

## **NextWave Pharmaceuticals Code of Commercial Conduct**

The commercial code of conduct applies to all NextWave employees interacting with healthcare professionals or organizations. The code also applies to others who are involved in the healthcare delivery process but do not have direct responsibility for prescribing (nurses, etc.). This policy does not cover responsibilities associated with sampling, these covered as a part of the NextWave Pharmaceuticals PDMA compliance training.

Any violations of the Commercial Code are subject to disciplinary action up to and including termination. NextWave Managers are not empowered to waive or modify this policy.

### **Promotional Activities**

Promotional messages are always within label, fact based and fair balanced. While a drug may be prescribed off label, the law prevents us from promoting a drug for an off label use.

Promotional discussions and materials must:

- Be consistent with approved product labeling
- Include fair balance of both benefits and risks
- Never extend claims
- Never seek to minimize safety risks
- Be supported by scientific and clinical data
- Be approved for use in the promotion
- Never discuss a new product or indication without express direction from the Home Office
- Never discuss comparative claims without approval of Home Office

Promotional materials must be approved by the Home Office prior to use in the field. These materials include detail aids, reprints, reminder items, and all other promotional items. Materials created by field representatives without prior approval are prohibited. This includes memos to physicians that mention products or creating any type of detail aid. Only those materials approved by the Home Office may be used for detailing.

### **Off-Label Discussions**

Employees may not discuss off-label uses of approved products. Further, employees may not seek to solicit questions physicians about off-label uses of promoted products. In a situation where a physician initiates a discussion about an off-label use, NextWave representatives are required to indicate that the product is not approved for that indication and refer the physician to NextWave Medical affairs.

### **Business Practices**

The federal Anti-Kickback law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal healthcare program business, including Medicare and Medicaid, can be held accountable for a felony. Therefore, it is illegal for NextWave to provide kickbacks or bribes to any healthcare professional or to another person in any business relationship. A kickback is providing anything of value in order to improperly influence physician prescribing habits. A bribe is a conditional exchange of something of value in order to obtain prescriptions etc. Kickbacks and Bribes are prohibited under US law and against NextWave policy.

### **Accessing Healthcare Professionals**

NextWave Pharmaceuticals has adopted the PhRMA Code on interactions with healthcare Professionals. Adherence to the PhRMA code is mandatory. A list of situational questions and answers are also included.

PhRMA Code on Interactions with Healthcare Professionals

#### **Preamble**

The Pharmaceutical Research and Manufacturers of America (PhRMA) represents research-based pharmaceutical and biotechnology companies. Our members develop and market new medicines to enable patients to live longer and healthier lives.

Ethical relationships with healthcare professionals are critical to our mission of helping patients by developing and marketing new medicines. An important part of achieving this mission is ensuring that healthcare professionals have the latest, most accurate information available regarding prescription medicines, which play an ever-increasing role in patient healthcare. This document focuses on our interactions with healthcare professionals that relate to the marketing of our products.

Effective marketing of medicines ensures that patients have access to the products they need and that the products are used correctly for maximum patient benefit. Our relationships with healthcare professionals are critical to achieving these goals because they enable us to –

- inform healthcare professionals about the benefits and risks of our products,
- provide scientific and educational information,
- support medical research and education, and
- obtain feedback and advice about our products through consultation with medical experts.

In interacting with the medical community, we are committed to following the highest ethical standards as well as all legal requirements. We are also concerned that our interactions with healthcare professionals not be perceived as inappropriate by patients or the public at large. This Code is to reinforce our intention that our interactions with healthcare professionals are to benefit patients and to enhance the practice of medicine. The Code is based on the principle that a healthcare professional's care of patients should be based, and should be perceived as being based, solely on each patient's medical needs and the healthcare professional's medical knowledge and experience.

Therefore, PhRMA adopts, effective July 1, 2002, the following voluntary Code on relationships with healthcare professionals. This Code addresses interactions with respect to marketed products and related pre-launch activities. It does not address relationships with clinical investigators relating to pre-approval studies.

#### PhRMA Code on Interactions with Healthcare Professionals

##### 1. BASIS OF INTERACTIONS

Our relationships with healthcare professionals are intended to benefit patients and to enhance the practice of medicine. Interactions should be focused on informing healthcare professionals about products, providing scientific and educational information, and supporting medical research and education.

##### 2. INFORMATIONAL PRESENTATIONS BY OR ON BEHALF OF A PHARMACEUTICAL COMPANY

Informational presentations and discussions by industry representatives and others speaking on behalf of a company provide valuable scientific and educational benefits. In connection with such presentations or discussions, occasional meals (but no entertainment/recreational events) may be offered so long as they: (a) are modest as judged by local standards; and (b) occur in a venue and manner conducive to informational communication and provide scientific or educational value. Inclusion of a healthcare professional's spouse or other guests is not appropriate. Offering "take-out" meals or meals to be eaten without a company representative being present (such as "dine & dash" programs) is not appropriate.

##### 3. THIRD-PARTY EDUCATIONAL OR PROFESSIONAL MEETINGS

a. Continuing medical education (CME) or other third-party scientific and educational conferences or professional meetings can contribute to the improvement of patient care and therefore, financial support from companies is permissible. Since the giving of any subsidy directly to a healthcare professional by a company may be viewed as an inappropriate cash gift, any financial support should be given to the conference's sponsor which, in turn, can use the money to reduce the overall conference registration fee for all attendees. In

addition, when companies underwrite medical conferences or meetings other than their own, responsibility for and control over the selection of content, faculty, educational methods, materials, and venue belongs to the organizers of the conferences or meetings in accordance with their guidelines.

b. Financial support should not be offered for the costs of travel, lodging, or other personal expenses of non-faculty healthcare professionals attending CME or other third-party scientific or educational conferences or professional meetings, either directly to the individuals attending the conference or indirectly to the conference's sponsor (except as set out in section 6 below). Similarly, funding should not be offered to compensate for the time spent by healthcare professionals attending the conference or meeting.

c. Financial support for meals or receptions may be provided to the CME sponsors who in turn can provide meals or receptions for all attendees. A company also may provide meals or receptions directly at such events if it complies with the sponsoring organization's guidelines. In either of the above situations, the meals or receptions should be modest and be conducive to discussion among faculty and attendees, and the amount of time at the meals or receptions should be clearly subordinate to the amount of time spent at the educational activities of the meeting.

d. A conference or meeting shall mean any activity, held at an appropriate location, where (a) the gathering is primarily dedicated, in both time and effort, to promoting objective scientific and educational activities and discourse (one or more educational presentations(s) should be the highlight of the gathering), and (b) the main incentive for bringing attendees together is to further their knowledge on the topic(s) being presented.

#### 4. CONSULTANTS

a. It is appropriate for consultants who provide services to be offered reasonable compensation for those services and to be offered reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services. Compensation and reimbursement that would be inappropriate in other contexts can be acceptable for bona fide consultants in connection with their consulting arrangements. Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time or their travel, lodging, and other out-of-pocket expenses. The following factors support the existence of a bona fide consulting arrangement (not all factors may be relevant to any particular arrangement):

- a written contract specifies the nature of the services to be provided and the basis for payment of those services;
- a legitimate need for the services has been clearly identified in advance of requesting the services and entering into arrangements with the prospective consultants;
- the criteria for selecting consultants are directly related to the identified purpose and the persons responsible for selecting the consultants have the expertise necessary to evaluate whether the particular healthcare professionals meet those criteria;
- the number of healthcare professionals retained is not greater than the number reasonably necessary to achieve the identified purpose;
- the retaining company maintains records concerning and makes appropriate use of the services provided by consultants;
- the venue and circumstances of any meeting with consultants are conducive to the consulting services and activities related to the services are the primary focus of the meeting, and any social or entertainment events are clearly subordinate in terms of time and emphasis.

b. It is not appropriate to pay honoraria or travel or lodging expenses to non-

faculty and non-consultant attendees at company-sponsored meetings including attendees who participate in interactive sessions.

#### 5. SPEAKER TRAINING MEETINGS

It is appropriate for healthcare professionals who participate in programs intended to recruit and train speakers for company sponsored speaker bureaus to be offered reasonable compensation for their time, considering the value of the type of services provided, and to be offered reimbursement for reasonable travel, lodging, and meal expenses, when (1) the participants receive extensive training on the company's drug products and on compliance with FDA regulatory requirements for communications about such products, (2) this training will result in the participants providing a valuable service to the company, and (3) the participants meet the criteria for consultants (as discussed in part 4.a. above).

#### 6. SCHOLARSHIPS AND EDUCATIONAL FUNDS

Financial assistance for scholarships or other educational funds to permit medical students, residents, fellows, and other healthcare professionals in training to attend carefully selected educational conferences may be offered so long as the selection of individuals who will receive the funds is made by the academic or training institution. "Carefully selected educational conferences" are generally defined as the major educational, scientific, or policy-making meetings of national, regional, or specialty medical associations.

#### 7. EDUCATIONAL AND PRACTICE-RELATED ITEMS

a. Items primarily for the benefit of patients may be offered to healthcare professionals if they are not of substantial value (\$100 or less). For example, an anatomical model for use in an examination room primarily involves a patient benefit, whereas a VCR or CD player does not. Items should not be offered on more than an occasional basis, even if each individual item is appropriate. Providing product samples for patient use in accordance with the Prescription Drug Marketing Act is acceptable.

b. Items of minimal value may be offered if they are primarily associated with a healthcare professional's practice (such as pens, notepads, and similar "reminder" items with company or product logos).

c. Items intended for the personal benefit of healthcare professionals (such as floral arrangements, artwork, music CDs or tickets to a sporting event) should not be offered.

d. Payments in cash or cash equivalents (such as gift certificates) should not be offered to healthcare professionals either directly or indirectly, except as compensation for bona fide services (as described in parts 4 and 5). Cash or equivalent payments of any kind create a potential appearance of impropriety or conflict of interest.

#### 8. INDEPENDENCE OF DECISION MAKING

No grants, scholarships, subsidies, support, consulting contracts, or educational or practice related items should be provided or offered to a healthcare professional in exchange for prescribing products or for a commitment to continue prescribing products. Nothing should be offered or provided in a manner or on conditions that would interfere with the independence of a healthcare professional's prescribing practices.

#### 9. ADHERENCE TO CODE

Each member company is strongly encouraged to adopt procedures to assure adherence to this Code.

Frequently Asked Questions

a. Question

Under the Code, may items such as stethoscopes be offered to healthcare professionals?

Answer

Yes, because these items primarily benefit patients, so long as the items are not of substantial value and are only occasionally offered to the healthcare professional. Items that are of more than minimal value and do not primarily benefit patients are also not permitted even if they bear a company or product name.

b. Question

Under the Code, may golf balls and sports bags be provided if they bear a company or product name?

Answer

No. Golf balls and sports bags, even if of minimal value, do not primarily entail a benefit to patients and are not primarily associated with the healthcare professional's practice, even if they bear the name of a company or product.

c. Question

Under the Code, may healthcare professionals be provided with gasoline for their cars if they are provided with product information at the same time?

Answer

No. Items intended for the personal benefit of a healthcare professional should not be offered.

d. Question

The Code says that informational presentations and discussions may be accompanied by occasional, modest meals. What types of presentations and meals would this include?

Answer

An informational presentation or discussion may be accompanied by a modest meal provided that the venue and manner of presentation/discussion is conducive to a scientific or educational interchange. For example, if a medical or scientific expert (who is a consultant to or employee of the company) is providing information about recently obtained study data to an audience of healthcare professionals, this could be done over lunch or dinner at a quiet restaurant providing the meal was of modest value as judged by local standards.

Following the same logic, if a sales representative is providing substantial scientific or educational information regarding a company's products to one or a few healthcare practitioners, this could also be done during a modest meal which could be at or outside of a physician's office.

However, if the nature or location of the meal would not facilitate communication of the information, then a meal would not be appropriate. Further, the use of modest meals on more than an occasional basis would not be appropriate.

e. Question

A representative of Company X provides pizza for the staff of a medical office. Is this consistent with the Code?

Answer

This would be consistent with the Code if the representative will provide an informational presentation to the medical staff in conjunction with the meal of modest value, so long as the location of the presentation is conducive to a scientific or educational communication. Merely dropping off food for the office staff, however, would not be consistent with the Code.

f. Question

A representative of Company X invites physicians to meet to hear a scientific and educational presentation about a new drug at the café at a nearby bookstore. Coffee and cake are provided by the representative and, following the presentation (which is in small groups), each physician is given a gift certificate for books in the amount of \$30. Does this conform to the Code?

Answer

No. While the presentation may present scientific or educational information and the coffee and cake may appropriately be provided, an open-ended gift certificate is a cash equivalent. A medical textbook, a book on patient care, or a gift certificate redeemable solely for a medical textbook or book on patient care could be provided if it is not of substantial value.

g. Question

Company C invites 30 physicians to a corporate suite at a professional baseball game for a 45-minute scientific and educational presentation followed by a buffet and the three-hour game. Does this conform to the Code?

Answer

No. A modest buffet meal accompanying a scientific or educational would be acceptable. However, the provision of entertainment and/or recreational activities, including entertainment at sporting events in connection with an educational or scientific presentation or discussion, is inconsistent with the Code.

h. Question

Under what circumstances would the Code permit a company to provide entertainment or recreational activities directly to healthcare practitioners?

Answer

Companies may provide modest entertainment or recreational activities to healthcare practitioners in a context where those practitioners are providing a legitimate service to the companies, such as when they act as bona fide consultants on an advisory board or are trained at a speaker-training meeting.

Companies should generally not provide entertainment or recreational activities to healthcare practitioners. Thus, companies should not invite healthcare professionals to sporting events, concerts, or shows, or provide them with recreational activities such as hunting, fishing, boating, ski trips, or golf outings, even if those entertainment events or recreational activities are used to facilitate informational interchanges between the company representative and the healthcare professional. Similarly, it would be inappropriate to provide these types of entertainment and recreational events in conjunction with promotional scientific presentations by medical experts.

i. Question

Company A retains a small group of 15 nationally known physicians regarding a therapeutic area relevant to company A's products to advise on general medical and business issues and provide guidance on product development and research programs for those products. These physicians are paid significant fees, but those fees are typical of the fees paid to thought leaders in this therapeutic area. They normally meet once or twice a year at resort locations to discuss the latest product data, research programs and Company plans for the product(s). Does this comply with the Code? If it does, is it appropriate to pay for the spouse of the healthcare professional to attend, as well?

Answer

This arrangement appears to comply with the Code. The number of advisors seems reasonably small. The advisors seem to have been selected based on their expertise in the areas where advice is needed. While the consultants are paid significant fees, these appear to be reasonable under the circumstances. Finally, while holding consultant meetings at resort locations is not prohibited, the facilities chosen should be conducive to the services provided as well as reasonable and appropriate to the conduct of the

meeting.

It would not be appropriate to pay for the cost of the spouse of the advisor. If the spouse attends, it should be at the cost of the advisor.

j. Question

Company A invites 300 physicians/consultants to a two-day and one-night speaker-training program at a regional golf resort. All attendees are compensated for their participation and their expenses are reimbursed. Prospective speakers are selected based on recommendations of the Company's district managers and an assessment of their qualifications by the Company's medical or scientific personnel. Each of the attendees is required to sign an agreement in advance covering the services they will provide. They are educated by a faculty on the full range of data surrounding the disease state and the Company's drug product, on presentation skills, and on FDA regulatory requirements. The Company plans to use at least 280 participants as speakers over the coming year, and it needs to train 300 speakers in order to ensure that 280 will actually be available when needed. Training sessions take both days, and the Company provides for a few hours of golf and meals. Does this program conform to the Code? If so, is it appropriate to pay for a spouse of the healthcare professional, as well?

Answer

This arrangement appears to comply with the Code. Speaker training is an essential activity because FDA holds companies accountable for the presentations of their speakers. In this case, the participants undergo extensive training that will result in a valuable service being provided to the company, and the arrangement meets reasonable indicia of a bona fide consulting relationship. While resort locations are not prohibited, the Company may want to consider whether it would be more appropriate to hold the training session at a non-resort location. In this case, the number of speakers being trained is important; if significantly more participants were trained than were to be used as speakers, this arrangement would not comply with the Code.

The amount of time spent training speakers should be reasonable in relation to the material that has to be covered. The compensation offered to prospective speakers, including the value of any entertainment, should be evaluated to assure that it is reasonable compensation for that time.

It would not be appropriate to pay for the cost of the spouse of the healthcare professional. If the spouse attends, it should be at the cost of the healthcare professional.

k. Question

A sales representative invites a physician out for a round of golf and lunch following the golf. The physician is very busy and is difficult to see in her office. The cost of the golf and the lunch combined are \$65. Does this comply with the code?

Answer

No. It is inconsistent with the Code to provide entertainment or recreational activities such as golf.

### **Expense Guidelines/Maximum Allowable Annual Amounts**

NextWave employees must record all healthcare practitioner meals, snacks and gifts in the Target Mobile System, and all expenses must be assigned to specific physician(s). The following guidelines must be adhered to;

- Meals held out of a physician's office must be occasional, reasonable by local standards, and no more than \$100 per person.
- In-office Meals – Should be occasional, and should not exceed \$20 per individual attending
- Snacks – Should be occasional and not exceed \$15 per person
- Gifts – Employees may provide medically related gifts to physicians. Examples include textbooks, medical supplies, and require Area manager approval. Cash or cash equivalents (gift certificates) are prohibited. Gifts can only be offered on an occasional basis and no more than two times per year per physician. The value of a gift may not exceed \$100.

#### Annual Aggregate Limit

NextWave has set an annual aggregate limit of \$2500 for out of office meals and gifts. In-office meals, snacks and nominal promotional items are not included in the \$1000 annual aggregate limit.

The state of Minnesota has established an annual limit of \$50 per physician and therefore NexWave employees are limited to a \$50 annual aggregate limit in Minnesota. Further, as required by applicable state law, NextWave shall disclose gifts to healthcare professionals within the state.

#### **Training/Auditing/Reporting**

Each NextWave employee shall be trained regarding complying with this Code of Commercial Conduct within 1 month of the Code's adoption. The employees who will be trained include all NextWave sales and marketing staff and any other employees subject to the Code of Commercial Conduct.

NextWave shall also adhere to its policies and procedures when investigating potential instances of non-compliance. NextWave shall also adopt and distribute to employees a method by which employees can report non-compliance. In addition, NextWave shall report instances of noncompliance to law enforcement authorities in appropriate circumstances.

NextWave will conduct annual audits to monitor compliance with this Code. As required by applicable state law, NextWave shall submit to the state authority a certification that it has conducted the required annual audit and is in compliance with its code of conduct (if applicable).