

Pharmaceutical Sales and Marketing - Compliance

Organisations that fail to properly implement and monitor the activities associated with field sales and marketing operations can face several business and compliance risks, including:

- Compliance exposure related to violations of various anti-bribery laws (e.g., the US Foreign Corrupt Practices Act) and product marketing statutes (i.e., ABPI, EFPIA, IFPMA) as well as industry standards.
- Internal financial losses associated with loose controls around expense reporting and discretionary spending processes.
- Loss of reputation in business, with consumer communities and with regulators caused by non-compliance.

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With sales and marketing teams stretching the ability of pharmaceutical companies to assess levels of compliance with internal policies and external requirements and a recognition of growing issues of reputation and financial politics, many organisations have sought assistance from PricewaterhouseCoopers (PwC) to assess their current operating environment and develop recommendations to enhance controls and mitigate compliance risk.

How can PwC help your organisation?

PwC has extensive knowledge of sales and marketing operations and best practices with which to mitigate compliance risk. We rapidly and effectively acquire the necessary information about an organisation to facilitate a compliance assessment of major sales and marketing activities.

We provide our clients with a broad range of regulatory compliance, risk management and performance improvement services specifically developed to meet the needs of pharmaceutical and life sciences companies. Some of our sales and marketing-focused offerings are:

- **Compliance Programme Development:** Using the firm's governance, risk and compliance (GRC) methodology as the foundation, PwC's compliance programme development capabilities are focused primarily on helping with new programme creation, strategic planning, globalisation of compliance and risk management functions, policy development/assessments and consulting services around organisational design, process improvement, culture transformation and training. Additionally, PwC has extensive experience in compliance monitoring and controls design.
- **Policy and Procedure Review & Integration Services:** PwC utilises a risk-based, top down approach to catalogue existing policies and procedures, identify gaps, assess adequacy, recommend best practice and verify that actual operating practices are consistent with the existing policies and procedures.

- **Sales and Marketing Compliance Risk Assessment:** PwC provides expertise to help pharmaceutical and life sciences companies identify risks related to sales and marketing activities. PwC offers services geared to understanding the necessary information about an organisation's sales and marketing activities to assess processes and controls related to core activities.

Key activities reviewed:

- Dissemination of Off-Label Information
- Provision of Consulting Services
- Contractual Payments/Arrangements
- Clinical/Research Study and Educational Grants
- Medical Education Programmes
- Professional Service Agreements with Physicians
- Discretionary Spending
- Sampling and Free Goods
- Product Trials
- New Industry Marketing Codes



- **Sales and Marketing Compliance Auditing:** PwC is able to leverage its Internal Audit Services expertise to help pharmaceutical and life sciences companies specifically identify control gaps related to sales and marketing activities. PwC will assess a company's operations, policies, processes and controls related to various sales and marketing activities as well as compare the company's methodologies and reporting practices with the pertinent legislation, regulations and PwC's industry experience to highlight potential matters that should be considered by the company.
- **Pharmaceutical Samples Management Compliance Services:** PwC can help pharmaceutical manufacturers navigate the local country laws and regulations related to ethical drug sampling by developing or reviewing control processes around a variety of functions including: samples management compliance and operating policies, procedures and training programmes; overall risk mitigation and investigation processes and systems; samples inventory testing/reconciliation outsourcing; and electronic systems compliance, design and integration.

Benefits you can realise

- Increased confidence in span of legal and regulatory compliance control of field sales operations
- Identification of correctable control and process weaknesses
- Improved travel and expense data quality, quantity, and integrity
- Demonstratable compliance programme review efforts
- Business efficiencies.

About PricewaterhouseCoopers

PricewaterhouseCoopers' Pharmaceutical Industry Group is dedicated to delivering effective solutions to the complex business challenges facing pharmaceutical and life sciences manufacturers. As the global leader in serving pharmaceutical and healthcare products companies, the firm offers a wide array of industry-tailored services designed to improve performance and processes in the areas of drug development, manufacturing, sales and marketing, information security and data management. In serving its clients, the firm draws on the full knowledge and skills of 125,000 professionals in 143 countries.

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