POLICY ON ANNUAL LIMITS ON COMPENSATION FOR HCPS](#)  
[CONSULTANTS AND SPEAKERS POLICY](#)  
[THE TRAVEL AND EXPENSE POLICY](#)



### PROTECTING TAXPAYERS' MONEY: THE FALSE CLAIMS ACT

Government healthcare programs pay for prescription drugs at prices set based on information supplied by drug manufacturers. The government therefore expects that the information supplied by drug manufacturers is accurate and complete.

There are a number of criminal and civil laws that prohibit individuals and organizations from submitting false information or false claims for payment to the government. For example, if a pharmaceutical company willfully omits certain product discounts in price calculations submitted to the government, the pharmaceutical company may be in violation of the Federal False Claims Act. Many states have similar laws governing direct or indirect claims for payment from state healthcare programs or private payors like insurance companies.

These "false claims" laws also prohibit helping someone else submit a false claim. For example, if a pharmaceutical company helps or causes a physician or pharmacy to submit a false claim for reimbursement, the government may seek to hold the company responsible for the physician's or pharmacy's action.

It is essential that all books and records maintained by EMD Serono, and all information reported by EMD Serono, be complete and accurate.

The Federal False Claims Act provides for civil penalties for each false claim submitted to the government. This statute, and similar state false claims acts, includes provisions under which individual citizens with evidence of fraud against the government may sue on behalf of the government and recover lost funds. If successful, the individual who initiated the suit is typically entitled to a share of the government's recovery. The statutes prohibit retaliation against persons who file these "qui tam" or "whistleblower" suits. More information about these laws can be obtained from the Legal or Compliance Departments.

As summarized in this Code, EMD Serono has established comprehensive policies and procedures to prevent, detect, and correct violations of law and company policy and requires employees to report actual or potential violations of law or company policy. A failure to report suspected violations may result in disciplinary action, up to and including termination. There are several mechanisms for reporting such issues. First, you may report compliance issues to your manager. Second, you may contact the Legal or Compliance Departments. You also may file an anonymous report through the Compliance Helpline at 877-846-8839. EMD Serono policy prohibits retaliation against employees for good faith reports of compliance issues.



### PROTECTING PUBLIC SAFETY: THE FOOD, DRUG, AND COSMETIC AND PRESCRIPTION DRUG MARKETING ACTS

The registration and promotion of prescription drugs is closely regulated by the U.S. Food and Drug Administration (FDA), which is charged with ensuring the safety and efficacy of drugs available to the public. EMD Serono must comply with FDA rules in many aspects of its business and relies on employees responsible for the study, manufacture, distribution and promotion of our products to keep the company in compliance. All employees should be mindful of FDA rules and regulations particularly:

- We must comply with rules mandating that product promotion be fair, balanced and consistent with the approved label. While physicians are generally free to prescribe approved drugs in their best medical judgment, manufacturers may not promote any use of a product that is inconsistent with the approved label. Accordingly, employees must only use approved marketing materials to avoid the risk of off-label promotion. The company has also developed procedures to handle requests for information about off-label use, and to ensure that sales personnel do not—even inadvertently—violate FDA restrictions.
- We must comply with the requirements of the Prescription Drug Marketing Act governing distribution of drug samples. Samples may only be distributed according to prescribed procedures with strict documentation requirements. The government has prosecuted pharmaceutical companies for encouraging physicians to bill the government (or private payors) for samples intended for free distribution to patients.

- We must comply with other FDA regulations that require us to monitor the safety of our products. As a mandatory reporter, the regulations require that we collect all adverse events and product complaints reported with the use of our products, and evaluate data to determine the relationship between an event and a product, if any. Therefore, all employees must report potential adverse events to the U.S. Drug Safety Department and product complaints to the U.S. Quality Assurance Department.

#### ETHICS IN INTERACTIONS WITH HEALTHCARE PROFESSIONALS

All employees who interact with healthcare professionals must carry out such interactions with the highest ethical standards. Employees who interact with healthcare professionals should:

**NEVER** engage in any deceptive or misleading marketing or sales activities;

**NEVER** use a title or designation that might lead a healthcare professional to believe that the employee is licensed to practice medicine, unless the employee holds an active license to practice that health occupation;

**NEVER** attend patient examinations without the prior expressed, written consent of the patient and permission from the attending physician;

**NEVER** harass, intimidate, or coerce a healthcare professional through any form of communication;

**NEVER** continue to make sales calls upon a healthcare professional after the healthcare professional has requested in writing not to receive any further sales calls;

**NEVER** offer an inducement or employ a misleading statement to gain access to a healthcare professional;

**ALWAYS** provide healthcare professionals information that is accurate, properly substantiated, fairly balanced, and consistent with FDA approved labeling.

FOR MORE INFORMATION  
PROMOTIONAL AND SCIENTIFIC  
MATERIAL REVIEW POLICY

U.S. DRUG SAFETY  
& U.S. QUALITY ASSURANCE  
ON NUCLEUS

## COMPLIANCE PROGRAM

### CORPORATE INTEGRITY AGREEMENT AND ADDENDUM

A Corporate Integrity Agreement (CIA) is an agreement with the United States Department of Health and Human Services, through the Office of Inspector General (OIG), in which a provider or entity enters into as part of a settlement of alleged violations of Federal healthcare programs. Under a CIA, providers or entities agree to implement and maintain specific compliance obligations for a number of years, and in exchange the OIG agrees not to seek their exclusion from participation in Federal healthcare programs such as Medicare and Medicaid.

If a provider or entity is found to be in violation of their CIA, the OIG may impose severe monetary penalties and choose to enact its exclusion authority, removing the provider or entity from participation in Federal healthcare programs.

CIAs have many common elements but attempt to also recognize many of the components of preexisting voluntary compliance programs.

In 2005, Serono (now EMD Serono) entered into a CIA as part of its Serostim settlement. In 2011, the company agreed to extend its CIA for an additional three years (the CIA Addendum) in connection with a settlement concerning fees paid to physicians for speaking and consulting on Rebif. In September 2014, EMD Serono was notified that it had successfully met the requirements of the CIA over its duration and was released from the agreement.

While this is a significant milestone for EMD Serono, the company remains committed to conducting its activities in full compliance with FDA regulations and healthcare program requirements. Furthermore, our compliance program still incorporates many of the compliance

obligations that were implemented during the term of the CIA and CIA Addendum, which are still considered industry best practices, to ensure identified compliance issues are appropriately addressed.

In particular, employees and certain contractors acting on behalf of the company must:

- Understand and comply with all company policies and procedures
- Certify compliance with the company's Code of Conduct annually
- Timely complete mandatory compliance training annually
- Report suspected violations of laws and company policies
- Notify Human Resources or the Compliance Department if at any time they become excluded, debarred, suspended, or otherwise ineligible to participate in Federal healthcare programs

EMD Serono is deeply committed to the highest standards of legal and ethical behavior. The compliance program has been established to help employees comply with this Code, laws, company policies, and the company's compliance obligations.

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Compliance training is an essential part of EMD Serono's compliance mission and must be completed on time to avoid disciplinary action.




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Because failure to address improper activity may be deemed approval of the conduct, we emphasize the importance of bringing matters to the attention of appropriate EMD Serono personnel.

## COMPLIANCE DEPARTMENT

The compliance program is led by the Chief Compliance Officer and the Compliance Department. A Compliance Committee comprised of senior leadership supports the Chief Compliance Officer and his team in fulfilling the responsibilities of the compliance program.

Member of the Compliance Department stand ready to help you with compliance matters. Among other things the Compliance Department:

- Coordinates a variety of training and education programs
- Provides policy guidance
- Audits and monitors to ensure processes are being conducted consistent with policies and procedures
- Facilitates the HCP engagement process
- Investigates reports of misconduct and potential violations of laws and company policies.

Violations of compliance policies, including the Code, are very serious matters and will result in disciplinary action, up to and including termination of employment. An employee who receives a written warning will lose any bonus or incentive payment for the quarter in which they receive discipline for the violation, if on a sales incentive plan, or 25% of a bonus otherwise earned if on a bonus plan.

## REPORTING SUSPECTED NONCOMPLIANCE

### GENERAL POLICY

Employees are required to report suspected violations of this Code of Conduct, law, or of EMD Serono policies, by EMD Serono or any EMD Serono employee or agent. Employees are required to come forward with any such information, without regard to the identity or position of the suspected offender. EMD Serono will treat the information in a confidential manner, to the extent possible.

Because failure to address improper activity may be deemed approval of the conduct, we emphasize the importance of bringing matters to the attention of appropriate EMD Serono personnel. Failure to report wrongdoing may itself result in disciplinary action, up to and including termination.

### COMPLAINT PROCEDURE

#### 1 REPORTING A SUSPECTED VIOLATION

Information about known or suspected violations by EMD Serono or any EMD Serono employee or agent must be reported promptly. Reports of a violation, possible violation or general compliance concern may be made by telephone, in person or in writing. Many situations can be handled by first reporting to your manager or Human Resources. You should also feel free to report the matter to the Compliance or Legal Departments, or other appropriate person or department as provided for in EMD Serono's policies and procedures or in this Code of Conduct.



You may also report any situation to the EMD Serono Compliance Helpline at (877-846-8839). The Helpline is particularly appropriate if you do not feel comfortable using traditional reporting channels or if you prefer to remain anonymous. The EMD Serono Compliance Helpline is available 24 hours a day, seven days a week, 365 days a year.

If you report an actual or possible violation to your manager or other person and do not believe that individual has taken appropriate action, notify the Compliance Department.

## 2 INVESTIGATING A REPORT

The Compliance or Legal Departments will coordinate the investigation of reports of violations and may enlist internal or external assistance. Employees are expected to cooperate in the investigation of reported violations, and a failure to do so may result in disciplinary action, up to and including termination.

Any employee accused of misconduct will be treated fairly. An investigation may result in, among other things, a written report, corrective action, employee discipline or no action if misconduct is not found.

## 3 CONFIDENTIALITY

The identity of all parties to an investigation – whether a source, witness or subject – will be protected to the extent possible, given the circumstances.

Employees should be aware that the Compliance Department, the Legal Department and persons assisting in an investigation are obligated to act in the best interests of EMD Serono, and do not serve as lawyers or personal representatives for employees.

## 4 PROTECTION AGAINST RETALIATION

EMD Serono prohibits retaliation against anyone for reporting a suspected violation in good faith. Retaliation in any form against an individual who reports in good faith a suspected violation of law or this Code, even if the report is mistaken, or who assists in the investigation of a reported violation, is itself a serious violation. Acts of retaliation should be reported immediately to your manager, Human Resources, the Legal or Compliance Departments and will be disciplined appropriately.

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The EMD Serono Code of Conduct cannot, and is not intended to, address every conceivable law, policy or situation. The Code is typically reviewed annually but may be revised at any time. The Code of Conduct does not create an expressed or implied contract between EMD Serono and any employee or third party. In particular, the Code does not constitute or create an employment contract. EMD Serono employees have an at-will employment relationship and nothing in this Code is a guarantee of employment for a particular period of time or restricts EMD Serono from taking disciplinary action, even if the conduct in question is not expressly addressed in this document.

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FOR MORE INFORMATION:  
[COMPLIANCE ON NUCLEUS](#)

## ACTING WITH INTEGRITY

EMD SERONO COUNTS ON ALL OF US TO UPHOLD OUR SHARED COMMITMENT TO HONESTY AND INTEGRITY. THE DISCUSSION OF LAWS AND POLICIES IN THIS CODE IS ONE TOOL TO HELP US MEET THAT COMMITMENT.

Just as important as the particular laws and policies discussed here is the overarching theme of acting with integrity. To thrive at EMD Serono and to help EMD Serono fulfill its mission:

- **Utilize the resources that are available to you.** Become familiar with this Code of Conduct, the Employee Handbook, the PhRMA Code, and the various policies and procedures posted on EMD Serono's NucleUS intranet site.
- **Understand the rules, and ask questions.** Understand the laws and rules that apply to your job. If you are not sure, ask.
- **Set a good example.** We all can serve as role models and—together—meet the highest standards of legal and ethical behavior.
- **Take responsibility.** Do not assume that others at EMD Serono already know about something, will take care of it for you or do not think it is important. We rely on each other to implement our policies and procedures and ensure the highest level of ethical behavior.
- **Don't ignore misconduct.** We all need to take the law and company policies seriously. If you think someone may be committing a violation, take steps to address the situation.
- **Stay fast and focused.** Dynamism and innovation are key to our success, but you are never expected to violate a law or this Code, and you should never feel pressured to do so.

BY ALWAYS ACTING WITH INTEGRITY AND DOING WHAT IS RIGHT,  
WE CAN BE PROUD OF OUR COMPANY AND PROUD OF OURSELVES.

**REMEMBER: IT'S UP TO YOU.**

## INFORMATION AND ASSISTANCE

Corporate Communications	781-681-2340
<b>Compliance</b>	
Compliance Helpline	877-846-8839
Compliance Email	compliance.us@emdserono.com
U.S. Chief Compliance Officer	781-681-2490
Compliance Mailing Address	EMD Serono, Inc. Attn: Compliance Department One Technology Place Rockland, MA 02370
Employee Assistance Program	www.wellnessworklife.com
General Counsel/Legal Department	781-681-2391
Government Affairs	202-637-7961
Human Resources	781-681-2262
Health and Safety Office	781-681-2250
Information Security	781-681-2210
Medical Information	888-275-7376
Regulatory Affairs	978-294-1637
<b>Security</b>	
Rockland, MA	781-681-2000
Billerica, MA	978-294-1199
Washington D.C.	202-347-7978
U.S. Drug Safety	800-283-8088

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