Anti-Bribery and Anti-Corruption (ABAC) Policy

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1. Introduction

1.1. Purpose of the Anti-Bribery and Anti-Corruption Policy

The objective of this Anti-Bribery and Anti-Corruption Policy is to establish high standards of ethical conduct under which Arcera and its divisions and legal entities will interact with external stakeholders and Third Parties, in full compliance with applicable anti-bribery/corruption laws and regulations, including the US Foreign Corrupt Practices Act, the UK Bribery Act, respective national anti-bribery/corruption laws and relevant industry codes of conduct.

Arcera interacts with, and provides support for, healthcare professionals ("HCPs"), healthcare organizations ("HCOs") and patient organizations ("POs"), with the goal and intention of improving and investing in healthcare and benefiting patients. Moreover, raising awareness about diseases of interest to Arcera and educating HCPs about the safe and effective use of Arcera products, including the safety profile of our drugs, is an important and necessary role for Arcera personnel.

In addition, Arcera also interacts with key decision-makers in the healthcare industry such as health officials, payers and policy makers in order to gain more insights into unmet medical needs and patient care throughout a product's lifecycle or to advance topics of mutual interest. Some of these parties are Government Officials (GOs), and interactions with them carry a heightened risk of a perception of bribery or corruption. Moreover, HCPs working in public hospitals are considered GOs according to most anti-corruption laws.

In its day-to-day business, Arcera and its entities also interact with many other Third Parties, including vendors, suppliers, consultants, advisors, distribution partners, wholesalers, logistics partners and others. Arcera relies on its strong relationships with Third Party business partners in order to manufacture, market and distribute our medicines in the most impactful way possible. Many such business partners act as intermediaries for Arcera ("Third Party Intermediaries", "TPIs"), by interacting or transacting business on behalf of Arcera and representing Arcera's interests towards other Third Parties, including in certain cases Government Officials. This Policy sets forth the high ethical standards Arcera must follow when engaging and interacting with Third Parties, as well as the standards we expect our Third-Party Intermediaries to follow.

It is vital that Arcera personnel understand the guardrails for legitimate interactions and follow the highest standards of ethical conduct. This Policy is a critical component of ensuring such standards, thereby strengthening the basis for Arcera's collaboration with the healthcare community and other Third Parties.

1.2. Related Documents

The Policy must be read and interpreted in conjunction with the following internal control documents as well as with every other Arcera Legacy Companies' Policies which were not revoked:

Document Title
Code of Ethics
Conflict of Interest Policy
Global Legal Policy
Third-Party Due Diligence Procedure

1.3. Changes

This Policy may be subject to review at any time. The most current version of this Policy will always be available on Arcera's Intranet with other non-GxP control documents.

In case any control documents currently in effect conflict with any of the standards, principles or requirements set forth in this Policy, the terms of this Policy shall prevail.

2. Scope of Application

This Policy applies to Arcera and all entities that are directly or indirectly controlled by it (together, "Arcera") and all employees, directors, managers and officers of Arcera, (including temporary, part-time and contracted employees) as well as any External Service Providers.

Moreover, we shall take reasonable steps to ensure that our TPIs are conducting business on behalf of Arcera consistent with the principles in this Policy.

2.1. Deviations

Where local laws, regulations or industry codes of conduct to which Arcera is bound are more stringent than the provisions of this Policy, the stricter standards always apply. Contact Regional Compliance/Regional Medical Affairs (RMA) if in doubt or you need more information. Where the rules described in this Policy are more stringent than local laws and regulations or applicable industry codes, the Policy is binding on Arcera unless a deviation receives written approval from Global Compliance in advance, and as appropriate, Global Compliance may include Global Medical Affairs (GMA) in the approval process. A request for deviation must contain sufficient detail, including the requested business practice, detailed rationale for deviation, and summary

in English of applicable local law/code, and a written copy or reference of the local law/regulation expressly permitting the requested practice must be attached.

3. Definitions

Abbreviation / Acronym / Term	Meaning of Abbreviation / Acronym / Term
Arcera	ARCERA LIFESCIENCES L.L.C- O.P.C. and all affiliated entities and subsidiaries
Advisory Board	An Advisory Board is an insight-generating activity that involves the engagement of external experts/advisors by Arcera. It is a group of external experts convened by Arcera to get their professional advice and insights on a specific topic for which the expertise and knowledge are not available within the company. Advisors (experts in their areas) could be healthcare professionals (HCPs), payers, patients, representatives of patient associations, patient advisors and non-HCP specialists, e.g. Market Access specialists.
Arcera Product	In the context of this policy, these are prescription-only and over-the-counter (non-prescription) medicinal products, food supplements, medical devices or other products that are marketed, promoted, co-promoted, distributed, or handled by Arcera or on Arcera's behalf.
Bribery	Is the offering, promising, giving, accepting or soliciting of an advantage as an inducement or incentive to act in a certain way that is illegal or a breach of trust. An example of bribery is the giving of money in order to unduly influence the performance of the recipient's (or someone else's) professional duties or to obtain an undue business advantage.
Compliance (Regional or Global)	Compliance is the Arcera function that has primary responsibility for the management of integrity and compliance matters.
Discount	Is the offer to purchase a good or a service at a reduced price. Discounts are frequently used in "sales situations" and can appear in different forms, like "buy one, get one free" arrangements. Similarly, the provision of "free" consulting services in connection with the purchase of Arcera products is not considered "free", but a discount.

Donation	Donations are support provided to a charitable organization, non-profit organization or public entity such as a public hospital to further that organization's / entity's mission. Donations may be financial support or in-kind donation of items or services for charitable or humanitarian purposes, and always without commercial motive. A Donation is distinguished from a Grant in that the latter is connected to Arcera's mission to advance scientific progress, medical education and healthcare generally with the support going to a particular initiative, project or activity, while the former addresses broader humanitarian causes (e.g., support for disaster relief; acute public health needs) and may include unrestricted support, meaning that the support is not tied to a particular project/activity/event, but rather, is general support for an organization's mission.
External Service Providers	An External Service Provider is any third party, individual, or organization that is not employed by Arcera but is engaged to provide services or expertise and who work with an Arcera email address or are given access to our premises and/or IT systems. This includes, but is not limited to, consultants, contractors, agents, and other business partners who perform work or services on behalf of, or for the benefit of, Arcera.
Facilitation Payment	Is the payment of a relatively small amount of money or the granting of some other benefit to usually low-ranking government officials, for their own personal benefit, with the aim of speeding up the performance of an official act to which the person making the payment/granting the benefit is entitled.
Fair Market Value	Is defined as the price at which goods or services would be exchanged between a hypothetical willing and able buyer and a hypothetical willing and able seller dealing at "arm's length" in an open and unrestricted market, where both parties are fully informed of the relevant facts and have no external pressures to complete the exchange.
Fee for service	It is a negotiated payment made in exchange for the delivery of services of equal value.
Government Official (GO)	GOs include any official, employee, agent or consultant of a government agency or other governmental unit, political party, party official or candidate, or public international organization, as well as officers and employees of government-owned companies, or companies substantially controlled by such governments.

	Health Ministries and government-owned hospitals often employ healthcare professionals (HCPs) who may be Government Officials under local law; for purposes of this Policy, however, such HCPs who are GOs are treated as HCPs rather than as GOs. As a general rule, GOs include any individual: (a) encountered while working at a government facility, (b) representing themselves as a GO, such as a custom official, inspector, auditor, investigator, elected official or employee of a government ministry or agency, (c) who provides a primary business address or email address associated with a government facility or entity, (d) who uses a military title or rank, or (e) who is otherwise known or believed to be a government or public employee.
Grant	Grants are support (financial or in-kind) provided to a healthcare organization where Arcera gets no benefit in return and has no influence over the underlying project/event. The ultimate purpose must be the support of healthcare-related education, information, research, patients or public health generally (absent prior written approval by Global Compliance, no support for ordinary business expenses). Research grants are a specific type of Grant (see Appendix C below). If the purpose is unrestricted (that is, not tied to a specific project/activity/event), then the support is properly characterized as a Donation (i.e., there are no "unrestricted grants").
Gift	Is any item given for the personal benefit of the recipient, without something of equivalent value being received in return
Healthcare Professional (HCP)	For the purposes of this Policy, a Healthcare Professional (HCP) is any member of the medical, dental, pharmacy, nursing, or allied health professions, or any other person who, in the course of their professional activities, may prescribe, recommend, purchase, supply, administer, sell or administer the use of an Arcera product. This definition excludes individuals whose responsibilities relate solely to procurement or purchasing activities at the national or governmental level (e.g., ministry of health officials, tender committee members). Such individuals should be treated solely as Government Officials.

Healthcare Organization (HCO)	An HCO is an organization that is comprised of HCPs and/or that provides healthcare or conducts healthcare research.
International engagement	Refers to any formalized arrangement that governs the interaction, collaboration, or transfer of value between Arcera and HCP/HCO situated outside the Arcera region. This also applies when both parties are located within the same country, but the engagement has operational, financial, or regulatory implications in a third country. International engagements are subject to additional compliance requirements due to cross-border legal, regulatory, and ethical considerations.
Items of medical utility	Are tools, devices, or materials provided to healthcare professionals to support the delivery of patient care or assist in diagnosis, treatment, or patient counseling.
Event	An Event is any meeting, congress, seminar, symposium, training, advisory board, promotional meeting, or other gathering organized, sponsored, or supported by Arcera, either directly or indirectly, where Healthcare Professionals, external stakeholders, or employees are invited to participate for educational, scientific, promotional, or business purposes.
International Event	Any Event, as defined above, that occurs in a country outside the Arcera region of practice of invited participants or outside the Arcera region that is responsible for the event. International Events are subject to additional compliance requirements due to cross-border legal, regulatory, and ethical considerations.
Non-Promotional	Non-promotional activities or content intend to provide unbiased educational or scientific information about a product, compound, or disease without recommending or seeming to recommend a specific product or service. Such activities may include but are not limited to disease awareness programs, medical education, medical-scientific liaison activities, Risk-management program materials and others. Note: The context in which certain content is used is important and may change the nature of the content. Non-promotional content used in a promotional context (e.g. during a sales call) may be considered Promotional content.

Promotional	Promotional is any activity undertaken, organized, or sponsored by Arcera which is intended to promote the prescription, recommendation, supply, administration or consumption of a specific product or brand, regardless of communication channel or method. Such activities or content may include but are not limited to sales visits, speaker events, advertising, sales aids, presentations, direct-to-consumer advertising (where allowed by local law), and other materials designed to increase sales of a particular product.
Medicinal Product	(a) any substance or combination of substances presented as having properties for treating or preventing disease in human beings; or (b) any substance or combination of substances which may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis.
Patient Organization (PO)	A PO is a not-for-profit institution that primarily represents the interests and needs of patients, their families and/or caregivers.
Product Sample	A sample of Arcera Product provided free of charge to HCPs qualified to prescribe or supply them so that they can familiarize themselves and patients/consumers with the products and acquire experience in handling them.
Rebate	A rebate is a return of part of the original payment for some services or products conditioned upon certain agreed upon criteria. Frequently rebates are given based on a quantity of products sold within a defined period of time ("volume rebates").
Rx	A commonly used abbreviation for "prescription," referring to a medication or therapy that is authorized by a licensed healthcare professional for use by a patient. In the pharmaceutical context, Rx products are those that require a prescription for dispensing and are regulated by law.
SKU	Stock Keeping Unit – A distinct code assigned to each individual product or product variant (e.g., size, color, packaging) within the company's inventory system. SKUs are used to accurately track, manage, and report inventory, facilitate sales analysis, and support logistics and supply chain operations.
Sponsorship	Sponsorship is the provision of support to a healthcare organization, or to a Third-Party organizing entity on behalf of a healthcare organization, where Arcera gets a commensurate

	benefit in return (e.g., a booth, a symposium slot). Absent prior written approval by Global Compliance, a sponsorship may not provide support for ordinary business expenses.
Support for Education	Financial support (reasonable travel expenses, accommodation expenses and/or registration fees) provided by Arcera to qualifying healthcare professionals, either directly or indirectly through their healthcare organizations, to attend relevant medical or scientific educational events, their attendance at which will bring value to the practice of medicine and/or scientific progress and ultimately to patients.
Third Party	A Third Party is a person or organization supplying products or services to Arcera or buying products or services from Arcera. Third Parties are not part of, nor directly employed by Arcera. Typically, Third Parties do not represent or act on behalf of Arcera, nor are they integrated into Arcera's commercialization structure (e.g. a wholesaler that is purchasing and selling products entirely at their own risk and account). A Third-Party Intermediary (TPI), see definition below, is a special type of Third Party.
Third Party Intermediary (TPI)	A TPI is a company or individual that represents, interacts or transacts business with another third party on behalf of, or in the name of, Arcera. Examples include a distribution partner that has a sales force detailing Arcera's products to HCPs, a consulting company representing Arcera's interests in exchanges with a regulatory authority or another third party, or any other business partner that may be interacting with Government Officials or other third parties on Arcera's behalf. In contrast, see definition of Third Party.

4. Roles and Responsibilities

Role	Core Responsibilities
Accountable Person	The Accountable Person is typically the individual who initiates the review and approval process. In some regions, the term "Requester", "Owner" or "Initiator" may be used to indicate the Accountable Person. The Accountable Person is the individual who has ultimate responsibility for an activity, interaction, engagement, or similar, and to ensure that the requirements of

	this Policy are fully met, appropriately documented (S. 5.7) and submitted for review. The Accountable Person is responsible for: a) ensuring that proof of approval and, where applicable, the supporting documentation/information, are retained, stored and archived appropriately for audit and inspection purposes. (S. 5.7.); b) that no commitments are made until the requisite approvals are obtained, and that the activity/interaction/engagement is executed as planned. On interactions with the Healthcare Community: c) submit the materials for approval; d) document the purpose of the meeting as well as the individuals present; e) collect an itemized receipt and proof of payment and submit both to Finance (S. 6.2.) In engagements with HCP/HCO: f) Ensure that the services provided are properly documented and evidenced; g) Keep records of the outputs generated from the services; h) Verify that the performance aligns with the terms of the written agreement; i) ensure appropriate use of output. j) In case of partial performance, request RMA advice. (S. 6.11.); k) Document the rationale behind requesting exceeding Maximum Local FMV Rates (S. 6.11.).
Global Compliance Committee	Review and approve donation requests that might be perceived as political, or in cases of highly politicized events surrounding the humanitarian purpose. (S. 10.)
Compliance **(Regional or Global)**	Compliance is the Arcera function that has primary responsibility for the management of integrity and compliance matters. It is tasked with defining appropriate corrective and preventive actions, ensuring these measures are effectively implemented and thoroughly documented. Additionally, Compliance actively seeks opportunities to share insights and foster dialogue around key learnings, promoting a culture of continuous improvement and advice with respect to the interpretation of applicable laws and this Policy (S. 15.).

	They may conduct periodic monitoring of Arcera employees and Third-Party Intermediaries (S. 14.)
Global Compliance (GC)	Global Compliance has primary responsibility for setting the minimum integrity and compliance standards for Arcera and its divisions and legal entities as well as addressing questions and issues escalated from the Regions Global Compliance is responsible for reviewing and approving: a) requests for deviations and exceptions to the principles and standards in this Policy; b) requests for international Grants or Sponsorships (S. 6.10.); c) regional request for variation on the FMV calculation, and d) together with GMA establishes the Maximum Local FMV Rates for engagements of European HCPs/HCOs (S. 6.11.); e) requests to exceptionally exceed the Maximum Local FMV (S. 6.11.); f) any request for political-related contribution (S. 11.)
Regional Compliance (RC)	Regional Compliance has primary responsibility for day-to-day management of compliance matters in the countries in their region. Regional Compliance is responsible for: a) implementing local/regional processes, including setting approval workflows, which are necessary and appropriate to operationalize the ethical principles set forth in this Policy (S. 5.6); b) and monitoring compliance with this Policy. c) tracking Arcera's local legal obligations with respect to transparency. (S. 5.8.); d) set regional/local requirements that are part of the approval workflows for certain interactions or activities that are addressed in this Policy, (S. 5.9.). On interactions with the Healthcare Community: e) Publishing local standards and establishing regional limits for hospitality, meals and refreshments offered (S. 6.3.); f) defining the reasonableness of the interactions that qualify for providing hospitality. RC may also publish a list of appropriate venues (S.

	6.3.); g) setting limits on legitimate transfers of value to HCPs and HCOs and ensure that there is an appropriate system for recording such items (S. 6.4.); h) setting reasonable per-item value limits for promotional aids, as well as aggregate annual limits per HCP. (S. 6.5.); i) Together with RMA, sets the FMV rates for HCP&HCO Engagements in each country of its region (S. 6.11.) and; j) Developing processes to ensure the proper documentation and approval of local/regional engagements of HCPs/HCOs ; k) upon Accountable Person's request, review and approve gift/hospitality which do not meet the stablished criteria (S. 9.) Regional Compliance may delegate specific tasks to local compliance colleagues/liaisons.
Legal Department (Global or Regional)	Advice with respect to the interpretation of applicable laws and this Policy (S. 15.).
Manager / Department or Function Head	Managers are responsible for: a) ensuring compliance within the departments they oversee, addressing any violations in collaboration with Global and/or Regional Compliance. b) Where transparency obligations or commitments exist, they must also ensure —supported by Regional Compliance— that all requirements are met and that effective systems are in place to collect and report the relevant data. (S. 5.8). c) Department or function heads are responsible for the implementation and adherence to this Policy; d) they must ensure proper retention and storage of relevant documentation in a centralized location for future audit and monitoring. e) If requested, department or function heads are also responsible for ensuring that periodic monitoring is conducted as evidence of process implementation and adherence. (S. 14.)
Medical Affairs (Global, GMA,	Medical Affairs is the Arcera function that is uniquely capable of assessing Arcera's legitimate need for medical/scientific advice, the medical/ scientific value of an activity, engagement or

Regional, RMA or local, LMA)	interaction, the background and qualifications of a healthcare professional and other medical/clinical/scientific matters. Medical Affairs function must act independently of commercial objectives.
Global Medical Affairs (GMA)	Has primary responsibility for setting medical compliance minimum principles and standards for Arcera, and for addressing questions and issues that are escalated from the Regions. Global Medical Affairs is responsible for reviewing and approving a) any deviations and exceptions to the principles and standards in this Policy; b) requests for international Grants or Sponsorships (S. 6.10.); c) requests to exceptionally exceed the Maximum Local FMV (S. 6.11.), and; d) together with GC establishes the Maximum Local FMV Rates for engagements of HCPs/HCOs who practice outside of an established Arcera region (e.g. US/Europe) (S. 6.11.). GMA may delegate specific tasks to RMA.
Regional Medical Affairs (RMA)	Has primary responsibility for day-to-day management of medical compliance matters in the countries in their region, including consulting with Accountable Persons. Regional Medical Affairs is responsible for a) setting regional/local requirements that are part of the approval workflows for certain interactions or activities that are addressed in this Policy. (S. 5.6). On interactions with the Healthcare Community: b) approving Informational/Educational Material and Items of Medical Utility that may be offered on an occasional basis to HCPs (S. 6.7.); c) review the process and documentation prior approving request for local/regional Grants or Sponsorships (S. 6.10.); d) assessing on Arcera's legitimate need for HCP/HCO's services, as well as the qualifications of the HCP or HCO to perform such services and the determination of FMV. (S. 6.11.); e) In engagements with

	HCP/HCO: advise on the rationale amount to be paid in case of partial performance. (S. 6.11.); f) review and approving requests to exceptionally exceed the Maximum Local FMV (S. 6.11.); g) together with RC, sets the FMV rates for HCP&HCO Engagements in each country of its region (S. 6.11.) h) Evaluate HCPs proposed for support to attend educational events: provide rationale for their participation or rejection to a specific event. (S.6.12) RMA may delegate specific tasks to LMA.

5. General Governing Principles

The following principles apply to Arcera's interactions with Third Parties, including but not limited to Healthcare Professionals (HCPs), Healthcare Organizations (HCOs), Patient Organizations (POs), Government Officials (GOs) and Third-Party Intermediaries (TPIs).

5.1. No Bribery or Improper Advantages or Incentives

The highest standards of integrity apply to Arcera's interactions with Third Parties. Arcera has zero tolerance for any form of corrupt business practice, including bribery.

There must be a legitimate business purpose behind everything we do. Moreover, the possibility that an activity could be perceived as an improper inducement or benefit must be considered when deciding whether to engage in that activity. The same standards apply to the receipt of benefits. It is forbidden to accept or request an improper benefit for the performance of professional duties.

Arcera has a zero-tolerance policy in respect of both direct and indirect bribery. Direct bribery occurs when an employee engages in an act that constitutes bribery. Indirect bribery occurs when a Third-Party Intermediary (TPI) commits bribery when representing or interacting on behalf of Arcera. Arcera has a legal obligation to take adequate measures to prevent indirect bribery by our TPIs. This Policy is one of the critical components of Arcera meeting this legal obligation.

5.2. Payment of Fair Market Value for Services Rendered

In line with applicable anti-bribery laws, other relevant regulations and industry codes, Arcera compensates Third Parties based on the fair market value of services provided to meet a

legitimate business need of Arcera ("Fair Market Value" or "FMV"). Direct or indirect payments in excess of Fair Market Value run the risk of being seen as improper incentives or bribery.

Fair Market Value must never take into consideration the recipient's ability to influence an improper business benefit or to generate business or referrals that could result in business.

Specific standards apply to the determination of Fair Market Value in respect of Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs) (see Section 6.11 below).

5.3. Strict Scrutiny of Interactions with Government Officials

In order to ensure strict compliance with national and international Anti-Corruption Laws, such as the US Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act, interactions with all Government Officials (GOs) must comply with the strictest standards in respect of transparency and conflicts of interest. Arcera only enters into agreements with GOs in cases where the business need is undeniable and no reasonable alternative exists. Section 7 below sets forth more detailed requirements regarding Arcera's interactions with GOs.

5.4. No Facilitation Payments

Facilitation payments are prohibited under all circumstances, regardless of local custom or practice. The sole exception is where there is an imminent threat to health, safety, or liberty. Any such instance must be reported immediately to Global Compliance with full documentation of the event and the circumstances necessitating the payment.

5.5. Separation between Promotional and Non-Promotional Activities

Arcera engages in various scientific/educational activities and provides support for certain scientific/educational initiatives as part of its commitment to improving healthcare and the quality of life of patients. All promotional and non-promotional communications follow the standards set forth in the applicable company policies.

Arcera maintains an appropriate separation between non-promotional and promotional activities and does not interject commercial influence into decision-making regarding Grants, Sponsorships, Donations, support for medical education and scientific research, or the generation and reporting of clinical information.

Arcera respects the scientific independence and integrity of Healthcare Professionals (HCPs) and Healthcare Organizations (HCOs). This requires the application of good business judgment to all interactions with HCPs/HCOs, including accurate and truthful documentation in furtherance of full transparency.

All interactions with patients and Patient Organizations (POs) are strictly non-promotional and must benefit them by raising disease awareness and education about the disease of interest, while contributing to the ethical delivery of healthcare.

5.6. Strictest Standards Apply in Case of Cross-border Interactions and Local Implementation.

This Policy sets forth the minimum ethical standards applicable to the entire Arcera, its divisions and legal entities. While this Policy contains certain bright-line rules, it is generally a principles-based policy that sets forth the overarching values and standards that must inform all operating decisions.

Local and/or regional standards may be stricter than the standards set forth in this Policy. In cases where applicable rules are stricter than the standards set forth in this Policy, the stricter rule or regulation must always take precedence.

Relevant jurisdictions include the country of the Third Party/HCP, country of each Arcera legal entity involved in the interaction, and the country where the activity/services are taking place. Where there is a conflict, the strictest standards must always be applied.

Regional Compliance is responsible for implementing local/regional processes, including setting approval workflows, which are necessary and appropriate to operationalize the ethical principles set forth in this Policy. Regional Compliance should consider the compliance maturity of their organizations in deciding whether additional local/regional policies are required, and whether such policies should follow a more rules-based approach with bright-line standards and more detailed guidance.

5.7. Accurate Books and Records

Arcera must document its interactions with all Third Parties thoroughly and accurately. All payments and any other transfers of value must be recorded accurately, completely, and in a timely manner in all appropriate Arcera systems at the level of detail required under applicable business rules and procedures (e.g., purchase orders, invoices, itemized receipts and other documents supporting the payment of expenses).

Where approvals and supporting documentation/information are required under this Policy, the Accountable Person is responsible for ensuring that proof of approval and, where applicable, the supporting documentation/information, are retained, stored and archived appropriately for audit and inspection purposes.

In the context of Arcera's engagements of HCPs/HCOs for services, evidence of delivery (e.g. photos/videos), where not obvious and indisputable, must be collected and retained prior to Arcera's payment of such services.

5.8. Transparency

There is a growing expectation worldwide for transparency into how life sciences companies such as Arcera conduct business with HCPs and other players in the healthcare community. Transparency requirements vary from country to country. Arcera complies with all applicable laws and any applicable industry codes regarding transparency reporting. Regional Compliance is responsible for tracking our local legal obligations with respect to transparency, as well as any voluntary commitments (e.g., membership of an industry association, contractual commitments). Where transparency obligations or commitments exist, local management is responsible for ensuring (with support from Regional Compliance) that the requirements are met, and that the appropriate systems are in place to collect and report the relevant data.

Arcera should, where applicable, provide prior written notification of any transparency obligations to HCPs, including purpose and scope. When required, Arcera shall obtain prior written approval of the HCPs to any disclosure of data relating to them, and, where relevant, obtain their consent to the processing of personal data; however, where reporting is required by law, Arcera does not require prior consent from the HCP for payment disclosure purposes, as the requirement imposed by national laws provides legal grounds for the process of HCP personal data.

5.9. Roles of Accountable Person and Mandatory Approvers

Appendix A sets forth information on the role of Accountable Person for the various types of interactions, projects and initiatives that are governed by this Policy (i.e., which functions can hold the role of Accountable Person), as well as any approvers whose review and approval is required under this Policy before the Accountable Person can proceed. This guidance should always be consulted to ensure that the correct functions are taking on the role of Accountable Person and all the mandatory approvals have been obtained. In addition to any mandatory approvers under this Policy, there may be approvals required under internal Arcera Finance or other business processes.

Regional Compliance is responsible for ensuring that the Region has a process in place for the review, approval, and monitoring of the various types of interactions, projects and initiatives that are governed by this Policy. Ideally, this process should be supported by a system that provides overviews of relevant information, supports auditing and monitoring and has safety features in place to ensure adherence with limits. See Section 14 of this Policy for a description of monitoring.

6. Interactions with Healthcare Community

In addition to the General Governing Principles set forth in Section 5 above, the following standards apply to all of Arcera's interactions with, and support for, the healthcare community, including Healthcare Professionals (HCPs), Healthcare Organizations (HCOs) and Patient Organizations (POs).

6.1. Interactions with HCPs

Arcera employees may interact with HCPs in a variety of ways. There must be a legitimate promotional, scientific, or educational purpose behind each such interaction.

Any discussion of a non-approved use of an Arcera product (including pre-approval and off-label uses) can only take place if allowed by local law and legislation, can only be conducted by Medical Affairs personnel, and only in response to an unsolicited request for medical information from an HCP. Sales employees (e.g., medical representatives) may promote Arcera products only within approved labels and in line with the standards set forth in the applicable laws, industry guidelines and internal policies and procedures governing permissible promotional practices.

The primary topics of conversation during interactions with HCPs must be technical (i.e., product related, patient care related), educational or scientific, and topics should be relevant to the practice or research of the HCPs. Patient privacy and the principles of data protection must always be respected.

Interactions with HCPs may take place at an HCP's professional office, at another location at their place of employment (e.g., a hospital meeting room), or at other external business-appropriate venues (e.g., at a scientific congress, at a restaurant (subject to requirements outlined below).

During an HCP interaction, modest and appropriate hospitality in line with the principles and standards set forth Section 6.3 and any applicable regional policies, may be offered by the Arcera employee to the HCP(s).

Any deviation from these requirements shall constitute grounds for disciplinary action, which may in certain cases include termination. A pattern of deviations from these requirements by a particular team may constitute grounds for suspension of certain categories of interactions until improvements can be assured.

6.2. Arcera organized events

Arcera may organize its own non-promotional events to provide scientific or educational information to HCPs, or promotional events to inform HCPs regarding Arcera products, their uses and safety profiles.

In addition to the requirements above, the following requirements must be met for any Arcera organized events.

- There shall be no accompanying persons present, either on the part of the Arcera employee or the HCP. As a narrow exception, in the case of meetings at the HCP's place of employment, when the discussion is relevant to disease awareness or the provision of patient care by staff, a reasonable number of such staff may be present. However, care must be taken not to promote Rx medicines to non-HCPs.
- If the interaction involves a group of HCPs, the number of individuals must be reasonable to allow for a meaningful discussion and exchange of information. Any limits set by the Region must be strictly followed.
- Promotion to the public must be avoided. The venue must have a confined closed area where the event can be held without any exposure to the public (visual or auditory).
- If the venue is a restaurant, it must:
    - Be a non-luxurious, business-appropriate restaurant.
    - the value and frequency limits set by the Region must be strictly followed.
    - All rules for hospitality as per section 6.3 must be followed
    - In case of meetings at a restaurant, there is a strong preference for lunchtime meetings over dinner meetings, subject to stringent local requirements.
- At least 70% of the time at an event (working hours/day) should be spent on the promotional/non-promotional purpose.
- For cross-border events, for hospitality the limits and rules of the host country apply; for payment to the speakers, FMV shall be according to the country of practice of the HCP.

In case soft-skills training is provided, this should:

- be relevant to the HCPs practice
- relevant to the educational purpose of the event
- not make up more than 20% of the agenda of the event, exceptions require Regional Compliance approval.

Approval and documentation requirements:

Arcera organized events must be approved internally before engaging with or committing to any external engagements, including venues and HCPs.
The following materials must be submitted by the Accountable Person prior to the event for approval, as per the applicable process:

- Program (reflecting the purpose, topic, venue, date, agenda)
- Planned participants list (invitees)
- Speakers slides (after the event itself is approved)
- Any materials that are planned to be disseminated at the event

The following information must be captured by the Accountable Person during and after the event:

- The individuals present (HCPs, staff and Arcera employees). The form and content of such documentation must adhere to the standards set by the Region.
- Proof of delivery (e.g., a photograph of the presentation) must be submitted after the event. The form and content of such documentation must adhere to the standards set by the Region.
- Itemized receipts and proof of payment, and both must be submitted to Finance (i.e., as part of the request for reimbursement or validation of credit card expenses).

6.3. Hospitality, Venue, Location and Expenses

Any hospitality, including meals and refreshments, offered by Arcera must be modest and reasonable. When interacting with HCPs, meals and/or refreshments are considered reasonable if: (a) they are moderate in frequency, nature and value as judged by local standards and consistent with limits published by Regional Compliance, and (b) they are offered in connection with an non-promotional/promotional event or a technical discussion/engagement of the HCP(s), and (c) are only offered to participants of the event/discussion/engagement.
It is the responsibility of Regional Compliance to define both the reasonableness of the interactions that qualify for providing hospitality as well as what counts as local standards and parameters that govern such interactions.

By way of example:

- If allowed under local law, a sales representative may bring a modest lunch to a lunchtime promotional or non-promotional meeting with an HCP.
- modest refreshments may be offered to participants during a break or at the conclusion of an Arcera-organized educational event.

For on-line/virtual events or interactions with HCPs, unless approval is obtained from Regional Compliance, meal vouchers, meal boxes, meal delivery, or any other hospitality or item of value are not allowed.

The venues and locations of Arcera-sponsored events, and of Third-Party events that are supported by Arcera (either directly via a Grant or Sponsorship, or indirectly by providing support to an HCP to attend the Third-Party event), must be appropriate and reasonable for the purpose of the activity/program/project. Venues should be business-oriented and never lavish. The Accountable Person should consult with Regional Compliance in case of questions, and Regional Compliance may publish a list of appropriate venues. Locations should be chosen due to the

logistical benefits to the greatest number of participants possible, and never due to their proximity to leisure activities or entertainment.

No Regional Affiliate may organize or sponsor an Event that takes place outside its home country unless:

- most of the invitees are from outside of its home country and, given the countries of origin of most of the invitees, it makes greater logistical sense to hold the Event in another country. In other words, meetings should be held in the country where the majority of the participants come from.
- given the location of the relevant resource or expertise that is the object or subject matter of the Event, it makes greater logistical sense to hold the Event in another country. However, this should be limited to specific cases – for example, if the objective of the meeting is visiting facilities like a state-of-the-art hospital or clinic, an R&D facility or manufacturing plant in another country.

Hospitality extended in connection with Events must be limited to travel, meals, accommodation and genuine visa and registration fees. Entertainment or leisure activities can never be sponsored or organized in connection with the event.

Hospitality offered at an event, either an Arcera event or a Third-Party Event, shall be according to the limits of the host country, not according to the countries of origin of the participants. Raffles, contests, or other give-away items at an event shall be approved by host country Regional Compliance.

All forms of hospitality expenses paid by Arcera must be reasonable, necessary, and strictly limited to the facilitation of the interaction or main purpose of the event. The hospitality provided must not exceed the limits set by the region.
Arcera must pay any flight and accommodation expenses directly to the vendor (e.g., airline/hotel), rather than through reimbursement to the HCP (any exceptions must receive prior written approval of Regional Compliance).

The duration of accommodation must match the HCP's need for accommodation required to achieve the legitimate business purpose. For example, if hotel accommodation is necessary to allow participation at an educational event, the dates of the event must match the duration of the hotel stay (maximum one night before and/or after the event). The standard of the accommodation must be reasonable (i.e., business-class hotels; no luxury or resort accommodation). Travel dates must likewise match the underlying event. Travel should be by reasonable means. Air travel under 6 hours must be economy class.

Hospitality and payment of expenses must be limited to HCPs that are directly involved in the event/interaction. Arcera must not pay any costs associated with individuals accompanying an

HCP, except in rare cases of medical necessity, following approval by Regional Medical and Regional Compliance.

In the context of Arcera's interactions with the healthcare community, entertainment or leisure activities are strictly prohibited (either direct or indirect (i.e., organized by a third party, but paid by Arcera).

6.4. Ban on Gifts vs. Legitimate Transfers of Value

Gifts to HCPs, HCOs and POs are strictly prohibited.

A gift is any item given for the personal benefit of the recipient, without something of equivalent value being received in return. Examples include sporting or entertainment tickets, electronics items, personal services, social courtesy gifts, cash, or cash equivalents (e.g., gift cards, vouchers, pre-paid credit cards) in cases where the giver is not receiving fair value in return.

In contrast, a fee for service is a negotiated payment made in exchange for the delivery of services of equal value, see section "Engagement of HCPs" (Section 6.11.).

In further contrast to gifts, there are legitimate transfers of value to HCPs, HCOs and POs that, due to the value that such transfers bring to the healthcare community and patient care in general, do not qualify as gifts so long as the standards set forth in this Policy are strictly adhered to.

In each of the transfers of value (other than small cultural gifts), the nature of the item or value being transferred is such that a legitimate business or scientific interest is being served. Each of the exceptions is to be narrowly construed.

Regional Compliance must set limits on legitimate transfers of value to HCPs and HCOs, in full compliance with local law, regulations and any applicable industry codes and the principles set forth below and is responsible for ensuring that there is an appropriate system for recording such items.

When providing something of value to an HCP/HCO under this Policy, there can be no expectation of reciprocity or intention of exerting influence over the prescription, referral, recommendation, purchase, sale or placement on a formulary of any Arcera Product, or to reward any such past behavior, or to gain or improve access to the HCP/HCO. The item must be accurately recorded in Arcera's books and records.

The following items are legitimate transfers of value and not considered "gifts" for purposes of this Policy: Grants and Sponsorship (Section 6.10.); Educational Support and Events for HCPs (Section 6.12.); price discounts or rebates granted for the purchase of Arcera Products, in line with applicable competition law and provided that they do not influence the choice of treatment

(Section 12); Product Samples (Section 6.14.); Free Goods (Section 6.8.); and reasonable and appropriate hospitality (Sections 6.3. and 7.2.).

The following are also legitimate transfers of value to HCPs/HCOs:

6.5. Promotional aids / Brand reminders

A promotional aid is a non-monetary item given for a promotional purpose. Examples include post-its, mouse pads, calendars, plasters, lanyards, bookmarks, etc.

- Promotional aids for prescription-only medicines:

Providing or offering promotional aids to HCPs, or members/representatives of HCOs or POs for the promotion of prescription-only medicines (Rx) is prohibited (unless explicitly permitted under applicable law in which case all other limitations with respect to promotional aids must be strictly adhered to).

In the context of Arcera promotional events for Rx products, pens and notepads can be provided to HCPs for the purpose of taking notes during the meeting, provided that they are Arcera company-branded only (no product branding), in line with value limitations set forth below, and distributed in necessary quantity for the purpose of the event.

- Promotional aids for OTC medicines or health-related consumer products:

Providing or offering promotional aids to HCPs, or members/representatives of HCOs or POs for the promotion of OTC medicines or health-related consumer products are allowed, only if all the following criteria apply: 1. permitted by local laws and regulations 2. in line with value limitations set forth below 3. relevant to the HCPs practice. All such items must comply with applicable local laws, industry codes, and company standards, including any value thresholds and reporting obligations.

Providing or offering promotional aids to consumers for the promotion of OTC medicines or health-related consumer products are allowed if they are in line with value limitations set forth below, product-relevant, and not likely to encourage inappropriate use. All consumer-facing giveaways must comply with applicable local laws and self-regulatory codes, and may not be false, misleading, or disproportionate to the product purchase. Items must not target vulnerable populations inappropriately (e.g., children, pregnant women) and should not create an undue inducement to purchase. Where required, promotional items must display mandatory product warnings or disclaimers.

Value limits for all promotional aids:

Regional Compliance should set, in line with the principles in this Policy, reasonable per-item value limits for promotional aids, as well as aggregate annual limits per HCP. Regional limits must never be more than double the following limits:

- Each individual item must have a maximum value of AED 40 (or local equivalent)
- The aggregate value of items per HCP per year must not exceed AED 40 (or local equivalent)

In case the above-mentioned limits need to be regionally exceeded, Global Compliance must provide prior written approval based on compelling rationale.

In case a Region has not set such limits, the foregoing limits apply.

6.6. Informational or Educational Materials

Educational materials are items or content provided to healthcare professionals or patients for the purpose of enhancing knowledge or understanding of a disease, medical condition, treatment option, or health-related topic. Such materials may be provided to HCPs but must:

- Contain accurate, balanced, and non-promotional information.
- Be directly relevant to the recipient's field of practice or patient needs.
- Avoid any content or claims outside of approved product labeling.
- Not be linked to any condition of prescribing, recommending, or purchasing a product.
- Not offset routine business expenses of the recipient.
- Not be product branded (unless the Medicinal Product's name is essential for the correct use of the material by the patient or HCP).
- May include Arcera or any of its legal entities' name.
- Comply with all applicable local laws, regulations, and industry codes.

Examples: Disease awareness brochures, clinical guideline summaries, patient leaflets, educational posters, slide decks for scientific meetings.

Any informational or educational materials that are specific to an Rx product may only be distributed to HCPs, even if the intended audience is patients, as it must be the decision of the treating physician as to whether and when to share such material with a patient.
Some examples of permitted informational or educational items include but are not limited to patient education materials, scientific books, journal articles and their electronic equivalents, or memory sticks pre-loaded with educational or informational data, if the storage capacity is commensurate with the materials provided. However, because a tablet computer may have an independent value for the healthcare professional, it must not be provided, even if it could be used to deliver education to patients.

The books and articles must have a reasonable market value. Other informational or educational items must be of modest value. Consideration should be given both to the cost of an individual book or subscription as well as the overall benefit to an individual healthcare professional each year and on an ongoing basis.

6.7. Items of Medical Utility

Items of Medical Utility may be provided to HCPs, subject to the following requirements:

- Be of low value and proportionate to their intended use.
- Be directly relevant to the recipient's clinical practice.
- Not provide personal benefit to the recipient.
- Not offset routine business expenses of the recipient.
- Not be contingent on prescribing, recommending, or purchasing a product.
- Not be product branded (unless the Medicinal Product's name is essential for the correct use of the material by the patient or HCP).
- May include Arcera or any of its legal entities' name.
- Comply with any local value thresholds, reporting obligations, and approval requirements.

Examples: Anatomical models for patient counseling, demonstration inhalers, diagnostic tools for in-office use.

The nature of Informational/Educational Materials and Items of Medical Utility considered, may not be used to circumvent the prohibition on gifts defined on Section 6.4. of this Policy. The transmission of such materials or items must not constitute nor create the perception to be an inducement to recommend and/or prescribe, purchase, supply, sell or administer any Arcera Product.

With approval of Regional Medical, Informational/Educational Material and Items of Medical Utility may be offered on an occasional basis to HCPs so long as they are of modest value when considered on an aggregate level per HCP and per annual period. Modest value must be determined based on local conditions and based on the actual fair market value to the HCP, without factoring in any volume or other discounts negotiated by Arcera.

Regions should set reasonable per-item value limits, as well as aggregate annual limits per HCP. If a Region has not set such limits, the following applies:

- the aggregate annual value of items of informational/educational material or medical/educational utility per HCP must not exceed AED 160 (or local equivalent)
- the per-item value must not exceed AED 80 (or local equivalent).

Exceeding these applicable limits may be possible in limited circumstances, but only with the prior approval of Regional Medical and Regional Compliance (e.g., the one-time provision of a medical textbook or one-year subscription to a medical journal).

6.8. Free Goods

The provision of free goods (meaning free Arcera Products) to HCPs or HCOs is generally not allowed due to the risk of being viewed as incentivizing or encouraging prescribing behavior, as well as the risk of misuse. In the limited circumstances set forth below, so long as local law and regulation does allow, free goods may be distributed.
Before the provision of any free goods, a system for controlling purposes (i.e., tracking of recipients, quantities, storage and expiration dates) must be in place, including adequate documentation. A written request letter should start the process and final approval of any distribution of free goods must include both RMA and Regional Compliance.

Free goods may be distributed in the following limited contexts, and only if allowed under local law:

- Products supplied for a clinical trial.
- Products supplied in the context of a compassionate use program.
- Products supplied for an investigator-initiated study; and
- Other limited situations where exceptional circumstances exist justifying the limited provision of free goods, and only with the pre-approval of Regional Compliance.

Any donation of Arcera Products to serve a humanitarian or charitable purpose is governed by Section 10 below.

In all other cases, the distribution of goods must be in exchange for Fair Market Value (FMV).

6.9. Cultural or Life Event Gifts

A cultural or life event gift is a modest, symbolic item given to an HCP to acknowledge a widely recognized cultural celebration or significant personal life event (retirement, birth of a child etc.). Examples include fruit baskets, chocolates, flowers etc.

These gifts may be given to HCPs but must:

- Be permissible under local law
- Consistent with local business customs and local industry practice
- A fungible/perishable item.
- Have no religious or political significance.

- Not contain alcohol.
- Be non-promotional and not product-branded (can be company branded).
- Not be linked to any condition of prescribing, recommending, or purchasing a product.

Regions should set reasonable per-item value limits, as well as aggregate annual limits per HCP. If a Region has not set such limits, the following applies:

- A gift is given no more than twice in any annual period to the same HCP.
- The per-item value of each such gift does not exceed AED 120 (or local equivalent).

6.10. Grants and Sponsorships

Arcera is committed to improving the lives of patients and contributing to advancements in healthcare. As a part of this commitment, Arcera or any of its legal entities may provide financial or non-financial support in the form of Grants and Sponsorships to healthcare organizations (HCOs) or Patient Organizations (POs) (or to Third Parties acting on their behalf) who propose initiatives, events, activities, or projects that will promote healthcare and scientific advancement or education.

A grant is a non-commercial, non-promotional provision of funds, goods, or services to support a bona fide educational or scientific activity, without expectation of any direct or indirect benefit to the company. Examples include unrestricted educational grants to medical societies or funding for independent patient/HCP education programs.
For the sake of clarity, financial support that is provided to individual HCPs to allow them to attend medical/scientific education is discussed in Section 6.12. (*Educational Support and Events for Healthcare Professionals*).

A sponsorship is a commercial arrangement where Arcera provides financial or in-kind support in exchange for defined, tangible benefits such as brand visibility, promotional opportunities, or event access (the mere disclosure of Arcera's support for transparency's sake does not qualify as a benefit in return). Examples include sponsoring a conference exhibition stand or branded promotional materials at an event.

For clarity: Opportunities for Non-Promotional activities (including but not limited to support of medical and disease education, scientific interactions, and disease awareness for HCPs and/or general public and patients) can also be considered a benefit in return, only if Arcera is owning the activity in question and can determine its content.

Sponsorships and Grants must:

- never be used as a direct or indirect inducement or reward for an HCO, HCP or PO to use, purchase, request or otherwise recommend Arcera products.
- Follow a written agreement detailing scope, purpose, amount, and conditions (if any)

Grants must:

- be unsolicited and Arcera's decision to provide support must have no commercial motive.
- Funding for grants must be tied to a specific project or educational/scientific purpose. However, the disbursement is at the discretion of the Grant recipient and must not be influenced by Arcera.
- The Accountable Person must be from a Medical function or other non-sales function.
- Commercial functions must not have any influence over the decision.

Requirements for sponsorships:

- The Commercial function may be involved if the benefit in return includes a promotional activity (e.g., a promotional booth), but Medical must approve the Sponsorship.

Further detailed requirements can be found in Appendix B (for Grants) and Appendix C (for Sponsorships).

Regional Compliance shall review the sufficiency of the processes for ensuring the proper documentation and approval of local/regional Grants and Sponsorships.

In the case of international Grants or Sponsorships, such as a Grant given to an international medical association based outside the Arcera entity's region or the sponsorship of an international congress abroad, Global Compliance and Global Medical Affairs must also approve, regardless of amount.

6.11. Engagements of HCPs and HCOs

Arcera relies on the expertise of healthcare professionals to gain scientific information and advice relevant to its business strategy and decisions. Moreover, Arcera turns to healthcare professionals (HCPs) and healthcare organizations (HCOs) to deliver on its commitment to support scientific advancement and education. HCPs and HCOs may be engaged by Arcera as consultants and advisors for services such as speaking at and/or chairing meetings and events, involvement in trainings, development of educational material, participation at advisory board meetings, participation in market research for which payment is made, and other similar services.

There must always exist a legitimate business need behind Arcera's engagement of HCPs and HCOs. Arcera may not engage an HCP or HCO with the intent of, implicitly or explicitly, influencing or encouraging HCPs or HCOs to, directly or indirectly, prescribe, refer, recommend, purchase, sell or place on a formulary any Arcera product, to reward any past such behavior, or to gain or improve access to the HCP/HCO.

All engagement of healthcare professionals (HCPs) must be governed by a written contract clearly outlining the scope of services, compensation terms, and compliance and/or transparency obligations (if any).

Speaker Programs must be managed and overseen by the Marketing and/or Medical functions (the former for promotional programs; the latter for non-promotional events); the Sales function may not manage these programs, except in exceptional circumstances expressly approved in advance by Regional Compliance.

Insight-generating activities where we engage HCPs or HCOs, such as advisory boards or steering committees, represent a special type of engagement with additional requirements. Such insight-generating activities may be organized by Arcera in order to obtain necessary scientific or medical advice to address a legitimate business need, only if such advice cannot be obtained internally, from within Arcera (e.g., the knowledge does not already exist within Arcera and is necessary for Arcera to achieve pre-defined objectives).

All payments to HCPs and HCOs for services rendered must be based on the Fair Market Value (FMV). The FMV of the country of practice of the HCP is controlling, regardless of where the services are performed. The methodology for FMV in the context of engagements of HCPs and HCOs are set forth in Appendix D.

In addition to the hourly rate for services based on FMV, so long as it is permissible under applicable law, HCPs and HCOs may be compensated for the following:

- Preparation time, so long as it is reasonable and necessary. By way of example, when an HCP is engaged to deliver a novel presentation, an HCP may be compensated for a reasonable amount of time spent collecting/organizing the information and preparing the presentation slides. The amount of preparation time may vary depending on the complexity of scientific field, the recurrence of an activity, etc. Recycling a presentation that the HCP has delivered in the past may not form the basis for the compensation of preparation time. Regional Compliance and/or Regional Medical may set the standards regarding the reasonable amount of preparation time; in the event no such regional standards are set, a maximum ratio of 1:4 (service time: preparation time) shall apply.
- Travel time, in cases where the services are being performed more than a certain minimum distance from the HCP's/HCO's principal place of business/practice and the engagement by Arcera is the primary reason for the travel. Regional Compliance may set the standards regarding the minimum distance above which compensation for travel

time is allowed; if no such regional standard is set, a minimum distance of 130 kilometers (80 miles) shall apply. Travel time may be compensated at no more than 50% of the applicable hourly rate for the services.

Regional Compliance and RMA are responsible for the setting of maximum FMV rates for HCP/HCO engagements in each country in their Region consistent with the FMV methodology ("Maximum Local FMV Rates"). Whenever possible, Regional Compliance should obtain reputable local benchmarking data when setting the Maximum Local FMV Rates. A variation from the methodology set forth in Appendix D may be possible in cases where local benchmarking data adequately supports the variation, and Global Compliance has reviewed and approved.

The Maximum Local FMV Rates for engagements HCPs/HCOs whose principal place of practice is outside an Arcera region are determined by Global Compliance and GMA.

The applicable Maximum Local FMV Rates may be exceeded[1] only in exceptional cases based on compelling grounds that establish the inappropriateness of the applicable maximum rate, and only with the prior approval of Global Compliance, GMA, and RMA. To request an exception, the Accountable Person must document the rationale behind an exception, including a description of: (a) the proposed engagement, (b) the business reason and objectives for the engagement, (c) the proposed FMV rate and proposed total compensation, and (d) the reasons why the applicable Maximum Local FMV Rate is too low. Such requests will be subject to strict scrutiny.

The Arcera Accountable Person is responsible for evidencing performance of the services, retaining the output, confirming that performance fulfils the terms of the written agreement, and ensuring that the output is used only for appropriate business purposes. If the HCP or HCO has not performed as contractually agreed, compensation should not be provided. In cases of partial performance, payments must be pro-rated; in such cases, the Accountable Person must obtain Regional Medical's advice on the reasonable amount.
Regional Compliance is responsible for developing processes for ensuring the proper documentation and approval of local/regional engagements of HCPs/HCOs based on the principles set forth above and the requirements for engagements set forth in Appendix E. In order properly to assess Arcera's legitimate need for services, as well as the qualifications of the HCP or HCO to perform such services and the determination of FMV, RMA must be involved in the review and approval process.

[1] *'Exceeding FMV' refers to objectively higher rates driven by external market/regional fee schedules (e.g., professional society affiliated speaker engagements). It does not include inter alia (i) contractual negotiations for additional services time post-engagement, or (ii) transitions to updated Regional FMV grids.*

6.12. Educational Support and Events for Healthcare Professionals

Arcera is committed to supporting the scientific and professional development of healthcare professionals (HCPs). As part of this commitment, Arcera provides support to HCPs to attend third party events such as continuing medical education and scientific congresses.

Neither the invitation to events nor the provision of support may act as an incentive for the HCPs or their respective HCOs to prescribe, recommend, purchase, supply, administer or promote any Arcera product.

It is not permitted to provide support to attend promotional events.

Because Medical Affairs is uniquely qualified to assess the value of a scientific/educational event and the value of attendance for a particular HCP, Medical Affairs must be involved in the review and approval process. The criteria and rationale for approval or rejection must be documented in writing.

Regional Compliance shall review the sufficiency of the processes for ensuring the proper documentation and approval of events and support for HCPs to attend events based on the principles set forth above and the requirements set forth in Appendix F.

In case of international events, Regional Compliance and RMA as first step, with Global Compliance and GMA as a second step shall approve the international events to which the physical attendance of an HCP may be supported by Arcera (support for virtual/on-line attendance of an HCP from their home location does not require such additional approval).

Global Compliance makes available an approval form for this purpose and has published a list of pre-approved international congresses. As a general matter, Arcera should limit such support for international events to those events organized by well-known medical societies. International Events organized by a pharmaceutical company or its designee (e.g., an event organizer agency) are subject to strict scrutiny and will be approved on an exceptional basis only.

6.13. Support for Scientific Studies

Arcera is committed to supporting scientific research in the form of Arcera-sponsored and investigator-initiated studies. Arcera may provide funding to support investigator-initiated studies that are intended to address an unmet scientific/medical need and are consistent with Arcera's medical and clinical plan for the Arcera product(s) involved. Requests for support for investigator-initiated studies must be unsolicited (unrequested) and based on research that is planned, designed, initiated and conducted by a non-Arcera researcher, with Arcera assuming no legal or regulatory accountabilities. The investigator must maintain full discretion and responsibility for

all aspects of the design, implementation, analysis, and publication and dissemination of the study data.

Scientific research and Arcera's support for studies must never be used as an opportunity to promote any existing or future Arcera product. Nor can research or support be used as a means of providing any sort of incentive to an HCP or HCO to prescribe, recommend, purchase, supply or administer any Arcera product.

All Arcera-sponsored studies and all investigator-initiated studies supported by Arcera must:

- serve a legitimate and robust scientific purpose;
- have the goal of generating/collecting relevant scientific information; and
- meet all applicable ethical guidelines, laws, regulations and codes, including all necessary approvals of the study protocol and informed consent form, as applicable.

Any engagements of HCPs in the context of an Arcera-sponsored study (*e.g.*, as clinical trial investigators) must conform to the requirements of an HCP engagement. Arcera may convene meetings of these investigators. The sole purpose of such meetings must be to provide investigators with relevant and important information on the study (*e.g.*, study protocol design, clinical background, data collection, monitoring requirements, study results), and/or to obtain feedback/advice from investigators that may be used to further revise the study protocol design in an effort to improve clinical relevance. The details of meetings (*e.g.*, venue, location, hospitality, payment of expenses) must adhere to the standards set forth in this Policy.

Regional Medical is responsible for oversight over Arcera-sponsored clinical trials in the Regions, including the engagement of, and interactions with, investigators and any Third-Party service providers (*e.g.*, a Contract Research Organization). Global Medical must be involved in the review and approval of Arcera's support for investigator-initiated studies.
See the applicable laws, industry guidelines and internal policies and practices related to the management of investigator-initiated studies for more information.

6.14. Product Samples

Where allowed by local laws, regulations, and industry codes, Arcera may provide free samples of (a) Rx Arcera Products in moderate quantities to HCPs authorized to prescribe or supply that product in accordance with their specialty, or (b) Non-Rx Arcera products to HCPs or consumers, both with the objective to familiarize themselves and patients with approved uses of Arcera's products and acquire experience in handling them, with the ultimate purpose of enhancing patient care and safety. Samples may never be supplied or recommended for a use not in the approved label.

Samples must not be given as an inducement to recommend, prescribe, purchase, supply, sell or administer specific Arcera Product. No person may sell, purchase, trade or offer to sell,

purchase or trade samples. Samples should not be used for commercial purposes or as part of a Post-Marketing Study. Samples may only be given for sound medical reasons; cultural reasons, relationship-building or other reasons are not valid purposes.

No samples of medicinal products containing psychotropic or narcotic substances within the meaning of international conventions, such as the United Nations Conventions of 1961 and 1971, may be supplied, unless allowed by local law.

Because the provision of samples carries the risk of being viewed as incentivizing or encouraging the prescription, recommendation, purchase, supply or administration of Arcera products, as well as the risk of misuse (e.g., the sale or improper distribution of the samples), strict requirements apply and sampling activities must be limited in both time and quantity to what is reasonably necessary to achieve the legal objective of familiarizing HCPs with a medicinal product.

The distribution of samples must always comply with applicable laws, regulations and industry codes of the country in which the HCP, the pharmacy or the consumer is located. The minimum requirements for the distribution of samples of Rx products are set forth in Appendix G, and for OTC products food supplements, medical devices and other Non-Rx Arcera products are set forth in Appendix H. If the laws of the relevant jurisdiction are silent on the subject of samples, but the provision of samples is a general practice of the industry in such jurisdiction, then samples are permissible so long as they comply with all the requirements set forth in this Policy, including Appendix G or Appendix H depending on the type of product.

Each division in Arcera must have adequate systems of documentation, control of, accountability for, tracking and monitoring of samples which they distribute, and for all medicines handled by its employees and authorized representatives.

Samples must always be handled in a safe and secure manner by the employees responsible for their distribution. As an example, samples should not be left in an automobile overnight or stored in plain sight in an automobile during the day. Any applicable storage and handling conditions must be strictly adhered to as per the requirements of the product (e.g. cold chain).

Local Marketing must create an annual product sample plan, which sets out the type and number of samples to be distributed and the rationale behind this in a compliant practice with any applicable legal limits and local industry codes. For Rx-Products, the plan should contain a list of HCPs with their specialty, the number of sample packs per HCP per Arcera Product to be given over the next 12 months, and the total number of samples per product SKU.

In the case of OTC medicines, health-related consumer goods and other Non-Rx Arcera products (e.g. supplements, medical devices), the plan should contain a list of pharmacies and HCPs (with their specialty), the type and number of sample packs to be given over the next 12 months.

In case the plan includes distributing OTC medicines, health-related consumer goods and other Non-Rx Arcera products (e.g. supplements, medical devices), to consumers, it should contain the total number of samples to be distributed per type, the location or event where the samples will be distributed and the number of samples to be distributed in such event, the number of samples to be given per person, and the business rationale behind this plan.

In no case and under no circumstances may OTC products, health related consumer goods, or Medical devices be distributed to minors (individuals below the applicable legal age).

The annual sampling plan must be approved by RMA and Regional Compliance and informed to GMA and Global Compliance. Any deviation on the course of the plan must be also approved by RMA and Regional Compliance and communicated to RMA and Global Compliance.
A higher limit may be approved by RMA and Regional Compliance based on a significant medical reason that supports an increase in the number of permissible sample packs for a particular product (e.g., sample number must be increased to allow for a full course of treatment based on the approved product label)

In case higher limits are approved by RMA and Regional Compliance, a final approval by Global Compliance and GMA is required.

If no such sample plan has been approved and is available, each individual distribution of samples must be approved.

7. Interactions with Government Officials

Because of the heightened scrutiny of interactions with Government Officials under various anti-bribery and anti-corruption laws, in addition to the General Governing Principles set forth in Section 5 above, the following standards apply to all Arcera's interactions with Government Officials (GOs):

7.1. Engagements of Government Officials

Arcera's engagement of a GO (e.g., as a speaker or consultant) in exchange for payment of an honorarium or consulting fee must be subjected to the strictest scrutiny to ensure that Arcera has a legitimate need for such services and the Government Official is uniquely qualified to meet this need, meaning that a non-Government Official cannot be easily substituted. Prior approval of Global Compliance is required. In addition, the written agreement with the GO shall include a provision that ensures the employer's prior approval of the engagement. Depending on the jurisdiction, the GO may need to provide proof of employer approval.

In the context of such an engagement of a Government Official, Arcera may only pay for services and expenses (including travel) if the services and expenses bear no relation to the official duties of the Government Official. Expenses payments must be based on a contractual obligation, must be modest in nature, and must be accompanied by reasonable proof.

7.2. Gifts and Hospitality

Unless the Government Official is also a Healthcare Professional (HCP) and one of the narrow exceptions to the ban on gifts applies (see Section 6.4. above), Arcera has a zero-tolerance policy with respect to gifts to Government Officials.

Reasonable and modest hospitality in the context of a legitimate business interaction with a Government Official (such as a business meeting) may be allowed with prior approval of Regional Compliance. For Government Officials who qualify as HCPs, the rules on hospitality to HCPs apply (see Section 6.3. above).

7.3. Transparency

Arcera is fully transparent with respect to its interactions with GOs. All benefits conveyed to GOs, including Grants to public institutions, must be properly documented and reflected in Arcera's books and records.

7.4. Endorsement of Written Agreement and Confirmation of Terms

All agreements with GOs and public institutions must be formalized in a formal written agreement that is endorsed by responsible representatives of the public institution. This includes, but is not limited to, any Sponsorships and Grants to public institutions, support to a GO for medical education, and any engagements of GOs.

Arcera shall require written assurance/confirmation from the public institution of the supported/engaged GO that benefit to be conveyed (e.g. providing support for attendance at an event or engagement as expert/speaker) do not violate applicable local law and regulations.

7.5. No Fulfilling Suggestions

Arcera may not act on the suggestion or fulfill the request of a GO of a public institution that is in a position to influence Arcera's business interests in any way. This includes, but is not limited to, providing a Grant or other support or engaging a particular vendor or consultant, in each case upon the suggestion of the GO.

8. Interactions with Third Parties and Third-Party Intermediaries

Arcera often engages companies or individuals to represent Arcera and interact with public authorities, Government Officials, and/or HCPs/HCOs on Arcera's behalf. Such companies and individuals are termed Third Party Intermediaries (TPIs). Examples of TPIs include, but are not limited to:

- Distribution partners acting as sales intermediaries on Arcera's behalf.
- Event planners and travel agencies engaging with HCPs in the name of Arcera.
- Clinical Research Organizations managing Arcera-sponsored clinical trials.
- Logistics intermediaries like freight forwarders and customs brokers interacting with public authorities on Arcera's behalf; and
- Consultants representing Arcera's interests in front of any public bodies, or any formulary committees, pricing bodies, reimbursement authorities, or payors.

TPIs represent a heightened risk of bribery and corruption for Arcera because of our lack of knowledge and control, combined with our legal obligation to take adequate measures to prevent bribery by Third Parties acting on our behalf. Arcera can be held liable for the actions of a TPI executed on behalf of Arcera, even if Arcera and its employees did not directly authorize or have actual knowledge of the TPI's improper activities. To mitigate this risk, TPIs must be properly vetted prior to engagement, and there must be appropriate oversight and monitoring of their actions post-engagement to help uncover any prohibited or illegal acts by the TPI. Moreover, TPIs must contractually commit to abiding by all applicable law as well as the principles and standards set forth in this Policy.

In addition to TPIs, Arcera interacts with many other Third Parties, at every state of the product lifecycle and every stage of the supply chain, that are not necessarily acting for or on behalf of Arcera, but are instead acting solely on their own account. Such Third Parties include wholesalers and other customers, vendors, suppliers, certain consultants and other providers of goods and services. These Third Parties should also be vetted prior to engagement because their business practices can have an impact on the reputation of Arcera. Moreover, sanctions regimes may determine whether we can work with them.

Arcera also interacts with Third Parties in the context of mergers & acquisitions, joint ventures, and in-licensing. In all these contexts, it is critical that Arcera does appropriate compliance and financial due diligence of the Third Parties involved. We may acquire assets or an entire company from a selling-Third Party, thereby potentially inheriting the effects of unethical or illegal business practices. In an in-licensing or joint venture context, Arcera's business practices, as well as our reputation, will be affected by those of the licensor-/joint venture-Third Party.

In addition to the General Governing Principles set forth in Section 5 above, the following standards apply to all Arcera's interactions with TPIs and other Third Parties:

8.1. Pre-Engagement Requirements

This Policy sets forth the following requirements that must be fulfilled before a TPI or Third Party may be engaged (other Arcera functions such as Data Protection, IT, EHS and Procurement may have requirements in addition to these):

- There is a legitimate need for the goods or the services provided by the Third Party/TPI.
- The compensation/price will not exceed the Fair Market Value (FMV) (involve Procurement for guidance).
- The Third Party/TPI has been assessed and approved through the appropriate due diligence process based on the risk profile of the Third Party/TPI and according to all internal policies and procedures related to third party due diligence and risk management. The contractual relationship with the Third Party/TPI is permitted under the law of the country of the contracting Arcera legal entity, the law of the country where goods or services will be provided or the activities will take place, and the law of the country where the Third Parties/TPI resides, as well as any other applicable sanctions or embargo regulations; and
- There is a written contract released by Legal in place with the Third Party/TPI.

8.2. Preference for Direct Engagements

Minimizing the layers between Arcera and the Third-Party performing services on our behalf is an important measure in mitigating the risk of illegal business practices being conducted in Arcera's name or on our behalf. It also reduces the risk of inadvertently working with Third Parties on a sanctions list or possessing problematic reputations. Whenever possible, we should contract with service providers directly, rather than through a subcontracting arrangement with an existing TPI or Third-Party business partner.

All internal policies and procedures related to third party due diligence and risk management set forth the standards and procedures that must be followed when a TPI wishes to engage a Sub-TPI to perform 50% or more of the TPI's services.

8.3. Ongoing Monitoring and Certification

Depending on the risk profile of the TPIs and other Third Parties, ongoing monitoring of the business activities should be done by the Accountable Person. Monitoring should include a review of all business plans, invoices and other documentation submitted by a TPI to confirm not only consistency with the contractual terms, but also the absence of any red flag indicating potential illegal or unethical behavior. If red flags are uncovered during monitoring or during any business interaction with a TPI or other Third Party, Regional Compliance shall be immediately consulted and appropriate investigative and/or remediation actions shall be planned and

implemented. Depending on the nature and severity of the red flag, this may include an informal interview, a questionnaire, a formal audit, increased monitoring, and/or training of key TPI/Third Party employees.

In addition, TPIs shall provide yearly certification to confirm, among other things, ongoing compliance with applicable anti-corruption laws, as well as the absence of material changes that would require additional due diligence. The details for this process are set forth in all the internal policies and procedures related to third party due diligence and risk management.

Finally, in order to manage bribery and corruption risks in our ongoing business relationships, a renewal of the due diligence review of TPIs should be done at least every three (3) years or sooner if red flags or material changes occur. The details for this process are set forth in all the internal policies and procedures related to third party due diligence and risk management. Additional sanctions reviews of Third Parties and TPIs in high-risk regions, or with a history of red flags, should be conducted at appropriate intervals, to be decided by Regional Compliance during the due diligence process.

In case any evidence of illegal practices by the TPI or any other Third Party is discovered or is suspected, Global Compliance and Legal must be immediately informed and involved in promptly addressing the situation.

8.4. Requirements in a Merger & Acquisition Context

In order to mitigate the risks of bribery and corruption in an M&A context, Arcera must conduct appropriate pre-closing due diligence as set forth in all the internal policies and procedures related to third party due diligence and risk management.

If an M&A deal proceeds to closing, the following needs to be addressed:

- What is the appropriate post-closing compliance integration to protect against bribery and corruption risks? For example, if new employees will be on-boarded as part of the deal, a training plan needs to be designed and implemented. Regional/Local Compliance should be involved in the design and implementation.
- What is the appropriate post-closing due diligence? If any compliance issues or high risks were identified during the pre-closing due diligence phase, additional compliance due diligence post-closing should be done. Global Compliance should be involved in scoping the post-closing due diligence.
- What existing TPI relationships are already in place? All internal policies and procedures related to third party due diligence and risk management set forth the standards for deciding whether additional due diligence is required to continue with the existing TPI relationships.

9. Gifts and Hospitality to or from Third Parties and Third-Party Intermediaries.

Normal and appropriate gifts and hospitality between business partners can serve a legitimate and legal purpose of expressing appreciation and fostering a business relationship; however, Arcera must exercise great caution before giving or receiving gifts or hospitality as either may be treated under the law as a bribe or may otherwise violate the law.

Hospitality, including meals and refreshments, as well as the payment of the expenses of a TPI or Third Party, such as accommodation expenses during a business trip, should be reasonable under the circumstances. In short, hospitality and expense payments should never act as an incentive for any business behavior or decision. Gifts and hospitality must not be motivated by a desire to exert improper influence, or the expectation of reciprocity.

Arcera must also exercise caution in receiving gifts, hospitality or expense payments, to avoid any possibility that the receipt could influence, or be perceived as having influenced, our business decisions and behavior.

The receipt of GHE constitutes a potential Conflict of Interest and therefore must be disclosed in accordance with the Conflict of Interest Policy.

Gifts and hospitality, either given or received, are generally permitted if all the following requirements are met:

- It complies with local law. If there is ever a doubt, consult with Legal or Compliance.
- The giver or receiver is not a Government Official (GO) (for gifts or hospitality to a GO, see Section 7.2 above).
- It is given/received in Arcera's name, and not in the name of an individual Arcera employee.
- It is consistent with general business practices in the relevant country/countries. Here, the perceived level of corruption in a country should be considered in determining whether the general business practices are acceptable and should have any bearing on the decision to offer or accept a gift or hospitality. Extra caution should be exercised in any "high risk" countries. "High risk" is defined as a score of less than 40 on the Transparency International Corruption Perception's Index (available on the public website: https://www.transparency.org/en/.
- No effort is made to hide or conceal it. Gifts and hospitality must be recorded accurately in Arcera's books and records.
- The giving or receipt of a gift is not during negotiations of a new business relationship, close in time to the launch of a tender or any similar business transaction involving Arcera and the other party (modest hospitality may be offered or received during such times).

- The gift or hospitality is not part of a pattern of providing/receiving gifts or hospitality between the same parties. Multiple gifts to or from the same Third Party within the same 12-month period should be avoided.
- The nature and type of gift/hospitality are business-appropriate and are given in a business-appropriate setting. Cash or cash equivalents (*e.g.*, gift cards, vouchers, pre-paid credit cards) are never business appropriate.
- The value of the gift/hospitality does not exceed limits set by Regional Compliance, unless a stricter limit is required under local law. If Regional Compliance has not set any such limits, then the limit of AED 160 (or local equivalent) for a gift and AED 400 (or local equivalent) for hospitality shall apply.
- No business advantage is offered or received in exchange for the gift or hospitality.

If these requirements are NOT met, and the Accountable Person feels the gift/hospitality is nevertheless appropriate, Regional Compliance must provide prior written approval.

10. Donations to Third Parties

Donations are financial support or in-kind support (e.g., donation of Arcera Products or other items or services) provided to credible and capable charitable organizations, non-profit organizations or public entities. Arcera may provide donations to further a humanitarian or charitable purpose.

In evaluating a donation request, the potential risks and benefits, broader impact on our stakeholders, shareholders and long-term sustainability should be considered. Donations can never be made with a commercial motive, nor can they exert any influence over the approval, purchase, use or recommendation of an Arcera product. Donations can never have a political or military cause. Recipients must have an unequivocal humanitarian mission. There is a general preference for recipients that are international organizations with a proven track record and solid reputation.

If a donation runs the risk of being seen as political or military, or in cases of highly politicized events surrounding the humanitarian purpose, the donation must be approved in advance by Global Compliance regardless of value. In such contexts, there is a strong preference for in-kind donations (e.g., a donation of medicines) rather than an unrestricted financial donation.
Charitable in-kind donations of medicinal products under AED 40’000 in value, do not require Global Compliance approval, unless the situation is sensitive from a political or other perspective as stated above.

Donations made by Arcera employees in their private capacity are not governed by this policy, but employees should refrain from communicating any affiliation with Arcera when they donate as a private individual.

The requirements for approving and distributing a donation are set forth in Appendix I.

11. 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 Global Compliance.

Arcera is religiously and politically neutral. For this reason, the company's Contributions may not foster in a targeted manner either one religious group or one partisan political ideology vis-à-vis other persuasions or political viewpoints. Therefore, all contributions that benefit the activities of a religious denomination (for example, of a church or a clergy for missionary work or liturgical activities) or that support partisan political purposes or the representation of partisan political interests (for example, election events for political campaigns) are prohibited.

Support may be provided to activities of religious organizations or politically affiliated organizations, provided that the latter are non-partisan as defined in their articles of association. Such contributions must align with the relevant strategic goals and requirements, and must receive prior approval from Global Compliance.

12. Discounts and Rebates

Arcera may grant discounts or rebates so long as all of the following are true:

- The terms of any discount/rebate are fixed and disclosed in writing to the purchaser at the time of the initial provision of the product.
- The discount/rebate is fully and accurately reported on all relevant invoices or other statements to the purchaser.
- The discount/rebate is consistent with applicable competition law. If Arcera holds a "dominant" position in the given product and given market, then Regional or Global Legal must approve (and Legal should be consulted if there is any doubt about whether the position is a dominant one). In no case can the discount/rebate result in the price of a product falling below Arcera's cost for manufacturing, marketing and distributing the product.
- The discount/rebate is not designed or intended to influence the choice of treatment.

13. Tenders

Arcera shall not make or offer any payment in value or in kind to any Government Official (GO), either directly or indirectly, in order to obtain favorable treatment in the tender process.

In many countries, national, regional, or local health authorities (e.g. public hospitals) purchase medicinal- and/or medical 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.

Arcera 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.

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 Policy 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.

Arcera and its employees may not seek to improperly influence the decisions of tender committee members.

In the pre-tender phase, no incentives may be offered or promised by Arcera. 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 avoided or only done under full transparency with guidance from Regional or Global Compliance.

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), Arcera 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 Regional or Global Compliance.

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), Arcera may offer only those 'additional' services (so-called VAS: Values Added Services) that meet the requirements of this Policy. That is, they must be closely related to provision of the Arcera product and meet the other criteria set out in this Section. All services must be transparently disclosed during the tender process.

Product-related items and services are sometimes referred to as “value-added” services in the context of tenders. 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.

Arcera 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, may not be offered for free or below market value cost.

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

1. Close relationship: A product-related item or service must be closely related to the specific Arcera 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 Arcera product is being used to treat.

2. Normal overhead: A product-related item or service must fall within an Arcera normal marketing and sales expenses and should not be a cost that the customer usually pays as part of its operating expenses.

3. Modest cost: The overall value of the product-related item or service must be modest in comparison to what the customers pay for the Arcera product being sold.

4. 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 Arcera. This means that the product-related item or service may not be substantially different for one customer in a class than another.

5. No provision of Services that are not solely related to Arcera 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 Arcera and/or to government payers.

6. Not otherwise offered for Sale: A product-related item or service may not be provided to a customer or HCP in connection with Arcera products for free, if another Arcera entity or Third Party 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.

14. Compliance Monitoring

Compliance shall conduct periodic monitoring of Arcera employees and may do so with Third Party Intermediaries to ensure compliance with this Policy. In situations where Compliance is involved in review and approval workflows, the monitoring is less critical. In cases where Regional Compliance has been part of an approval workflow but decides to step out, a monitoring plan should be in place, including more frequent monitoring during a transition phase.

Arcera employees are required to cooperate fully with Compliance in all monitoring activities. Department or function heads are to ensure the following type of documents are retained and stored in a centralized location for future monitoring:

- All relevant internal approvals and communications.
- All required documentation of events and interactions, including the documentation of the purpose, the materials shared, the individuals in attendance, and any hospitality offered.
- Evidence of the proper fulfilment of our contracts with HCPs, HCOs and other Third Parties, where an obligation to collect such evidence is set forth in this Policy.
- Proof of payments and relevant original receipts and supporting reconciliation documents.

Any compliance issues identified through monitoring efforts shall be remediated with the participation of all responsible parties. Compliance shall define reasonable corrective and/or preventive actions, and such actions and their achievement shall be properly recorded. Compliance shall identify and pursue opportunities to disseminate and discuss learnings, in the spirit of continuous improvement.

Department or function heads are responsible for ensuring that this Policy is implemented and followed appropriately. If requested, department or function heads are also responsible for ensuring that periodic monitoring is conducted as evidence of process implementation and adherence. The monitoring results shall be reported to Compliance if required.

15. Breach of Policy & Reporting Obligations of Potential Misconduct

Violations of this Policy may subject Arcera employees to disciplinary action, including termination. Violations of the laws underlying this Policy can give rise to criminal prosecution and possible monetary fines and imprisonment.

Arcera employees, directors and officers are strongly encouraged to report any suspected or actual violation of this Policy in accordance with the procedures set forth in the Arcera Code of Ethics and related Policies. A reporting line for any suspected violations is available to employees. Reports can be made anonymously.

Threats or acts of retaliation against individuals who make a good faith report of suspected inappropriate conduct pursuant to Arcera guidelines and policies will not be tolerated. Disciplinary action will be taken against any employee who retaliates against others who reported such violations. Disciplinary action may include the immediate termination of employment.

Legal or Compliance is responsible for furnishing advice with respect to the interpretation of applicable laws and this Policy. Compliance shall also ensure that Arcera employees are informed and trained, as appropriate, with respect to this Policy. Upon notification of a suspected violation, they will ensure that an appropriate investigation is carried out in accordance with the procedures set forth for such investigations and that remedial action is taken, if appropriate.