Pharmaceutical Sales And Marketing Compliance

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Selling Sickness NetworkPharma Ltd
Marketing to Pharmacists: Understanding Their Role and Influence will help pharmaceutical marketers better understand pharmaceutical practice in order to develop better relationships with pharmacists and effectively market products. This book examines important trends in pharmaceutical health care, including patient education and compliance, quality of life assessment, disease management, and cost containment strategies that assist pharmacists in providing better care to patients which results in increased sales for your business. From Marketing to Pharmacists, you?ll learn how pharmacists influence product selection, monitor drug therapy, and serve as a primary source of patient education in order for you to create successful marketing strategies for your company. Recognizing that cost control is a key goal for all members of the health care system, Marketing to Pharmacists provides you with advice and strategies that emphasize working together with pharmacists. This will help you determine demand for a specific product so you can devise your own marketing strategies to meet the needs of both the pharmacist and patient. With Marketing to Pharmacists, you?ll improve your marketing skills by using innovative techniques and suggestions, including: understanding pharmacists'influence in prescription product selection to help develop effective marketing strategies asking for pharmacists'assistance in designing care management programs, participating in the development and negotiation of care management contracts, and offering knowledge as pharmacotherapeutic experts to emphasize patient advocacy and accessibility to patients understanding the dimensions of the quality of life and other aspects of pharmaceutical care to design effective sales tactics to pharmacists communicating with pharmacists to learn about the needs of certain patients in order to create effective marketing strategies that will lessen the occurrence of unclaimed prescriptions and decrease the loss of revenue to pharmaceutical companies developing a positive relationship between pharmacists and pharmaceutical companies by displaying genuine customer interest, providing pharmacists with useful and accurate information about products, and establishing ethical guidelines Containing charts, tables, and graphs to give you a comprehensive look at techniques and data, Marketing to Pharmacists will help you create marketing strategies that will successfully meet the needs of your customers and result in economic benefits for your company.
Compliance with Changing State Pharma Marketing Laws Macmillan
Now more than ever, doctors are being targeted by government prosecutors and whistleblowers challenging the legality of their relationships with drug and device companies. With reputations at stake and the risk of civil and criminal liability, it is incumbent upon doctors to protect themselves. Managing Relationships with Industry: A Physician's Compliance Manual is an indispensable resource for doctors, professional societies, academic medical centers, community hospitals, and group practices struggling to understand the ever changing law and ethical standards on interactions with pharmaceutical and device companies. It is the first comprehensive summary of the law and ethics on physician relationships with industry written for the physician. Authored by a former state Attorney General, Harvard Medical School Professor, health care lawyer and professor of ethics, Managing Relationships approaches the topic from a balanced and reasoned perspective

adding to the on-going national dialogue and debate on the proper limits to medicine's relationship with industry. The first complete and up-to-date summary and analysis of the law and ethics on physician-industry relationships Focuses on major enforcement actions and whistleblower lawsuits and the lessons learned for physicians Provides options and guidance for maintaining compliant relationships and avoiding traps for the unwary Covers both drug and device company relationships Summarizes the types of industry relationships that are necessary and productive and those that are harmful and abusive Details the law and ethics for each type of relationship including gifts, off-label uses and marketing, CME, speaker's bureaus, free samples, grants, consulting arrangements, etc. Includes sample contracts for permissible consulting and CME speaker engagements

Off-label Communications iUniverse

Thirty years ago, Henry Gadsden, the head of Merck, one of the world's largest drug companies, told Fortune magazine that he wanted Merck to be more like chewing gum maker Wrigley's. It had long been his dream to make drugs for healthy people so that Merck could "sell to everyone." Gadsden's dream now drives the marketing machinery of the most profitable industry on earth. Drug companies are systematically working to widen the very boundaries that define illness, and the markets for medication grow ever larger. Mild problems are redefined as serious illness and common complaints are labeled as medical conditions requiring drug treatments. Runny noses are now allergic rhinitis, PMS has become a psychiatric disorder, and hyperactive children have ADD. When it comes to conditions like high cholesterol or low bone density, being "at risk" is sold as a disease. Selling Sickness reveals how widening the boundaries of illness and lowering the threshold for treatments is creating millions of new patients and billions in new profits, in turn threatening to bankrupt health-care systems all over the world. As more and more of ordinary life becomes medicalized, the industry moves ever closer to Gadsden's dream: "selling to everyone."

Principles of Pharmaceutical Marketing Nation Books

Familiarly known as the Orange Guide, this title is an essential reference work for all those involved in the manufacture and distribution of medicines in Europe. It is compiled by the UK drug regulatory body, MHRA, and brings together the European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. It contains EU guidance on good manufacturing and good distribution practice along with relevant information on EU and UK legislation. Changes in this new edition: Revised Annex 15. The revision of Annex 15 takes into account changes to other sections of the EudraLex, Volume 4, Part I, relationship to Part II, Annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation, and changes in manufacturing technology. Revised Annex 16. The GMP Guide Annex 16 has been revised to reflect the globalisation of the pharmaceutical supply chains and the introduction of new quality control strategies. The revision has been carried out in the light of Directive 2011/62/EU amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This version also implements ICH Q8, Q9 and Q10 documents, and interpretation documents, such as the manufacturing and importation authorisation (MIA) interpretation document, as applicable. Also, some areas, where the interpretation by Member States has not been consistent, have been clarified. This revised Annex came into operation 15 April 2016. The introduction of guidelines on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities. The introduction of guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients. The addition of the Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01). These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for manufacturers, importers and distributors of active substances for medicinal products for human use. These guidelines should be followed as of 21 September 2015. The addition of the principles and guidelines of Good Manufacturing Practice (GMP) for active substances for medicinal products for human use, including active substances intended for export. Revisions to the UK Human Medicines Regulations 2012. MHRA GMP Data Integrity Definitions and Guidance for Industry is now included which sets out MHRA expectations for data integrity in good manufacturing practice (GMP). The Guidance complements existing EU GMP guidance and should be read in conjunction with national medicines legislation and the GMP standards published in Eudralex volume.

The Effectiveness of Compliance Gaining Techniques Used by Pharmaceutical Sales Representatives CRC Press

Vast global resources are ploughed into the delivery of treatment interventions ranging from diet and lifestyle advice to complex surgery. In all cases, whatever the intervention, unless the recipient is engaged with the process and understands why the intervention has been offered and the part they play in its success, compliance is an issue. Even where the individual does engage and understand, he or she may choose not to comply. Non-compliance is estimated to cost the pharma industry US$70 billion per year. No figures exist for the cost to healthcare insurers and public health but non-compliance is undoubtedly one of the top five issues facing both drug developers and healthcare providers. During clinical trials, non-compliance undermines the accuracy of the data generated from the whole trial as well as particular aspects such as the efficacy of different dosages. This book explores the key factors which drive compliance and the part that healthcare professionals can play in improving this, with the key underlying goal of improving public health in its broadest sense.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017 Universityofhealthcare

"Our Daily Meds" shows how corporate salesmanship has triumphed over science inside the biggest pharmaceutical companies and, in turn, how this promotion-driven industry has taken over the practice of medicine and is changing American life.

The Global Guide to Pharma Marketing Codes Drugs and the Pharmaceutical Sciences

The online channel offers a key opportunity for pharma companies to restructure their sales and marketing model, improving their relationships with physicians and increasing compliance among patients.

EHealth Solutions for Pharma Vault Inc.

This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications.

Vault Career Guide to Pharmaceutical Sales & Marketing Routledge

Worldwide, there are varying Codes of Practice/Conduct for the pharmaceutical industry that ensure the industry self-regulates to promote the appropriate use of medicines by operating in a professional, ethical and transparent manner and ensuring high standards. The aim of this book is to aid the understanding of the many pharmaceutical Codes of Practice/Conduct throughout the world. It contains an overview of the guidelines for the promotion of pharmaceutical products in all geographical areas. Each section includes a "general overview" providing a discussion on that particular Code of Practice and differences/similarities with other countries

Global Pharmaceutical Marketing Tom Ruff Company

[This book is an] organized 'formulary' written for those who are considering a specific field - 'drug reps', as they are known in the industry.-Introd.

GMP Compliance, Productivity, and Quality Lulu.com

Providing in-depth coverage of the procedures utilized by pharmaceutical companies for regulatory compliance, this reference describes the history and development of regulations, standards, and guidelines that affect pharmaceutical product approval and commercial sale in the United States-standing alone as the only authoritative guide to address the complex web of regulatory requirements, application processes, and quality control issues influencing the pharmaceutical industry.

Global Pharmaceutical Marketing CRC Press

Drugs, biologics and devices increasingly are used to treat patients in ways that were not specifically approved by FDA. While FDA does not regulate off-label use nor forbid off-label prescribing, it does heavily regulate off-label promotion. This book provides comprehensive, practical advice on how to comply with those regulations. This guide gives a valuable historical perspective on off-label medicine. The authors discuss specific problems arising from off-label use and promotion, while providing practical instruction on how to deal with them, including: managing clinical trial disclosures; reimbursement; training and monitoring sales and marketing representatives; risk management; product liability litigation; ethical considerations and how the government is enforcing off-label sales and marketing compliance.

Our Daily Meds CRC Press

Careers "Put into practice today's winning strategies and tactics for breaking into pharmaceutical sales!" 'Working in the pharmaceutical industry is dynamic and competitive. It is also quite rewarding, as it allows you to make a meaningful difference in the quality of peoples' lives. Landing the 'right" job as a pharmaceutical sales representative will be challenging and require a well-thought-out plan of action. Kaputa and Zimmerman have put together some insightful 'Secrets" that will put readers ahead of their competitors in the job search and prepare them for a successful start to a career in the industry."-Carrie Cox, Executive Vice President and President, Global Pharmaceuticals, Schering-Plough Corporation "Learn The Secrets" is a how-to and how-to-think book that will show you how to land that first job as pharmaceutical sales representative. It will give you the secrets, new guidelines, unwritten rules, practical tools, and resources you need. You'll even learn industry jargon and how to position yourself in interviews so that you are what companies are looking for. You'll find interactive exercises, sample sales aids, and practice role-plays to prepare you for the most challenging questions and group interviews. "Learn The Secrets" is your field guide to breaking into and succeeding in pharmaceutical sales.

Indian Pharmaceutical Regulations CRC Press

Principles of Pharmaceutical Marketing, Third Edition offers the perspectives of both those who teach and those who practice pharmaceutical marketing. This reflects the need for and the effort to provide the most relevant "real world" approach to this complex and fascinating field. This text is designed for undergraduate students in pharmacy whose background in marketing is limited, those actually involved in pharmaceutical marketing, and anyone desiring an introduction to the intricacies involved in the marketing of pharmaceutical products.

Compliance Navigator Routledge

Off-Label Navigator: On the Road Guide for Pharmaceutical Sales Representatives Off-label promotion of prescription drugs is perhaps the most challenging area for sales representatives when detailing to physicians. Any suggestion by the pharmaceutical professional of uses for a product not on the product's FDA-approved label can have significant consequences, usually in the form of hefty fines. It is imperative that your sales force know what they can and cannot say to physicians while marketing your products. The Off-label Navigator: On the Road Guide for Pharmaceutical Sales Representatives is a convenient pocket guide that will educate pharmaceutical sales staff on how to promote products while remaining in compliance. The guide contains important information about off-label regulations established by the OIG, and practical case studies that demonstrate how to handle certain "gray areas" your staff may encounter while detailing to physicians. Customize with your company logo and policies Ask us for a free sample! The Off-Label Navigator can be customized with your company's logo and policies and procedures. Ask us for a free sample! For more information please call Maureen Croce at 866/464-2776 or email: mcroce@hcpro.com. Relevant as a training tool for your new sales staff or a refresher for your seasoned sales representatives, the Off-label Navigator: On the Road Guide for Pharmaceutical Sales Representatives is sold in packs of 25 pocket guides for distribution to your team. It contains clear explanations and practical examples of important off-label compliance topics to ensure staff will be able to: Identify violations of the off-label rules and regulations Describe the consequences of promoting products for off-label uses Respond to inquiries from customers about off-label uses Promote approved uses of the company's products Instructional Design Principles The Off-Label Navigator incorporates the principles of adult learning to engage learners quickly and show them how to apply what they have learned: Case scenarios allow learners to apply the information they have learned to common scenarios with compliance implications Icons alert learners to key concepts, including important laws and compliance risk areas Tabs allow learners to easily navigate through the pocket guide A quiz documents training and measures how well learners can apply the off-label compliance rules and regulations Table of contents Learning objectives Introduction Off-label overview What does off-label mean? Dangers of promoting off-label Practice of medicine exemption Handling off-label inquiries Off-label regulations The False Claims Act Spoken word versus written word Comparing product labels The Food, Drug, and Cosmetic Act FDAMA 1997 The Washington Legal Foundation Litigation Distributing off-label information Who can receive off-label information? Format for off-label information under FDAMA Supplemental drug application Additional submissions to the FDA Selling tips Ten selling dos Six selling don'ts Conclusion Test your knowledge Final exam Answer key Glossary Customize with your company logo and policies The Off-Label Navigator can be customized with your company's logo and policies and procedures. For more information please call Maureen Croce at 866/464-2776 or email: mcroce@hcpro.com.

Laugh and Learn Pharmaceutical Sales Code Academic Press

The pharmaceutical industry has battled increased negative public perception for the past decade. Much of the scrutiny involved a perception of undue influence between pharmaceutical sales representatives and physicians. As part of an ongoing industry effort to be transparent and responsive to the concerns of healthcare stakeholders through self-regulation, the Pharmaceutical

Research and Manufacturers of America (PhRMA) and its member companies revised and strengthened the Code on Interactions with Healthcare Professionals (PhRMA, 2009). This study examined the impact of the 2009 PhRMA Code on four functions including sales and marketing, compliance, training, and information systems at a biotech company in southern California. Throughout the present study, the company was referred to as 123BIO. The study objectives were to evaluate the various training vehicles utilized and 13 separate tracking systems that were enforced by six different functions that required modification. The study also explored the internal structures implemented in each function, assessed the effectiveness of the changes, and made recommendations. Qualitative analysis methods were used to explore how the 2009 PhRMA Code was operationalized at 123BIO. Thirteen in-depth semi-structured interviews with decision makers in each function were conducted. Findings indicated that the 2002 and 2009 PhRMA Codes were contributing factors to a large-scale change effort at 123BIO. The effort began as an embedded compliance functional model within the sales and marketing department. In 2009, compliance was re-launched as a corporate function through a more restrictive and top-down approach. Two internal 123BIO assessments showed that the embedded model did not help the company comply with 2002 PhRMA Code guidance. Interview data indicated that the corporate compliance model had not effectively partnered with business strategy to support adherence to the 2009 PhRMA Code. The field sales force was confused about the unclear compliance changes and fearful of making a wrong move. Corporate sales and marketing management indicated that the top-down compliance approach ignored input by sales and marketing regarding guidelines that greatly impact the way 123BIO does business. Information systems respondents were hopeful that the corporate compliance group will share ownership of the 13 tracking processes created to track adherence to the Code. It was concluded that 123BIO waited too long to establish a compliance infrastructure and may have selected the wrong type of infrastructure when the embedded compliance model was launched in 2005. 123BIO did not utilize changes made by the 2009 PhRMA Code to create a more educated sales force because the company was forced to focus on more immediate compliance concerns in a short period of time.

Off-Label Navigator CRC Press

The book covers key Indian pharmaceutical regulations in an easy-to-understand presentation, will be useful for Pharmacy and Life sciences graduates seeking to make a career in Pharmaceutical Industry. The book is also beneficial to key professionals in the pharmaceutical industries including those working in Product development, Quality Assurance, Regulatory Affairs, Finance, Marketing, Sales, senior executives including CEO's who should be familiar with these legislations to ensure compliance. Useful also for start-ups and those entrepreneurs planning to be a part of the Pharmaceutical industry as Manufacturer, Marketer or retail and wholesale medicines business through single or multiple outlets or set up Drug testing laboratories. The book covers salient features of Drugs and Cosmetics Rules and New Drugs and Clinical trial Rules. Pricing of drugs as prescribed in Drugs price control order is described. Nutraceutical related regulations are also included. It has a chapter on Marketing of drugs which covers the Uniform Code of Pharmaceuticals Marketing Practices . Regulations related to setting up of a Public testing laboratory is also included. The content is as under: Chapter 1 - Introduction 1.1 Global Pharmaceutical Industry1.2 Global Pharmaceutical Industry1.3Pharmaceutical Regulations1.4Expectations from stakeholders Chapter 2 - Regulatory Agencies Chapter 3 - Manufacture of drugs for Examination, Test, or Analysis 3.1 Introduction 3.2 License for examination, test, or analysis of drugs 3.3 Import of drugs for the purpose of examination, test, or analysis 3.4 Labelling of Medicines 3.5 Other labeling requirements 3.6 Standards for Ophthalmic preparations 3.7 Use of letter I.P. on the labels3.8 Packing of drugs 3.9 Use of Package inserts in product packs3.10 Quick Response code on the label of Active Pharmaceutical Ingredients3.11 Diseases which a drug may not purport to prevent or cure3.12 Shelf life of drugs3.13 Stability studies 3.14 Permitted Colours3.15 Standards of drugs 3.16 Schedule V and Vitamin Products3.17 Labels on packs of drugs for export Chapter 4 - Clinical Trials 4.1 Introduction4.2 constitution of ethics committee for clinical trials 4.3 Clinical trial of new drug or Investigational New Drug4.4 Academic clinical trial4.5 Inspection of clinical trial premises 4.6 Bioavailability or bioequivalence study of new drug or investigational new drug4.7 General Principles and practices of clinical trials (first schedule)4.8 Conduct of clinical trials 4.9 Compensation in case of injury or death in clinical trial or bioavailability or bioequivalence study of new drug or investigational new drug 4.10 Manufacture of new drugs or investigational new drugs for clinicalTrial, bioavailability or bioequivalence study or for examination, testand analysis 4.11Manner of labeling4.12 Import of new drugs and investigational new drugs for clinical trialor bioavailability or bioequivalence study or for Examination, test and analysis4.13 Permission to manufacture unapproved active pharmaceutical ingredient for development of formulation for test or analysis or clinical trial or bioavailability and bioequivalence Study Chapter 5 - Manufacture of Drug for sale or distribution Chapter 6 - Import or Manufacture of New drug for sale and distribution Chapter 7 - New Drug Application - similar biologics Chapter 8 - Import of drugs for sale or distribution storage, sale and distribution of drugs Chapter 9 - Storage, sale and distribution of drugs Chapter 10 - Narcotic and Psychotropic substances Chapter 11 - Drugs Price Control Order Chapter 12 Manufacture of Nutraceuticals Chapter 13 - Marketing of Drugs Chapter 14 - Public Testing Laboratories

Managing Relationships with Industry Jones & Bartlett Publishers

Get the inside scoop on pharmaceutical sales careers with this new Vault Guide. Overview of the industry; functions in pharmaceutical sales: field sales, sales management, training and development, instructional design/content development, project management; jobs and career paths; getting hired - education, interview preparation, and more.

Pharmaceutical Marketing CRC Press

Pharmaceutical sales and marketing IS in turmoil. Eroding trust for industry, overabundance of reps, and limited physician time are leading to a "perfect storm" for the death of the pharmaceutical sales rep. Threats also present opportunities in disguise. Can you see the opportunities in front of you?In this book, Dr. Pawar provides creative new concepts and exercises to take individuals and teams through these challenges successfully.Whether you are a senior-level leader in pharmaceutical sales or marketing, or whether you are "in the field", this book will stimulate the "mind shifts" you need to succeed for the long run.

Pharmaceutical Sales in Turmoil: Physician Access and Engagement Strategies for a New Era

Career in Pharmaceutical Sales

In a dozen comprehensive chapters, author Mickey Smith highlights the economic social, and legal aspects of marketing pharmaceutical products, examines the consumers and prescribers, and explores successful marketing, pricing, and distributions strategies.