



IFPMA Note for Guidance on Ethical Third Party Intermediary Relationships in the Biopharmaceutical Sector

Introduction

The IFPMA Code of Practice sets global standards for industry business practices and includes guiding principles of ethical conduct as well as requirements for the promotion of medicines to, and interactions with, healthcare professionals (“HCPs”) and other stakeholders. To ensure and improve ongoing access for patients and HCPs to innovative, reliable and effective medicines and vaccines, it is often necessary for research and development-based biopharmaceutical manufacturers (“Companies”) to contract with third parties to support their business activities. These third parties can operate as clinical research organizations, distributors, wholesalers, distribution or sales agents, consultants, brokers, commission agents, and/or independent sales representatives (“Third Party Intermediaries” or “TPIs”). They serve an integral role in the biopharmaceutical sector and health systems, helping ensure patients, HCPs, institutions and associations have access to Company products and services. A significant majority of TPIs in the biopharmaceutical sector around the world are small and medium-sized enterprises (SMEs).

To ensure high-standard ethical business practices are utilized, it is essential that Companies’ interactions with TPIs, as well as TPIs’ interactions on behalf of Companies (including with HCPs, healthcare organizations and government agencies and officials) adhere to applicable international and local laws, regulations, industry codes, standards and ethical principles (“applicable requirements”).

This Note for Guidance intends to provide non-binding best practices for Companies when working with TPIs. To the extent applicable requirements (e.g. local laws) differ, Companies should adhere first to requirements established in their respective countries.

Associations may reflect this Note for Guidance within their compliance efforts and programs. Companies are encouraged to work with their associations to offer opportunities for TPIs to access resources (e.g. trainings and online tools) to foster alignment with ethical practices.

The objective of this document is to provide additional guidance on the provisions of Article 12 of the IFPMA Code of Practice (Company Procedures and Responsibilities) and add clarity to point IV of the IFPMA Code of Practice Preamble which mentions that ‘IFPMA member companies and **anyone acting on their behalf** must comply directly with applicable national codes of member associations where such codes exist’. In addition, the IFPMA Ethos which underpins the rules of the IFPMA Code of Practice and is centered on trust, stipulates to act with fairness, and to ‘be accountable for our actions and decisions, including the appropriate oversight of external third parties that act on our behalf.

Guidance

IFPMA encourages Companies to develop and adopt a TPI Risk Management Program as part of their overall compliance program and code of ethics. IFPMA also encourages Companies to determine the appropriate resources required to carry out the TPI Risk Management Program. Taking into account a variety of risk-based factors, as well as applicable requirements, the TPI Risk Management Program should take a holistic governance approach that includes a thorough risk assessment, as described below.

Risk Assessment should include the following elements: (1) the local risk identified through external experts (e.g. published corruption indices), as well as specific risk profiles of potential or existing TPIS, based on services provided; (2) the correct application of applicable requirements (e.g. local regulations and/or codes) for ethical TPI relationships; (3) information from TPIS for potentially unusual arrangements, such as unusually high commissions, or other unusual payment patterns or financial arrangements (e.g. request for cash payments and/or off-shore payment accounts), marketing budgets, facilitation payments, high degree of interaction with government officials, HCP corporate affiliation or ownership; (4) information available from public sources or employees for potential issues associated with a TPI; (5) information relating to TPI's reputation, ethical standards, compliance/anti-corruption program and ability to perform services to be obtained; and (6) the scope and substance of the TPI's codes of ethics and internal policies on relevant risks, for example:

- a. **Anti-Bribery/Anti-Corruption:** The TPI's internal policies and controls prohibiting all forms of bribery or any other form of corruption by the TPI or by any person or entity acting on the TPI's behalf. Such policies and controls should cover common business activities such as travel/accommodation, gifts, hospitality/venue, sponsorship, grants or donations, research, fees for services, sales and marketing, samples, customs clearance, procurement processes and capital equipment as well as interactions with HCPs and/or government agencies or officials.
- b. **Appropriate Promotion:** The TPI's internal policies and controls to permit only appropriate promotion of products. Such policies and controls should be designed to ensure that promotion is consistent with the product information, accurate, fair, balanced, not misleading, and substantiated.
- c. **Other relevant risks** include, for example, data protection, information security and conflicts of interest.

The outcome of the Risk Assessment should inform the below elements:

- I. **Due Diligence Program:** Companies should establish a risk-based pre-engagement and renewal due diligence program to identify, prevent, and mitigate risks identified in the Risk Assessment, as well as risks relating to the country in which the TPI is engaged or plans to operate. It should also cover any specific activities or services the TPI is conducting or plans to conduct on behalf of the Company. In cases where identified risks cannot be mitigated, companies should exit or not proceed with the engagement.
- II. **Written Contract:** Companies should sign a contract with the TPI before services begin. Contractual terms that should be agreed on with the TPI include controls and other requirements to mitigate or address identified risks, such as:

- a. The TPI's compliance with applicable requirements and relevant Company policies related to anti-bribery/anti-corruption and other risk areas related to the services, including fair trade, sanctions lists, pharmacovigilance, data protection, and information security, as applicable;
 - b. The right for the Company to conduct audits and ongoing monitoring of the TPI, including access to relevant books and records;
 - c. The right for the Company to terminate an engagement for failure to comply with applicable requirements and relevant Company policies; and
 - d. Due Diligence rights upon renewal of the contract.
- III. **Training and Education:** Companies should require initial and regular training and education for relevant TPI personnel supporting the Company business (e.g. its owners, its members of the board of directors and the supervisory board, directors, and employees providing the services) on applicable requirements and relevant Company policies, including policies on raising questions or concerns. Training should be conducted in the language most appropriate to the audience and training should be documented.
- IV. **Monitor/Audit:** Companies should maintain ongoing oversight of the TPI engagement and the TPI's reputation, as well as risk-based, routine assessment, such as monitoring, auditing, and other assessments of the TPI's services for compliance with applicable requirements and relevant Company policies; Companies should seek regular certification by TPIs on compliance with applicable requirements and relevant Company policies. Assessment outcomes should be addressed in a timely and effective manner by the TPI.
- V. **Appropriate Corrective Action:** Corrective measures should be taken by Companies if a TPI fails to comply with applicable requirements, relevant Company policies or contract terms, or engages in other impermissible or unethical conduct.