TRANSPARENCY INTERNATIONAL
Pharmaceuticals & Healthcare Programme

BUSINESS PRINCIPLES FOR PROMOTING INTEGRITY IN THE PHARMACEUTICAL SECTOR

A REGIONAL MULTI-STAKEHOLDER INITIATIVE FOR LATIN AMERICA LED BY TRANSPARENCY INTERNATIONAL UK'S PHARMACEUTICALS & HEALTHCARE PROGRAMME

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The Pharmaceuticals & Healthcare Programme is a global initiative based in Transparency International UK. Applying Transparency International's strengths and expertise, the Programme's overall goal is to improve global health and healthcare outcomes for the benefit of all people of all ages. It aims to achieve this by reducing corruption and promoting transparency, integrity and accountability within the pharmaceutical and healthcare sectors.

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Business Principles for Promoting Integrity in the Pharmaceutical Sector

A Regional Multi-Stakeholder Initiative for Latin America led by Transparency International UK's Pharmaceuticals & Healthcare Programme

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Foreword

Transparency International UK's Pharmaceuticals & Healthcare Programme (PHP) is pleased to present the *Business Principles for Promoting Integrity in the Pharmaceutical Sector* ("*the Pharma Integrity Principles"*) for use by pharmaceutical companies in Latin America.[1] These Principles largely derive from the Business Principles for Countering Bribery developed by Transparency International ("TI Business Principles"), augmented by the Mexico City Principles and other voluntary codes of business ethics developed in the pharmaceutical sector.[2]

Pharmaceutical companies make an essential contribution to public health and welfare, as well as to the economies in which they operate. This application of the TI Business Principles recognizes that pharmaceutical companies across Latin America are frequently confronted with the problem of bribery and related conflicts of interest. Pharmaceutical companies face many of the same challenges as counterparts in other business sectors, in relation to government licensing, inspection and procurement activities. But they also have a special responsibility and challenge to ensure the integrity of patient and healthcare provider decisions about the use of prescription drugs.

The *Pharma Integrity Principles* build on substantial efforts over the past decade by key actors in the region and are meant to be used in conjunction with established industry codes. They focus on challenges specific to the pharmaceutical sector, combining anti-bribery principles of general applicability with sector-specific guidelines for preserving the integrity of prescribing practices. We also aim to provide a practical guide for implementing integrity commitments. Guidance provided through these standards reflects the latest innovations from international practice.

Transparency International UK's Pharmaceuticals & Healthcare Programme believes the time is right for issuance of these regional integrity principles and that their widespread adoption will strengthen standards across the region and contribute to the goals of good governance and ultimately improved healthcare outcomes. Companies that adopt the *Pharma Integrity Principles* will be committing to two fundamental actions – a commitment to ethical business practices and to an effective programme of internal controls for implementing this policy. In practical terms, this will mean either implementing anti-bribery and conflict of interest practices based on these *Principles* or, for companies with established programmes, using them to benchmark existing practice.

This document has been designed to provide companies with practical guidance and a reference point for developing their own policies and procedures for promoting integrity. Future efforts will focus on securing commitment and sustainable adherence to the *Pharma Integrity Principles* across the region and to working with public and private sector institutions to take complementary steps.

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1 As used in these *Principles*, a "pharmaceutical company" is any company, regardless of ownership structure, that develops, manufactures, markets or distributes a pharmaceutical product, including biologics. Such products are also referred to in these *Principle*s as "medicines."

2 The Mexico City Principles, developed in 2011 under APEC (Asia-Pacific Economic Cooperation) auspices, establish minimum ethical standards for voluntary codes of business ethics in the biopharmaceutical sector. They reflect more detailed standards established by the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), the Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (CETIFARMA), and other leading international and regional pharmaceutical associations.

Stakeholder Development

The TI Business Principles were developed by a Steering Committee of leading companies and organisations under the Chairmanship of Transparency International. First issued in 2003, they underwent minor revision in 2009 and again in 2013 to incorporate advances in the design and implementation of anti-bribery programmes.

Since their introduction, the TI Business Principles have encouraged the development of other anti-bribery codes and companies and researchers now look to them as a global benchmark. The Business Principles have been translated into more than ten languages and introduced through seminars and workshops to corporate and governmental audiences in countries around the world. They have also informed official guidance for anti-bribery programmes published by authorities in the United Kingdom, United States and elsewhere, including Latin America.

This sectoral adaptation of the Business Principles has been developed under the direction of Transparency International UK's Pharmaceuticals & Healthcare Programme, in coordination with TI chapters in Latin America and with input and guidance from a multi-stakeholder Advisory Committee. It reflects extensive consultations undertaken with national and multinational industry associations, patient advocacy organisations and public sector agencies, described in Annex B.

Guidelines on sector-specific conflicts of interest draw heavily on the IFPMA Code of Practice and related industry codes, and the extensive industry consultations supporting their development and periodic updating.

1. Introduction

The aim of the *Pharma Integrity Principles* for Latin America is to provide a framework for good business practices and risk management strategies for promoting integrity in the pharmaceutical sector. They are intended to assist companies and industry associations across the region in:

- eliminating bribery and related conflicts of interest;
- demonstrating their commitment to doing business with integrity; and
- making a positive contribution to improving business standards of integrity, transparency and accountability.

The *Pharma Integrity Principles* combine anti-bribery principles of general applicability developed by Transparency International with more specific guidelines for preventing conflicts of interest in the pharmaceutical sector in relation to prescribing practices by healthcare professionals and interactions with healthcare institutions, patients and patient organisations.

The *Pharma Integrity Principles* commit signatory companies to two basic actions: the adoption of a "zero tolerance" policy on bribery and related conflicts of interest and the development of a practical and effective internal "Programme" for implementing that policy.[3] These *Principles* are designed to provide companies of all sizes with practical guidance for developing their own policies and Programmes for promoting integrity in their business. They are meant to be used in conjunction with more detailed guidelines on ethical practice developed and administered by industry associations.

This initiative reflects an appreciation that bribery and conflicts of interest are corrosive of economic progress and good governance and can negatively impact public health. It recognizes the need for business principles that can be applied industry-wide and that are based on a meaningful commitment to fundamental values of integrity, transparency and accountability. The initiative also recognizes that strengthening integrity is a complex and multifaceted challenge that cannot be fully met by pharmaceutical manufacturers acting alone, but requires a shared commitment to high ethical standards and practices by government, health care professionals and other providers.

3 As used in these *Principles*, "zero tolerance" means a commitment to rigorous compliance with applicable laws prohibiting bribery and with industry association codes or other guidelines regulating conflicts of interest that can improperly influence prescribing practices by healthcare professionals. For signatory companies with established compliance programs, this commitment may be satisfied through continuation and periodic testing and refinement of existing policies and practices.

2. The Pharma Integrity Principles

These are the business values by which signatory Companies agree to conduct business. A signing statement for committing to these *Principles* is attached at Annex A.

Signatory Companies commit to:

- Conducting their business fairly, honestly and transparently. This includes neither making nor accepting bribes, in any form.[4]
- Implementing an effective Programme to support the *Principles*.

These *Principles* are based on a leadership commitment to fundamental values of integrity, transparency and accountability.

An "effective" programme is the entirety of an enterprise's anti-corruption efforts, specifically including its code of conduct, policies and procedures, administrative processes, training, guidance and oversight. This commitment is to develop and administer an internal compliance programme that effectively makes a company's integrity policy an integral part of daily practice.

4 Bribery means any improper promise, offer or payment to obtain an undue business advantage. For purposes of the *Pharma Integrity Principles*, this includes benefits offered or given to a healthcare professional, institution or patient organisation with the intent to inappropriately influence prescription, procurement or other medical or business decisions.

3. Development of a Programme for Promoting Integrity

A signatory Company's Programme should reflect these foundational practices, drawn from substantial experience in designing effective integrity programmes.

3.1. The Company should develop and maintain a Programme that clearly, and in reasonable detail, articulates the values, policies and procedures that will be used to prevent bribery and conflicts of interest from occurring in all activities under its effective control.

3.2. The Programme should be tailored to reflect the Company's particular business circumstances and culture, taking into account such factors as size, enterprise structure, the nature of the business, operational risks and locations of operation.

3.3. The Programme should be consistent with all laws relevant to countering bribery and conflicts of interest in each of the jurisdictions in which the Company operates.

3.4. The Company should ensure that it is aware of matters material to the effective development and implementation of its Programme, including emerging industry practices.

3.5. The Programme should reflect and communicate the essential contribution of modern medicine to public health and welfare and the fundamental importance of integrity to this mission.

4. Scope of the Programme

In developing its Programme for promoting integrity, a signatory Company should identify specific areas that pose the greatest risks from bribery and potential conflicts of interest.

All Programmes should at a minimum cover the following areas:

4.1. Bribes

4.1.1. The Company should prohibit all forms of bribery in connection with its business activities, whether carried out directly or through an agent, distributor or other third party.[5]

4.1.2. The Company should also prohibit its employees and agents from soliciting or accepting bribes in the conduct of their responsibilities on behalf of the Company, including procurement.

4.1.3. The Programme should provide guidance on the meaning and scope of this prohibition, with particular attention to areas of high risk to pharmaceutical companies.

4.2. Political contributions

4.2.1. The Company, its employees, agents, lobbyists or other intermediaries should not make direct or indirect contributions to political parties, organisations or individuals engaged in politics, as a subterfuge for bribery.

4.2.2. All political contributions should be transparent and made only in accordance with applicable law.

4.2.3. The Programme should include controls and procedures to ensure that improper political contributions are not made.

4.3. Charitable contributions and sponsorships

4.3.1. The Company should ensure that charitable contributions and sponsorships are not used as a subterfuge for bribery.

4.3.2. All charitable contributions and sponsorships should be transparent and made in accordance with applicable law.

4.3.3. The Programme should include controls and procedures to ensure that improper charitable contributions and sponsorships are not made.

5 This prohibition applies to all manner of improper payments, without regard to amount or a recipient's level of authority. Consistent with applicable national laws across the region, no de minimis exception is recognized, including for so-called "grease" or facilitation payments.

4.4. Gifts, hospitality and expenses

4.4.1. The Company should prohibit the offer or receipt of gifts, hospitality or expenses whenever such arrangements could inappropriately affect, or might be perceived to inappropriately affect, the outcome of a procurement or other business transaction and are not reasonable and bona fide expenditures.[6]

4.4.2. The Programme should include controls and procedures, including thresholds and reporting procedures, to ensure that the Company's policies relating to gifts, hospitality and expenses are followed.

4.5. Interactions with healthcare professionals

4.5.1. The Company should ensure that all interactions with healthcare professionals[7] are conducted in a transparent and ethical manner.

4.5.1.1. Nothing should be offered or provided by the Company, its employees or agents in a manner that is intended to inappropriately influence a healthcare professional's prescribing practices.

4.5.1.2. Medicines should only be provided or promoted in a national market, and for a specific use, consistent with applicable law and regulation.

4.5.1.3. Promotional information should be clear, accurate, balanced and sufficiently complete to enable a healthcare professional to form an independent opinion about a medicine's therapeutic value.

4.5.1.4. Medicines provided by the Company should conform to applicable legal standards of quality, safety and efficacy, including requirements for prompt reporting of adverse events or drug reactions.

4.5.2. The Company should limit sponsorship of symposia, conferences or other meetings for healthcare professionals to events that have a legitimate scientific or educational purpose and meet the following precautionary criteria.

4.5.2.1. Any sponsorship provided to individual healthcare professionals should not be conditional upon an obligation to prescribe, recommend or promote any medicine.

4.5.2.2. Sponsorship of healthcare professionals should be limited to payment of travel, meals, accommodation and registration fees, and should not involve any payment for time spent attending the event.

4.5.2.3. Events should be held in an appropriate venue that is conducive to the scientific or educational purpose of the event.

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6 Guidelines in this section are general, applicable to the full range of a signatory Company's business activities. More restrictive standards apply to interactions with healthcare professionals, detailed in section 4.5.4.

7 A "healthcare professional" is any member of the medical, dental, pharmacy or nursing professions or any other person who, in the course of his or her professional activities, may prescribe, recommend, purchase, supply or administer a pharmaceutical product.

4.5.2.4. Hospitality should be provided only to actual participants of an event (and not their guests, unless qualified in their own right to attend), and should be moderate and reasonable in value as judged by local standards.

4.5.2.5. No entertainment or other leisure activities should be provided or paid for by the Company, its employee or agents.

4.5.3. The Company should ensure that consulting, research or other contractual relationships entered into with healthcare professionals are not a subterfuge for bribery.

4.5.3.1. Fee-for-service arrangements should be pursuant to a written contract or agreement specifying the services to be provided and basis of payment.

4.5.3.2. A legitimate need for the services and criteria for selecting consultants should be clearly identified and documented in advance.

4.5.3.3. The number of consultants retained should not be greater than the number reasonably necessary to achieve the identified need.

4.5.3.4. The hiring of a consultant should not be an inducement or reward for recommending or prescribing a particular medicine.

4.5.3.5. Compensation should be reasonable and reflect the fair market value of services provided.

4.5.4. The Company should prohibit the offer of gifts or other things of value in a manner that is intended to inappropriately influence a healthcare professional's prescribing practices.

4.5.4.1. Payments in cash or cash equivalents (such as gift certificates) should not be provided or offered to healthcare professionals.

4.5.4.2. Gifts for the personal benefit of healthcare professionals (such as entertainment or sporting tickets) also should not be provided or offered.

4.5.4.3. Promotional items of minimal value and quantity may be offered or provided to healthcare professionals if relevant to the practice of the healthcare professional.

4.5.4.4. In accordance with local laws and regulations, items of medical practice and health care may be offered or provided if such items are of modest value, do not offset routine business practices and are beneficial to enhancing the provision of medical services and patient care.

4.5.5. The Company should ensure that samples of medicines are provided for legitimate purposes and in accordance with controls to protect patient health and prevent abusive practices.

4.5.5.1. Samples of prescription products should only be provided to qualified healthcare professionals authorized to prescribe or dispense that medicine, in amounts that are moderate and reasonable and with appropriate guidance on their proper use and storage.

4.5.5.2. Samples should not be used as payment for services, return for past or future favourable treatment, or other inappropriate inducements.

4.5.5.3. The Company should have adequate systems for control and accountability for samples provided to healthcare professionals, consistent with applicable law and regulation.

4.5.6. The Company should prohibit the offer or provision of grant, scholarship or other financial support to a healthcare professional in exchange for recommending or prescribing medicines, or otherwise in a manner that would interfere with the ethics and independence of a healthcare professional's prescribing practices.

4.5.6.1. The Company should have a reasonable expectation that grant or other financial assistance to a healthcare professional is for the purpose of supporting legitimate education, scientific or medical research.

4.5.6.2. The Programme should include objective criteria for ensuring the existence of a bona fide educational programme and that financial support is not an inducement to recommend or prescribe a particular medicine or course of treatment.

4.6. Interactions with patient organisations

4.6.1. The Company should ensure that all interactions with patient organisations[8] are conducted in a professional and ethical manner. The independence of patient organisations should at all times be respected.

4.6.2. When working with patient organisations, the Company should ensure that the existence and nature of the relationship is clear from the outset. No company should require that it be the sole funder of the patient organisation or any of its programmes.

4.6.3. Financial or in-kind support provided to patient organisations should be memorialized in a written document setting out the nature of the support, including the purpose of any activity and its funding.

4.6.4. Patient support programmes should be for a legitimate medical purpose, and offered only to patients with an appropriate diagnosis and pursuant to direction from a patient's healthcare provider.

4.6.5. Support provided to patient organisations should not be conditional on the promotion of a specific medicine or course of treatment.

4.6.6. The Company should have controls and procedures to ensure that support for patient organisations is for a legitimate purpose, and not intended to inappropriately influence the prescribing practices of healthcare professionals.

8 A "patient organisation" for purposes of these *Principles* includes any not-for-profit organisation that has as a primary purpose representing the interests of patients, their families and/or caregivers.

4.7. Interactions with healthcare institutions

4.7.1. The Company should ensure that all interactions with healthcare institutions[9] are conducted in a transparent and ethical manner.

4.7.2. Nothing should be offered or provided by the Company, its employees or agents in a manner that is intended to inappropriately influence a healthcare institution's procurement or other business decisions.

4.7.3. Samples of medicines should only be provided for legitimate purposes and in accordance with controls to protect patient health and prevent abusive practice.

4.7.4. Grant, scholarship or other financial support to healthcare institutions should only be provided for activities that have a legitimate scientific, public health or educational purpose, and in accordance with controls to prevent bribery or conflicts of interest.

4.7.5. The Company should prohibit direct or indirect donations of medicines or in-kind services intended to inappropriately influence the purchasing practices of healthcare institutions. All donations should be transparent and made only in accordance with applicable law.

4.7.6. All clinical trials and scientific research involving patients sponsored or supported by the Company should be conducted in an ethical manner and with the intent to develop bona fide scientific knowledge that will benefit patients and advance science and medicine. Appropriate measures should be in place to ensure transparency and accountability in the presentation of research and publication of study results.

9 The term "healthcare institution" refers to hospitals and clinics, whether publicly or privately-owned, healthcare and social security agencies, medical associations, scientific institutions and similar entities.

5. Programme Implementation Requirements

The following section sets out the requirements that a Company should meet, at a minimum, when implementing the Programme.

5.1. Organisation and responsibilities

5.1.1. The Board of Directors (or equivalent senior management body for the region or country) is responsible for ensuring that the Company has an effective Programme for combatting bribery and conflicts of interest.

5.1.2. The Chief Executive Officer (or equivalent senior business manager for the region or country) is responsible for ensuring that the Programme is carried out consistently with clear lines of authority.

5.1.2.1. Authority for implementation of the Programme should be assigned to senior management with direct line reporting to the chief executive officer (or equivalent senior business manager for the region or country).

5.1.2.2. Compliance officers should have appropriate experience, authority and resources to effectively undertake their responsibilities.

5.1.3. The Board of Directors and senior management (or regional equivalents) should demonstrate visible and active commitment to the implementation of the *Pharma Integrity Principles*.

5.2. Business relationships

A signatory Company's commitment to implement an effective Programme for combatting bribery and conflicts of interest should extend to all of its business activities, whether conducted directly or through a business partner.

5.2.1. Subsidiaries

5.2.1.1. The Programme should be designed and implemented on an enterprise-wide basis, applicable in all material respects to controlled subsidiaries and affiliates in Latin America.

5.2.1.2. The Company should encourage an equivalent programme in non-controlled affiliates and other business entities in Latin America in which it has a significant investment.

5.2.2. Joint ventures[10]

5.2.2.1. Due diligence should be conducted before entering into a joint venture, and on an on-going basis as circumstances warrant.

5.2.2.2. The Company should undertake appropriate measures, including contract protections, to ensure that the conduct of a joint venture is consistent with the *Pharma Integrity Principles*.

5.2.2.3. The Company should monitor the Programmes and performance of joint ventures, and take appropriate action when policies or practices inconsistent with its own are identified.[11]

5.2.2.4. The Company should have a right of termination in the event that associated business entities engage in bribery or act in a manner inconsistent with the Company's Programme.

5.2.3. Agents and other intermediaries

5.2.3.1. The Company should undertake due diligence before appointing an agent or other intermediary, and on an on-going basis as circumstances warrant.

5.2.3.2. The Programme should provide guidance for conducting due diligence, entering into contractual relationships, and monitoring the conduct of an agent or other intermediary.

5.2.3.2.1. Due diligence review and other material aspects of the relationship with the agent or other intermediary should be properly documented.

5.2.3.2.2. All agreements with agents and other intermediaries should require appropriate prior approval of management.

5.2.3.2.3. Compensation paid to agents and other intermediaries should be appropriate and justifiable remuneration for legitimate services rendered and paid only through bona fide channels.

5.2.3.2.4. Agents and other intermediaries should contractually agree in writing to comply with the Company's Programme and be provided with appropriate guidance and documentation explaining this obligation.

5.2.3.2.5. The Company should contractually require its agents and other intermediaries to keep proper books and records available for inspection by the Company, auditors or investigating authorities.

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10 The provisions in 5.2.2 apply also to non-controlled subsidiaries, consortium partners, teaming arrangements and other forms of business partnership.

11 Depending on the circumstances, appropriate response action may include: requiring correction of deficiencies in the joint venture's Program; application of sanctions; or exiting from the joint venture.

5.2.3.2.6. The Company should monitor the conduct of its agents and other intermediaries and should have a contractual right of termination in the event they pay bribes or otherwise act in a manner inconsistent with the Company's Programme.

5.2.4. Contractors, suppliers and distributors

5.2.4.1. The Company should conduct its procurement practices in a fair and transparent manner.

5.2.4.2. The Company should undertake due diligence, as appropriate, in evaluating contractors, suppliers and distributors to ensure they have effective anti-bribery and conflict practices, monitor their conduct, and have a contractual right of termination in case of conduct inconsistent with the Company's Programme.

5.2.4.3. The Company should communicate its anti-bribery and conflict of interest policies to contractors, suppliers and distributors, and work with significant partners to help them develop their own anti-bribery and conflicts practices.

5.3. Human resources

5.3.1. Human resources practices, including recruiting, promotion, training, performance evaluation, remuneration and recognition, should reflect the Company's commitment to the Programme.

5.3.2. The Company should make clear that no employee will suffer demotion, penalty or other adverse consequences for refusing to pay bribes even if such refusal may result in the Company losing business.

5.3.3. The Company should make compliance with the Programme mandatory for all personnel, including directors and senior management, and apply appropriate sanctions for violations of its Programme.

5.4. Training

5.4.1. Directors, managers, employees and agents should receive appropriate training on the Programme.

5.4.2. Where appropriate, contractors, suppliers and distributors should receive training on the Programme.

5.4.3. Training activities should be assessed periodically for effectiveness.

5.5. Raising concerns and seeking guidance

5.5.1. The Programme should encourage employees and others to raise concerns and report suspicious circumstances to responsible Company officials as early as possible.

5.5.2. To this end, the Company should provide secure and accessible channels through which employees and others can raise concerns and report suspicious circumstances ("whistleblowing") in confidence and without risk of reprisal.

5.5.3. These channels should also be available for employees and others to seek advice on the application of the Programme, generally and with respect to specific circumstances.

5.6. Communication and reporting

5.6.1. The Company should establish effective mechanisms for internal and external communication of the Programme.

5.6.2. The Company should publicly disclose its Policy for countering bribery and conflicts of interest.

5.6.3. The Company should be open to receiving communications from relevant interested parties with respect to its Policy for countering bribery and conflicts of interest.

5.7. Internal controls and audit

5.7.1. The Company should establish and maintain an effective system of internal controls to counter bribery and related conflicts of interest, comprising financial and organisational checks and balances over the Company's accounting and recordkeeping practices and other business processes related to the Programme.

5.7.2. The Company should maintain available for inspection accurate books and records that properly and fairly document all financial transactions. The Company should not maintain off-the-books accounts.

5.7.3. The Company should subject its internal control systems, in particular its accounting and recordkeeping practices, to regular review and audit to provide assurance on their design, implementation and effectiveness.

5.8. Monitoring and review

5.8.1. The Company should establish feedback mechanisms and other internal processes supporting the continuous improvement of the Programme.

5.8.2. Senior management for the region or country (or appropriate designees) should monitor the Programme and periodically review its suitability, adequacy and effectiveness and implement improvements as appropriate. They should periodically report the results of Programme reviews to the Board and Audit Committee (or equivalent senior management body for the region or country).

5.8.3. The Board and Audit Committee (or equivalent senior management body for the region or country) should receive and evaluate periodically an assessment of the adequacy of the Programme.

5.9. Additional Provisions

5.9.1. The Company should cooperate with relevant authorities in connection with bribery and corruption investigations and prosecutions.

5.9.2. The Company should support voluntary self-regulatory efforts to strengthen anti-bribery and conflict of interest standards and practices across the pharmaceutical sector, including through appropriate oversight mechanisms established by representative associations.[12]

12 The term “appropriate oversight mechanisms” refers both to traditional complaint procedures established by pharmaceutical associations and assurance reviews to confirm that member companies have implemented meaningful anti-bribery and conflict of interest programs.

Annex A

Signing Statements

The following section contains signing statements for:

- Companies
- Associations
- Medical Societies
- Payor Agencies

Signing Statement
(Companies)

Commitment to Integrity

As business leaders, we have individual and organisational responsibilities to make a strong and active contribution to promoting integrity in the pharmaceutical sector in Latin America. By committing to the *Pharma Integrity Principles*, we join together to support an initiative to strengthen standards across the region and contribute to the goals of good governance, integrity and patient welfare.

We support the *Pharma Integrity Principles*, derived from Transparency International's Business Principles for Countering Bribery and relevant industry codes of practice. These *Principles* call for a commitment to two fundamental actions:

- A zero-tolerance policy towards bribery and related conflicts of interest, and
- Development of a practical and effective implementation programme.

Our support means that we will either implement anti-bribery and conflict of interest practices based on these *Principles* or use them to benchmark and improve our existing programmes so that they achieve the objectives of these *Principles*.

Signature: _____

Date: _____

Full Name (Print): _____

Title: _____

Company: _____

Signing Statement
(Associations)

Commitment to Integrity

As leaders of associations of pharmaceutical manufacturers, we have individual and organisational responsibilities to make a strong and active contribution to promoting integrity in the pharmaceutical sector in Latin America. By committing to the *Pharma Integrity Principles*, we join together to support an initiative to strengthen standards across the region and contribute to the goals of good governance, integrity and patient welfare.

We support the *Pharma Integrity Principles*, derived from Transparency International's Business Principles for Countering Bribery and relevant industry codes of practice. These *Principles* call for a commitment by our member companies to two fundamental actions:

- A zero-tolerance policy towards bribery and related conflicts of interest, and
- Development of a practical and effective implementation programme.

Our support means that we will either establish anti-bribery and conflict of interest standards of conduct for our member companies based on these *Principles* or use them to benchmark and improve our existing standards so that they achieve the objectives of these *Principles*.

Signature: _____

Date: _____

Full Name (Print): _____

Title: _____

Association: _____

Signing Statement
(Medical Societies)

Commitment to Integrity

As leaders of medical societies, we have individual and organisational responsibilities to make a strong and active contribution to promoting integrity in the pharmaceutical sector in Latin America. By committing to the *Pharma Integrity Principles*, we join together to support an initiative to strengthen standards across the region and contribute to the goals of good governance, integrity and patient welfare.

We support the *Pharma Integrity Principles*, derived from Transparency International's Business Principles for Countering Bribery and relevant industry codes of practice. These *Principles* call for a commitment by pharmaceutical companies to two fundamental actions:

- A zero-tolerance policy towards bribery and related conflicts of interest, and
- Development of a practical and effective implementation programme.

Our support means that as medical societies we will undertake appropriate measures to advance the goals of the *Pharma Integrity Principles*, including through encouragement of complementary integrity standards for health care professionals.

Signature: _____

Date: _____

Full Name (Print): _____

Title: _____

Medical Society: _____

Signing Statement
(Payor Agencies)

Commitment to Integrity

As leaders of payor agencies, we have individual and organisational responsibilities to make a strong and active contribution to promoting integrity in the pharmaceutical sector in Latin America. By committing to the *Pharma Integrity Principles*, we join together to support an initiative to strengthen standards across the region and contribute to the goals of good governance, integrity and patient welfare.

We support the *Pharma Integrity Principles*, derived from Transparency International's Business Principles for Countering Bribery and relevant industry codes of practice. These *Principles* call for a commitment by pharmaceutical companies to two fundamental actions:

- A zero-tolerance policy towards bribery and related conflicts of interest, and
- Development of a practical and effective implementation programme.

Our support means that as payor agencies we will undertake appropriate measures to advance the goals of the *Pharma Integrity Principles*, including where appropriate provision of complementary policy guidelines, technical assistance and incentives for integrity programmes.

Signature: _____

Date: _____

Full Name (Print): _____

Title: _____

Organisation: _____

Annex B

Consultation and Acknowledgements

The *Pharma Integrity Principles* were developed in consultation with national and multinational industry associations, patient advocacy organisations and two national chapters of Transparency International in Latin America – Poder Ciudando and Transparencia Mexicana.

This sectoral application of the TI Business Principles has been created under the direction of Transparency International, in coordination with TI chapters in Latin America and with input and guidance from a multi-stakeholder Advisory Committee:

- Federacion Latinoamericana de la Industria Farmaceutica (FIFARMA)
- Council of Ethics and Transparency of the Mexican Pharmaceutical Industry (CETIFARMA)
- Transparencia Mexicana
- Transparency International UK

The development of these *Principles* has been led by Michael Fine of the law firm NXG Law & Compliance PLLC (United States), Alma Balcazar, regional compliance expert (Colombia) and Transparency International UK's Pharmaceuticals & Healthcare Programme (PHP).

The 2013 edition of the TI Business Principles provides a baseline for this sectoral application, establishing the same general commitments to a zero tolerance policy on bribery and an effective implementation programme applied to companies in other sectors. In addition, specific provisions have been added elaborating the application of these general commitments to challenges unique to the pharmaceutical sector. These reflect consensus standards developed pursuant to the Mexico City Principles and other sectoral codes.

The TI Business Principles were developed by a Steering Committee of leading companies and organisations under the Chairmanship of Transparency International. First issued in 2003, they underwent minor revision in 2009 and again in 2013 to incorporate advances in the design and implementation of anti-bribery programmes. Details on the membership and work of the Steering Committee can be found at:

http://www.transparency.org/whatwedo/tools/business_principles_steering_committee.

In addition to members of the Advisory Committee and national chapters of TI in Latin America, we would also like to thank participants from the many organisations who contributed to these *Pharma Integrity Principles* by sharing their suggestions and experiences through the consultations process. Participants included representatives from Associação da Indústria Farmacêutica de Pesquisa (Interfarma) (Brazil), Cámara Argentina de Especialidades Medicinales (CAEMe) (Argentina), National Academy of Medicine (Mexico), patient organisations and health and regulatory government agencies from across the Region.

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