



Modi-Mundipharma Pvt. Ltd.

Modi-Mundipharma Anti- Corruption Policy [“MMACP”]

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Modi-Mundipharma Private Limited

Modi-Mundipharma Anti-Corruption Principles (MMACP)

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Foreword

Modi-Mundipharma Private Limited, (hereinafter referred to as “MODI-MUNDIPHARMA”) is committed to the highest standards of integrity and complying with applicable legal and ethical values.

MODI-MUNDIPHARMA acts in a heavily regulated business environment, and its activities often require significant interactions with Government Officials (hereinafter referred to as “GOs”) and Healthcare Professionals (hereinafter referred to as “HCPs”) worldwide. A variety of legal and ethical standards apply to these activities. The MODI-MUNDIPHARMA is committed to conducting their business in a compliant manner that meets all of the different applicable rules and standards.

As such, MODI-MUNDIPHARMA has adopted Anti-Corruption Guidelines (the MODI-MUNDIPHARMA Anti- Corruption Principles “MMACP”) which supplements the MODI-MUNDIPHARMA Promotional Practices Principles (M3P) and the MODI-MUNDIPHARMA Code of Business Ethics.

The following Principles demonstrates that MODI-MUNDIPHARMA strives to achieve highest compliance with international rules and regulations on payments to any third party, in particular GOs, including (but not limited to) the U.S. Foreign Corrupt Practices Act (the “FCPA”), the U.K. Bribery Act and similar laws implementing the Organization for Economic Co-operation & Development (OECD) Convention on Combating Bribery of Foreign Public Officials in International Business Transactions (hereinafter referred to as “International Anti-Corruption Laws”). However, all national, more stringent, laws and regulations will take precedence.

International Anti-Corruption Laws usually set forth liability of both the provider of corrupt payments and the recipients of such payments. As such, these Principles strive to not only protect the interests of MODI-MUNDIPHARMA and its employees, directors and officers but to also protect the interests of MODI-MUNDIPHARMA’s business partners, especially those of HCPs. Violations of these Principles will be ground for disciplinary action.

Please note that MODI-MUNDIPHARMA may revise any part of the MMACP anytime when deemed necessary or required by changes in law.

1. Introduction

1.1 Purpose

These Principles have been adopted to further compliance with the MODI-MUNDIPHARMA Code of Business Ethics as well as M3P, specifically to help ensure compliance with the prohibition on improper payments to any third party, in particular to GOs and HCPs.

Beyond Anti-Corruption Laws, the activities of the MODI-MUNDIPHARMA are governed by a broad range of other legal, regulatory and private standards, including:

- Country laws governing the advertising and promotion of medicinal- and medical device products
- Country laws governing the public tender process
- Country laws governing fair competition/anti-trust issues
- The IFPMA Code (International Federation of Pharmaceutical Manufacturers & Associations) and corresponding country codes
- Other relevant codes

These Principles set forth our commitment to preventing and detecting bribery and corruption of all types, and set the basic standards for our interactions with all third parties.

1.2 Scope

Adherence to the content of these Principles is the responsibility of all employees, directors, managers and officers of MODI-MUNDIPHARMA and any Intermediary acting on its behalf. Furthermore, these Principles apply to each:

- Employee of MODI-MUNDIPHARMA regardless of level or seniority;
- “**Third-Party Intermediary (TPI)**” (as defined in section 2.2 below) conducting business on behalf of MODI-MUNDIPHARMA; and
- Business relationship with third parties in both the private and public sectors (the latter including GOs (as defined in section 2.1 below) and in particular HCPs).

These Principles are intended to supplement all national and international legislation and applicable industry codes. Where local laws or regulations or codes of conduct to which we ascribe are more stringent or specific than the provisions of these Principles, the stricter standards apply and must always take precedence. Otherwise the rules and standards established in this document must be strictly followed, unless a written exception has been granted according to the “Exceptions Process” (as defined in **section 6.** below).

2. Definitions

2.1 Identification of Health Care Professionals (HCPs) and Government Officials (GOs)

Before entering into business transactions it is essential to understand with whom MODI-MUNDIPHARMA is about to do business.

MODI-MUNDIPHARMA does not distinguish between government (public) officials (GOs) and employees of private sector organizations so far as bribery is concerned, however, it is important to recognize that government officials are often subject to additional rules and restrictions that do not apply to persons who operate in the private sector.

Any relationship with GOs must be in strict compliance with the rules and regulations to which they are subject (i.e. any applicable rules or regulations in the particular country relating to GOs or that have been imposed by their employer) and any benefit conveyed to a GO must be fully transparent (and might be subject to his employer’s approval), properly documented and accounted for.

MODI-MUNDIPHARMA is differentiating between 3 (three) important business partner categories:

- Category 1: HCP
- Category 2: HCP-GO (HCP, who because of his/her particular responsibilities, will be considered to be a GO under US- or International Anti-Corruption Laws, even if under local law that HCP is not considered a GO)
- Category 3: GO as defined under the respective local law (including one who may be a HCP)

I. Identification of HCPs

MODI-MUNDIPHARMA must determine whether or not an individual or entity is a HCP or GO (US or outside of US) before committing to enter into any transaction with that individual or entity. For the purpose of these Principles, a HCP is defined as:

- a) Physician
- b) Any other individual, institution, or entity that has the ability to prescribe, dispense, acquire, or influence the prescription or acquisition of the MODI-MUNDIPHARMA products and/or services at issue, which are
 - i. Regulated or registered as medicinal products or medical devices in the applicable country; or
 - ii. Subject to reimbursement by government or third parties.

II. Identification of HCPs who are considered GOs (HCP-GO)

The definition of a GO includes any official or employee of a government agency or other governmental unit, political party, party official or candidate, or public international organization. The US Department of Justice has concluded that officers and employees of government-owned companies, or companies substantially controlled by such governments, are also GOs.

They have therefore interpreted the FCPA to apply to HCPs who are employed by or acting on behalf of a health care entity, if that entity is owned or controlled by a government body. Examples would include HCPs who work at public hospitals or public universities. MODI-MUNDIPHARMA is obliged to consider these HCPs as GOs – even where they are not considered GOs under local law.

III. Identification of GOs and Government Employees

The laws and regulations that govern interactions with GOs and Government Employees may vary by local jurisdiction, by regulating entity within the government, and sometimes by the seniority or status of the Government Employee. In some cases, it may be difficult to determine whether an individual is a GO or Government Employee. Because this determination is essential, MODI-MUNDIPHARMA must determine to the extent possible whether proposed interactions are with GOs or Government Employees.

As a general rule, GOs include any individual:

- Encountered while working at a government facility (a definition that includes but is not limited to Ministries of Health, product and pricing regulators, military hospitals, government or publically run hospitals);
- Representing himself or herself as a GO, for example, a customs official, inspector, auditor, investigator, elected official, or employee of a government ministry or agency. Note that this definition includes agents or employees of some non-governmental organizations where those organizations perform quasi-governmental services such as distribution of drugs and medical devices or delivery of health care services;
- Who is an agent or consultant to a government agency;
- Who provides a primary business address at a government facility;
- Who supplies an e-mail address associated with a government entity;
- Who uses a military title or rank;

- Who is otherwise known or believed to be a government or public employee.

Health Ministries and government-owned hospitals often employ HCPs who may be GOs under local law. Sometimes a private HCP may provide consulting services or otherwise act as an agent of the government. These individuals should be considered GOs for the purpose of these Principles.

2.2 Third Party Intermediary (TPI)

A TPI is any party retained to represent MODI-MUNDIPHARMA in respect of any transaction or relationship with an end customer or any other third party.

Where possible and feasible, MODI-MUNDIPHARMA should conduct all payment related activities with any third parties directly and not through Intermediaries. Where direct payments to third parties are not possible or not feasible, MODI-MUNDIPHARMA might use a TPI to conduct business. TPIs that interact or transact business with HCPs and/or GOs on MODI-MUNDIPHARMA's behalf ("in-scope TPIs") require additional due diligence measures as described in **section 4.2** below.

Intermediaries under these Principles shall be classified into the categories "High Risk TPIs" and "Low Risk TPIs"; examples for Intermediaries belonging to the category "high risk" may include, depending on the (contractual or factual) circumstances:

- Distributors/Agents;
- Lobbying agencies;
- Regulatory consultants;
- Intermediaries that may have a significant interest (direct or indirect) to influence HCPs (especially GOs) in order to meet contractual obligations (e.g. distributors and Clinical Research Organizations (CROs)); or
- any party acting on behalf of MODI-MUNDIPHARMA to secure or maintain registration, pricing or reimbursement of MODI-MUNDIPHARMA products.

3. Underlying Anti-Corruption Key Principles

Many countries throughout the world have adopted laws, rules, regulations or codes of conduct that shall prohibit companies from engaging in any corrupt practices, including but not limited to paying bribes to (foreign or domestic) GOs, HCPs or other third parties in the private sector for the purpose of obtaining or retaining business.

In accordance with the International Anti-Corruption Laws, no MODI-MUNDIPHARMA employee, director, officer or Intermediary may "corruptly" offer, pay, promise to pay, reward or promise to reward or authorize the giving of anything of value ("payments"), directly or indirectly, to any third party for the purpose of:

- Persuading, inducing or influencing any act or decision within the scope of authority of that third party, including (but not limited to), if applicable, selecting which products to purchase, prescribe or use;
- Persuading, inducing or influencing such third party (1) to do or refrain from doing any act in violation of his or her lawful duty or (2) to abuse his or her position to influence any act or decision;

- Securing any improper advantage; or
- Giving unwarranted benefits or preference to such third party.

Such payments are prohibited without regard to the question whether there is a pending, a future or a concluded business matter between MODI-MUNDIPHARMA and the third party.

A “corrupt” payment is one made with an improper motive, involving the intent to achieve an unlawful objective or to achieve a lawful objective through unlawful means.

This Principle applies to any direct relationship (MODI-MUNDIPHARMA - third party) or indirect relationship (MODI-MUNDIPHARMA - Intermediary - third party).

These Principles also prohibit MODI-MUNDIPHARMA employees, directors and officers from receiving corrupt payments in connection with MODI-MUNDIPHARMA’s business as further set forth in MODI-MUNDIPHARMA’s Code of Business Ethics.

In other words, MODI-MUNDIPHARMA will not offer, promise or provide any inducements, such as payments or other things of value or perceived value. The key principles can be summarized as follow:

- No Inducements in any of our business transactions or interactions;
- Legitimate Purpose and proper motive for everything we do;
- Transparency and Documentation of all interactions with third parties (especially HCPs, GOs);
- Reasonableness of Value, Amount and Frequency.

3.1 General Rules

MODI-MUNDIPHARMA enters into a wide variety of scientific, sales, promotional and marketing arrangements with both public and private entities and individuals (including HCPs). A broad range of laws and regulations aimed at preventing bribery and corruption exist, and the MODI-MUNDIPHARMA must always comply with these. Under these laws and regulations, the terms GOs and HCPs have specialized meanings that are defined in **section 2.1**.

As not every business situation can be captured in a policy, MODI-MUNDIPHARMA has created a set of principles that provide general guidance for business situations and activities that are not specifically described in an existing policy or other guidance document.

These Principles need to be observed in direct and indirect interactions (i.e. through a third-party) with individuals or entities.

1. Totality of the Circumstances: Consider the Entire Relationship

The appropriateness of a specific interaction between a HCP or GO and MODI-MUNDIPHARMA must be considered in light of the entire relationship. An individual service to a HCP or GO may be permissible in isolation or as a standalone transaction, but may raise questions if there are other significant financial ties with that HCP or GO and MODI-MUNDIPHARMA.

2. Potential to influence MODI-MUNDIPHARMA product sales

The more ability a HCP or GO has to influence the use or sale of MODI-MUNDIPHARMA products or services, the more scrutiny the relationship should receive.

3. Fair Market Value

In all transactions, it is important to ensure that the amount of compensation is consistent with the Fair Market Value (FMV) of the products or services provided.

4. Nature of Activity

Funding and support activities provided to third parties (especially HCPs or GOs) should result in a verifiable benefit or interest to MODI-MUNDIPHARMA (other than increased product sales or increased prescription of MODI-MUNDIPHARMA products).

5. No Reliance on Product Recommendations

Arrangements may not depend on the HCP's or GO's agreement or promise to purchase or recommend the use of MODI-MUNDIPHARMA products and services.

6. No "De Minimis" Transactions

Under the US FCPA and most other Anti-Corruption Laws, there is no "de Minimis" rule or exception for small funding amounts. Nevertheless, the greater the value provided to a HCP or GO, the greater the degree of care that must be taken when considering the proposed arrangement.

7. Unfair Competition

Arrangements which could provide unfair competitive advantages or which otherwise hinder competition may raise concerns. The Legal- or Compliance Department should be consulted on any anti-competitive concerns.

8. Accurate Documentation and Recordkeeping

MODI-MUNDIPHARMA must maintain sufficiently detailed documentation to meet legal requirements and other applicable policies and standards (e.g. tax, accounting, etc.). As such, each transaction entered into by MODI-MUNDIPHARMA must have proper supporting documentation, internal authorization and approval. All expenditures, including (but not limited to) expenditures for gifts or business entertainment, must be accurately reported and recorded, and all accounting records, expense reports, invoices, vouchers and other business records must be accurately completed and properly maintained. False or misleading entries and undisclosed or unrecorded payments or accounts are strictly prohibited, as are any acts intended to circumvent or frustrate the operation of MODI-MUNDIPHARMA's internal accounting controls and Internal Audit Function ("IAF").

9. Substance Prevails over Form

The real intent of an interaction will always determine the applicable rules. MODI-MUNDIPHARMA employees may not try to avoid complying with applicable rules by changing descriptions of interactions and arrangements.

10. MODI-MUNDIPHARMA Liability

MODI-MUNDIPHARMA and its employees do not protect themselves from liability by acting through third parties. In case that a conduct would be improper or illegal, if done directly, MODI-

MUNDIPHARMA would be held liable for the same conduct performed by a third party (i.e. TPI, Sub-TPI, etc.) on its behalf.

Also, employees cannot undertake an impermissible payment or activity by using their personal funds or acting during non-working hours.

11. Transparency

In order to comply with existing transparency requirements, MODI-MUNDIPHARMA should, where applicable, provide prior written notification to a HCP's supervisor, manager, or other designated authorities, fully disclosing the purpose and scope of the interactions and obtain prior written approval, where required by local laws or other applicable regulations.

3.2 Ensuring Fair Competition

MODI-MUNDIPHARMA accepts that not all competitors will necessarily adhere to the same standards. The failure of other companies to compete lawfully and ethically does not excuse similar conduct by our company. In cases that you become aware of other companies misconduct that may place MODI-MUNDIPHARMA at a significant competitive disadvantage, please bring the matter to the attention of the MODI-MUNDIPHARMA Legal- or Compliance Department.

4. Process and Procedures

4.1 General Information

Interactions between MODI-MUNDIPHARMA and any third party (especially GOs) of the sort addressed in this document (i.e. interactions involving possible payments to or on behalf of such third parties) must always comply with rules set forth in this document and M3P. Where appropriate, a Business Unit may develop its own formal written Standard Operating Procedures (SOPs) to address special circumstances applicable to that Business Unit, provided that this SOP is meeting all of the requirements set forth in this document (MMACP) or has been approved through the exception process as described in **section 6**.

4.2 Third Party Intermediaries (TPIs)

There are a number of situations where MODI-MUNDIPHARMA has to conduct business via TPIs for a variety of reasons (i.e. no direct operations of MODI-MUNDIPHARMA are available in a country, etc.). Typically TPIs represent or act on behalf of MODI-MUNDIPHARMA for specific purposes.

Where MODI-MUNDIPHARMA conducts business through TPIs, it will oblige the TPI to continually report to MODI-MUNDIPHARMA on their interactions with third parties on behalf of MODI-MUNDIPHARMA in sufficient detail, focusing especially on payment activities.

However, improper behavior of TPIs may be attributed to MODI-MUNDIPHARMA and may thus expose MODI-MUNDIPHARMA to liability. Therefore, caution should be applied when selecting a TPI. TPIs that interact or transact business with HCPs and/or GOs ("in-scope TPIs") require additional due diligence measures as described in below.

4.2.1 Scope and Frequency of Due Diligence

In-scope TPIs, as defined under **section 2.2**, include but are not limited to:

- Sales Intermediaries (including distributors)
- Logistics Intermediaries, including freight forwarders and customs brokers
- Tender Intermediaries or advisors
- Lobbyists/lobbying agencies
- Contract/Clinical Research Organizations (CROs)
- Regulatory consultants
- Event planners
- Travel agencies
- Media agencies
- Market research organizations
- Other functions that present significant corruption risk

MODI-MUNDIPHARMA must conduct a careful substantive review and evaluation of the proposed TPIs and its key employees.

A full due diligence is required only for in-scope TPIs which includes a full background check by open sources and by the used databases (e.g. Dow Jones Risk and Compliance Data Base or similar data bases).

For other third parties that do not fall into the group of in-scope TPIs a reduced due diligence (“Due Diligence Light”) may be conducted.

Full due diligence on TPIs must be updated periodically, at least every 3 (three) years, with recertification every year in between.

Due Diligence on TPIs should also be updated:

- Whenever there is a major change in the ownership or organization of the TPI (e.g. a merger with or acquisition by another company, a change in chief executive or bankruptcy, etc.),
- when there is a substantial change in the nature or geographic scope of work performed by the TPI, or
- Significant change in the use of Sub-Intermediaries to complete such work.

4.2.2 Use of Sub-Intermediaries

On occasion, a TPI engaged by the MODI-MUNDIPHARMA will itself engage one or more Sub-Intermediaries to interact with HCPs or GOs in connection with MODI-MUNDIPHARMA products or services. Unless prohibited under local law, MODI-MUNDIPHARMA will perform due diligence on “Covered Sub-Intermediaries”, defined as follows: “Covered Sub-Intermediary” means a Sub-Intermediary that has a substantial or important role in the overall arrangement for services, to be determined by an assessment of factors including whether:

- a) MODI-MUNDIPHARMA has a direct role in the selection, approval, management or supervision of the Sub-Intermediary or

- b) The Sub-Intermediary performs or is expected to perform a significant portion (approximately half or more) of the primary, Intermediary’s contractual obligations to the MODI-MUNDIPHARMA or
- c) The Sub-Intermediary generates or is expected to generate a significant portion (approximately half or more) of the primary Intermediary’s overall revenues.

These listed factors are not exhaustive and other relevant or unique aspects of a Sub-Intermediary’s relationship with the primary Intermediary and/or MODI-MUNDIPHARMA may be considered to determine an entity’s status as a potential “Covered Sub- Intermediary.”

4.2.3 Management of TPIs and covered Sub-Intermediaries

Effective management of TPIs and Covered Sub-Intermediaries within the scope of this document requires MODI-MUNDIPHARMA to have adequate processes and procedures including:

- An up-to-date inventory of TPI Relationships
- Risk based categorization of in-scope TPIs
- FMV Assessment for each Intermediary category (and in case of FMV change compared to previous years)
- Documentation of Due Diligence Review
- Escalation procedure for “red flags”
- Appropriate Review and Approval Processes
- Written Agreement for each TPI retained (incl. appropriate Anti-Corruption clauses and a hand-out of these Principles)
- Training programs, including training certifications
- Testing-, Monitoring- and Oversight-Plans (risk based)
- Appropriate Documentation and Recordkeeping

4.2.4 Cross-Border Interactions

Many laws, regulations, or industry codes applicable to HCP interactions have extra-territorial application. Therefore, when an arrangement is made between parties located in different countries, one or more regulations may apply to the interacting parties. An assessment of the laws, regulations, and industry codes for all countries involved in a particular interaction is necessary. No two cross-border situations are alike; therefore MODI-MUNDIPHARMA has established the following general rules for cross-border situations:

In the case of a MODI-MUNDIPHARMA organizing an event outside its home country, the primary organizing company is responsible for ensuring compliance of the event with applicable rules of all respective countries. That responsibility includes ensuring compliance of the event in the country in which it occurs, and ensuring that each invited attendee complies with her/his own country’s laws and codes of conduct.

- A cross-border process should be established that outlines responsibilities of MODI-MUNDIPHARMA.
- MODI-MUNDIPHARMA that is the primary organizer should also be the company entering into the contract with all third parties.

- Templates approved by the Legal Department must be used.
- Payments and reimbursements must be reasonable and in line with prevailing market rates (FMV), and only for services actually provided.
- Determination of the Fair Market Value (FMV) must be performed prior to event and the fee must be based on the applicable country's FMV guidelines.

4.2.5 Tender Procedures

MODI-MUNDIPHARMA shall not make or offer any payment in value or in kind to any GO, either directly or indirectly, in order to obtain a favorable treatment in the tender process.

I. Introduction

In many countries, national, regional, or local health authorities (e.g. public hospitals) purchase medicinal- and/or medical device products through a public procurement process (“tenders”). Tenders typically are made through a formal bidding process, in which a number of companies submit offers for products and related services to the purchaser.

Employees of the purchasing authorities or institutions (including the individuals managing the bidding process) that are owned or operated by national, regional, or local governments, are considered GOs under this document and local Anti-Corruption Laws. In certain jurisdictions, HCPs are appointed to represent the government authorities or institutions in the tender processes or otherwise participate in the process. These HCPs must also be considered GOs for these purposes.

MODI-MUNDIPHARMA and its employees may not seek to improperly influence the decisions of tender committee members. Furthermore, MODI-MUNDIPHARMA should require from all consultants to disclose whenever they attain a position to influence purchasing decisions of their employers (e.g. becoming member of a tender committee). Where such disclosure is not permitted MODI-MUNDIPHARMA must request the consultant who attains such position to fully disclose the financial relationship with the MODI-MUNDIPHARMA to their employer or tender committee who may take decisions on the purchase of MODI-MUNDIPHARMA products.

II. Tender Specifications and other Tender Conditions

In the pre-tender phase, no incentives may be offered or promised by MODI-MUNDIPHARMA. Only objective information that is directly responsive to the specific requests made, may be provided to the tender authority.

The principles of transparency, non-discrimination, and equal treatment need to be respected at all times. Once the tender notice is published, interactions with the tender authority should be done under full transparency with guidance from the Legal- or Compliance Department.

III. Product-Related Items and Services in Tenders

In some settings, tender authorities request additional services, which will be taken into account by the authorities to determine the best offers. In a “closed” tender (i.e. a tender where all specifications on product and requested services are determined by the tender authority), MODI-MUNDIPHARMA can include in its bid the services requested. In closed tenders, the conditions are the same for all bidders, and there is no room for negotiation. If unsure about the nature of the tender, please consult with the MODI-MUNDIPHARMA Legal- or Compliance Department.

In an “open” tender (i.e. a tender where the specifications for products are determined and additional services are requested by the tender authority but are not specified), MODI-MUNDIPHARMA may offer only those ‘additional’ services (so-called VAS: Value Added Services) that meet the requirements of this document. That is, they must be closely related to provision of the MODI-MUNDIPHARMA product and meet the other criteria set out in **section 4.2.5 V**. All services must be transparently disclosed during the tender process.

IV. Tenders and Anti-Trust Rules

MODI-MUNDIPHARMA must not enter into any discussions, or agree or collude with any other bidder(s) on whether or not to bid on a tender or agree on terms and conditions of a bid. This practice is also known as “bid rigging” and in most jurisdictions may result in criminal prosecutions and sanctions under anti-trust rules.

V. Product-Related Items and Services

Product-related items and services are sometimes referred to as value-added services in the context of tenders (see section III above).

The rules described in this section apply in the context of open tenders (i.e. where additional product or service offering is requested but not specified) and in general product sale situations.

MODI-MUNDIPHARMA may provide various forms of product-related items and services as part of their marketing and sales activities. Services or items that provide a general benefit to the customer or HCP, such as practice management consulting or office equipment, (e.g. copy machines or PCs) may not be offered for free or below market value cost.

Acceptable product-related items and services must meet all of the following six cumulative criteria:

(i.) Close relationship

A product-related item or service must be closely related to the specific MODI-MUNDIPHARMA product(s) that is being sold to the customer. For example, a product-related item or service may consist of patient educational materials about a disease that the MODI-MUNDIPHARMA product is being used to treat.

(ii.) Normal overhead

A product-related item or service must fall within a MODI-MUNDIPHARMA normal marketing and sales expenses and should not be a cost that the customer usually pays as part of its overhead.

(iii.) Modest cost

The overall value of the product-related item or service must be modest in comparison to what the customers pay for the MODI-MUNDIPHARMA product being sold.

(iv.) Available without charge to all customers

An appropriate no-charge product or service must be available to all customers in a particular class without charge by MODI-MUNDIPHARMA. This means that the product-related item or service may not be substantially different for one customer in a class than another.

(v.) **No provision of Services that are not solely related to MODI-MUNDIPHARMA Product**

A product-related item or service may not customarily be performed by the customer's employees and may not serve to shift financial risk from the customer to the MODI-MUNDIPHARMA and/or to government payors.

(vi.) **Not otherwise offered for Sale**

A product-related item or service may not be provided to a customer or HCP in connection with MODI-MUNDIPHARMA products for free, if MODI-MUNDIPHARMA sells that same service to other customers for a price. Similarly, the company may not offer an item or service that another company typically sells for a price to that customer or HCP, such as office equipment, advertising or promotional services.

4.3 Interactions with Third Parties

In all cases, interactions between MODI-MUNDIPHARMA, or TPIs acting on behalf of MODI-MUNDIPHARMA, and HCPs, HCP-GOs and GOs (e.g. distributors or their employees, GOs etc.) must be consistent with local laws and regulations, applicable industry association codes, the MODI-MUNDIPHARMA Code of Business Ethics and other applicable MODI-MUNDIPHARMA principles and policies, including M3P, and any applicable local MODI-MUNDIPHARMA procedures.

Where a conflict in rules exists, the most stringent rule applicable in such a case shall prevail. In addition, the following requirements generally apply to the more common types of such interactions:

4.3.1 Travel and Hospitality

Expenditures associated with travel, hospitality, meals or entertainment for third parties (e.g. HCPs) must generally meet the following criteria:

- (i.) Be directly related to a legitimate business-, medical- or scientific exchange but secondary to the promotion, demonstration or explanation to a third party of MODI-MUNDIPHARMA products or services or the execution or performance of a contract with or for a third party;
- (ii.) With respect to accommodation, be provided in hotels of not higher than good international quality, i.e. without luxury status (necessary cost of accommodation; adequate and appropriate accommodation);
- (iii.) With respect to meals, be of good quality and quantity, but must not be excessive; lavish meals are not permitted;
- (iv.) With respect to entertainment, not to be offered at all, i.e. neither in connection with meals/refreshments (except for minimal performance, e.g. background music) nor as stand-alone entertainment or leisure activity, e.g. golfing, theatre, sight-seeing, sports events etc.;
- (v.) Not be made with such frequency or regularity as to undermine the objectives of these Principles or create an appearance of impropriety;
- (vi.) If required by local law, for anything other than meals, be preceded by notice to the employer or supervisor of the person(s) being offered travel or hospitality (in certain circumstances, it may be necessary to require written acknowledgment from a relevant

government employer) detailing the exact monetary value of the offered travel or hospitality;

The receipt of the notice by the employer or supervisor must be evident and documented, e.g. by signature of the employer or supervisor on the notice or by registered mail;

- (vii.) Not include the sponsorship or provide logistical support for spouses, family members or other guests;
- (viii.) Not include paid or reimbursed unjustifiable stopovers or travel extensions. Generally, travel and accommodation support given by MODI-MUNDIPHARMA to HCPs should be tailored to the duration of the event. However, where the travel expenses incurred are significantly reduced by the HCP travelling at alternate times, the travel arrangements may be extended to the next available cost-efficient date. Any additional expenses (i.e. accommodation, meals etc.) relating to the extended stay must be covered by the HCP.
- (ix.) With respect to travel and lodging expenditures, not be made directly to the third party in the form of up-front payments. Where possible, travel arrangements should be made by pre-paid tickets and lodging paid for directly by MODI-MUNDIPHARMA. In the case of GOs, if prepaid travel arrangements are not feasible, MODI-MUNDIPHARMA should, where possible, reimburse the relevant government employer rather than the GO. Per diem payments (i.e. specific amounts of money, checks, gift certificates, and other cash equivalents that are given to third parties to spend per day, to cover lodging and travelling expenses) are generally not permitted; and
- (x.) Be properly recorded and adequately documented.

4.3.2 Conferences and other Sponsorships, Honoraria and Grants

Expenditures associated with hosting conferences and sponsorships or paying honoraria and grants that could result in payments to, for the benefit of, or at the request of a third party should meet the following criteria:

- (i.) A sponsored third party must have relevant expertise;
- (ii.) The sponsorship must not include spouses, family members or other guests of such third party. Only the sponsored third party may benefit from the payment, logistical support or sponsorship;
- (iii.) If required by local law, the sponsorship must be preceded by notice to the employer or supervisor of the sponsored individual as set forth in **section 4.3.1 (vi.)** above;
- (iv.) Any travel arrangements must meet the requirements set forth in **section 4.3.1** above;
- (v.) Program registration fees and the like should generally be paid directly to the organization hosting the event; and
- (vi.) Must be properly recorded and adequately documented.

4.3.3 Engaging Services of Third Parties

Any engagement by MODI-MUNDIPHARMA of the services of a third party (e.g. as a clinical investigator, research collaborator, speaker or consultant) must:

- (i.) Stem from a legitimate need for the service, with such services provided by someone qualified to meet such need;
- (ii.) Involve remuneration commensurate to the services provided;
- (iii.) If required by local law, be preceded by notice to the employer or supervisor of the person(s) whose services will be engaged as set forth in **section 4.3.1 (vi.)** above;
- (iv.) If involving travel, lodging or other expenditures, should be in conformity with the parameters outlined in this **section 4.3.1**; and
- (v.) Should be properly recorded and adequately documented.
- (vi.) Heightened sensitivity is merited in situations in which MODI-MUNDIPHARMA seeks to engage the services of a GO that is involved in awarding business to, or influencing government action with respect to, MODI-MUNDIPHARMA.

4.3.4 Medical Ghost-Writing

Special attention shall be given to so-called “medical ghost-writing”, i.e. where pharmaceutical companies pay professional writers or agencies to produce scientific papers and then include the name of one or more HCPs in the list of authors of these papers before they are published in medical or scientific journals. Such practices are prohibited. For any kind of activities related to the development and approval of scientific information from MODI-MUNDIPHARMA sponsored clinical studies or other research performed by or under the direction of MODI-MUNDIPHARMA for publication in scientific journals/books and/or communication at scientific meetings shall be as per the rules set forth in the applicable SOP.

4.3.5 Gifts and Promotional Items

Gifts and promotional items offered or given to third parties must:

- (i.) Not be given to GOs as defined under the respective local law;
- (ii.) Not be offered in explicit or implicit exchange for specific favors or benefits from the recipient (in his or her public or private capacity) or from his or her employer;
- (iii.) Not be offered or given by reason of the position or office of the recipient;
- (iv.) Never include cash payments, checks, gift certificates or other cash equivalents;
- (v.) Be modest and reasonable in frequency, quantity and value (on specific occasions as well as in the aggregate);
- (vi.) If at all possible, bear the MODI-MUNDIPHARMA company logo as a general promotion gift;
- (vii.) Be properly recorded and adequately documented and
- (viii.) In accordance with applicable local laws, regulations and industry codes of conducts.

4.3.6 Grants to Public Institutions

Please refer to **M3P section 7.2**.

4.3.7 Political Contributions

In most countries, the activities of corporations in the political process are strictly regulated. As such, no corporate funds, facilities or services of any kind may be paid or furnished to any political candidate for public office, to any political party or to any political initiative, referendum or other form of political campaign except in accordance with local law. All such expenditures must be approved in advance by the Legal- or Compliance Department.

4.3.8 Charitable Contributions

Charitable contributions are not to be used as a marketing tool with respect to specific customer transactions. Charitable contributions may only be awarded and paid to bona fide charitable organizations and beneficiaries, as determined by local laws.

MODI-MUNDIPHARMA must undertake appropriate due diligence with respect to officials, boards of directors, and membership of charitable organizations to ensure that such organizations are not substantially connected (or relatives of) to GOs or HCPs who may be in a position to influence the use of MODI-MUNDIPHARMA products.

In case that the requested contribution from MODI-MUNDIPHARMA constitutes a high percentage (50% or more) of a requestors' total annual budget, high scrutiny has to be applied. "Mono-sponsoring" of an organization, is normally not permissible (in case of questions, consult with your Legal- or Compliance representative).

The MODI-MUNDIPHARMA should have no control over the use of the funds by the charitable organization. MODI-MUNDIPHARMA must not make charitable contributions to organizations of a customer's or GO's choice or at their request.

4.3.9 Facilitation Payments

"Facilitating Payments" are small payments to a GO to expedite or secure performance of a routine governmental action that is non-discretionary, and for which a small payment is necessary to get or expedite the requested action. Even though this practice can be found in some cultures, Facilitating Payments are strictly prohibited.

5. Complying with these Principles

5.1 Violations of these Principles, Reporting and Investigation

Violations of these Principles may subject MODI-MUNDIPHARMA employees to disciplinary action, including termination. Violations of the laws underlying these Principles can give rise to criminal prosecution and possible monetary fines and imprisonment. MODI-MUNDIPHARMA employees, directors and officers are strongly encouraged to report any suspected or actual violation of these Principles in accordance with the procedures set forth in the MODI-MUNDIPHARMA Code of Business Ethics; Intermediaries must be contractually obliged to do so as well. Under no circumstances will a report of such information made in good faith be the basis for retaliatory action against the individual making the report. A report of any suspected or actual violation may be made anonymously to the MODI-MUNDIPHARMA Ethics Hotline to the extent permitted by local law.

5.2 Certification

In the annual Compliance Certification Statement, the undersigned shall certify, among other things, whether to the best of his/her knowledge company funds have been used to make improper payments to third parties, whether transactions have been accurately recorded and reported and whether the undersigned are aware of any unreported violations of these Principles and/or of MODI-MUNDIPHARMA's Code of Business Ethics.

5.3 Point of Contact for Questions or Concern

MODI-MUNDIPHARMA employees are encouraged to discuss, in a timely manner, with their supervisor and management questions or concerns that relate to issues covered by this document. The Legal- or Compliance Department is responsible for furnishing advice with respect to the interpretation of applicable laws and these Principles. The Legal- or Compliance Department shall also ensure that MODI-MUNDIPHARMA employees are informed and trained, as appropriate, with respect to these Principles. Upon notification of a suspected violation, they will ensure that an appropriate investigation is performed in accordance with the procedures set forth for such investigations and that remedial action is taken, if appropriate.

6. Exception Process

6.1 In General

The Principles established under this document might be more rigorous than what certain local laws require. From time to time, there might be circumstances that do not fit into the Principles established by this document or where further clarity is needed.

Where the rules described in this document are more stringent than local laws and regulations, the Principles should be regarded as binding on MODI-MUNDIPHARMA unless local laws or regulations expressly permit the activity. In circumstances where local laws or regulations expressly permit the activity in question, the practice is permissible upon completion of the required approval process described in this section.

It is generally not sufficient that local law or other standards are simply silent regarding the practice in question. In those circumstances, the practice is not permitted unless expressly approved following completion of the required approval process described in this section.

Exceptions should be rare and limited in time and scope and must be properly documented. "Standing exceptions" should not be authorized.

6.2 Authority to grant Exceptions

An exception to these Principles must be approved by Chairman of the Company.

A request for exception must have sufficient details (incl. requested business practice, rationale for exception request, custom in local market, etc.) and a written copy or reference of the local law/regulation expressly permitting the requested practice must be submitted as well.