

MSL-KOL Engagement: Ensuring Compliance

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Abstracts

After its initial function to build rapport with KOLs, the MSL role has evolved from being a support to sales reps to the forefront of pharmaceutical practice. Lode Dewulf, chief medical affairs officer at Brussels-based UCB, reflects on this central transformation in the pharma business. “In many ways, MSLs have developed as a new role over the past two decades as did the Medical Affairs function itself,” he says. “Medical Affairs now has the mandate for all medical activities related to marketed products and also provides input to both clinical development and to commercialisation. Within Medical Affairs, the MSLs are the field-based medical partners for physicians and other healthcare stakeholders.”

Yet with that role has come a responsibility to comply with regulations governing off-label promotion. Once deemed ‘a cost of business’, fines are now ‘big business’: In September 2009, Pfizer paid \$2.3 billion to settle charges of improperly promoting four products. The question is, how does the industry ensure, and be seen to ensure, no off-label promotion?

Report Overview

How can MSLs reduce their risk of breaching regulatory requirements when their company’s products are used off-label? MSL-KOL Engagement: Ensuring Compliance examines how MSLs are being used to engage physicians in a way that traditional sales no longer can. Casting a net over the current regulatory environment both in the US and EU, the report addresses the increasingly critical need for MSLs to be compliant with the rules on off-label promotion while also connecting with physicians who may be using a product for “off-label” use. Offering insight into the increased scope of the MSL and the importance of having Standard Operating Procedures in place, the report delves into tracking and reporting, compensation metrics and key enforcement policies.

Scope

MSLs, their function and how they manage promotion vs education with reports of off-label usage

Overview of the rules governing MSL activities in the US and EU

Review of Corporate Integrity Agreements

Importance of Standard Operating Procedures for MSLs

MSL training and enforcement policies

Analysis of tracking and reporting systems as well as compensation metrics

Expert views from Bristol-Myers Squibb, UCB, Philips Healthcare, Medical Science Liaison World (MSL WORLD), Scientific Advantage, Lener Medical Consulting and Cutting Edge Information

Insightful case studies examining how high-risk situations are mediated by two leading companies

Key Benefits

Unique and rare insight into the evolution and role of MSLs and how companies manage their risks where off-label promotion is concerned

Compellingly written analysis of the current state of play in regulations across two continents

Insightful case studies examining how high-risk situations are mediated by two leading companies

Key Questions Asked

How is the role of MSLs changing?

How are other leading companies utilizing and protecting their MSL team?

How are industry leaders building compliant MSL-KOL relationships?

How are industry leaders protecting themselves from an external audit?

How is MSL performance evaluated?

Contents

EXECUTIVE SUMMARY

EVOLUTION OF THE MSL ROLE

What do MSLs do?

Education versus promotion

REGULATIONS GOVERNING MSLS

US rules on off-label promotion

EU rules on off-label promotion

OFF-LABEL MARKETING CASES

A growing concern

Off-label prescribing

 The clinician's perspective

Off-label strategies

CORPORATE INTEGRITY AGREEMENTS

Increased scope of CIAs

STANDARD OPERATING PROCEDURES

Firewalling

Clarification

What SOPs should address

Globalisation

MSL TRAINING

Frequency of training

TRACKING AND REPORTING SYSTEMS

Technological advances

COMPENSATION AND METRICS

Quantitative metrics

Qualitative metrics

CASE STUDY 1: MID-SIZE PHARMACEUTICAL COMPANY

CASE STUDY 2: MEDICAL DEVICE COMPANY

BOARD CONSIDERATIONS

ENFORCEMENT POLICIES

Enforcement policy in the UK

Enforcement policy in the US

Individual responsibility

ACKNOWLEDGEMENTS

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