
From: Killion, Mark
To: Jennifer Altier; Nathalie Leitch
CC: Miller, Scott
Sent: 7/18/2011 12:16:48 PM
Subject: Compliance presentation
Attachments: Compliance Update NSM v1 071811.pptx

Jennifer and Nathalie,

Attached is the compliance presentation for the NSM. In the business rules section I used the business rules as they were written and submitted to Actavis. I don't think Legal has approved all of them yet so they may have some updates to the presentation. I did include the updated AE reporting information that was requested. Although there are a number of slides here I shouldn't have any problem getting them done in the time allotted.

Obviously this needs to be in the NSM template as well. Sorry I didn't get that done. Please let me know if you have any questions. Thanks.

Mark Killion
Midwest Regional Business Director
Actavis Pharmaceuticals
mkillion@kadian.com
317-837-8345 (office)
317-501-0588 (cell)

PLAINTIFFS TRIAL
EXHIBIT
P-25270_00001

ACTAVIS0357903

P-25270 _ 00001



Compliance Update
July 25, 2011
Presented by Mark Killion and Scott Miller





Overview

- Update on business rules
 - HCP interaction
 - Educational Materials
 - Off-label information requests
 - Medical Conventions/Exhibits and Displays
 - Business meal guidelines
 - Adverse event and product complaint reporting
- Sunshine Act Update



Product Promotion

- General Policy:

- Promotional materials provided to HCPs by or on behalf of a company should: (a) be accurate and not misleading; (b) make claims about a product only when properly substantiated; (c) reflect the balance between risks and benefits; and (d) be consistent with all other Food and Drug Administration (FDA) requirements governing product promotion

- Policy Guidelines: Discussions with HCPs & Patients

- inVentiv sales representatives **MUST**:
 - promote products to HCPs whose medical specialties or medical practice involve treating patients for which the product is indicated
 - respond to “off-label inquiries” in accordance with client’s “Off-Label Inquiries” policy
 - ensure all discussions with patients or patient support groups are consistent with client approved product labeling
 - always advise consumers that only their HCP can determine what product is appropriate for them



Product Promotion (*cont'd*)

- Policy Guidelines: Discussions with HCPs & Patients
 - inVentiv sales representatives **MUST NOT**:
 - initiate, prompt, or engage in off-label product discussions with HCPs
 - promote or encourage an unapproved product use or indication
 - directly or indirectly solicit “off-label” questions from HCPs
- Policy Guidelines: Appropriate Target Audience
 - Client products may only be promoted to HCPs whose medical specialties or practice involve treating patients for which the product is indicated
- Policy Guidelines: Use of Promotional and Educational Material
 - inVentiv sales representatives **MUST**:
 - only use client approved promotional and/or educational materials and presentations when promoting client products
 - adhere to client business rules for the appropriate use of promotional and/or educational materials



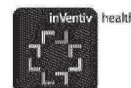
Product Promotion (*cont'd*)

■ Policy Guidelines: Use of Educational and Promotional Material

- Sales representatives must always be mindful that call notes could be subject to subpoena and therefore, should be written with care and consideration as to their intent and content. This includes e-mail and social media (e.g. Facebook, Twitter).
- inVentiv sales representatives **MUST NOT:**
 - modify client approved materials in any way (i.e. underlining, highlighting, adding notes or comments)
 - use “homemade” materials under any circumstance
 - photocopy or reproduce client approved materials without client approval
 - use, show, distribute or discuss materials approved for “internal use only” with HCPs, patients or consumers (e.g. sales training materials)

■ Interactions with Healthcare Professionals must focus on:

- Providing current, accurate, and balanced information about Kadian
- Transmitting sound and accurate scientific and educational information
- Actavis will in no case offer or pay anything of value to induce a healthcare professional to purchase, prescribe, use or dispense Kadian



Responding to Unsolicited Requests for Off-label Information

- General Policy Guidelines:

- inVentiv sales representatives **MUST** respond to unsolicited requests for off-label information in the following manner:
 - advise the requestor that the product is not approved for the intended use
 - advise the HCP that you are only permitted to discuss FDA approved uses and/or indications; then
 - follow client business rules for responding to “Unsolicited Requests for Off-label Information”

- Actavis Business Rules:

- Sales representatives are to refer all questions regarding Off-Label inquiries to Actavis Medical Affairs at:
 - **1-888-496-3082**



Medical Conferences and Conventions

- All Company sponsored commercial booths and exhibits at medical conferences and conventions must be authorized by the appropriate Marketing representative in accordance with this policy and receive approval from the Legal Department.
- The Company may sponsor commercial booths or exhibits only at conferences or conventions where attendees would have reason to use the Actavis products consistent with the product labeling.
- All advertising and promotional pieces used at conventions and meetings must be approved and authorized by the PRC prior to the use of the pieces in accordance with applicable PRC procedures.



Medical Conferences and Conventions, cont'd

- All statements made by Actavis employees (or its agents) about marketed products at meetings and conventions must be:
 - Consistent with the approved labeling;
 - Be truthful and not misleading; and
 - Reflect a fair balance of the benefits and the risks of a product.
- Actavis employees are prohibited from soliciting (i.e., prompting) requests for information about unapproved products or indications.



Medical Conferences and Conventions, cont'd

- Reprints of any type of publication that discuss unapproved products or indications must not be disseminated on the commercial floor of any convention or meeting,
- Any meals or gifts provided at the convention must be provided in accordance with the rules set forth in the Customer Meals, Gift, and Entertainment policy as set forth in the Actavis Health Care Compliance Guide (Policy Number 7).



Exhibits and Displays

- All requests to sponsor local, regional or national exhibits or displays about a marketed product should send the request to the appropriate Marketing personnel for review and approval. All such exhibits or displays must be approved by the Legal/Compliance Department.
- Actavis may sponsor exhibits or displays only at conferences or conventions where attendees would have reason to use the Actavis products consistent with the product labeling.
- Approval Procedure
- Actavis personnel who wish to organize and conduct a promotional program, or who wish to provide funding for a promotional program conducted by a third party, must obtain approval from the PRC.



Educational & Medically Relevant Items

■ General Policy:

- It is appropriate for companies, where permitted by law, to offer items designed primarily for the education of patients or HCPs if the items are not of substantial value (\$100 or less), offered on an occasional basis and do not have value to HCPs outside of their professional responsibilities
- Items must primarily benefit patients or patient care (e.g. anatomical model)
- Must serve a genuine educational or clinical need (e.g. text book)

■ Policy Guidelines:

- inVentiv sales representatives **MAY NEVER** provide HCPs: :
 - any item of value in an attempt to reward their prescribing practices or to influence them to purchase, prescribe, dispense, recommend or provide favorable formulary status for client products
 - gifts for any reason



Educational & Medically Relevant Items (*cont'd*)

- Policy Guidelines:

- inVentiv sales representatives **MAY NEVER** provide HCPs:
 - medically relevant items in the form of cash or other cash equivalent for which a HCP could purchase an item on their own
 - items intended for the personal benefit of a HCP (e.g. floral arrangements, bottle of wine, tickets to sporting events, CDs, music)
- inVentiv sales representatives **MAY** provide HCPs:
 - client approved educational and medically relevant items



Business Meals

- General Policy:

- In order to provide important scientific information and to respect HCPs abilities to manage their schedules and provide patient care, sales representatives may take the opportunity to present information during HCPs' working day, including mealtimes
- In connection with such presentations or discussions, it is appropriate for occasional meals to be offered as a business courtesy to HCPs and members of their staff attending presentations, so long as the presentations provide scientific or educational value and the meals (a) are modest as judged by local standards; (b) are not part of an entertainment or recreational event; and (c) are provided in a manner conducive to product or informational presentations

- Policy Guidelines:

- inVentiv sales representatives must never provide meals or hospitality in an attempt to reward prescribing practices or to influence client customers





Business Meals (*cont'd*)

■ Policy Guidelines:

- Sales representatives and their immediate manager may not provide restaurant meals to HCPs unless inVentiv's Commercial Compliance and client business rules allow
- If client business rules allow, sales representatives may provide occasional in-office or in-hospital modest meals to HCPs in conjunction with a product or informational presentation
- Sales representatives may only provide business meals to client customers and their staff who have reasonable interest in patient treatment

■ Actavis Business Rules:

- inVentiv sales representatives will adhere to the Actavis meal spend limit
- In-Office Breakfast/Snack - \$10 per person
- In-Office Lunch - \$25 per person



Entertainment

- General Policy Guidelines:
 - inVentiv sales representatives may not provide social activities, recreation or any entertainment (i.e. golf, sporting events, theatre tickets, etc.) to HCPs



Adverse Events & Product Complaints

- Actavis Business Rules:

- To report or access information, regarding Adverse Events and Product Complaints sales representatives are to call within 24 Hours of learning of the AE:
- 1-888-496-3082
- Actavis requires the report to include only the information received by the sales representative. At a minimum, the report should include:
 - Product name (and strength, if available);
 - Product NDC or lot number if either are available



Adverse Events & Product Complaints, cont'd

- Reporters name, (healthcare professional) address, and telephone number;
 - Description and date of the event;
 - An identifiable patient (Gender and age of the person affected by the Adverse Event if available);
 - Date of the report to the Sales Representative;
- Sales Representative's name and contact information





Available Resources

- InVentiv Resources:

- Director Commercial Compliance: Scott Miller
- Chief Compliance Officer, inVentiv Health: Tricia Glover
- Confidential Hotline: **800-673-7309**

- Actavis Resources:

- Representatives are to contact their Regional Business Director (RBD)



┐ Federal Disclosure Law: Patient Protection and Affordable Care Act



CMS Questions and Requests

- An open call was held on March 24, 2011, in regards to Transparency Reports and Reporting of Physician Ownership of Investment Interests. Questions posed:
 - What is the method CMS will use to collect data, as a mid-size firm stating they had relationships with 300,000 doctors would result in millions of transactions>
 - How will CMS handle revisions to reporting errors?
 - What types of electronic forms are currently available that CMS can leverage for use as a model to satisfy the reporting requirements?
 - Ability of the public to utilize and readily understand the information?
- Requests:
 - A request was made on the call for CMS to release the formal regulations in time for the reporting deadline
 - Request was made that CMS be **VERY CLEAR** and **DETAILED** with the definitions of nature of payments and transfers of value



CMS Questions and Requests

- Request was made that CMS ensure payments are not reported more than once
- A suggestion was made for CMS to release a MASTER LIST of teaching hospitals and physicians



Payments Disclosure: Federal Law P.L. 111-148

- On March 23, 2010, H.R. 3590 became law. Public Law 111-148 amended the Social Security Act, Title XI, Part A (42 U.S.C. after section 1320-7f)
- Payments Disclosure Federal Law P.L. 111-148
- What must be included on the Payments Disclosure Report?
 - Recipient:
 - Name
 - Business Address
 - Specialty
 - National Provider Identifier (NPI)



Payments Disclosure: Federal Law P.L. 111-148

- Payment:
 - Value
 - Date
 - Product Name
 - Form of Payment (cash or equivalent, in-kind items, stock /dividends)
 - Nature of Payment, this may include;
 - Consulting, Compensation, Speaker Fee(s), Honoraria, Gift(s), Entertainment, Food, Travel, Education, Research Grant(s), Charitable Contribution(s), Royalties, Ownership or Investment Interest(s)



Payments Disclosure: Federal Law P.L. 111-148

- Preemption:

- The provision under P.L. 111-148 Preempts any state or local law or regulation that requires an applicable manufacturer to disclose or report the same information required by the Federal Law

BUT

- Does not Preempt any state or local law or regulation that requires the disclosure or reporting of information not required to be disclosed or reported as stated under the law

- Penalties:

- \$1,000 to 10,000 for each failure to submit required information in a timely manner (Penalty not to exceed \$150,000 per annual submission)
- \$10,000 to 100,000 for knowingly failing to submit required information (Penalty not to exceed \$1,000,000 per annual submission)





Payments Disclosure: Federal Law P.L. 111-148

- Reporting Threshold
- Disclosure Required For:
 - Any transfer of anything of value that is less than \$10 DOES NOT require disclosure
 - The Exception to this is when the aggregate amount transferred to a singly covered recipient exceeds \$100 for the calendar year (this basically means you need to capture all spend regardless of amount)



Federal Disclosure Law

- Section 6002: Covers Transparency Reports on payments or other transfers of value provided to Covered Recipients That Require Disclosure;
 - Covered Recipient – Physicians
 - Doctors of Medicine
 - Osteopathy
 - Dental Surgery, Dental Medicine
 - Podiatry
 - Optometry
 - Chiropractors
 - TEACHING HOSPITALS (WHICH ARE NOT DEFINED IN THE LAW, AND HAVE YET TO BE CLEARLY DEFINED BY CMS)
- The collection of required data for reportable payments and transfers of value begin on January 1st, 2012



Federal Disclosure Law

- Reporting begins on March 31st, 2013, and is inclusive of all data for the preceding calendar year
- Payment Transparency Report
- Who is required to report:
 - Applicable Manufacturers that are entities in production, preparation, propagation, compounding, or conversion
 - Of a drug, device, biological, or medical supply available under a federally subsidized program;
 - Operating in the United States, a territory, possession, or commonwealth of the United States;
 - Or an entity under common ownership with such entity that provides assistance or support for production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution





Federal Disclosure Law

- Preparing to Disclose Payment Information
 - Track all payments, even those under \$10
 - Train all representatives to maintain all payment information, not just for reimbursement purposes
 - Create/Purchase an automated system to maintain this data

