



## **Compliance Manual for For Europe, Middle East, Africa ("EMEA") Operations**

In consideration of the fact that the policies and procedures contained in this compliance manual may change from time to time, the official copy of this compliance manual is located on the Compliance Department pages at the following links:

<http://mposite/index.cfm/departments/compliance/documents/>

<https://www.jointacademymicroport.com/>

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Although updates to this compliance manual may be directly communicated to you, it is imperative that your behaviour and actions are consistent with the policies and procedures set forth in the official copy of this compliance manual.

**Effective: July 1, 2018**

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## 1. SCOPE AND PURPOSE

All Europe, Middle East and Africa (“EMEA”) MicroPort Orthopedics Inc. (“MPO”) Representatives are expected to be familiar with and perform their operations and business functions in accordance with the MPO Code of Business Conduct (the “Code”) guidelines available at <http://mposite/index.cfm/departments/compliance/documents/>.

Company Representatives, as defined in the Code, include the following: employees (both full-time, part-time and temporary), executive officers, members of the Board of Directors, independent contractors, consultants, sales agents, distributors, distributor employees, sub-distributors and all others performing requested and specific services on behalf of MicroPort Orthopedics Inc. (“MPO” or “Company”).

Health Care Professionals (“HCPs”) are individuals and entities that are (1) involved in providing health care services and/or items to patients and (2) in a position to purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe MPO’s products in the EMEA region. The phrase Health Care Professional is to be interpreted broadly and includes both persons providing services (such as physicians, doctors of podiatric medicine (DPMs), physician assistants, nurses, operating room staff or consultants) and persons who do not provide services directly (such as administrative hospital or office staff), but who may be involved in the decision to purchase, lease, or recommend MPO products.

All Company Representatives who interact with HCPs or with any government officials (as defined in Section 8) are expected to comply fully with all relevant international, national or local country anti-corruption laws, regulations, and professional codes of conduct requirements as well as with this MPO Compliance Manual, and all Company policies and procedures applicable to EMEA Operations.

Because the healthcare industry is so highly regulated, MPO believes it is important and necessary to provide our employees and representatives with more detailed guidance than is provided in the Code on how to interact with our customers, vendors, and government agencies in a manner that is compliant with applicable law. This Compliance Manual governs many aspects of MPO’s relations with customers, including customer education and training; sponsoring customers’ attendance at professional conferences and Continuing Medical Education (“CME”) programs; contracting for site visits; grants to doctors and hospitals; services agreements; speaking sponsorships; entertainment; and gifts and charitable contributions. In order to understand how the Compliance Manual applies to certain common interactions with customers, we have also developed a set of “Frequently Asked Questions,” which are available on the company intranet site, <http://mposite/index.cfm/departments/compliance/documents/>.

Our relations with our customers are legally governed by, and the guidance addressed in our Compliance Manual principally emanates from, international, national or local country anti-corruption laws, regulations, and professional codes of conduct of the country where our customers are licensed to practice (e.g. the MedTech Europe Code of Ethical Business Practice).

International, national, and local anti-corruption laws establish severe civil and criminal penalties for anyone who knowingly and wilfully offers or pays (or solicits or receives) any “remuneration” in cash or in kind, directly or indirectly, to induce someone (e.g., a physician, government official, or a hospital) to purchase, lease, order, arrange for or recommend purchasing, leasing, or ordering any item for which payment may be made. A violation may be found even if only one purpose of the “remuneration” is to induce the purchase of products; it does not matter if there are other legitimate purposes for the payment. In addition, there does not have to be an agreement to purchase in exchange for the remuneration.

This Compliance Manual applies to interactions with HCPs to the extent that they provide services or medical technologies anywhere in the world MPO conducts business. This would include interactions with HCPs who work in the EMEA region, even if the interaction occurs outside the region (such as at a conference or other event in North America, Latin America, Asia, or Australia). Compliance with regional and national industry codes, laws, and regulations must take precedent if the standards are more restrictive than the standards presented in this manual.

In countries where transparency laws (e.g. France) or local code requirements exist, all value exchanges between MPO and HCPs need to be captured appropriately by MPO employees and third parties conducting business on the MPO's behalf, and should be properly disclosed in accordance with applicable regional and local laws and industry code requirements. Of course, additional foreign legal and ethical considerations may pertain to interactions with HCPs located both inside and outside the EMEA region. If you have questions relating to your interaction with international HCPs, please contact the Compliance Department. Furthermore, to the extent you are interacting with foreign HCPs in the EMEA region (especially HCPs from the United States) regarding promotional services, please consult the Compliance Department in the United States, such as the Deputy Compliance Officer, one of their direct reports, or refer to the "Ask Us" hotline for more guidance +1.866.830.0890 or email at [askus@ortho.microport.com](mailto:askus@ortho.microport.com).

## 2. REVIEW AND DISTRIBUTION OF COMPLIANCE TEXT MATERIALS

MPO is committed to appropriate and timely communications to all employees regarding significant changes in the Compliance Manual and the MPO Code of Business Conduct (the “Code”) materials.

MPO will annually or more often if necessary, review the Code, Compliance Manual, and the compliance training texts to determine if revisions are appropriate. Any necessary revisions will be published based on this review.

Note: The official copy of this Compliance Manual, which will be updated regularly, is available on the Compliance Intranet site at:

- Intranet - <http://mposite/index.cfm/departments/compliance/documents/>
- Joint Academy MicroPort - <https://www.jointacademymicroport.com/>

Code revisions are distributed to all employees within 30 days of finalizing such changes. Company Representatives must certify that they have received, read, understood, and will abide by the revised Code within 30 days after distribution of revisions.

The relevant portions of any revised sections in this Compliance Manual will be distributed to all employees whose job functions are related to the revised sections within 30 days of the effective date of the revision.

EMEA Compliance related materials are available in the following languages: English, French, Spanish, Italian, German, and Russian. If you need translation assistance related to MPO’s Compliance documents, please contact the Compliance Department.

The compliance training programs are updated as necessary and/or as a result of the text reviews.

### 3. COMPLIANCE TRAINING

Within 60 days of being hired or entering into a contract, the Company Representative must complete all compliance new hire training. This could be live training or web-based training depending on job title and level.

Company Representatives must receive compliance training each year that covers:

- the MPO Compliance Program; updates or changes that impact EMEA Operations;
- changes in law or new requirements that impact EMEA Operations;
- any new regulations and reporting requirements related to disclosure of payments and transparency with HCPs;
- proper methods of marketing and selling products that are reimbursed by government programs;
- the employee's personal obligation to ensure that government-reimbursed products are marketed and sold in accordance with all applicable requirements of the government programs; and
- the legal rules and sanctions for violations that relate to government programs.

In addition, all MPO Company Representatives will receive a copy (written or electronic) of the MPO Code of Business Conduct within 30 days of joining MPO. Every two years, MPO Company Representatives are required to retake the new MPO Business Code of Conduct course and provide a certification that he/she has received, read and understood the Code.

#### **Certification**

All Company Representatives will be required to complete a certification, which may be in electronic form, confirming that they have completed the applicable training.

If a new Company Representative does not complete the new hire training courses within 60 days of hire, the Company Representative may be subject to disciplinary sanctions, up to and including termination of employment or termination of agreement.

**The determination of what constitutes appropriate disciplinary action is subject to applicable regional and local laws, the terms set forth in a distributor agreement, labor laws, labor agreements, regulations, professional requirements and industry standards.**

#### 4. THE “TELL US” CONFIDENTIAL DISCLOSURE PROGRAM

Company Representatives may disclose to the MPO Chief Compliance Officer, confidentially and without retaliation, any identified issues, questions, or suspected violations of the laws and company policies, practices, or procedures. If you learn of, or suspect, a violation of the MPO Code of Business Conduct, related policies or procedures, or applicable laws and regulations in connection with the conduct of the Company's business, you have a mandatory duty to report the matter to the Chief Compliance Officer. You have the duty to report even if you believe a report has already been made or will be made by another person.

All persons have the option to directly contact the Chief Compliance Officer or a member of the Corporate Compliance Department.

##### **Mechanism**

MPO has established an ethics reporting system for anyone to make reports of violations or suspected violations anonymously via the Ethics Hotline, 24 hours a day, seven days a week, as follows:

- <https://secure.ethicspoint.com/domain/media/en/gui/39041/index.html>
- Via email at [ethics@ortho.microport.com](mailto:ethics@ortho.microport.com)

**Certain jurisdictions limit the availability of anonymous reporting, due to privacy standards and/or local labor laws. If you reside in such a jurisdiction, you will be informed of those limitations at the time of reporting.**

If you are found to have participated in a violation, directly or indirectly, the fact that you reported such violation, together with the degree of cooperation displayed by you and whether the violation was intentional or unintentional, will be given appropriate consideration by the Company in its investigation and resulting disciplinary action.

The Company prefers that you identify yourself when reporting violations in order to permit the Company to contact you in the event further information is needed to properly conduct a thorough investigation. Your identity will be maintained in the strictest of confidence to the extent practicable under the circumstances and consistent with enforcing the Code. Regardless of whether a report is made anonymously, reporting persons should maintain all information related to any report in strict confidence and not discuss such information except with Company officials and agents conducting the investigation.

No individual reporting a violation will be subject to retaliation based on any good faith report he or she makes. Any Company Representative associated with retaliating against individuals who in good faith report known or suspected violations will be subject to disciplinary action, including termination where appropriate. Any MPO employee who feels he or she has been or may have been the target of any form of retaliation, should report it immediately to his or her supervisor, the Human Resources Department or Legal Department. In addition, any person who knowingly submits a false report will be in violation of the Code of Business Conduct and will be subject to disciplinary action, including termination of employment, where appropriate, and allowable by local laws.

## 5. THE “ASK US” COMPLIANCE QUESTION PROGRAM

The Compliance Department strives to be a trusted advisor to all MPO Company Representatives. “Ask Us” is a resource developed by MPO to provide personnel around the world with an opportunity to ask compliance questions that arise in a day-to-day business context. The “Ask Us” resource is available to all MPO Company Representatives. The “Ask Us” number is +1.866.830.0890 or email at askus@ortho.microport.com.

The Compliance team at MPO will consult with subject matter experts at MPO and affiliates and provide you with guidance on how to accomplish your business objectives legally and in compliance with our Code of Business Conduct and other MPO policies.



## 6. DISCIPLINARY STANDARDS

Compliance is mandatory for all MPO Company Representatives. Compliance means adherence to legal regulations, a violation of which can lead to sanctions under criminal or administrative law, as well as adherence to internal rules relating to such regulations.

In accordance with Section 3.10 of the Personnel Policy Manual: “Progressive Discipline”, employees who are found to have violated compliance policies are subject to discipline. The Personnel Policy Manual may be found at <http://mposite/index.cfm/departments/human-resources/documents>

The provisions set forth in the Progressive Discipline policy are the default for disciplinary standards. However, the determination of what constitutes appropriate disciplinary action is subject to applicable regional and local laws, terms set forth in a distributor agreement, labor laws, labor agreements, regulations, professional requirements and industry standards. Instead of Human Resources, the Legal Department in coordination with the Compliance Department will be the primary advisor on disciplinary actions governed by contracts, local laws, labor agreements, etc.

Depending on the severity of the compliance violation and the local legal situation, the following disciplinary measures may be used:

- Verbal Documented Warning
- Formal Written Reprimand
- Probation and Reprimand
- Termination of Employment

The Compliance and Human Resources Departments coordinate efforts to deal with compliance violations. A monitoring process has been established to ensure that all disciplinary actions imposed on a Company Representative for compliance violations are addressed in a consistent and effective manner. Certain deliberate and/or material violations of Compliance policies and procedures may result in immediate termination of employment.

### **Impact of Disciplinary Actions**

Progressive disciplinary actions may have a direct and adverse impact on any or all of the following: performance reviews, transfers, promotions, base pay raises, incentive or bonus payments or equity awards.

Stage 1: A VERBAL DOCUMENTED WARNING is provided to the employee to explain the issue and includes a directive to not repeat the behaviour or action. This should be treated as a learning opportunity for the employee. Repeated or multiple verbal documented warnings may result in action being taken at the next level.

Stage 2: A FORMAL REPRIMAND carries with it the following actions: (1) No merit or step base pay increase will be given at the time for the next base pay changes. (2) Based on the severity of the reprimand, the employee may also lose 20% of their annual bonus and may lose 50% of their next equity award.

Stage 3: An employee put on PROBATION and REPRIMAND will be terminated if there is a reoccurrence of the issue(s). This stage carries with it the following actions: (1) No merit or step base pay increase or hourly wage rate schedule increase will be given at the time for the next base pay changes. (2) The employee will not be eligible for any further annual incentive or bonus payments until there has been a forfeiture of 100% of their annual incentive or bonus target. (3) The employee will not be eligible to be included in the next equity award.

Stage 4: There are certain issues which require the company to not use the progressive discipline policy approach and move directly to termination of employment. Causes for immediate termination may include: felony convictions; deliberate and/or major violation of the Code of Business Conduct; a deliberate and/or material violation of Compliance policies and procedures; use or possession of illegal drugs or alcohol on company property or in company vehicles; stealing or deliberately damaging the company's or another employee's property; sleeping on the job; threatening, assaulting, fighting with or harassment of another employee or anyone encountered during the course of business; and possession of firearms in any MPO facility. This is not an exhaustive list and other causes for immediate discharge may be determined following an investigation of the facts and circumstances surrounding an issue.

Deliberate and/or major violations of the Code of Business Conduct and deliberate and/or material violations of Compliance policies and procedures, or other issues listed above may, in most cases lead to termination of employment without severance. Severance in these cases will only be provided if the Human Resources and Compliance Departments both agree it is appropriate.

## **7. PROMOTION IN ACCORDANCE WITH REGULATIONS**

It is the policy of MPO to comply fully with all requirements in every aspect of its business involving MPO products that are reimbursed by local governments.

All Company Representatives are expected to comply fully with all relevant international, national or local country anti-corruption laws, regulations, and professional codes of conduct requirements as well as with this MPO Compliance Manual. Additionally, Third party intermediaries, both sales intermediaries and other third party agents, including but not limited to consultants, distributors, sales agents, marketing agents, brokers, missionary commercial agents or Company Representatives, who interact with HCPs in connection with the sale, promotion or any other activity involving MPO's products, must comply with all relevant international, national or local country anti-corruption laws, regulations, and professional codes of conduct requirements as well as this MPO Compliance Manual. Officers, managers, distributors, and other persons in a supervisory capacity must make the contents of the Compliance Manual known to the appropriate employees in their organizations and ensure the execution of all applicable provisions.

It is not expected that every Company Representative will be fully versed in the laws affecting his/her responsibilities. However, it is expected that every Company Representative with significant responsibilities will have a working knowledge of the permissible activities involved in his/her work and will seek guidance from a superior, the Corporate Compliance Department, or the Legal Department concerning any matter on which there is any question. Sales practices should be consistent with corporate sales training, and with training received from local marketing representatives. Every Company Representative is personally accountable for assuring his/her business decisions and actions are consistent with MPO policy and standards.

## 8. INTERACTIONS WITH GOVERNMENT OFFICIALS

Laws and regulations governing gifts, business meals, speaker grants, educational grants, and travel compensation provided to Government Officials, including part-time government employees, are sometimes more strict and specific than the laws and regulations for private customers. This Section is designed to help avoid any conduct that presents the appearance of impropriety.

### **Government Officials**

The definition of Government Official is very broad, especially in countries with nationalized healthcare. For the purposes of this document, HCPs in the EMEA region are considered Government Officials. Government Officials also include: any officer or employee of a foreign government or any department, agency or instrumentality thereof; any political party, party official, or candidate for political office; officials or employees of “public international organizations” (organizations that have been designated as such by executive order of the President, such as the World Bank, IMF and the United Nations); or any person acting in an official capacity for or on behalf of a foreign government or anyone who exercises official authority. Government Official includes any individual who receives any part of his or her compensation from the government, either through direct compensation or through the filing of claims. Government Officials are those who work both full-time and part-time for a government agency. Government agencies include not only ministries and departments, but also organizations that are owned or operated by the government, such as universities, clinics, hospitals, community centers, etc.

### **Foreign Corrupt Practices Act (“FCPA”)**

MPO is subject to the United States Foreign Corrupt Practices Act (“FCPA”). The FCPA may be implicated for inappropriate business practices that involve non-United States Government Officials, regardless of whether those actions take place in the United States.

The FCPA anti-bribery provisions prohibits paying, offering, or authorizing anything of value to a foreign official, political party, party official, or candidate for political office, or to a third party while knowing that the thing of value will be offered or paid to one of the foregoing corruptly for the purpose of influencing the official in some official act or to secure an improper advantage in order to obtain or retain business.

The following business activities should be evaluated and appropriately managed to assure compliance with the FCPA:

- Any transfers of value to an HCP or other Government Official, including cash, consulting payments, expense reimbursements, airfare, lodging, meals, transportations, gifts, charitable donations, event tickets, event registration fees, free merchandise/products.
- Employment of a Government Official or family member or business partner of a Government Official.
- Payments related to imports and exports, such as fees.
- Regulatory fees, such as payments related to product registration, licensing, and inspections.
- Payments to tax authorities; payments resulting from an audit or in response to a letter/invoice demanding payment.
- Payments for business licenses and permits.
- Payments for work permits/visas, labor related dues.

## **United Kingdom Bribery Act (“UKBA”)**

The United Kingdom recently enacted a law similar to the provisions set forth in the FCPA. The UKBA should be interpreted as applying broadly to all of MPO’s business practices, regardless as to whether those actions take place in the United Kingdom. The UKBA may apply to corrupt practices involving parties in the private sector. Furthermore, under the UKBA, a company may be liable for a corrupt payment made through an agent or third party even if the company was not aware of the corrupt intent of the payment.

### **General Rule**

MPO’s policies and procedures, such as the Needs Assessment Process, or Medical Education Policy are designed to ensure that anything of value given to HCPs cannot be viewed as having been given “corruptly.”

For any questions related to transfers of value and whether the transaction is appropriate should be directed to the Corporate Compliance Office.

There are special rules governing interactions with U.S. Government Officials and Employees. Please see the Compliance Manual of US and Canada Operations at <http://mposite/index.cfm/departments/compliance/documents> for more information regarding interactions with U.S. Government Officials and Employees.

## 9. PROHIBITION ON ENTERTAINMENT AND RECREATION

### General Policy

MPO interactions with healthcare professionals (“HCPs”) should be professional in nature and the primary focus should be to facilitate the exchange of medical or scientific information that will benefit patient care. To ensure the appropriate focus on an educational and/or informational exchange and to avoid the appearance of impropriety, MPO will not provide, arrange for, or pay for any entertainment or recreational event or activity for an HCP.

Prohibited entertainment and recreation activities include, for example, theatre excursions, sporting events, golf, skiing, hunting, the provision of sporting equipment, dancing or arrangements where live music is the main attraction, sight-seeing trips and leisure or vacation trips. Such entertainment or recreational events, activities, or items should not be provided, regardless of: (1) their value; (2) whether the healthcare professional provides services to MPO under an agreement; or (3) whether the entertainment or recreation is secondary to an educational purpose. These prohibitions remain even if local laws and standards permit such conduct. Questions related to the applicability of this prohibition must be directed to the Compliance Department prior to engaging in any activity with an HCP that may involve entertainment or recreation.

## 10. BUSINESS MEALS

MPO may pay for an occasional, modest meal when meeting with a customer and discussing business. MPO policy prohibits Company Representatives from offering anything of value to a healthcare professional (“HCP”) or provider to encourage that person to purchase, order, or recommend MPO products, as this could violate international, national or local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice.

### **Scope**

This section covers interactions with all HCPs who may purchase, lease, recommend, use, or prescribe or arrange for the purchase or use of MPO products. Note that the definition of HCP is very broad and includes individuals other than physicians and nurses, such as laboratory directors, purchasing agents, technicians, and medical office assistants. In countries with nationalized healthcare, HCPs may also be considered Government Officials. Please see Compliance Manual Section 8, “Interactions with Government Officials”, for further information regarding interactions with Government Officials.

### **General Rule**

It is generally appropriate for MPO to provide occasional and modest meals to HCPs in connection with a discussion of MPO products, disease states relevant to MPO products, medical education, or other legitimate discussions related to MPO products. Taking a healthcare professional to dinner or other meal solely for “relationship building” is not acceptable.

These business meals should involve only individuals who are necessary for the conduct of MPO business. This means that meals should not be provided to spouses\*, guests, or office staff personnel who do not actually attend the meeting, or any other person who does not have a bona fide professional interest in attending the meeting.

\* However, exceptions to this rule may be granted if the spouse/guest has to attend due to religious reasons. In these cases, contact the "Ask Us" hotline for more guidance.

It is not appropriate to:

- Simply drop food off with a customer
- Provide a meal for an entire office staff where everyone does not attend the meeting
- Reimburse a healthcare professional for personal meals
- Pay for a meal organized by the healthcare professional(s)
- Pay for the meal of an HCP’s spouse, guest or “significant other”

Business meals may not be provided to encourage any individual or account to purchase, use, prescribe, or recommend MPO products.

### **Setting for Business Meals**

The business meal must occur in a place and manner conducive to business discussion. Meals may occur at the customer’s place of business. However, offering meals without a MPO representative present or providing “take-out” meals (for attendees to eat later or for non-attendees) is not allowed.

### **Spending Guidelines**

Meals provided to a healthcare professional in connection with a meeting involving the exchange of scientific, educational, or business information must be “modest”, according to local standards.

Dinners costing the equivalent of €100 or less per person, including tax/VAT and gratuity, generally meet the “modest” standard. However, the definition of “modest” will often depend on circumstances surrounding the event, such as time of day, venue, and geographic location. For example, for conferences and speaker events, a modest meal might be what a healthcare professional would routinely spend on dining at his or her own expense. For more informal occasions, such as hospital or office visits, business meals should generally be limited to snacks or sandwiches. In general, meal amounts should not be higher than the reasonable amount per local standards.

MPO has established the following caps on meal expenses, which are inclusive of tax/VAT, tip, and service fees:

Country (Currency)	Breakfast	Lunch	Dinner
United States (USD)	40	50	150
Euro (EUR)	25	50*	100*
British Pound (GBP)	20	40	80
Russian Ruble (RUB)	1,000	2,000	4,000
South African Rand (ZAR)	250	500	1,000

\* Caps for lunch and dinner may vary slightly with respect to rules in specific EMEA countries/regions/territories. In such areas where the afternoon meal is normally the “heavier” meal, the dinner meal cap will apply.

Additionally, in countries that utilize currency other than the ones stated above, the current currency exchange rate against the Euro should be applied to establish the meal cap.

Business meals with any one customer should be infrequent. You are responsible for using good judgment to ensure the aggregate value and quantity of permissible gifts and/or business meals to any recipient is reasonable, modest, and occasional. Additionally, the maximum aggregate value and quantity of permissible meals and gifts should be in accordance with local legal or professional industry code restrictions and disclosed where necessary. It is important to remember that a government entity may view gifts and/or meals that are provided too frequently or are too expensive as an improper inducement to purchase MPO products.

If hosting a customer for the entire day, the meal amounts cannot be aggregated. For example: assuming that by local standards the equivalent of €25, €50, and €100 were the maximum acceptable caps for breakfast, lunch, and dinner respectively, you cannot spend the maximum equivalent of €15 for breakfast, €20 for lunch, and then make up the difference by spending €140 for dinner. Regardless of what was spent on the previous meals, the dinner allowance remains €100.

**Other Limits:**

- **No Spouses or Guests** — A business meal should involve only individuals who have a bona fide professional interest in the MPO product discussion. Therefore, spouses or other guests should be strongly discouraged from attending. However, if spouses or other guests of the HCP(s) do attend, the HCP or the guest is responsible for payment of the individual’s meal. In the event that an HCP is accompanied by a spouse/guest at MPO-sponsored product training, participation in MPO-related activities, including meals (regardless of who pays for the meal), is not appropriate. In the event a spouse or guest does attend, the organizer of the event will have a proactive duty to notify the Corporate Compliance Office for guidance.
- **Office Staff Attendees** — A business meal may only be provided to those members of an HCP’s office staff who have a bonafide professional interest in the information being shared at the meeting.
- **No Cash or Cash Equivalents** – You may never give an HCP cash or cash equivalents (e.g. gift certificates, your credit card) to purchase a meal.



The following are examples of meals that are **NOT** appropriate:

- Taking the same physician to dinner at a three-star Michelin rated restaurant every month (not occasional/too expensive to be modest).
- Meeting a surgical nurse at a restaurant and discussing MPO products while waiting for take-out food (venue/location not conducive to an educational discussion/inappropriate purchase of food).
- Giving your credit card to a healthcare professional and telling him/her to “buy lunch” or make some other purchase (credit card provided in this manner is a “cash equivalent”; no MPO employee present; no conduct of MPO business can be confirmed).
- Taking a customer and spouse to a business dinner in a “foursome” with your spouse is inappropriate and discouraged. Reference Section 12, “Social Interactions with Healthcare Professionals”, for additional guidance.
- Providing pizza or sandwiches for all physicians and staff at the office or surgical center even though the only attendees at the MPO meeting were the two surgeons learning about benefits of a new product (food provided to an audience larger than that being presented to is inappropriate).

## **Procedures**

Before providing a business meal, ask yourself:

- Will MPO business be discussed?
- Is the venue appropriate?
- Will the meal have a bona fide commercially reasonable purpose?
- Is the amount of the meal modest (i.e., is it the equivalent or less than the meal caps established for breakfast, lunch, or dinner)?
- Is a MPO representative present?
- Will the frequency and the total value for all gifts and business meals to this HCP and/or organization be considered modest and reasonable?
- Am I reasonably certain that there are no additional considerations, such as whether the HCP practices in a country with special reporting requirements?

The answers to all of these should be “yes” for the business meal to be appropriate.

## **Documentation of Business Meals**

Business meals must either be direct billed or paid by Corporate Check (recorded in the Company’s Accounting System and processed as a voucher) or recorded through the Concur expense reporting system. For all business meals, every customer who attended must be listed in the expense details.

The total amount of the expense will be divided among the number of attendees to determine the amount spent on each person. For example, if you take two surgeons to lunch and the total bill is the equivalent of €75, €25 will be attributed to each surgeon (with the remainder reflecting the cost of your meal) ( $€75/3 = €25$ ).

The Concur expense system requires you to identify the purpose of the business discussion. All business meal disclosures, regardless of amount, require itemized receipts. The failure to submit an itemized receipt will delay processing of the expense report. All business meal disclosures involving Customers must be submitted within 30 days, but by no later than the 10<sup>th</sup> calendar day of the following month. For example, if a business meal took place on April 25, then the meal must be reflected in the Concur system by May 10.

If you are an employee or independent Company Representative without access to Concur, you are responsible for documenting all expenditures related to each HCP and maintaining all original expense reporting records for five years.

### **Record Retention**

You should maintain in your personal work files original expense reporting documents for at least five years. The Accounts Payable Department maintains expense records for a period of ten years or longer as required by law.

### **Audits**

Spending for business meals is subject to audit to ensure compliance with this section, including proper documentation, spending limits, and company spending policy. Government authorities may also request to audit/review expense reports.

## 11. BUSINESS GIFTS AND EDUCATIONAL ITEMS

MPO policy and this Compliance Manual prohibit employees from offering anything of value, including a business gift, to an HCP to encourage the HCP to prescribe, purchase, or order MPO product(s), or to recommend the prescription, purchase, or ordering of MPO product(s). Offering or providing gifts or items of value to encourage HCPs to prescribe, order, or recommend MPO products could violate international, national, or local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice.

### Scope

This section covers interactions with all HCPs who may purchase, lease, recommend, use, or prescribe MPO products. Note that the definition of HCP is very broad and includes individuals other than doctors and nurses, such as purchasing agents, technicians, medical office assistants, and Government Officials. In countries with nationalized healthcare, HCPs may be considered Government Officials. See Section 8, "Interactions with Government Officials", for more information. This section also applies to MPO suppliers and independent Company Representatives.

### Acceptable Business Gifts – General Rule

Gifts may be provided if they are inexpensive and in accordance with the national and local laws, regulations and professional codes of conduct of the country where the HCP is licensed to practice. All gifts must be modest in value, relate to an HCP's practice, benefit patients, or serve a genuine educational function.

Gifts must not be given in the form of cash or cash equivalents. The fair market value of any gift provided to an HCP may not exceed the equivalent of €100 (in some cases this limit may be lower) except for anatomical models, properly labelled demonstration products, and medical textbooks. In all cases, national and local laws, regulations and professional codes of conduct of the country where the HCP is licensed to practice, and limits on gift values should be verified before a gift is given. The following are known country specific limitations:

Belgium	Maximum of 125€ per year and a maximum of 50€ per gift. (MDEON)
France	Maximum of 30€ per year permitted
Greece	15€ per item, including VAT
Netherlands	Maximum of 150€ per year and a maximum of 50€ per gift.
Poland	<ul style="list-style-type: none"><li>• Items up to 100 PLN gross are permitted</li><li>• Gifts may be related to HCP's practice; however, flowers &amp; nominal gifts are permitted if they relate to custom or special occasion (POLMED Code).</li></ul>
South Africa	Scientific medical reference books, journals, periodicals and anatomical models intended for teaching or patient benefit: <ul style="list-style-type: none"><li>• For individual practicing HCP or practices, it should not exceed R 2 500 inclusive of VAT/year</li><li>• For training or academic institutions, it should not exceed R 10 000 inclusive of VAT/year</li><li>• The value of items other than scientific reference, books/journals and periodicals should not exceed R300 inclusive of VAT / per item with a cap of R 1000 / practice or institution</li></ul>

Spain	Gifts must be less than 10€. However, books and publications that are of a material value greater than 10€ are permitted. (FENIN)
Switzerland	300 CHF per year per HCP (Swiss Penal Code)
United Arab Emirates	<ul style="list-style-type: none"> <li>• 500 USD cap for textbooks or medical journal subscriptions.</li> <li>• Courtesy gifts for national, cultural, or religious days permitted but annual limit is 50 USD per year.</li> </ul>

Medical textbooks, models and posters may be offered through Marketing. Pre-approved items are available through International Marketing or the US Sales Support Team and may be purchased and distributed without obtaining additional approval. For medical education items that are not available through the US Sales Support Team, pre-approval from Compliance is required. Submit requests to [askus@ortho.microport.com](mailto:askus@ortho.microport.com). In general, medical education items valued at more than €100 may be provided only to a hospital, practice group, or other entity where the number of physicians in the group ensures that the value of the medical education items does not exceed the maximum equivalent of €100 per physician.

You must follow this procedure carefully for your own protection and for the protection of MPO. Medical education gifts are only allowed if you comply with this procedure. You must always consider the retail value of an item along with other business gifts and meals in determining if the items provided to any one physician and/or practice could create the appearance of an improper inducement. Also, this section should not be interpreted as permission to “build a personal library” for any physician or physician practice group.

All questions regarding availability and title suggestions for textbooks and other printed booklets should be communicated to the Marketing Department.

All booklets and printed materials must be reviewed and approved by the Legal and Regulatory Departments consistent with MPO policies before they can be distributed. Distribution of any printed material, textbook, or any other publication without proper technical review and approval is a direct violation of MPO’s Code of Business Conduct.

**Acceptable Cultural Courtesy Gifts – General Rule**

The giving of cultural courtesy gifts (e.g. marriage, birth, or birthday) is generally prohibited except in the case of death, where it may be appropriate to make a tasteful gift as a mark of respect. However, exceptions for modest, infrequent, and appropriate gifts may be granted for established and widely practiced cultural events or holidays in the location where the HCP practices. Before giving a cultural courtesy gift, MPO personnel must confirm such gifts are permissible according to national and local laws, regulations and professional codes of conduct of the country where the HCP is licensed to practice. To do so, Company Representatives must submit a request to [askus@ortho.microport.com](mailto:askus@ortho.microport.com).

**\*\*Written confirmation must be received from the Compliance Department before providing any gifts of this type.\*\***

**Prohibited Business Gifts**

Except for in very limited circumstances due to local laws and customs, the following types of gifts must never be given to HCPs: a) ones that do not relate to the HCP’s practice, b) ones that do not benefit patients, or c) ones that do not serve a genuine educational function.

Under no circumstances should gifts ever include payments in cash or cash equivalents, such as (a) gift cards; (b) gift certificates; (c) loans; (d) savings bonds; (e) lottery tickets; or (f) airline upgrade coupons.

### **Pre-Approval Requirement**

All gift requests that are not purchased from a pre-approved catalog or website, must be approved in advance by Compliance by submitting a Compliance Request to [askus@ortho.microport.com](mailto:askus@ortho.microport.com).

### **Spending Limits for Gifts**

Amounts spent on gifts should be considered inexpensive. The limit for gifts is €100 per gift (other than anatomical models, properly labeled demonstration products, and medical textbooks where the limit per educational item can be no more than the maximum equivalent of €350). No more than three modest gifts may be given to a single HCP in a given calendar year. The limit for gifts is the maximum value to be used and is not a standard value. You are responsible for using good judgment to ensure the aggregate value and quantity of gifts and/or business meals to any recipient is reasonable, modest, and occasional. It is important to remember that a governing body may view gifts and/or meals that are provided too frequently or are too expensive as an improper inducement to purchase MPO products.

### **Amount to be Recorded**

When listing the value of any gift, textbook, or anatomical model, you should always list the amount you or MPO paid for the item. For example, if the educational gift is purchased through US Sales Support, the amount recorded in Concur should be the per item value as provided.

If you are an employee or independent Company Representative without access to Concur, you are responsible for documenting all expenditures related to each HCP and maintaining all original expense reporting records of these expenditures for five years.

### **Examples**

The following are examples of appropriate business gifts:

- Resident handbooks
- Anatomical models
- Educational DVD on medical conditions and treatment

The following are examples of business gifts that are NOT appropriate:

- Cash or cash equivalents, such as (a) gift cards; (b) gift certificates; (c) loans; (d) savings bonds; (e) lottery tickets; or (f) airline upgrade coupons.
- Tickets to a football game (personal items that do not benefit patients and do not serve a genuine educational function).
- Any gift, regardless of cost, that rewards an HCP for purchasing MPO products.
- CDs with the latest popular music, golf balls, sports bags, cuff links or clothes – even if they contain a MPO logo or product logo (no benefit to patients; no educational function).
- Any “dual-purpose” gift, such as television, VCR, computer equipment, DVD player, iPod, or MP3, even if the cost is inexpensive and the HCP indicates it will be used for medical purposes (gift does not primarily benefit patients).

## **Procedures**

Before providing a gift, ask yourself:

- Is it an item that could be considered a professional practice related item?
- Will it benefit patients?
- Does it serve a genuine educational function?
- Is the amount modest or considered to be inexpensive?
- Will the frequency and the aggregate value for all gifts and business meals to this HCP and/or organization be considered modest and reasonable?
- Am I reasonably certain that the recipient does not require additional considerations, such as whether he/she is an HCP who practices in a country with special restrictions or reporting requirements?

## **Documentation of Gifts in Concur**

Items purchased by an employee (e.g. on a corporate or personal credit card) must be recorded through the Concur expense reporting system. The Concur expense system requires you to identify the purpose of the educational gift.

All gifts, regardless of amount, require itemized receipts. The failure to submit an itemized receipt will delay processing of the expense report. All HCP-related expenditures must be submitted by the 10 day following the month in which gift was given. For example, if you transferred an anatomical model to an HCP on April 25, then the gift must be reflected in the Concur system by May 10.

If you are an employee or independent Company Representative without access to Concur, you are responsible for documenting all expenditures related to each HCP and maintaining all original expense reporting records of these expenditures for five years.

## **Document Retention**

You should maintain in your personal work file original expense reporting documents for at least five years. The Accounts Payable Department maintains expense records for a period of ten years or longer as required by law.

## **Audits**

Spending for gifts is subject to audit to ensure compliance with this section, including proper documentation, spending limits, and company spending policy. Government authorities may also request to audit/review related spending.

## 12. SOCIAL INTERACTIONS WITH HEALTHCARE PROFESSIONALS

### **Purpose**

This section of the manual addresses those interactions that may occur with Healthcare Professionals (HCPs) outside the normal course of business ("Social Interactions"). MPO recognizes that every community has a large number of HCPs (e.g. doctors, fellows, residents, nurses, medical technicians, etc.). Furthermore, many of MPO's representatives are related to HCPs. There are many instances in which MPO Company Representatives will naturally have to interact with HCPs outside the normal course of business, such as school, church, weddings, funerals, sport leagues, neighborhood associations, charity events, etc.

### **General Rule**

Social Interactions, while permitted, should never allow for the appearance that MPO is affiliated with the event. MPO representatives must proactively take steps to mitigate any appearance of MPO's involvement in Social Interaction events.

### **Costs**

Social Interactions with HCPs are permitted as long as the MPO representative does not provide anything to an HCP or purchase anything for the HCP (even if personal funds are used) and does not submit any personal expenses for reimbursement to the Company. All personal costs associated with Social Interactions (e.g. a representative's individual cost to play golf with an HCP during their personal time) are the burden of the representative and may never be submitted for reimbursement from MPO. If a representative does purchase anything for or provide anything to HCPs, the activity is no longer deemed Social Interaction. The transfer of value must be associated with a legitimate business discussion, all expenses must be submitted, and all activities must follow MPO's HCP business interactions guidelines outlined in this manual and consistent with the Code of Business Conduct.

### **MPO Sponsored and Industry Events**

Social Interactions with HCPs, while traveling to a MPO sponsored or industry event is limited to meals and beverages. For example, a representative may have breakfast with an HCP in the lobby of a hotel or coffee shop at an event. However, a representative may not pay for golf, pay for a sporting event, or pay for theatre tickets (or similar activities) for an HCP while traveling for MPO business. The MPO representative may attend such events with fellow MPO Company Representatives and HCPs when appropriate, allowable by local law and professional industry code, and if the event follows the General Rules stated in the Business Meals and Gifts section of this Compliance Manual. As a whole, MPO employees are generally prohibited from providing entertainment for HCPs. For additional guidance, please see Compliance Manual Sections 9, "Prohibition on Entertainment and Recreation", 10, "Business Meals", and 11, "Business Gifts and Educational Items." All other questions related to this topic should be addressed in advance by contacting the Compliance Department.

### **Duty to Notify Compliance**

If a representative does have a personal relationship (e.g., spouse, sibling, child, personal friend) with an HCP, then the Compliance Office must be notified in advance regarding that relationship. Company Representatives should e-mail the Compliance Department at [askus@ortho.microport.com](mailto:askus@ortho.microport.com) with a brief description of the relationship, whether the HCP is a customer or potential customer, and whether it is likely that you may provide any item of value to the HCP (e.g., hosting dinner, providing Christmas or birthday gifts, etc.). The notification to Compliance should be spontaneous, without delay, and without being requested.

All employees, distributors and independent contractors who have sales responsibilities or receive compensation based on sales to HCPs must immediately disclose all familial relationships with any HCPs within their prospective sales territory of that of their Distributor. "Family Relationships" include siblings, parents, spouses, in-laws, cousins, etc. All disclosed relationships will be reviewed by the Compliance Department to ensure that no individual will call on or receive compensation based on sales to a Family Member's account.



### 13. MANUFACTURING SITE VISITS AND PLANT TOURS

Site visits provide a significant vehicle for customers to learn of and evaluate MPO equipment and MPO's research and development activities that cannot practically be provided in another forum. This provision only applies to visits to MPO facilities (e.g. office locations in Amsterdam, Memphis, etc.). Please reference Compliance Manual Section 17 "MPO Sponsored Product Training and Education Events" for customer attendance at events and facilities for the specific purpose of Medical Education.

If MPO or a Company Representative is to incur any expenses related to a customer or HCPs travel or lodging, the visit must be approved by the Corporate Compliance Office. This Compliance Manual and the Manufacturing Site Visit process and associated forms govern such visits.

#### **Process and Forms**

All Manufacturing Site Visits must be approved by Compliance and International Medical Education in advance of MPO incurring any expenses with a vendor (e.g. airfare and/or rail cannot be booked without Compliance approval). To obtain approval, you should access the electronic request forms available on the MPO Intranet. The request must be submitted at least four weeks in advance of the planned visit. Any questions regarding the process should be submitted to the International Medical Education Department.

#### **Purpose of Site Visits**

MPO cannot conduct a site visit and demonstration where there is no legitimate business need for the visit.

Current and prospective customers may visit a site for purposes of becoming familiar with MPO products and observing product demonstration(s) in environments similar to that of their work environment. Such visits generally include sales presentations, product demonstrations, scientific discussions, and/or tours of the manufacturing and operational facilities.

For visits that involve a Government Official in countries with nationalized healthcare, please see Section 8, "Interactions with Government Officials".

#### **Reimbursement of Expenses**

MPO may pay reasonable and necessary travel expenses of customers visiting sites for legitimate business purposes in situations where the business purpose cannot be achieved without such a visit (e.g., the manufacturing process and machinery of an implant, the storage and packaging of biologic material, etc.).

MPO can also reimburse reasonable and necessary travel expenses for a customer for purposes of providing information, education, or a demonstration of a product. However, MPO may not reimburse the customer or pay the customer a fee for taking time off from the customer's business to attend the site visit.

MPO must directly purchase airline tickets and make arrangements to pay hotels, so that business guests do not incur these costs and MPO can ensure that arrangements are consistent with applicable MPO policies on reimbursement for business travel. MPO is not permitted to reimburse travel or other expenses of spouses or guests in connection with site visits.

**NOTE:** A Manufacturing Site Visit Request is not required for a Customer visiting an office location if travel and lodging expenses will not be incurred.

## 14. FREE GOODS

“Free goods” is the term for a product or service labeled for sale that is provided at no charge. Providing products to HCPs at no charge for evaluation or demonstration purposes can benefit patients by improving patient care, facilitating the safe and effective use of products, improving patient awareness, and educating HCPs regarding the use of products.

### General Policy

Under certain circumstances, MPO may provide reasonable quantities of products to HCPs at no charge for evaluation and demonstration purposes. MPO products may be provided to HCPs for evaluation as single use (e.g., consumable or disposable products) and multiple use products (sometimes referred to as “capital equipment”). These products may be provided at no charge to allow HCPs to assess the appropriate use and functionality of the product and determine whether and when to use, order, purchase, or recommend the product in the future. The transfer of an evaluation product must be clearly documented (e.g., invoices must reflect “No-charge Evaluation Product”). MPO may never provide free goods to customers, such as hospitals or healthcare professionals, if the purpose of such action is to encourage them to use or purchase MPO products.

**Single Use/Consumables/Disposables.** The number of single use products provided at no charge should not exceed the amount reasonably necessary for the adequate evaluation of the products under the circumstances, which is usually three (3) or less for any single customer.

**Multiple Use/Capital.** Multiple use products (e.g. instrument kits) provided without transfer of title for evaluation purposes should be furnished only for a period of time that is reasonable under the circumstances to allow an adequate evaluation, usually no more than ninety (90) calendar days. The terms of an evaluation of such multiple use products should be set in advance and set forth in writing. MPO shall retain title to such multiple use products during the evaluation period and will promptly remove such multiple use products from the HCP’s location at the conclusion of the evaluation period unless the HCP purchases or leases the products. This provision does not apply to instruments provided under an executed consignment, lease or purchase agreement.

**Demonstration.** Company demonstration products are typically unsterilized single use products or mock-ups of such products that are used for HCP and patient awareness, education, and training. For example, an HCP may use a demonstration product to show a patient the type of device that will be implanted in the patient. Demonstration products are not intended to be used in patient care. Demonstration products must also be identified as not intended for patient use by use of such designations as “sample-not intended for human use,” or other suitable designation on the product, the product packaging, and/or documentation that accompanies the product.

**Grants and Charitable Donations.** Free goods provided to qualified charities should follow Compliance Manual Section 18, “Charitable Contributions.” Free goods may NOT be provided for any other purpose. Free goods provided in connection with a product sale (i.e., “buy one, get one free”), must comply with Compliance Manual Section 16, “Providing Discounts and Rebates.”

### Additional Guidance

Products may be marketed as free goods. However, they must be reflected as a discount on the invoice. For example, it is permissible to state “buy one get one free;” however, the invoice should reflect this as a 50% discount. For further information, consult the Compliance Manual Section 16 “Providing Discounts and Rebates”.

MPO may provide free goods to individuals or entities involved in performing research services for MPO pursuant to a written research services agreement. For additional information, see Compliance Manual Section 23, “Clinical Research and Clinical Study Support”.

Goods provided as an “apology” are “free goods” subject to this policy and are not permitted. When there are bona fide warranty/service/performance issues, replacement product or a credit may be offered provided that the transaction is documented with the applicable warranty language, which must be evaluated and obtained from the Legal Department.

### **Questions**

All questions regarding free goods should be referred to Compliance at [askus@ortho.microport.com](mailto:askus@ortho.microport.com) or via the "Ask Us" program telephone number +1.866.830.0890.

## 15. LOANER EQUIPMENT — SALES

This section provides guidance only with regard to loaner equipment provided in the sales context. “Loaner equipment” is the term for equipment that may or may not have commercial value and is provided at no charge. Except as described elsewhere in this Compliance Manual, MPO may never provide loaner equipment to customers, such as hospitals or healthcare professionals, if even one purpose of such action is to encourage them to use or purchase MPO equipment or products. Loaner equipment is not for “evaluation”; see Section 14 on “Free Goods” for guidance on product samples and evaluation products.

### **General Policy**

Any loaner equipment provided must be provided pursuant to a written agreement approved by the Legal and Compliance Departments. A request to loan equipment must be submitted to [askus@ortho.microport.com](mailto:askus@ortho.microport.com).

Equipment not associated with a sale or without proper documentation may not be loaned to customers. Instrument sets may remain at a Customer location so long as the Customer actively implants associated products. If an implant case has not taken place in over 90 days, the instrument set should be removed from the Customer location until a case requires use of the instruments. The 90 day provision applies to instrument sets held by the Customer through a consignment agreement.

### **Questions**

All questions regarding loaner equipment should be referred to the Compliance Department. Questions related to instrument sets associated with the sale of an implant should be referred to Customer Service.

## 16. PROVIDING DISCOUNTS AND REBATES

MPO may generally provide discounts, rebates, and other price concessions to customers provided the conditions of this section are met and MPO complies with international, national and local country anti-corruption laws, regulations and professional codes of conduct for the country.

### **General Limits**

All discounts, rebates, or other price concessions given on sales must be openly and fully reported on the invoice for such sales. Any products given to the customer must be reported on an invoice noting the fair market value (net price with discount customary to this customer). No items or services should be provided “below the line.” Additionally, “Side Letters” or price concessions, and product feature and configuration promises (e.g. custom instruments, special services) offered outside of written contracts, are strictly prohibited. Notwithstanding the foregoing, the Legal Department may be consulted to draft letters that reflect unanticipated credits or changes to the contract. It is the responsibility of the requestor to ensure that these letters be included in the contract history files.

### **Discounts**

Discounts are price concessions that are provided and disclosed on the invoice or the contract at the same time of execution at the time the product is sold. MPO must fully and accurately report discounts on the invoice submitted to the customer at the time the product is furnished and inform the customer on the invoice of its potential obligation to report the discount to payers and insurers, as appropriate.

### **Rebates**

Rebates are price concessions based on purchase volume or the fulfilment of other established criteria where the final amount of the price concession may not be known at the time of product invoice or contract signing. If the value of a rebate is not known at the time of invoice or contract signing, the invoice or contract should reflect that additional discounts may be provided and provide the “formula” for subsequent calculation of the discount. MPO should provide credit memos that accurately explain the reason for the credit and reflect the true value of the rebate. In the written contract and on invoices or credit memos, MPO must notify customers that they may be required to report discounts and other price concessions to government payers.

### **Questions**

All questions regarding discounts or other price concessions should be referred to Compliance or the Legal Department.

## 17. MPO-SPONSORED PRODUCT TRAINING & EDUCATION EVENTS

MPO recognizes the importance of providing training on the company's products and education on topics directly relating to the company's products to healthcare professionals ("HCPs") and purchasers.

"Training" means training on the safe and effective use of the company's products.

"Education" means communicating information directly concerning or associated with the use of the company's products such as surgical technique, information about disease states and the benefits of the product to certain patient populations.

It is generally appropriate for MPO to financially sponsor or furnish such product training and education to HCPs. MPO-sponsored education events are typically scientific events at which the presenter is speaking on MPO's behalf. This can include MPO-sponsored events that are ancillary to third-party events, but must be scheduled and organized consistent with the third-party's rules.

MPO employees may only control and influence the speaker or program content in cases when the only topics of discussion are approved uses of MPO products.

A representative from MPO must be present at all MPO-sponsored Training Events.

### **Speakers and Training Faculty**

The use of an HCP Consultant to train or speak is permitted at MPO-sponsored Training Events. However, all HCP Consultants must be engaged through MPO's Service Needs process. Company Representatives who work in a sales capacity are not permitted to invite or engage HCPs, including MPO HCP Consultants, to participate as a speaker at any event. The use of any HCP Consultant must be coordinated by MPO's International Medical Education Department.

All speaker presentation materials must be reviewed and approved by MPO's Regulatory and Legal Department prior to delivery. The event owner (e.g. Medical Education, Product Manager, Marketing representative) is responsible for ensuring all materials used at the event are approved.

### **HCP Attendees**

HCP Attendees may not receive anything of value (cash, cash equivalent, gifts, etc.) in connection with the event other than meals and refreshments (and travel and standard lodging when applicable). Any such meals and refreshments should be modest in value and subordinate in time and focus to the educational or training purpose of the meeting.

MPO will only pay for reasonable travel and modest lodging costs incurred by an attending customer if travel is necessary in order for MPO to efficiently deliver training on the company's products and when compliant with the regulations of the country where the HCP is licensed to practice. It is not appropriate for MPO to pay for the meals, refreshment, travel, or other expenses for guests of customers or for any other person who does not have a bona fide professional interest in the information being shared at a training program or education meeting.

### **For Training Events that Require Travel and Lodging**

The brochure or event invitation must provide a description of the intended training audience for the Training Event. The Training Event registration tool will request the trainee's name, address, contact information, specialty, and if applicable, place of licensure. The completed registrations will be evaluated by the Medical Education Department Leader or designee. Registration will be accepted on a first qualified, first registered basis until the event has reached capacity. Registration requests for HCPs that do not satisfy the defined intended training audience will be denied. If space permits,

other HCPs such as members of an operating room surgical staff may attend if they are qualified to objectively learn from the Training Event.

### **MPO Personnel**

All MPO attendees must pre-register and sign in daily to participate in a Training Event. MPO Sales Representatives or independent Company Representatives may attend a Training Event with an HCP trainee to technically assist the trainee with the use of MPO products. Selling is not considered a legitimate need to attend a Training Event. For didactic courses, there must not be more than one Sales Representative in attendance for each HCP attendee. For skills courses, a 1:1 ratio of Sales Representatives to HCP attendees is the goal; however, there may be instances where two Sales Representatives servicing a trainee both need to attend the skills lab (e.g., a newer representative who is also learning from the more senior representative). This type of information must be detailed and evaluated by the International Medical Education Department. The ratios described in this section are not applicable to manufacturing site visits, although Sales Representative attendance must be for an appropriate purpose.

Corporate employees (non-Sales) and Sales Management employees (Sales Representatives with supervisor responsibilities) may attend a Training Event. Many employees are often needed to support the execution of the event itself; these non-sale attendees do not count towards the attendance ratios. For each MPO attendee registering for an event (Sales Representatives or Corporate employees), a corresponding reason must be provided at the time of registration to support his or her participation. The International Medical Education Department is responsible for capturing this information in the registration report and controlling the overall attendance of the event as it relates to capacity, compliance documentation and overall meeting budget.

### **Program Topics and Location**

Topics must address approved uses of MPO products and be of a scientific or medical nature. For example, training and education programs can include “hands-on” training, cadaver workshops, educational lectures, and grand rounds. Topics such as “Office Management” or “Billing” do not meet these criteria.

The location of the program must be conducive to the exchange of information and to the presentation format planned for the program. Training and education programs should be conducted in clinical, educational, conference, or other settings, including hotels or other commercially available meeting facilities conducive to training. Programs providing “hands-on” training should be held at training facilities, medical institutions, laboratories, or other appropriate facilities. Locations that are, by their nature, entertainment (such as a dinner riverboat cruise) are not appropriate.

The training staff should have the proper qualifications and expertise to conduct a training program. Training staff may include qualified MPO employees who have the technical expertise necessary to perform the training.

MPO employees participating in training are prohibited from soliciting or providing information on unapproved uses of MPO equipment/devices. If asked to assist in specific prescribing or billing decisions, do not do so.

Any healthcare professional who requests information on an unapproved use should be directed to Regulatory Affairs.

## **CME Accreditation**

Under the EACCME and ACCME Standards for Commercial Support, CME credits may not be issued for MPO product training programs. However, other accrediting bodies may provide CME credits upon MPO's requests. Such requests will be managed by MPO's Medical Education. Company Representatives and advertising materials must accurately reflect the CME status of any MPO meeting. Examples include: "Non-CME MPO Event"; "Seeking CME credits by X Accrediting body"; "8 CME Credits for HCPs in the countries of France, Italy and Belgium".



## 18. CHARITABLE CONTRIBUTIONS

MPO may make donations for a charitable purpose, such as supporting indigent care, patient education, public education, or the sponsorship of events where proceeds are intended for charitable purposes. Donations should be made only to charitable organizations that are separate from the customer (i.e., an independent charitable foundation, which may be affiliated with a customer). However, provision of charitable donations can still be subject to international, national, or local country anti-corruption laws, regulations, and professional codes of conduct of the country. This section is designed to enable MPO and its employees to provide legitimate charitable donations in a manner that does not create an appearance of impropriety.

### **General Rule**

It is generally appropriate for MPO to support charitable organizations and local or community-oriented non-profits and their missions by making donations for charitable purposes. The amount of any charitable donation made by MPO to any particular charitable organization may not be based on, or related to, the past, present, or future volume or value of business generated for MPO by that charitable organization or related organization. MPO will not make charitable donations directly to hospitals, physicians, or other customers; political parties or causes (e.g. ethnic or religious). Charitable donations may only be made to non-profit charitable organizations, including charitable foundations affiliated with hospitals, as long as the foundation is truly a separate entity from the hospital.

### **Process**

All grant and charitable contribution requests must be submitted by the requestor to [grants@ortho.microport.com](mailto:grants@ortho.microport.com). See Section 19 "Grants for CME, CEU, and 3<sup>rd</sup> Party Educational Conferences."

MPO employees and representatives cannot submit a request on any organization's behalf. The Grants and Charitable Donations Guidelines can be found on MPO's homepage at [http://www.ortho.microport.com/MPO/assets/File/Final\\_MicroPort%20Grants%20and%20Charitable%20Donations%20Policy.pdf](http://www.ortho.microport.com/MPO/assets/File/Final_MicroPort%20Grants%20and%20Charitable%20Donations%20Policy.pdf). All grants and charitable donations related to Healthcare Organizations are evaluated by the Arrangements Review Committee, a subcommittee of the Executive Compliance Committee ("ARC").

General donation requests for non-healthcare related organizations should be directed to the Human Resources Department. For example, a donation to a local primary school or UNICEF would not be reviewed through the ARC.

### **Requirements**

Charitable contributions are permitted only if they meet the following requirements:

- I. The contribution is intended solely for charitable purposes, such as providing funds or equipment for patient care, patient education, or public education. If MPO receives anything of value in return, the value must be deducted from the portion of the request that would be considered charitable; therefore, the requesting organization should make this distinction on any documentation it provides as support for the request.
- II. The recipient is a qualified non-profit charitable organization (a copy of the organization legal status must be included in any request for a donation or must be readily available).
- III. The recipient is a truly separate charitable organization from the customer with a board of directors and management independent of the customer.

A charitable contribution is not permitted if it is any of the following:

- Intended as a price term or offered in place of a price concession.

- Contingent on the purchase of any MPO products.
- Intended to encourage the recipient to use, purchase, or recommend MPO products. Intended to reward or compensate the recipient for purchasing, using, or recommending MPO products. Made at the request of a healthcare professional in his/her individual capacity (e.g. a request by a physician to fund his/her favorite charity). Funding an endowed chair at an educational institution since it is the same as providing an unrestricted cash gift to a healthcare professional.

All requests for charitable contributions must be supported by a letter from the entity requesting the contribution and the purpose of the contribution (for example, to donate to the World Cancer Research Fund and confirming that the requesting party is a charitable entity). This letter should have as much supporting information as possible in order for MPO to conduct its due diligence upon request.

MPO Company Representatives may not make charitable donations on behalf of MPO. For example, you cannot use personal funds and claim the donation is on behalf of MPO. Additionally, sales, marketing, independent Company Representatives, or service personnel should not approve requests for charitable donations or attempt to influence MPO decision-making with respect to a request for a charitable donation.

If an employee wants to support a charity in his/her individual capacity and that charity is a customer or affiliated with a customer, then the donation must meet the following criteria:

- The donation is made directly to the charity.
- The donation is made anonymously.
- The customer is never informed directly or indirectly about the donation.

For example, employees can make an individual donation to a local children's research hospital in the manner outlined above. There are no restrictions for employees wishing to personally support unaffiliated charities, such as to UNICEF.

Any other questions regarding charitable contributions should be submitted to Compliance or Human Resources.

### **Charity Events**

If MPO makes a donation to a charity event sponsored by a charitable organization (e.g., golf tournament, charity gala) the proceeds of the event must be used for charitable purposes rather than for purposes of funding capital, operating, or overhead expenses of an affiliated customer (e.g. Building of a new orthopedic wing at a hospital).

Attendance by designated MPO employees at charitable events may be permitted in order for MPO to demonstrate support for the charity through personal attendance at a charitable event. However, inviting customers or HCPs to these charity events is not appropriate under any circumstance. By way of further example, if the event is a golf outing or gala dinner, MPO may not golf with a customer representative in a foursome.

In the event MPO has fewer attendees than the number of allotted event tickets or golf slots, the remaining tickets or slots should be returned to the charity. The charity, in its sole discretion, may decide to place other paying attendees at the MPO table or with the MPO golf group. MPO may not, directly or indirectly, influence who the charity may place with MPO.

If MPO denies a request to fund a charity event, it is not appropriate for the MPO employee to, nevertheless, provide sponsorship to the event using his or her own personal funds or attend the event on behalf of or in representation of MPO.

## **Contributions for Community Health Events**

Charitable contributions may be requested to support community health fairs or medical screening days intended to promote disease awareness and provide testing for early diagnosis. Examples include any medical test or screening event offered free to the community such as prostate cancer screening. Such requests must be submitted to [grants@ortho.microport.com](mailto:grants@ortho.microport.com) and will be evaluated by the ARC.

MPO may contribute funds or product to an independent third party that qualifies as a non-profit charitable organization to support health fairs or screenings if the following requirements are met:

- The request for funds must be received from an independent third party that qualifies as a non-profit charitable organization. MPO cannot provide funds or product to a private healthcare professional or practice group or any charity that is controlled or operated by a private healthcare professional or practice group;
- More than one medical group or more than one healthcare professional, each from different medical groups, must take part in the health fair or medical screening; and
- The health fair or medical screening must be free and open to all community members.

If you receive a request for a charitable contribution that does not comply with MPO's policies or this Compliance Manual, as a courtesy to the requestor, you should proactively inform the person that MPO's policies do not permit the contribution.

## **Product Donations**

The Company may donate product for charitable missions and/or the benefit of indigent patients. Requests for product donations will require certification by the requestor that the patient's physician(s) and/or the hospital or other facilities will not bill the patient, local government, or any other person or third party payor for the cost of any of the health care services for which donated Company products will be used.

## **Audits**

All charitable contributions are subject to audit to ensure compliance with MPO policies and this Compliance Manual. Government authorities may also request to audit/review charitable contributions.

## 19. GRANTS FOR CME, CEU, AND THIRD-PARTY EDUCATIONAL CONFERENCES

MPO provides educational grants solely to support independent, educational conferences and meetings that promote scientific knowledge, medical advancement, and/or the delivery of efficient healthcare (“educational conferences”). Offering an educational grant to encourage healthcare professionals to prescribe, purchase, use, recommend, or promote off-label promotion or inappropriate use of MPO products could constitute a violation of international, national, or local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice.

### **General Rule**

Educational grants may be paid only to support independent educational conferences sponsored by the following Conference Sponsors: (1) national, regional, or specialty medical associations; (2) charitable foundations or medical schools affiliated with teaching institutions, or (3) continuing medical education (“CME”) or continuing educational unit (“CEU”) providers that have been accredited by an organization such as the European Accreditation Council for Continuing Medical Education (“EACCME”) or Accreditation Council for Continuing Medical Education (“ACCME”) or other relevant accreditation organizations.

Grants should be made consistent with relevant guidelines established by professional associations, including EACCME, MedTech Europe and any other relevant country and local regulations. An educational conference supported by a MPO educational grant must be for scientific or educational purposes and not for the purpose of promoting any MPO product. Any discussion of MPO’s products at the educational conference must be objective, balanced, and scientifically rigorous. Any MPO product exhibit booth at these events must meet all sponsor and/or accreditation organization rules and the exhibitor fee must be based on fair market value. MPO will not pay an exhibitor fee that reflects a premium assessed for access to healthcare professionals.

Grants may not be conditioned, in whole or in part, on the purchase of MPO products or directed toward specific HCPs who are in a position to use or order MPO products. MPO may not contribute to programs sponsored by a customer unless the program is accredited for education credits (e.g. CME, CEU, or other applicable credit) or is sponsored by a charitable foundation or medical school affiliate. The terms, conditions, and purposes of the MPO grant must be included in a written agreement between MPO and the Conference Sponsor as further described below.

### **Recipient of the Grant**

MPO may provide a grant\*:

- I. Directly to a Conference Sponsor to reduce educational conference costs. Grant funds cannot be used to offset expenses not directly related to the educational conference, such as rent for the Conference Sponsor’s office or other overhead costs the Conference Sponsor incurs.
- II. Directly to a Conference Sponsor to help cover reasonable travel and modest lodging expenses of healthcare professionals in training (e.g., residents, fellows, and medical students) or faculty attending the educational conference, if the Conference Sponsor selects the attendees or faculty.

\* In some countries, approval from the local ministry of health or local regulating body may be required before a grant may be provided to an HCP either directly or through a third party. Review international, national, and local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice before approving grant funds.

## **Control of the Conference**

The Conference Sponsor, not MPO, must have independent control of and be responsible for the content, faculty, educational methods, materials, and selection of attendees for the educational conference. The Conference Sponsor must make all decisions regarding the use of financial support from MPO. MPO can recommend speakers or comment on the program only when requested to do so by the third party organizer.

## **Modest Meals & Hospitality**

A portion of a MPO educational grant may be used by the Conference Sponsor to defray the cost of modest meals and refreshments for attendees at the educational conference.

MPO may also directly provide meals and refreshments for educational conference attendees if such meals and refreshments are: (1) provided to all attendees; (2) provided in a manner that is consistent with the applicable standards established by the Conference Sponsor and, if applicable, the entity accrediting the educational activity; (3) modest in value; (4) subordinate in time and focus to the purpose of the educational conference; and (5) clearly separate from the educational portion of the conference.

MPO employees may conduct sales or promotional meetings with one or more attendees at an educational conference and provide meals or refreshments as long as the meetings are conducted and the meals and refreshments are provided in accordance with the Conference Sponsor's guideline, Section 10, "Business Meals", and Section 21, "Contracting, Engagement and Payments for HCP Consulting Services."

## **Faculty Expenses**

All or a portion of MPO educational grants may be applied by the Conference Sponsor to pay for reasonable honoraria, travel, lodging, and modest meal expenses for educational conference faculty members selected by the Conference Sponsor.

MPO may not direct a Conference Sponsor to use the grant funds for specific faculty members. MPO may not pay individual faculty members for participation at an independent Conference. Should the Conference Sponsor permit vendors to conduct marketing activity, such as at a booth or industry funded workshop, MPO may retain the service of an HCP to perform such services pursuant to a written speaker or services agreement that complies with Section 21, "Contracting, Engagement and Payments for HCP Consulting Services."

## **Programs with CME Credit**

If a faculty member has a financial relationship with MPO, MPO Consultants should ensure that the financial relationship is disclosed to the Conference Sponsor since the program presented by such faculty member may be ineligible for CME credits under the appropriate accrediting body (e.g. EACCME) standards for Commercial Support.

## **MPO Involvement in Educational Grants**

MPO employees may NOT be involved in the following activities associated with educational grants:

- Selecting the content, faculty, educational methods, materials, or venue for the educational conference. MPO may respond to unsolicited written requests from a Conference Sponsor for suggestions of names for possible speakers only. MPO must provide (where reasonable) the names of more than one speaker and when appropriate, the list should not be limited to those with a contractual relationship with MPO.

- Promoting MPO or MPO products during any educational conference funded, even partially, by an educational grant.

MPO employees may participate in educational conferences supported by MPO grant funds as attendees but, if they are attendees, they may not engage in formal or informal promotional activities inside or outside the meeting room(s). It is acceptable for MPO employees not attending the educational conference to conduct appropriate promotional activities outside program meeting rooms, such as at an adjacent exhibit.

### **Exhibit Booths and Sponsorship**

If no educational grant funds are provided, MPO employees may attend and exhibit at the educational conference. Exhibit Booths and Sponsorships must be approved by the Compliance Department or ARC (if applicable) before committing any funds to the Conference Sponsors. All Exhibit Booths and Sponsorship requests are coordinated by the International Medical Education Department. In general, a minimum of 4 hours per day (averaged) of meeting time must be provided for MPO to Exhibit at an independent Conference, and a minimum of 6 hours per day (averaged) of meeting time must be provided for MPO to sponsor an independent Conference.

### **Contractual Provisions**

Educational grants may only be awarded to Conference Sponsors that have entered into a written agreement with MPO and approved through the ARC. The agreement must require that the Conference Sponsor disclose the following information to all attendees, when factually relevant:

- MPO's funding of the educational conference and any significant relationships between the Conference Sponsor and MPO.
- Financial or other relationships between individual presenters or moderators and MPO.
- Fact that a presenter was suggested by MPO.
- Any limitations on information that is presented at the programs, such as data represents ongoing research, interim analysis, preliminary data, or unsupported opinion.
- When a MPO product or a competitor's product is to be the subject of substantial discussion, the data must be objectively selected and presented. Both favorable and unfavorable information about the product must be fairly represented and any discussion of the prevailing body of scientific information on the product must be reasonable.
- If applicable, the fact that uses of MPO product(s) that were discussed are not approved by the national or local regulatory body.

### **Unacceptable Educational Grants**

A grant is not permitted if it is any one of the following:

- Intended as a price term, or offered in lieu of a price concession.
- Intended to encourage off-label use.
- Contingent on the purchase of MPO products.
- Intended to encourage the recipient to use, purchase, or recommend MPO products.
- Intended to reward or compensate the recipient for having purchased, used, or recommended MPO products. Made at the request of a healthcare professional (e.g., request to fund a "pet project"). It is acceptable for a healthcare professional to request a grant in his/her official capacity, such as the lead fundraiser for a not for profit organization.
- Made in return for anything of value provided to MPO by the recipient, with the exception of disclosure in program materials that the program is funded by MPO.

## **No Promotional Activity**

MPO may not engage in any promotional activities, such as presentations by sales representatives, or promotional exhibits, in the same room or in an obligate path to the educational activity, unless the exhibit is within an area that is designated for general exhibits and includes exhibits from different companies marketing alternative or competing therapies. Materials disseminated in conjunction with the program may not include advertisements for MPO's products.

## **Relationship to Other Policies**

Grants for clinical trials or medical research are not "educational grants" for purposes of these policies and must be provided in accordance with Section 24, "Clinical Research and Clinical Study Support". Educational or other speaker events controlled by MPO are not considered "educational grants" for purposes of these policies and must be provided in accordance with Section 17, "MPO-Sponsored Product Training and Education Events".

## **Electronic Process**

All grant requests must be submitted by the requestor to [grants@ortho.microport.com](mailto:grants@ortho.microport.com). MPO employees and representatives cannot submit a request on any organization's behalf. The Grants and Charitable Donations Guidelines can be found on MPO's homepage at [http://www.ortho.microport.com/MPO/assets/File/Final\\_MicroPort%20Grants%20and%20Charitable%20Donations%20Policy.pdf](http://www.ortho.microport.com/MPO/assets/File/Final_MicroPort%20Grants%20and%20Charitable%20Donations%20Policy.pdf). All grants and charitable donations related to Healthcare Organizations are evaluated by the ARC. See Section 18 "Charitable Contributions" for general donations related to non-Healthcare Organizations.

## **Record Retention**

The Legal Department maintains copies of all contracts and supporting documentation surrounding educational grants for a period of six years or longer if required by law or the Corporate Record Retention Policy.

## **Audit**

All educational grants are subject to audit to ensure compliance with these policies. Government authorities may also request to audit/review educational grant documents.

## 20. DRAWINGS, CONTESTS, AND LOTTERY

Drawings, contests and sweepstakes/lotteries, which offer the opportunity for a customer, patient, healthcare professional or anyone else to receive something of value, such as a prize, from MPO in a drawing, contest, sweepstakes, or similar situation are to be avoided. Requests by a conference organizer for MPO to supply funds for drawings, sweepstakes, or similar situations must be approved by the ARC (the allocation and/or purpose of MPO funds should be clear in the documentation submitted to the Committee). Furthermore, items to be used for a drawing, contest or sweepstakes must comply with the requirements of Compliance Manual Section 11, "Business Gifts and Educational Items."

All requests to support a third-party drawing, contest, sweepstakes, or similar situation must be approved in advance by Compliance and Legal by submitting a Compliance Request to [askus@ortho.microport.com](mailto:askus@ortho.microport.com).



## **21. CONTRACTING, ENGAGEMENT AND PAYMENTS FOR HCP CONSULTING SERVICES**

MPO relies on HCPs to perform services that MPO personnel cannot effectively or efficiently perform. It is appropriate to pay HCPs reasonable compensation for meaningful bona fide services, including, but not limited to, research, participation on advisory boards, presentation at member-sponsored training or third-party conferences, product development, surgical training, and clinical studies.

### **General Policy**

All services provided by an HCP at the direction of MPO must be performed under a fully executed agreement that specifies the services to be provided, and must be consistent with the regulations of the country where the HCP is licensed to practice. There must be a bona fide need for services to contract an HCP. In addition, the bona fide need should be identified and documented in advance of contacting an HCP. Selection of HCPs must be based on qualifications and expertise to address the identified purpose, not the volume or value of business generated by the HCP. HCP Consultants must be qualified to perform such services and the agreement(s) in place must reflect the Fair Market Value for such services. All arrangements must be documented in writing even if no payment is required or the arrangement only involves a one-day event.

### **Contracting, Engagement and Payments**

Sales personnel should not discuss Contracting, Engagement, or Payment issues with HCP Consultants, even if the HCP Consultant is a customer. All questions related to an HCP's Consulting arrangement with MPO should be referred to the Compliance Department (specifically Professional Affairs). Engagement specific questions may be addressed by the event owner (the MPO business person coordinating the event).

Sales personnel are not permitted to request an HCP to perform services on behalf of MPO. If a sales representative identifies a need for a specific consulting service (e.g. Medical Education), the representative should contact the Medical Education, Marketing, or Clinical Department to discuss the need. All payments to HCP Consultants are processed by Contract Compensation Analysts in the Finance Department in the Arlington Corporate Office.

### **Fair Market Value**

In order to avoid any violation of international, national, or local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice, MPO has established Fair Market Value (FMV) guidelines that focus on our financial relationship with HCPs and provide us with a methodology to assess the maximum compensation level that must not be exceeded for their services. As a result of continual updates in the industry's FMV rates, the guidelines and corresponding rates are reviewed on an annual basis. Rate changes are reflected in amended and new agreements. MPO may pay for reasonable and actual expenses for travel, meals, and accommodations, which should be described in the written agreement.

## 22. ADVISORY BOARDS

Advisory Boards provide MPO with significant and valuable feedback on its products and product plans. Engaging and paying an HCP for Advisory Board services is subject to MPO's Service Needs review process. Advisory Boards may only be coordinated by members of MPO's Marketing, Clinical, or Research and Development Departments. Sales personnel cannot coordinate or propose an Advisory Board meeting.

### **General Rules**

If, at the request of MPO, a contracted MPO Consultant visits a MPO facility or some other location specifically to review and comment on a product, to discuss a research product, or explore collaborative research, a fair market value payment for time spent may be paid, so long as the services to be provided are for a legitimate purpose, genuine, and not token.

The Consultant may be paid a fair market value fee for time spent participating in the advisory board and reimbursement for reasonable, out-of-pocket expenses. MPO may not provide a "thank-you gift" to Advisory Board participants.

For advisory boards, the following applies:

- The purpose of the meeting must not be to promote a product.
- The selection of participants must be based on the consultant's qualifications and expertise to address the purpose.
- The number of physicians in the advisory board must be reasonable (e.g., generally less than 15 participants).
- The MPO employee hosting the advisory board must take minutes of the meeting that are sufficient to document the time and effort contributed by the participants.
- The compensation time involved for a particular advisory board must be reasonable and may not exceed the time allowed on the approved engagement letter.
- Any payment to a Consultant in connection with an advisory board must be made pursuant to a written agreement as described in Section 21, "Contracting, Engagement and Payments for HCP Consulting Services."
- To the extent required by contract or terms of employment, participants must obtain permission from their companies prior to participating in an advisory board.
- Any meals or refreshments must be provided in accordance with Section 10, "Business Meals."
- All venues for Advisory Board meetings must be conducive to an effective exchange of information. A hotel meeting room or office conference room is typical and acceptable. A room at a restaurant in which majority of the meeting will take place over a meal is not acceptable.
- Advisory Board meetings must not take place at resorts, luxury hotels or entertainment venues unless such location is chosen as a result of health or safety concerns. Entertainment and/or Recreational activities may not be organized or funded by MPO.

For information regarding your interaction with foreign HCPs, please see Compliance Manual Section 1, "Scope and Purpose".

## 23. CLINICAL RESEARCH AND CLINICAL STUDY SUPPORT

All clinical research and clinical studies supported by MPO should promote legitimate research goals. A research grant may come in the form of equipment, services and supplies, and/or monetary/non-capital support. MPO may enter into an arrangement to sponsor or authorize clinical research or clinical studies for the purpose of developing clinical information concerning MPO products, both pre- and post-market, provided that the clinical information sought is reasonably necessary to achieve a commercially reasonable business purpose. Support for any research or clinical study cannot be provided with the requirement or expectation that MPO's support will induce or encourage the purchase or order of MPO products.

Additionally, there may be requirements unique to clinical collaborations that involve international HCPs. If you are involved in such a clinical collaboration and have questions, please address your questions to the Compliance or Clinical Department.

When MPO contracts with a healthcare institution for research, the research relationship should be clearly spelled out in a written contract and approved by the Legal Department that, at a minimum, includes:

- A statement of the research or clinical objectives;
- A comprehensive written formal contract between the institution and MPO including a research protocol specifying the equipment, services and supplies, and/or monetary support to be provided by MPO to the institution;
- Identities of the principal investigator(s);
- Handling of intellectual property rights;
- Milestone timing;
- Relevance to MPO;
- A written budget at fair market value detailing the financial and other support to be provided by MPO;
- A requirement for progress reports and, where applicable, a final written report.
- Adverse event reporting requirements.
- Full disclosure shall be made to relevant regulatory authorities and the contracting partner shall acknowledge MPO's support in all oral and written presentations of the results.

The proposed research must be evaluated by and any resulting research agreements must be negotiated and managed by MPO employees who have no role in selling products or services to the research institution. Such negotiations are reserved for the Clinical, Legal and Compliance Departments.

Recipients of MPO's financial support for research and clinical studies should be made aware that MPO reserves the right to audit the use of its money and will expect documentation, such as progress reports, to show that its financial support has been used properly.

MPO may not sponsor or authorize clinical research that is not intended to, or does not, develop clinical information concerning MPO products. MPO may not compensate a clinical investigator based on the volume or value of business generated or to reward him/her for past purchases. MPO cannot seek to further the pre-approved or unapproved use of MPO devices under the guise of a less-than-adequate study.

MPO may not retroactively contract or pay for clinical services. For example, if an investigator approaches MPO and claims to have data on MPO products, MPO cannot compensate the investigator for prior work. However, MPO may engage the investigator to perform a retrospective study at the fair market value for reviewing files and compiling data.

“Investigators’ Meetings,” where MPO gathers people doing clinical research studies to discuss the status of their research, are not promotional in nature and must not be utilized for such purposes. These may occur in the country where the Business Unit and/or factory are located. Travel expenses for investigator travel to such destinations may be paid by MPO (consistent with travel expense policies. See Compliance Manual Section 17, “MPO-Sponsored Product Training & Education Events”, for further information regarding travel policy), provided the purpose of the travel legitimately serves existing Master Research Agreement activity. Sales representatives must not attend such meetings.

## 24. PURCHASING DATA FROM CUSTOMERS

This section describes the circumstances under which MPO may purchase data from customers. MPO may purchase data that is necessary for reasonable business purposes, such as to support the marketing of MPO products or to demonstrate safety and efficacy. This section prohibits purchasing data from a customer or potential customer if any one purpose of the data purchase is to encourage the purchase, use, or recommendation of MPO products, as this could constitute a violation of international, national, or local country anti-corruption laws, regulations, and professional codes of conduct of the country where the HCP is licensed to practice. Any data purchase must be at fair market value for data actually used by MPO.

### **Acceptable Data Purchases**

Data purchases include any compiled information offered by a customer that may have commercial value, such as product utilization information. Permissible data purchases and other arrangements are those designed to (1) foster increased understanding of scientific or clinical issues in order to improve patient care, and/or (2) provide information not otherwise available to MPO in areas relevant to MPO's business activities. MPO must have a legitimate need for the data and, in fact, use the data for legitimate business purposes.

Any data that is purchased should be de-identified and/or maintain confidentiality in line with international, national, and local country privacy laws. Data must be purchased at fair market value, compared to data that is similar in quality and quantity. The Legal Department makes the final determination as to the reasonableness of fair market value.

### **Unacceptable Data Purchases**

The following are not permissible data purchases:

- Intended as a price term or given in place of a discount or price concession.
- Purchasing data already available to MPO or data that MPO does not intend to use.
- Contingent on the purchase of MPO product(s).
- Purchased at an inflated cost.
- Purchased separately if the data is already provided pursuant to another arrangement, such as an administrative fee arrangement.
- Designed to substitute for or subsidize activities that are a part of the customer's normal business expenses.
- Intended to provide information in areas that are not relevant to MPO's business.
- Intended to induce the customer to purchase or recommend MPO products.

All purchases of data from a MPO customer must be supported by: 1) a documented business need for the data; 2) a written request from MPO for the data; and 3) a fully executed contract prior to the transfer of data. If a MPO customer provides data to MPO without an executed contract in place, MPO will not compensate the customer after the fact for the data.

All needs that result in requesting a customer or HCP Consultant to provide data must be approved by the ARC before contract drafting or a written request can be presented to the customer.

### **Record Retention**

The Accounts Payable Department will maintain the payment request package for a period of six years or longer as required by law or the Corporate Record Retention Policy. The Department requesting the data will maintain the data received for a period of six years or longer as required by law or the Corporate Record Retention Policy.

## **Audit**

All data purchases are subject to audit to ensure compliance with this section, including proper documentation, spending limits, and company spending policy. MPO may also choose to exercise the contract provision with the customer that allows review of the services purchased. Government authorities may also request to audit/review data purchases.

## 25. INQUIRIES ABOUT OFF-LABEL USES OF MPO PRODUCTS

MPO strictly prohibits promoting its products for uses not specified in our approved product labeling. In other words, the Company strictly prohibits promoting our products for unapproved or “off-label” uses. This includes providing healthcare professionals with verbal or written information relating to techniques or treatment outcomes. The prohibition exists even though some physicians have already decided, based on their own medical expertise, to utilize our product for these procedures. We as a company are governed by different rules than healthcare professionals. Sales representatives may not distribute information externally or internally, attempt to answer questions, or respond to inquiries about an off-label procedure. All inquiries, questions, and requests for information must be referred to the Research & Development Group by submitting a Customer Inquiry Form. Alternatively, a Company Representative may directly contact a member of the Regulatory Affairs Department if the question raised is specific to a product’s labeling or registration.

### **Procedures**

If a discussion of an off-label use is initiated by anyone outside MPO, employees may confirm with the Regulatory Affairs Department whether MPO is aware of that use, but they must then advise the inquirer that MPO policy prohibits them from discussing off-label uses. The employee should refer the inquiry to the Regulatory Affairs Department by providing to the requestor the telephone number or email of the Director of Regulatory Affairs. Alternatively, the question can be documented in a Customer Inquiry Form, which will be sent to Research & Development. Regulatory Affairs will be contacted if necessary to address the question raised in the form.

### **Additional Guidance**

**Soliciting Discussion:** It is against MPO policy for a sales representative to hand an article discussing approved or unapproved uses to a doctor or purchasing agent with the intent of eliciting inquiries related to unapproved use. Similarly, MPO representatives may not encourage off-label discussion at events such as doctor dinners or “plant” questions in the audience that are likely to lead to an off-label discussion.

**Budget or quotas:** Budget or quotas are not to be construed as an instruction to promote unapproved uses.