

Ferring Pharmaceuticals Inc.

Policy Series 100

Ethical Promotion of Pharmaceutical Products

Ethical promotion of our products is critical to our mission of providing products and information for the benefit of patients. Our promotional efforts are focused on informing healthcare providers about the benefits and proper use of our products, providing scientific and educational information and supporting medical research and education.

Ferring Pharmaceuticals Inc.

Policy Number 101

Sales Representative Record Keeping

Revision No. 2, Effective Date: 04/28/09

Policy:

It is the responsibility of all Ferring sales representatives to completely and accurately record all aspects of their interactions with physicians and other healthcare providers.

Procedures:

Each salesperson must report his/her sales calls through a centralized sales information system, Target SFA. Information required to be entered into the system is stated in the Ferring Expense Guidelines from Sales Operations and Accounting and is built into the software system. Such entries are monitored by the district managers. The failure to enter information per instructions can lead to disciplinary action up to and including termination.

EXAMPLE: As a sales representative, you have just finished your sales call with Dr. Jones and his staff. During this call you gave a presentation and brought in lunch for Dr. Jones and his staff. How do you document the lunch expense for reimbursement?

Incorrect: You fill out an expense report and submit it by e-mail to your manager.

Correct: You enter the expense for meals into the Target SFA system pursuant to the instructions from Ferring Sales Operations and Accounting.

Ferring Pharmaceuticals Inc.

Policy Number 102

Product Marketing and Promotional Materials

Revision No. 2, Effective Date: 04/28/09

Policy:

Ferring will market and promote its products in strict compliance with all laws and regulations pertaining to the promotion of prescription medicines. Only materials which have been approved by the Legal, Medical, Regulatory Promotional Review Committee (“LMR Committee”) will be utilized in the marketing and promotion of our products. Ferring sales representatives are prohibited from making, using or referring to any other materials and from making any verbal statements about the products which are inconsistent with the approved materials and FDA approved labeling.

Procedures:

1. All Ferring sales representatives will be fully trained on product labeling and the proper use of promotional materials.
2. Use of any unapproved materials or references to off label use of our products may be grounds for disciplinary action up to and including termination.
3. Healthcare providers may occasionally ask sales representatives about unapproved uses for our products. Such questions must be referred to a medical sales liaison (MSL) or to Medical Information.

Related Information:

SOP – CS-COMP-005.

EXAMPLE: While discussing a product using company approved promotional materials with a physician, you are asked about results regarding an on-going trial for a new dosage regimen for the drug. You know the data is positive so far. How do you respond?

Incorrect: You tell the physician the data looks positive and the company plans to submit the data to FDA for a new approved dosage regimen.

Correct: You refer the physician to an MSL or Medical Information for a response.

Ferring Pharmaceuticals Inc.

Policy Number 103

Payments to Physicians and Other Healthcare Providers

Revision No. 2, Effective Date: 04/28/09

Policy:

No Ferring employee may provide anything of value to a healthcare provider for the purpose of inducing the provision of services or the sale or prescribing of our products. Under certain circumstances Ferring may pay healthcare providers for services rendered as speakers and consultants. Rules related to the permitted transactions are set forth in this policy manual. All fees paid to physicians as well as the value of any patient benefit items must be accurately recorded. Some states have rules requiring the reporting of all such transactions.

Procedures:

Any violation of this policy may be grounds for disciplinary action up to and including termination.

Related Information

U.S. Addendum to Business Ethics and Conflict of Interest Policy

Policies 104, 105 and 106.

EXAMPLE: You visit a physician in your territory to provide information on the company's product line. This physician uses a competitor's products and wants to continue using them. How do you leave the visit with this physician?

Incorrect: You offer him a new stethoscope in exchange for commitment to prescribe the company's products.

Correct: You thank the physician for his/her time and request a follow-up to further discuss Ferring's products.

Ferring Pharmaceutical Inc.

Policy Number 104

Group Selling Events

Revision No. 2, Effective Date: 04/28/09

Policy:

Convening small gatherings of physicians for the purpose of presenting scientific information about our products has been shown to be an effective educational method. Speakers at such meetings may be paid a reasonable fee, based on fair market value for preparation and presentation of scientific information. All such presentations must be confined to the approved uses of our products. In conjunction with such presentations, attendees may be provided with a meal provided the cost of such meal is modest. The venue for such presentations must be conducive to providing educational information.

Procedures:

1. Speakers must be chosen by Sales, Medical Affairs and Marketing. Speakers must be chosen based on certain criteria which include on the prospective speaker's knowledge of the therapeutic area in the scientific community and knowledge of Ferring's products. Speakers should not be chosen based on prescribing habits and/or any potential to change prescribing habits based on being chosen a speaker.
2. Speakers selected for an event must sign a Speaker Consultant Agreement and complete Ferring's speaker training course prior to speaking at the event.
3. All speaker presentations must be made from a Ferring approved slide deck.
4. Attendees are not to be paid for attending a speaker event, however a meal may be provided during the presentation so long as the meal is modest and costs less than \$175 per physician.

Related Information

Policies 105 and 106 and SOP CS-COMP-007

EXAMPLE: A speaker for the company is making a presentation to other physicians in order to educate the physicians in a therapeutic area as well as Ferring products related to the therapeutic area. The speaker is well-known in the field and has knowledge of the use of the products. Due to his busy schedule, he is not able to attend the speaker training prior to the presentation. What is the proper course of action?

Incorrect: Since the speaker is very familiar with Ferring's product line and well-known in his field in the industry, he should make the presentation.

Correct: The present speaker must be replaced with another qualified speaker who has received speaker training or the program must be cancelled.

Ferring Pharmaceuticals Inc.

Policy Number 105

Speaker Training

Revision No. 2, Effective Date: 04/28/09

Policy:

In order to ensure that speakers at Group Selling Events described in Policy 104 are adequately trained with respect to Ferring's products and the regulations pertaining to proper promotional practices, Ferring will conduct Speaker Training Sessions from time to time. Attendees at such training sessions may be compensated a reasonable amount based upon fair market value for the time spent attending the sessions and any travel, lodging and meal expenses may be paid by Ferring. The total number of speakers trained by and available to the company must be commensurate with the need for speakers for a given product. In no event is a healthcare provider to be recruited to be a speaker based on his volume of prescribing of our products, but rather on the knowledge of our products and credibility of the speaker.

Procedures:

Speakers are selected based on their expertise in the clinical area for discussion by Marketing and Medical Affairs. Such expertise is based on the speaker's credentials and years in practice. Presentations by speakers are reviewed and approved by Ferring's internal LMR Promotional Review Committee. Speakers are trained to speak on Ferring's products in a fair and balanced manner by Medical Affairs.

Related Information:

Policy 104, Policy 106 and SOP CS-COMP-006.

EXAMPLE: Dr. Dan is a regular speaker for the company and he recently attended a speaker training program. He submitted an expense report for \$40,000 for his time away from the office and travel expenses. Should Dr. Dan's expenses be paid?

Incorrect: Yes, since it is reasonable to anticipate loss revenue from his practice and traveling expenses to be \$40,000.

Correct: No, Dr. Dan can be reimbursed for his travel, lodging, meals, and a reasonable amount for his time, based on fair market value to attend the training session.

Ferring Pharmaceuticals Inc.

Policy Number 106

Consultants

Revision No. 2, Effective Date: 04/28/09

Policy:

Ferring may from time to time retain the services of healthcare providers as consultants and speakers. This may include the establishment of an advisory board of several providers who regularly consult with Ferring on scientific and marketing issues. Compensation for those services must be reasonable and may include reimbursement of travel, lodging and meal expenses incurred in providing those services. Ferring must have a *bona fide* need for such services, and consulting or speaking fees may never be used as an inducement to use or prescribe Ferring's products.

Procedures:

1. The need for the consulting services to be rendered by the healthcare provider must be clearly documented. The documentation must include a justification for the number and qualifications of consultants. The person selecting the consultant must have the training and experience necessary to determine whether the healthcare provider has the necessary qualifications. Under no circumstances should sales representatives select consultants, although sales representatives may suggest candidates who they believe have the necessary qualifications.
2. Ferring must enter into a written contract with the consultant which clearly specifies the services to be rendered and the compensation to be paid for the services.
3. Any meeting with consultants must be held in a time and manner consistent with the services to be rendered. Any social events connected with the meeting must be modest in scope and clearly subordinate to the consulting services to be rendered.
4. The information, recommendations and advice received from consultant must be accurately recorded, and the actions taken by Ferring in response to such information, recommendations and advice must be documented.

Related Information:

Policies 103,104,105 and SOP COM-001.01.

EXAMPLE: As a sales representative, you recommend that Ferring enter into a consulting arrangement with a physician who is a high-prescriber to discuss what selling techniques were most effective. Is this arrangement acceptable?

Incorrect: Yes, because it is a legitimate business need and the physician has a large knowledge base of the company's products.

Correct: No, one physician is not a sufficient number to receive meaningful information. The consultant should not be selected based on volume of prescribing. Sales representatives may recommend consultants needed for the business, but not enter into consulting arrangements.

Ferring Pharmaceuticals Inc.

Policy Number 107

Gifts to Healthcare Providers

Revision No. 2, Effective Date: 04/28/09

Policy:

Sales representatives may offer healthcare providers items that are primarily for the education of the healthcare provider or so long as the item doesn't have a value outside of his/her professional responsibility and costs \$100.00 or less. Such items include medical text books, anatomical models and patient self assessment and tracking tools. Practice-related items of minimum value such as pens, note pads, mugs and similar reminder items should not be distributed.

Procedures:

1. Items may be offered to providers only on an occasional basis (roughly once a year).
2. Each item given to a provider must be accurately recorded and reported as required under state law.
3. Ferring's Compliance Officer will regularly update the list of states where it is unlawful to provide anything of value to a healthcare provider. The **Business Unit Heads** are responsible for disseminating that information to sales representatives.

Related Information:

Policy 103.

EXAMPLE: You would like to give a textbook on Reproductive Medicine to one of your providers as a gift. Is this a proper gift?

Incorrect: No.

Correct: Yes, as long as the textbook has been approved for distribution by the Legal, Medical and Regulatory Promotional Review Committee and is less than \$100.

Ferring Pharmaceuticals Inc.

Policy Number 108

Samples

Revision No. 2, Effective Date: 04/28/09

Policy:

The distribution of samples of prescription drugs is strictly regulated by the Prescription Drug Marketing Act (PDMA) and regulations which, among other things, prohibit the sale of samples. Violations of the PDMA can result in civil and criminal penalties for any the company and any employee who commits the violation. No Ferring employee shall sell drug samples. Distribution samples by Ferring employees must be in strict compliance with this policy.

Procedures:

For some products, we use an outside vendor to ship samples. The procedure for this method is:

1. The Sales Representative obtains the prescriber's signature on a sample request form.
2. The signed form is sent to the Associate Manager of Sales Operations for physician identification verification. Upon verification, the sample request is forwarded to a fulfillment house for processing.
3. Samples are sent to the physician from the fulfillment house with a receipt form for signature.
4. The signed receipt form is sent to the Associate Manager of Sales Operation for reconciliation.
5. If the signed receipt form is not received within 60 days of receipt of samples, a letter will be sent to the physician requesting acknowledgement of the samples. If the signed receipt form is not received within 90 days of receipt of samples, the sales representative may not present any further sample request forms to physicians until reconciliation.

For some products, samples are delivered directly by Ferring sales representatives. The procedure for those samples is:

1. Ferring will ship samples to the Ferring sales representative.
2. Ferring sales representatives will be able to sample prescribers based on eligibility within the Target SFA system.

3. If the prescriber is eligible to receive samples, the prescriber will be required to sign the PDA as proof of receipt of those samples. If the PDA is not functional, a paper form will be used and accounted for accordingly.
4. The Ferring sales representative will conduct a monthly audit to verify that the number of samples in its possession of its representatives is consistent with the shipments, requests and receipts.
5. The Ferring sales representative will immediately report and discrepancies to Sales Operations.

EXAMPLE: You are on a sales call and a potential prescriber would like some samples to try with his patient base. You know another physician down the hall has some samples, should you request some samples and take it to the potential prescriber?

Incorrect: Yes, the physician had more than he needed and the potential prescriber seems very interested in the product.

Correct: No, under no circumstances does a sales representative distribute samples from one physician to another. Provide the potential prescriber with a sample request form.

Ferring Pharmaceuticals Inc.

Policy Number 109

Pricing, Discounts and Rebates

Revision No. 2, Effective Date: 04/28/09

Policy:

Ferring Pharmaceuticals shall establish the prices for its products independently, based on the value of the products and market considerations. Ferring may offer discounts or rebates on those prices based on quantities purchased or other considerations. With respect to sales to healthcare providers (as opposed to drug wholesalers and retail pharmacies) existence of the discount or rebate must be clearly stated on the invoice along with a statement that the purchaser has an obligation to report the discount or rebate with respect to any claims for remuneration made to Medicare or a State Medicaid program. Under no circumstances will the company provide any discounts, rebates, free goods, services or other incentives which do not comply with the notice requirements of this policy.

Procedures:

All prices, pricing plans, discounts, rebates or other incentive plans must be clearly stated in Marketing Plans which are approved by Senior Staff. Any deviation must be reviewed by the Pricing Committee prior to execution. The Pricing Committee shall consist of representatives from relevant disciplines which include Sales, Marketing and Legal..

EXAMPLE: A large healthcare group has agreed to make the company's drug the preferred drug and to buy large yearly quantities. In exchange for this commitment, the company is giving a 10% discount on price related to the volume and a large computer system to assist with claim management. Is this arrangement something the company would endorse?

Incorrect: Yes, it is fine to provide such discount and services for large volume customers.

Correct: No, the computer system is a service which can be evidence of the unlawful inducement to purchase a product which triggers the anti-kickback statutes and the False Claims Act.

Ferring Pharmaceuticals Inc.

Policy Number 110

Educational Grants

Revision No. 2, Effective Date: 04/28/09

Policy:

Ferring makes funding available to support various educational programs that contribute to the improvement of patient care. These medical educational grants may include financial support for Continuing Medical Education (CME) or other third-party educational conferences or professional meetings, and patient or community education. These programs must be sponsored by an appropriate organization, and all funding must be given to the sponsor of the event and not to any individual practitioner, participant or attendee.

Medical educational grants may only be made to an organization, such as a hospital, medical professional society, conference sponsor or CME organization for the purpose of fostering increased understanding of scientific, clinical or healthcare issues that contribute to the improvement of patient care. Medical Educational grants may not be provided to individual practitioner, participant, attendee or group practice.

The use of funds provided by medical educational grants is limited to legitimate expenses related to the education or training of healthcare professionals or patients in connection with the improvement of patient care. These can include (i) general expenses of the conference (e.g. costs of travel, lodging and meals of the faculty) (ii) sponsorship of meals or receptions and/or (iii) financial assistance for medical students, residents, fellows or other healthcare professionals in training (selected by the sponsor of the conference or academic/training institution) to attend major educational conferences. Ferring shall have no control or influence over the selection of the content, faculty, location, audience or agenda for the conference.

Procedure:

Medical educational grant requests shall be submitted directly to Medical Affairs for review by the Grant Review Committee. Medical Affairs is the only department that may engage in discussion with requestors concerning grants. Therefore, requests received by any other department outside Medical Affairs should be redirected to the Medical Affairs Department. Sales and Marketing should neither solicit nor discuss educational grants with providers. If Sales or Marketing is approached by a provider regarding a grant, they should refer the provider to Medical Affairs.

Medical Educational Grant funding shall be considered for all submissions that demonstrate the ability to meet unmet educational needs of the target audience and encourage improvement of

patient outcomes while furthering an educational goal, promoting excellence in patient care, providing effective learning, containing efficient meeting format, and educating the broadest healthcare professional and/or patient. Medical Educational Grants will be awarded in accordance with the FDA's *Guidance on Industry-Supported Scientific and Educational Activities*, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, *PhRMA Code on Interactions with Healthcare Professionals*, *ACCME Standards for Commercial Support of Continuing Education*, and all other applicable legal standards related to ethical corporate conduct.

All documentation related to the Grant Review Committee approval process shall be retained by Medical Affairs. All expenditures for approved grants are provided to the appropriate individual within Ferring for payment and state tracking purposes.

EXAMPLE: Ferring Medical Affairs has received a request for a grant from an accredited CME provider to support an educational conference. The provider requested funding to be used for faculty honoraria and travel expenses, however asked that Ferring choose the location and physician speakers for the event. They also asked that payment be provided directly to the individual physicians who will be presenting the material at the conference. May the Grant Review Committee approve this request for support by providing a medical educational grant?

Correct: NO. Medical Educational Grants will be awarded in accordance with the *FDA's Guidance on Industry-Supported Scientific and Educational Activities*, *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, *PhRMA Code on Interactions with Healthcare Professionals*, *ACCME Standards for Commercial Support of Continuing Education*, and all other applicable legal standards related to ethical corporate conduct. Therefore, the request for a list of suggested locations and faculty makes this request ineligible for a medical educational grant due to compliance reasons. Ferring shall have no control or influence over the selection of the content, faculty, location, audience or agenda for the conference. Additionally, even though the use of funds was limited to legitimate expenses related to education, funding must be given to the sponsor of the event and not to any individual practitioner, participant or attendee. Medical educational grants may only be made to an organization, such as a hospital, medical professional society, conference sponsor or continuing medical education organization for the purpose of fostering increased understanding of scientific, clinical or healthcare issues that contribute to the improvement of patient care.

Ferring Pharmaceuticals Inc.

Policy Number 111

Physician-Assisted Training Programs

Revision No. 2, Effective Date: 04/28/09

Policy:

Physician-Assisted Training Programs can be an effective tool for training sales representatives. A Physician-Assisted Training Program is usually one-half to a full day spent with a physician observing his/her interactions with patients such as examinations, consultations and treatments. By observing these interactions, the sales representative can learn the needs of patients and the needs of physicians treating them.

Observations of physician-patient interactions necessarily involves the disclosure to the sales representative of the patient's medical information. The consent of the patient to the presence of the sale representative must be obtained prior to any observations. It is the obligation of the sales representative to maintain the confidentiality of any patient information and not to disclose it anyone including Ferring.

Procedures:

1. The sales representative may select a physician to be a Trainer. The Trainer should be chosen based on the following criteria.
 - The Trainer should specialize in or devote a significant part of his/her practice to treatment of diseases for which our products are approved for use.
 - The Trainer should be recognized as a leader in the field within his/her community.
 - The Trainer should have previous experience in providing education to pharmaceutical sales representatives, and be knowledgeable about the issues of patient privacy associated with this type of training.
2. The Trainer and the sales representative should complete the authorization forms available from the District Manager. These forms are to be approved by the District Manager and forwarded to the Vice President of Sales for his/her business unit or designee for approval and forwarded to his/her manager (e.g. Regional Director, Director of Sales etc.).

3. If the Training is approved, an engagement letter will be sent to the Trainer which shall specify the terms of the agreement and the amount of compensation. Terms of the agreement will include:
 - The Trainer will agree to inform each patient that the sales representative is an employee of Ferring Pharmaceuticals who is present to learn more about the physician-patient relationship, diseases and the effects of diseases on the lives of patients.
 - The Trainer will agree to obtain each patient's consent that the sales representative may be present during the examination, treatment or consultation and that the sales representative may be informed of medical information concerning the patient.

4. It is of the utmost importance that a patient's privacy be respected at all times. A variety of state and federal laws are in place to protect that privacy, most notably the Health Insurance Portability and Accountability Act. Although these laws generally apply to providers and not to the Company, it is our intent to comply with the spirit of these laws. Therefore the sales representative must not:
 - Be present at any examination, treatment or consultation unless the physician has obtained the patient's consent to the presence of the sales representative.
 - Make any notes, reports or other written documents concerning what is seen or heard, or obtain any copies of any medical records from the physician.
 - Discuss with anyone the information received during the Training Program in any way that would allow another person to learn medical information about a specific person.

Related Information:

SOP COMP-003.01