APACMed
The voice of MedTech

GUIDEBOOK
ON CHANNEL PARTNER TRAINING - MEDICAL DEVICES (INDIA)

Compliance Handbook

This Channel Partner Guidebook is provided for **general guidance and informational purposes only** to support Channel Partners in understanding Company's expectations relating to compliance, quality, and ethical business practices.

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This Guidebook **does not constitute legal advice**, does not replace or modify any contractual obligations, and should not be relied upon as a complete statement of applicable laws, regulations, or industry codes. Channel Partners remains **solely responsible** for ensuring full compliance with all applicable local laws and regulations, applicable industry codes, and the terms of their written agreements the Company.

In the event of any inconsistency between this Guidebook and:

- applicable laws or regulations; or
- the executed agreement between the Company and the Channel Partner, **the applicable law or the executed agreement (as applicable) shall prevail**.

Introductory Statement

Purpose & Scope

The dynamics of our market are complex and constantly evolving. This guidance document provides clear direction to Channel Partners operating in India’s medical device sector. It consolidates expectations for ethical conduct, regulatory compliance, documentation standards, and operational controls. The guidance applies to distributors, dealers, and any third parties acting on behalf of the Company. Where local law or Company policy is stricter, the stricter rule applies.

Objectives:

- Promote ethical, patient-first business practices.
- Ensure compliance with Indian laws and applicable international codes.
- Standardize operations, record-keeping, and reporting across the partner network.

Contents

Section 1:
Compliance guidelines for ethical business practices

1. Understanding Anti-Bribery and Anti-Corruption (ABAC)

Bribery & corruption are global issues and are taken seriously by governments worldwide. Failing to follow anti-bribery and anti-corruption laws can result in severe civil and criminal penalties as well as reputational harm to your company & business partners.

What is corruption	What is a Bribe?
Dishonest or illegal behavior, especially by those in powerful positions. Corruption may encompass acts such as • Bribes • Kickbacks • Abuse of public office	An offer, promise or agreement to provide or receive payment directly or indirectly: • Of “anything of value” • To or by a government official or a private party; and • For the purpose of obtaining or retaining business or securing an improper business advantage • With the intention to influence the recipient to misuse his/her official position

Examples of anything of value
- Cash and cash equivalents
- Gifts, meals, travel and entertainment
- Donations, grants and sponsorship
- Free charge of products and special discount on products
- Employment, consulting and educational opportunities
- Free or discounted services

Key principles:
- Conduct business with ethics and integrity.
- Never give, offer, promise or accept anything of value to improperly influence decisions or gain an unfair advantage.
- Never use or request a third party to commit acts of bribery or corruption.
- Follow all applicable local & international anti-bribery and anti-corruption laws.
- Train relevant personnel regularly and document participation.
- Accurately document decisions and maintain complete records of transactions.

Keynote:
You must comply with all applicable local & international anti-bribery and anti-corruption laws.

2. Interaction with Healthcare professionals (HCPs) and Government Officials (GOs)

Trust in healthcare is essential. You should respect the independent clinical judgment of HCPs. Their decisions regarding the best product and treatment for their patients should never be compromised. Inappropriate interactions can negatively impact patient care and damage the reputation of your company and customers.

HCPs	GOs
Any individual or entity that provides healthcare services or is involved in the purchase, lease, recommendation or use of products or services. This may include:	Any official or employee of a government agency or other government unit or public international organization, along with officers and employees of government owned companies or companies substantially controlled by such governments. This may include:
✓ Physicians, nurses, pharmacists, technicians, residents and emergency medical services personnel	✓ A medical doctor working in a public hospital or teaching in a public university
✓ Healthcare organizations (HCOs), such as hospitals, clinics, surgery groups	✓ Doctors, nurses, pharmacists, or contracting officers employed by a government owned or controlled hospital
✓ Hospital administrators and decision makers within group purchasing organizations	✓ The technical engineer of a public hospital
✓ Individuals involved in clinical research	✓ The employee of the procurement department at a public hospital
	✓ Any government candidate, elected, appointed, or career officials
	✓ An employee of the Ministry of Health

Key principles

- **Never promise or provide anything of value** to HCP/ GO in exchange for or as a reward for past, present or future business.
- Act with the **right intent** when interacting with HCP/ GO.
- Any interactions must be supported by a **legitimate clearly defined business need**.
- Be **mindful of the perception** and reputational impact of your interactions with HCPs.
- **Accurately document** business activities, conflict of interest, payments and expenses involving HCPs, including transactions paid with personal credit cards and cash.
- **Follow** the applicable government laws and industry codes.

a. Business meals

You may provide modest meals to HCPs/GOs in connection with scientific, educational or business events. It must be modest, infrequent, reasonable and secondary to the exchange of scientific, educational or business information.

When you offer meals in connection with meetings and events, it is important that they are not used or seen as attempts to improperly influence HCPs to prescribe or purchase products.

Permitted (Meal may be provided when)	Not Permitted (Meals may not be provided when)
There is a legitimate business purpose	The interaction is for personal celebration or social occasions
They are within the defined meal limit and are reasonable	The interaction creates the appearance of a social gathering or detracts from the legitimate business purpose (e.g., HCP spouses or guests in attendance, excessive consumption of alcohol)
HCPs have a bonafide professional interest in attendance	Inappropriate setting like location with loud/live music, live sports
Setting is conductive to the exchange of professional interest	

Keynote:
Maintain detailed records of meals provided to HCPs/ GOs, including the purpose of the meeting, receipts and list of participants.

b. Educational items, gifts and entertainment

Educational items	Gifts	Entertainment
Include medical textbooks, anatomical models used for educational purposes, starter kits and educational brochures.	Include non-educational or non-patient use items, non-educational company-branded promotional items (like pens, notepads), and traditional gifts like wine, flowers, chocolates, gift baskets, gift cards and cash.	Includes tickets to attend concerts, theater, sporting and charity events, vacation trips and recreational activities including but not limited to golfing, skiing, fishing and hunting.

Educational items

You may provide modest and appropriate educational items to HCPs in line with the below principles.

- There is a **legitimate need** that serves an educational purpose or benefit patients.
- These items must have **fair market value** in accordance with the local regulations.
- It **must not** be provided frequently.

Gifts and Entertainment

Do not provide gifts and entertainment to HCPs or their staff to avoid being misinterpreted or appearing inappropriate.

c. Commercial sponsorship

You may provide commercial sponsorships or purchase exhibit space in support of third-party programs to advertise, market and promote your brand and products.

You must ensure commercial sponsorship fees are commercially reasonable, support appropriate programs and events and are not used or perceived as attempts to improperly influence HCPs to purchase or use products.

Key Principles

- **Carefully select commercial sponsorship opportunities**
  - Evaluate the request based on marketing and promotional benefits received
  - The location of the meeting is modest and appropriate
  - Your sponsorship for the meeting does not contribute to entertainment or recreational activities
  - You should not be a sole sponsor; third party programs must be sponsored by other companies as well.
  - The program does not benefit a single institution and is open and advertised to a wide audience.

- **Ensure commercial sponsorships are reasonable and independent**
  - Assess third-party programs thoroughly, including the agenda and venue.
  - Ensure the commercial sponsorship fee reflects fair market value for the marketing and promotional benefits received.
  - Avoid influencing the third-party program agenda or the selection of the faculty/ participants.

- **Maintain detailed receipts and records of commercial sponsorships.**

Keynote:
Must not pay for HCP's registration, travel or lodging expenses to attend the Third-Party Program.

d. Charitable donation

You may participate in charitable efforts by offering monetary or in-kind donations to support bona-fide organizations and missions, provided that the donation is not intended as an inappropriate inducement and does not privately benefit an HCP.

Key Principles

- **Carefully evaluate and select charitable donation opportunities**
  - Document requests and select recipients based on their charitable initiative
  - Maintain independence from individual HCPs benefiting or endorsing the initiative
  - Donation must not be used as a sales tool or to improperly influence HCPs to purchase or use products.

- **Ensure donations are directed to the right organizations**
  - Ensure charitable donations are directed to charitable organizations or non-profit organizations and not to individual HCPs.
  - Confirm products donated for underserved populations and supporting indigent care are not resold or billed to third parties.

e. HCP consultancy

You may engage HCPs for services to meet identified needs, such as providing feedback on products in development, conducting clinical research and delivering medical education on the safe and effective use of medical technologies.

Key Principles

- **Engage HCPs with the right intent**
  - Ensure there is a legitimate need to engage HCPs.
  - HCPs must not be selected to reward or incentivize the purchase or use of products.
  - Sales must not control or unduly influence the selection of HCPs for services.

- **Select HCPs that have the qualifications and expertise**
  - Selections must be based on HCP's qualifications to meet the identified need, such as HCP's reputation, specialty, expertise and experience with a specific product or medical technology.
  - Avoid engaging more HCPs than necessary to fulfill the legitimate need.

- **Clearly and transparently onboard HCPs**
  - Establish fair and reasonable compensation for HCPs that reflects market value for the services to be provided.
  - Execute written contracts with HCPs that reflect the full terms and conditions, including the services to be provided and compensation to be paid.

Keynote:
Maintain records of all transfer of value to HCPs (including proof of performance).

f. Managing field assets (Evaluation & Demonstration)

Field assets are capital and disposable products that are placed or used at customer facilities, but for which you maintain title or ownership. Field assets may include evaluation and demonstration.

Evaluation

Evaluation products are provided to end customers to evaluate and familiarize themselves with the safe and effective use and functionality of a product. This is used in patient care.

Evaluation product can be multiple use or single used products

- **Multiple use product (Equipment)**: It should remain with the HCP only for a reasonable period.
- **Single use product (Consumable or disposable)**: The number of single use products provided should not exceed the amount reasonably necessary for the evaluation.

Demonstration

Demonstration products are typically unsterilized single use products or mock-ups that are used for HCPs and patients' awareness, education or training. This is not used on patient care.

Key Principles

- **Establish clear objectives** for the deployment of field assets that support business strategies.
- Provide opportunities for customers to use field assets for **appropriate reasons**.
- **Maintain visibility of field assets**
  - Maintain accurate records of field assets regardless of useful life or book value, including movement, location and duration.
  - Track and manage the delivery, return and disposal of field assets if applicable.
- **Being accountable for managing field assets**
  - Develop a documented process to drive accountability for tracking and monitoring assets.
  - Promote open communications with customers about field assets and manage any sales contracts that involve the placement of field assets.

Keynote:
The company must follow the UCMPMD guidance on evaluation and demonstration.

g. Managing sales contract

Sales contracts are agreements with customers to provide company products and services. Sales contracts can include invoice terms and conditions and any documents that govern the sale or use of company products and services.

To effectively execute and manage sales contracts, it is important to establish business controls to ensure contract compliance.

Key Principles

- **Establish sales contracts that are right for you and your customers**
  - It must start with the right intent.
  - Negotiate fair and reasonable sales terms
  - Set contract terms that are commercially reasonable, transparent, achievable and clearly reflected in the contract.
  - Ensure contracts meet internal and external requirements.
- **Clearly and transparently document sales terms**
  - Establish clear documentation that reflects the entirety of the terms and conditions.
  - Ensure contracts are appropriately executed by the right individuals.
  - Make contracts available throughout the contract term.
  - Establish an effective process to track performance-based discounts
- **Accountable for managing contract performance**
  - Assign roles, responsibilities and establish processes to effectively manage contract performance throughout the contract term.
  - Promote open communications with customers about contract performance.

Keynote:
Credit notes may be issued only for legitimate reasons subject to appropriate documentation.

Section 2:
Books and record guidance

1. Key principles of effective bookkeeping

Companies are required to maintain accurate record keeping practice. Accurate books and records are crucial to the success of your business in addition to complying with local laws, regulations and industry codes.

Why are books and records crucial?
Financial transparency: Accurate books and records accurately reflect the true financial position of your business. They give a clear picture of your business' health, which is essential for sound decision-making.

Compliance: Maintaining accurate records ensures compliance with legal and regulatory requirements. This helps avoid penalties and legal issues.

YOU MUST	YOU MUST NOT
Accurately and timely describe transactions in your records	Create intentionally vague or misleading descriptions to hide improper payment or expenses
Keep accurate and transparent records of all expenses	Create false accounts
Itemize products and promotional activities	Mischaracterize payments
Maintain reliable and transparent record of cash transactions	Hide payments or gifts in the cost of products or discount offered
	Create and/ or provide false documentation or other false information

Key principles of effective bookkeeping

- **Accuracy**: All financial transactions must be recorded correctly in the General Ledger (GL) accounts, which are the core of your financial reporting system.
- **Completeness**: Document all business transactions fully and without omission. This ensures all financial activity is captured and accounted for.
- **Timeliness**: Keep your records up to date. Update records promptly to reflect the most recent activity. Delays can lead to errors and inconsistencies.
- **Documentation**: Maintain sufficient supporting documentation like invoices, contracts, and receipts for all transactions. This is crucial for audits and verification purposes.

2. Documentation standards

Documentation and retention

- Ensure appropriate supporting documentation (invoices, receipts, and agreements) is in place for all transactions and retain all records and support for at least 5 years or more (as required by local law).
- Ensure maintaining all documents such as reports, proof of service, and deliverables from professional consultant engagements.
- Keep records of attendance and participation for meals, group hotel stays, meetings, and events related expenses (including name, designation, or affiliation).

Agreement and scope of work

- Have agreements in writing with HCPs, GOs, or high-risk third parties dealing with HCPs or GOs.
- Clearly document the scope of work and associated fees for any professional/ consultant engagement (e.g., agreement, engagement letter, purchase order, email).

Business purpose and expense reporting

- Document the business purpose: In the expense voucher/report or narration, clearly explain the business purpose of the transaction.
- Avoid personal charges: Ensure there are no personal charges recorded as business expenses. All expenses recorded must be directly related to your company's business.

Cash payments and salary documentation

- Maintain a detailed cash log for all cash payments and avoid splitting transactions.
- Ensure salary payments are accurately recorded, with details matching employment contracts and payroll records.
- Keep detailed records justifying sales incentives, including criteria, calculation methods, and approvals, ensuring alignment with sales performance metrics.

Completeness and categorization

- Records should be thorough and cover all necessary aspects.
- Categorize expenses by nature such as meals, hotel, travel, professional fees, etc. (Any HCP-related expenses must be recorded in the HCP account).

Transparency and compliance

- Not, directly or indirectly, falsify or cause to be falsified, any book, record, or account. Transparently declare business transactions in compliance with applicable laws.

Policies and approval workflow

- Establish and maintain written policies, such as an Employee Reimbursement Policy, Petty Cash Policy, and HCP Interaction Policy, to ensure compliance with the company.
- Ensure segregation of duties and an approval workflow as appropriate and scalable to the size and complexity of the business.

Section 3:
Additional Guidance

1. Compliance with laws, rules and regulations

The company must conduct its business and affairs in compliance with applicable local and international laws, rules, regulations and industry codes. This applies equally to companies and their dealers.

Key expectations

- **Follow local and regional laws** including:
    - Medical Devices Rules, 2017 under the Drugs and Cosmetics Act
    - Prevention of Corruption Act
    - Competition Act, 2002
    - Taxation laws (Income Tax Act, GST)
    - Data protection and privacy regulations
    - Applicable trade compliance laws and regulations
    - Labelling and advertising requirements

- **Follow international anti-corruption laws** where applicable such as
    - US Foreign Corruption Act (FCPA): It prohibits bribery of foreign officials and requires accurate books and records and robust internal control
    - UK Bribery Act: It prohibits bribery in both public and private sectors and includes strict liability for failure to prevent bribery
    - Any other extra-territorial laws that may apply due to the company's operations, ownership or market served.

- **Adhere to industry codes** such as APACMed code of ethical conduct, AdvaMed code of ethics and UCMPMD guidance.
- **Maintain product compliance**: Ensure registration, labelling, storage, distribution, and marketing meet requirements in all relevant jurisdictions.
- **Uphold fair competition**: Avoid Anti-competitive practices such as price-fixing, bid rigging, or sharing commercially sensitive information.

Keynote:
It is your responsibility to understand and comply with both global and local ABAC laws and regulations.

2. Audit Readiness

The purpose of an audit is to evaluate and gain an understanding of compliance programs, policies, procedures and internal controls over activities that may be susceptible to corruption risks. This process helps to ensure that companies are acting with integrity and conducting business in accordance with written agreements and in a compliant manner.

Objective

- To ensure Anti-bribery Anti-corruption ("ABAC") compliance, which includes the following focus areas:
  - The types of financial transactions and compliance-related activities
  - Accurate and complete books and records
  - Appropriate internal controls and governance
- To help identify risk factors and potential areas for improvement
- At the conclusion of the audit, recommendations for enhancements to business functions and compliance program, enables to grow the business and mitigate risks.

Audit preparation and expectations

- Complete documentation
- Transparency during audits: Provide accurate and timely responses to auditors
- Ready for site visit by the auditor
- Provide walkthroughs of accounting systems to auditors, when necessary
- Stakeholder access for follow-up requests and additional questions

Things you can do today to ensure you are prepared for any audit

- **Policies and procedures:** Ensure current versions of policies and procedures are easily accessible and available
- **Books and records:** If applicable, segregate any manufacturer-specific business transactions within accounting systems. Any general and administrative activities that relate to multiple manufacturers or general business can be in-scope for audit.
- **Internal controls:** Document finance and accounting procedures in protocols or workflows to allow for efficient process walkthroughs.
- **Manufacturer agreements and policies:** Review contracts with manufacturers to better understand compliance commitments and obligations should they request an audit. Refamiliarize manufacturers' policies, such as third-party codes of conduct to ensure you understand and are complying with all requirements.
- **Self-assessment:** Regularly review internal records and practice to identify and address gaps before they escalate.

3. Training Expectations

Regular training ensures all employees and partners understand compliance obligations and can apply them consistently in business activities.

Key expectations

- **Mandatory training for all employees**, with a special focus on sales and marketing staff, given their frequent interactions with HCPs and GOs.
- **Channel Partners must ensure** that their own employees, sales teams, and sub-distributors receive the same level of compliance training.
- **Frequency:** Conduct training at least annually, and whenever significant changes occur in laws, regulations, or policies (local, regional or international).
- **Active engagement:** Encourage participation, scenario discussions and clarifications to ensure concepts are fully understood.
- **Knowledge sharing:** Cascade learnings within teams and across the distribution chain.
- **Record keeping:** Ensure training records are maintained.

4. Reporting a Concern

Prompt reporting of suspected misconduct safeguards patients, protects reputation, and ensures legal compliance.

Key expectations

- **Report immediately** any suspected breach of law, regulation, industry code or company policy.
- **Use multiple channels**: Report to the company's compliance contact, dedicated ethics hotline, or APACMed's reporting channel.
- **No retaliation**: Individuals reporting in good faith are protected from retaliation.
- **Provide details**: Include date, facts, and supporting evidence where possible.

ABOUT APACMed India

APACMed established its in-country office in India in 2020 and currently has over 40 MedTech organizations as members. We have strategic partnerships with local trade associations, such as NATHEALTH, MTAI, and FICCI, and collaborate with them on important issues. In India, we operate through our Centre of Excellence, which focuses on Government Affairs, Market Access, Regulatory Affairs, and Health Data. This centre is led by an Executive Council comprising CEOs from Indian companies that are members of APACMed. Additionally, we are a member of the Steering Committee of the National Medical Devices Promotion Council (NMDPC) and regularly participate in industry consultations organized by the Department of Pharmaceuticals (DoP) and the Central Drugs Standard Control Organisation (CDSCO) and stakeholders to demonstrate the value of medical technology, promote innovation, and impact policy that advances healthcare access for patients in Asia Pacific.

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ABOUT LEC India Chapter

Established in 2024, the APACMed India Chapter under the Legal, Ethics and Compliance (LEC) Committee reflects the growing strategic importance of India within the MedTech ecosystem and the need to address the unique legal, ethical, compliance, and regulatory challenges of this critical market. The India LEC Chapter serves as a focused platform for industry members to deliberate on evolving policy developments, ethical business practices, third-party risk management, data privacy, AI-related compliance considerations, and the implementation of industry codes and regulations relevant to India.

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About APACMed

The Asia Pacific Medical Technology Association (APACMed) represents manufacturers and suppliers of medical equipment, devices and in vitro diagnostics, industry associations, and other key stakeholders associated with the medical technology industry in the Asia Pacific region. APACMed's mission is to improve the standards of care for patients through innovative collaborations among stakeholders to jointly shape the future of healthcare in Asia-Pacific. For more information, visit **www.apacmed.org**