Risk Communication
- Healthcare Provider focused Communications

Dr Nayan Acharya & Helen Hochstetler

9th Annual DIA Conference on Contemporary Pharmacovigilance and Risk Management Strategies
Jan 2009

Lilly
Answers That Matter.

What is Risk Communication?

What is Risk Communication?

Risk Communication is a science-based approach for communicating effectively in high-stakes, emotionally charged, controversial situations.

"The ultimate job of risk communication is to try to produce a citizenry that has the knowledge, the power, and the will to assess its own risks rationally, decide which ones it wants to tolerate and which ones it wants to reduce or eliminate, and act accordingly."

- Dr. Peter Sandman

Reference: Sandman, P. Responding to Community Outrage: Strategies for Effective Risk Communication. AIHA Press. 1993.

PhRMA Survey on FDA Safety Alerts

- undertaken by KRC in 2009

- The **Potential Signals report** is **not reaching** either **physicians or consumers**—most are not aware of it.
- **Consumers** are pleasantly surprised when they learn about the Potential Signals report. In fact, it appears to **increase their confidence** in both the FDA and the drug safety system.
  - Physicians also appreciate the information, and many were surprised that they had not seen it, but some worry that their patients will misinterpret it.
- **Most consumers interpret** what the FDA is communicating **accurately**, and although many are concerned, few feel alarmed.
- **Most consumers feel more secure**—especially those taking the drugs—knowing the drugs are being evaluated.
- Consistently, **20-25%** of **consumers** are **confused by or misinterpret** the information and **50% believe drugs** on the list **pose a serious risk**. This suggests that the **report could be written more clearly**.
  - Many consumers and physicians alike feel the language is too technical and there is not enough context to provide perspective.

Physician Response to Safety Warning
The Process

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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Safety warning is issued

- Physicians learn of safety warnings and alerts from a variety of sources.
  - Mainstream and online media
  - Online healthcare sites
  - Colleagues
  - FDA – email or mail
  - Patients

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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Do I have enough information, or do I need more?

- Physicians will always use their clinical experience to provide context to the issue.
- There are critical questions the physicians want answered in order to move forward.
  - How serious is this issue?
    - Life threatening or bothersome
  - How concerned should I be?
    - Incidence
  - What is suggested I do about this issue?
    - Do I need to monitor something?
    - Do I need to warn patients?
    - Do I need to avoid prescribing to specific patients?
    - Do I need to limit or stop prescribing?

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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I have enough information | **Do nothing and/or wait for additional data**

- If the critical questions are answered in the warning itself, physicians are unlikely to continue searching for more information.
- For example, if the safety risk has a low incidence of occurrence, or the physician does not classify the risk as severe, or the benefits of the product outweigh the potential risks.
- Not every warning prompts a change in behavior especially if the warning simply repeats a risk that is already established. (Tylenol)
- At times, waiting for additional data is the best option during which time physicians may or may not alter their behavior. (Lantus)
- They will be more likely to alter their behavior if there are equivalent alternatives.

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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I have enough information → **Alter my current behavior**

- Although physicians do not want to be told what to do, any suggestions for altering behavior (or not) within the warning provide context and help them formulate a plan.
- Likely actions to be taken based on the warning…
  - Monitor for the specific adverse event
  - Warn patients currently on product
  - Warn new patients who are prescribed product
  - Avoid prescribing to specific patients, e.g. those with pre-existing condition
  - Limit or stop prescribing
- Patients have tremendous influence on how physicians react to a safety warning even if the physician had planned to do nothing.
  - If a patient learns of the safety warning through media sources and they are concerned, they will often pressure their physician to take action.
  - Physicians are extremely likely to comply unless there is not a viable alternative and the risk of not taking the medication is greater than the risk of taking it.

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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I need more information → **Go to my "trusted" sources**

- If a physicians needs further information, they are looking for very specific information related to the specific safety issue, and will utilize sources they have learned to trust to find it.
  - Colleagues
  - PDR
  - Google search
  - Website of choice
    - WebMD, Medscape, uptodate.com
    - Pharma product site
  - Reps

WebMD Better information. Better health.

Google

webmd.com

UpToDate ONLINE

- They are very unlikely to go to the corporate site of the manufacturer.
- Will these sources have the specific information they desire?

Eli Lilly and Company. Qualitative Study: Explore Physician Needs and Associated Bahaviors Specific to Accessing or Receiving Emerging Drug Safety Information on the Internet; Market Research Data on File; 2009.

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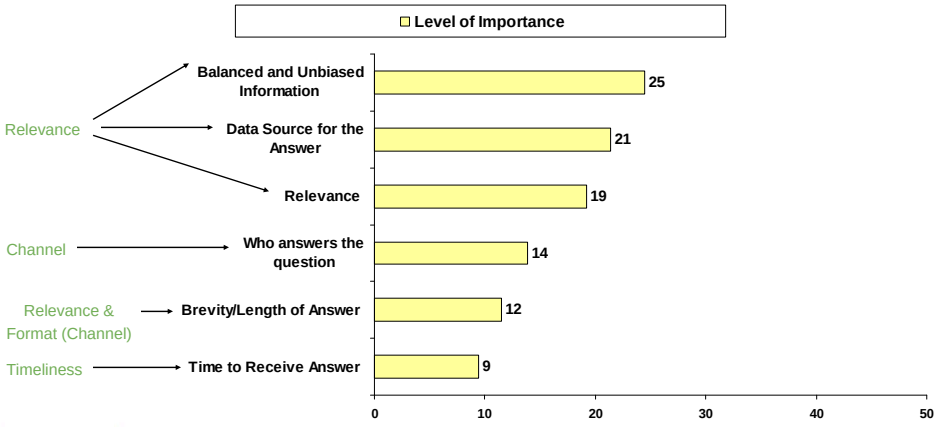
HCP Communication - Physician Priorities

- What matters most - Timeliness, Relevance, or Channel?

Q. Regarding your general product-related questions, please distribute 100 points among the following attributes,



Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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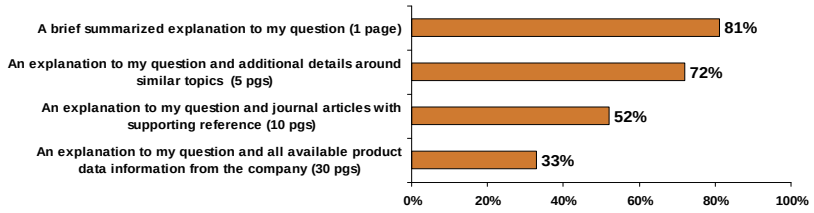
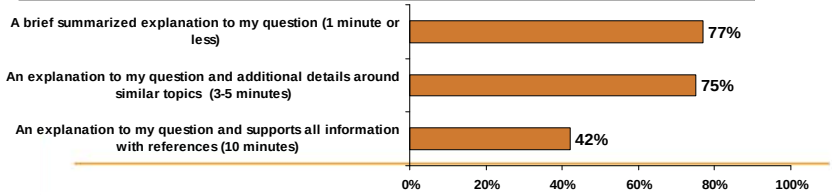
Relevance (Brevity) – Overall

Satisfaction with Types of Responses - Top 2 Satisfied/Very Satisfied

Q: How satisfied would you be given the following **written communications** from a company to your product-related questions?



Q: How satisfied would you be given the following **verbal communications** from a sales representative to your product-related questions?



Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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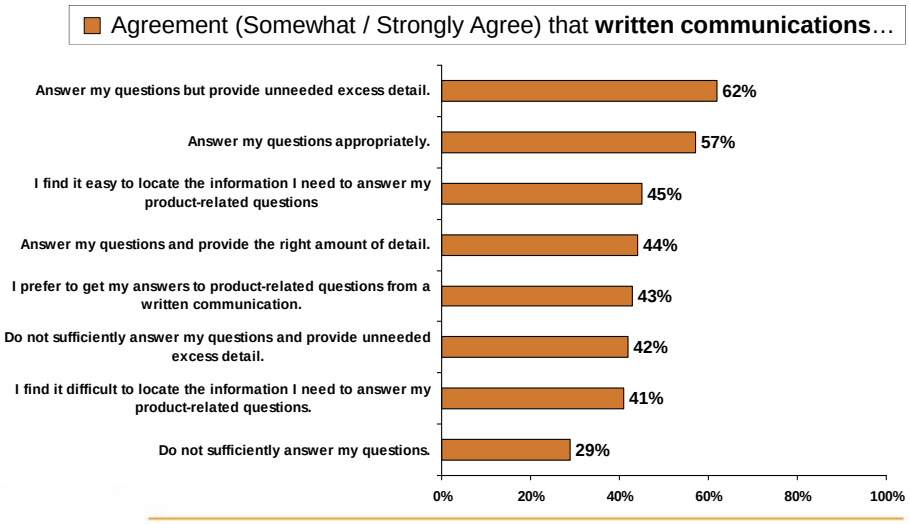
Company **Written Communications** Regarding Product-Related Questions



Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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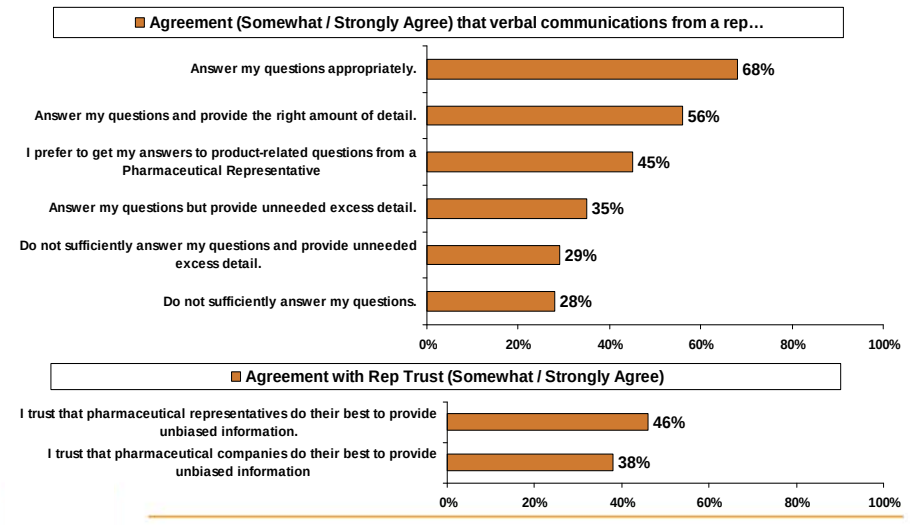
Pharmaceutical Representative Communications Regarding Product-Related Questions



Lilly USA. Responding to Unsolicited Requests; Market Research Data on File; March 31, 2008.

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There are barriers that keep physicians from reporting adverse events.

- **Physicians** in this research indicate that they have **reported adverse events very infrequently** in their careers.
- In general, **physicians believe** that they should **report only** those adverse events that are **"unusual", "unexpected" or "serious"**.
  - The definition of an "unusual", "unexpected", and "serious" adverse event is very subjective to each physician.

Physicians seem to use a high threshold to determine what needs to be reported because…

- there is a general impression that the process is cumbersome and time consuming.
- there is a lack of awareness of what happens to the information in the report.
- they may expose themselves to greater liability.

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Opportunities

- Increase transparency in Safety Surveillance
- Improve awareness on Pharmacovigilance
  - E.g.: Lilly's Safety Matters Website http://safetymatters.lilly.com
- Improve Content of Risk Communication
  - Safety Alert Response Document (SARD)
- Embrace New Technology

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Transparency is not easily achieved with one initiative – **it will take several initiatives** to demonstrate true transparency to physicians.

Transparency in safety surveillance

Encourage me to report adverse events and make it easier for me to do so	Tell me how often this adverse event has been reported – summary not details	Allow me to see all adverse events reported for this product – summary not details	Be open and honest about what I should do in response to a specific event – don't ignore it and do more than acknowledge it

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Lilly
login contact us worldwide sitemap search this site Search
Safety Matters Home
Provider's Role
Lilly's Role
FDA's Role
Patient's Role
Provider's Role
Why Provide Follow-up to Lilly about Adverse Events?
Quick Links
How do I report an Adverse Event?
US Prescribing Information
Medication Guides for Patients
FDA Safety Communications
HIPAA Concerns
Why Follow-Up is Important
Safety Matters Overview
Healthcare Provider's role in reporting and providing follow-up on Adverse Events
Why Report AEs?
Why Provide Follow-up to Lilly?
How to Report an AE
Lilly's on-going role in monitoring benefits and risk profile
FDA Safety Resources
Medication Safety for Patients
Have a question about a Lilly Product?
Lilly Medical Web Site
Contact the Lilly Answer Center at 1-800-Lilly-Rx
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Safety Matters Home
Provider's Role
Lilly's Role
FDA's Role
Patient's Role
Provider's Role
How Do You Report an Adverse Event?
Everyone is unique; therefore, individuals may respond quite differently to the same medication.
Patients that have questions or concerns about a medication they taking are always encouraged to first discuss them with their doctor, pharmacist, or other healthcare provider.
Physicians, other healthcare providers and patients are encouraged to voluntarily report adverse events involving drugs or medical devices. To make a report you can:
Visit www.fda.gov/medwatch , or call 1-800-FDA-1088 to report an adverse event related to any U.S. product to the FDA.
For Lilly U.S. marketed products, you may also call 1-800-LillyRx
Quick Links
How do I report an Adverse Event?
US Prescribing Information
Medication Guides for Patients
FDA Safety Communications
FDA
Medical Product Safety Alerts
MedWatch
MedWatch Home
Product Safety Information
Report Adverse Events
Join the MedWatch E-list
Safety Matters Overview
Healthcare Provider's role in reporting and providing follow-up on Adverse Events
Why Report AEs?
Why Provide Follow-up to Lilly?
How to Report an AE
Lilly's on-going role in monitoring benefits and risk profile
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Lilly Medical Web Site
Contact the Lilly Answer Center at 1-800-Lilly-Rx
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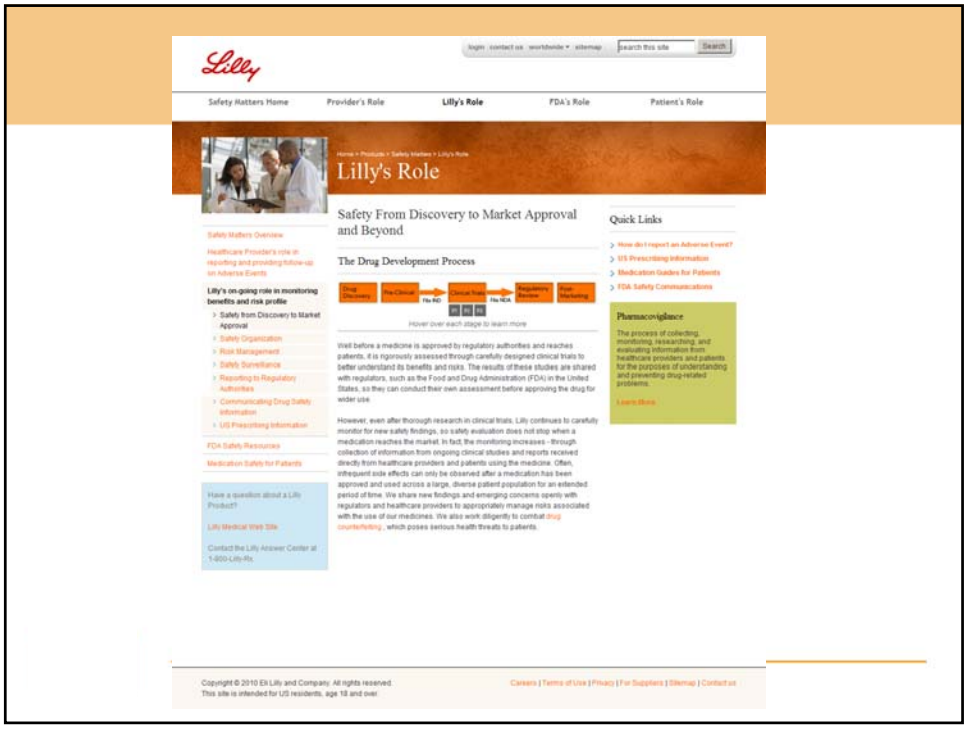
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Lilly's Role
FDA's Role
Patient's Role
Lilly's Role
Safety From Discovery to Market Approval and Beyond
The Drug Development Process
Quick Links
Pharmacovigilance
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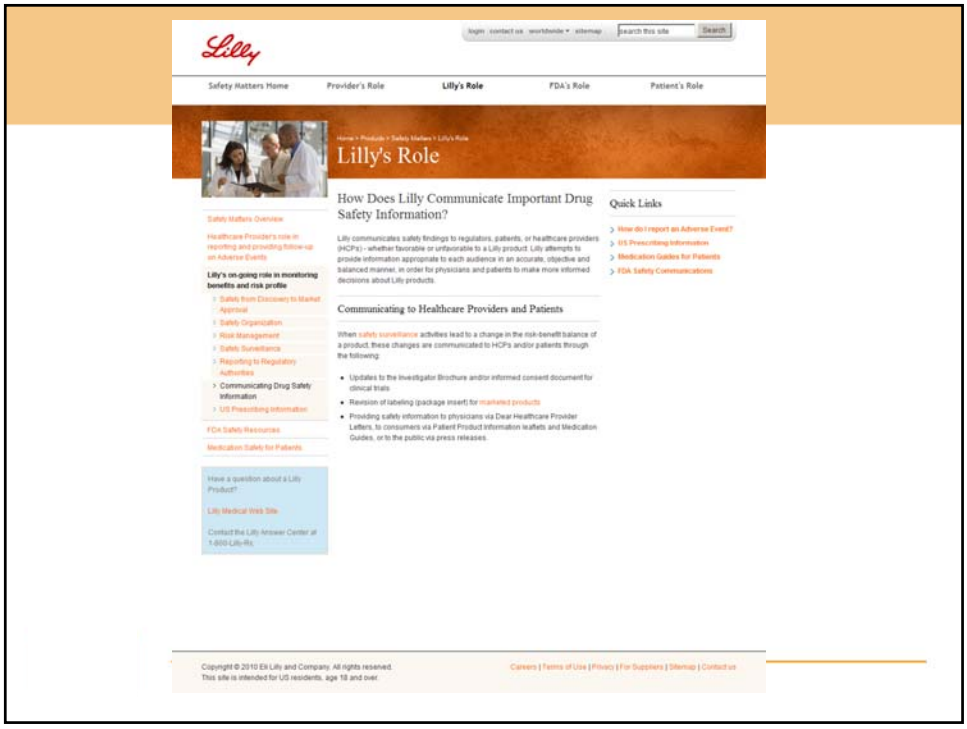
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Provider's Role
Lilly's Role
FDA's Role
Patient's Role
Lilly's Role
How Does Lilly Communicate Important Drug Safety Information?
Quick Links
Communicating to Healthcare Providers and Patients
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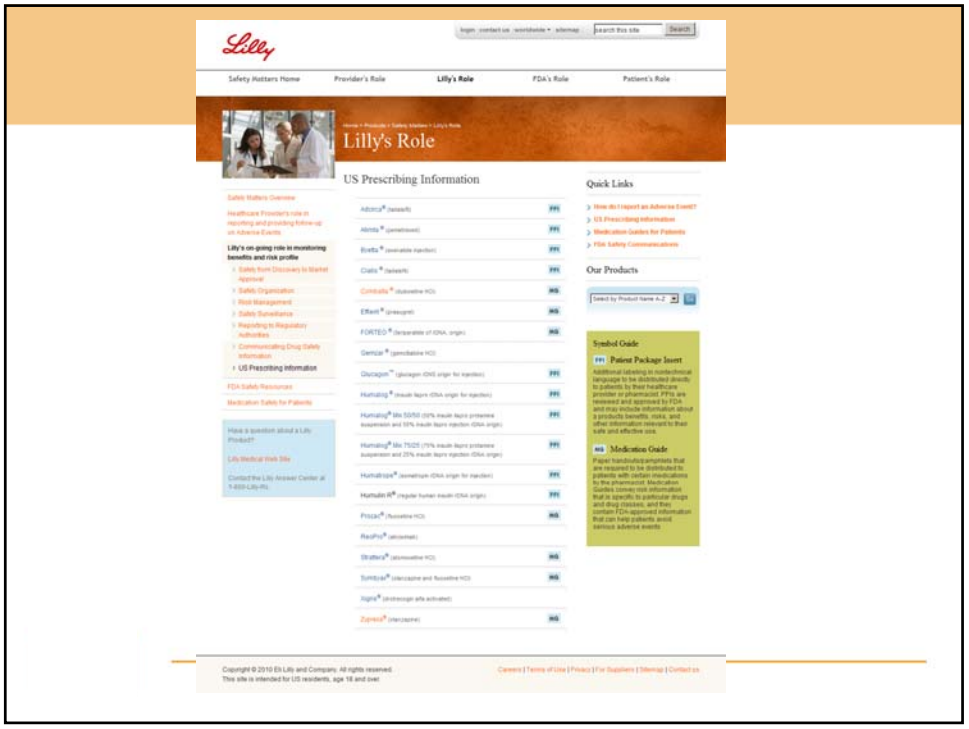
Lilly
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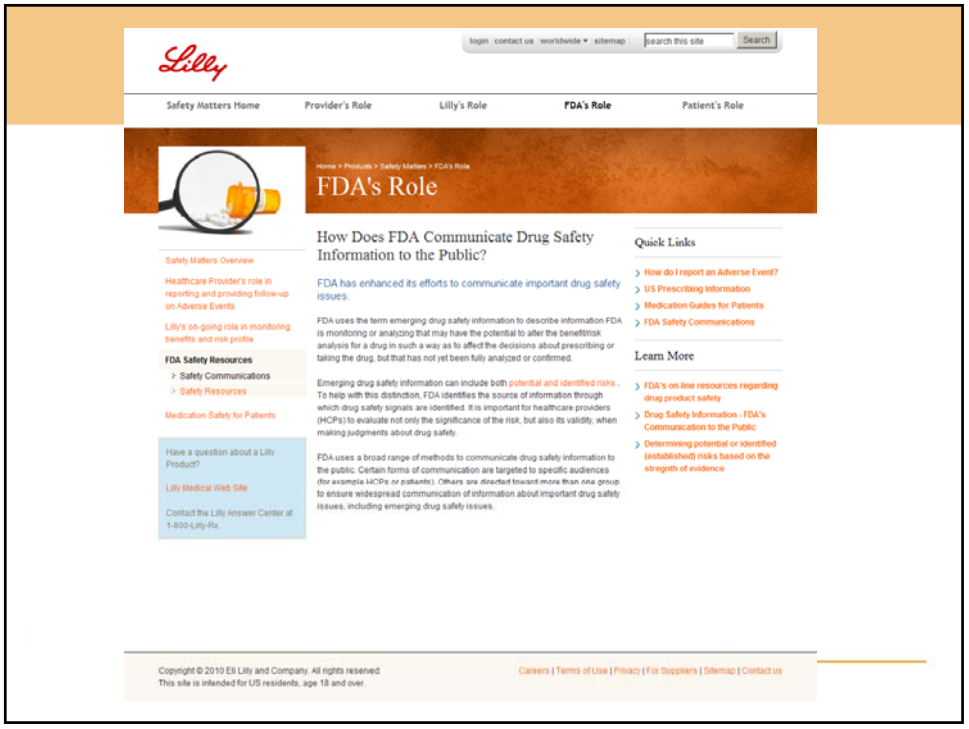
Provider's Role
Lilly's Role
FDA's Role
Patient's Role
Lilly's Role
US Prescribing Information
Quick Links
Our Products
Symbol Guide
Patient Package Insert
Medication Guide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Safety Matters Home
Provider's Role
Lilly's Role
FDA's Role
Patient's Role
Home > Products > Safety Matters > FDA's Role
FDA's Role
How Does FDA Communicate Drug Safety Information to the Public?
FDA has enhanced its efforts to communicate important drug safety issues.
FDA uses the term emerging drug safety information to describe information FDA is monitoring or analyzing that may have the potential to alter the benefit/risk analysis for a drug in such a way as to affect the decisions about prescribing or taking the drug, but that has not yet been fully analyzed or confirmed.
Emerging drug safety information can include both potential and identified risks . To help with this distinction, FDA identifies the source of information through which drug safety signals are identified. It is important for healthcare providers (HCPs) to evaluate not only the significance of the risk, but also its validity, when making judgments about drug safety.
FDA uses a broad range of methods to communicate drug safety information to the public. Certain forms of communication are targeted to specific audiences (for example HCPs or patients). Others are directed toward more than one group to ensure widespread communication of information about important drug safety issues, including emerging drug safety issues.
Safety Matters Overview
Healthcare Provider's role in reporting and providing follow-up on Adverse Events
Lilly's on-going role in monitoring benefits and risk profile
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FDA's on-line resources regarding drug product safety
Drug Safety Information - FDA's Communication to the Public
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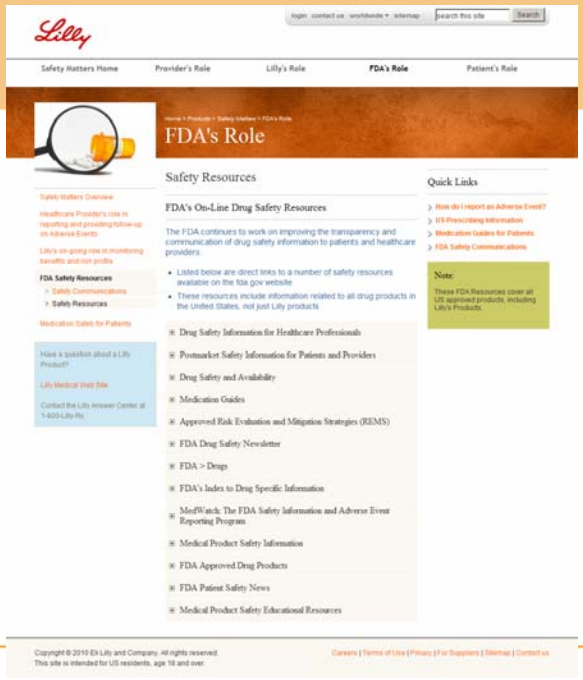

RESPONDING TO HCP QUESTIONS:

Safety Alert Response Documents

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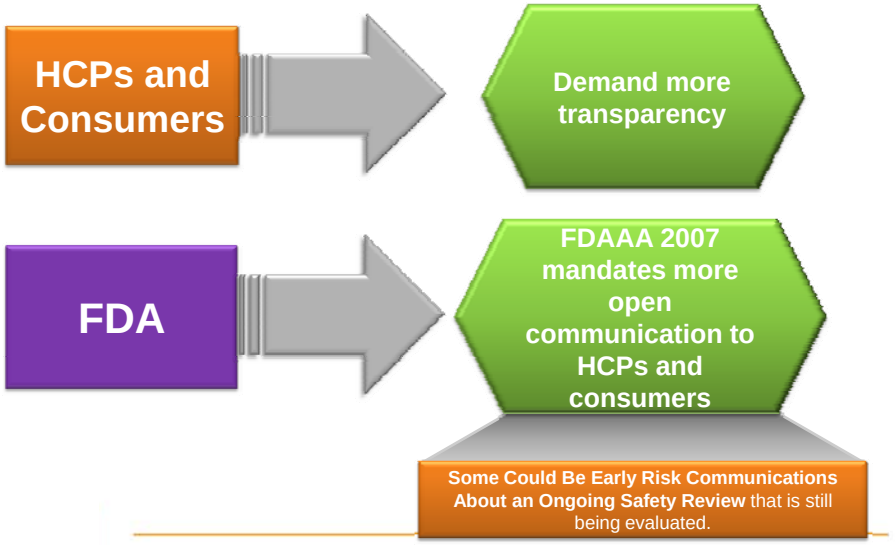
Current Landscape



FDA Communication with Manufacturers when Posting a Safety Alert

- FDA intends to notify the relevant sponsor that emerging drug safety information about its drug will be posted on the FDA Web site at least **24 hours** before posting.
- The posting is intended to represent **FDA's independent analysis** of emerging information and FDA's scientific judgment as to the appropriate communication of this emerging drug safety information to the public.
- FDA may solicit sponsor input when appropriate; for example, to confirm the accuracy of factual information.

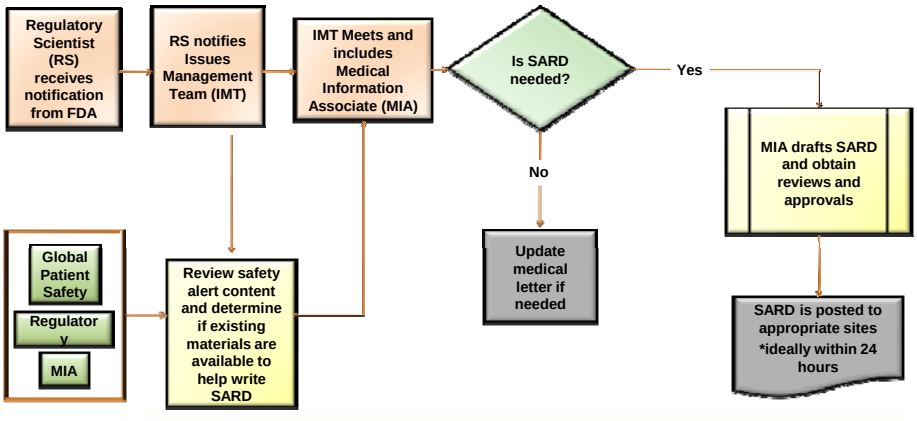
WITHOUT A **TIMELY RESPONSE** FROM THE SPONSOR, CUSTOMERS COULD BE LEFT WITH UNANSWERED QUESTIONS REGARDING THE FDA COMMUNICATION. THIS COULD LEAD TO POTENTIAL INAPPROPRIATE PATIENT TREATMENT DECISIONS.

Safety Alert Response Documents (SARD)

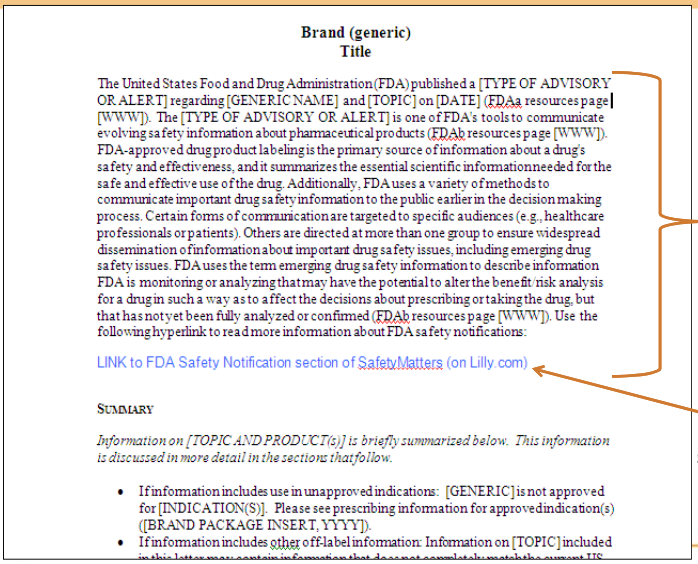
- **Medical Response** created when **FDA** publishes a **Safety Alert** involving a Lilly product
- Will be sent in response to **HCP unsolicited requests**
- **Written by the Medical Information Associate (MIA)** in coordination with other roles
- Utilizes a document template designed to **provide context and additional clinical and scientific information**
- Will include a **link to** the **specific FDA safety notification**
- **Intended for U.S.,** but will be available for OUS affiliates with statement that information is specific to U.S. approved labeling

SARD General Process Overview

IMT: provides cross-functional and cross-geography leadership and direction to **manage critical safety issues** that may globally impact patient care



SARD Template: Introduction



Brand (generic)
Title

The United States Food and Drug Administration (FDA) published a [TYPE OF ADVISORY OR ALERT] regarding [GENERIC NAME] and [TOPIC] on [DATE] (FDAa resources page [WWW]). The [TYPE OF ADVISORY OR ALERT] is one of FDA's tools to communicate evolving safety information about pharmaceutical products (FDAb resources page [WWW]). FDA-approved drug product labeling is the primary source of information about a drug's safety and effectiveness, and it summarizes the essential scientific information needed for the safe and effective use of the drug. Additionally, FDA uses a variety of methods to communicate important drug safety information to the public earlier in the decision making process. Certain forms of communication are targeted to specific audiences (e.g., healthcare professionals or patients). Others are directed at more than one group to ensure widespread dissemination of information about important drug safety issues, including emerging drug safety issues. FDA uses the term emerging drug safety information to describe information FDA is monitoring or analyzing that may have the potential to alter the benefit/risk analysis for a drug in such a way as to affect the decisions about prescribing or taking the drug, but that has not yet been fully analyzed or confirmed (FDAb resources page [WWW]). Use the following hyperlink to read more information about FDA safety notifications:

LINK to FDA Safety Notification section of SafetyMatters (on Lilly.com)

SUMMARY

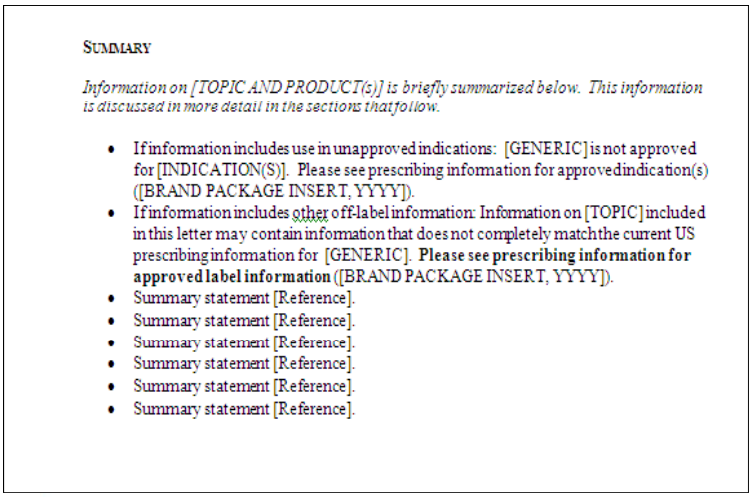
Information on [TOPIC AND PRODUCT(s)] is briefly summarized below. This information is discussed in more detail in the sections that follow.

- If information includes use in unapproved indications: [GENERIC] is not approved for [INDICATION(S)]. Please see prescribing information for approved indication(s) ([BRAND PACKAGE INSERT, YYYY]).
- If information includes other off-label information: Information on [TOPIC] included

Standard introductory language to be included in all SARDs.

Link to Lilly's SafetyMatters.com

SARD Content: 1-page Bullet Summary



SUMMARY

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- If information includes use in unapproved indications: [GENERIC] is not approved for [INDICATION(S)]. Please see prescribing information for approved indication(s) ([BRAND PACKAGE INSERT, YYYY]).
- If information includes other off-label information: Information on [TOPIC] included in this letter may contain information that does not completely match the current US prescribing information for [GENERIC]. **Please see prescribing information for approved label information** ([BRAND PACKAGE INSERT, YYYY]).
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].
- Summary statement [Reference].

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SARD Content: 1-2 Pages Details

The following topics may be included, as appropriate, depending on factors such as the focus of the FDA Advisory or Alert, the type of safety information communicated in the FDA notification and the data source(s) from which the safety information has arisen.

- Description/definition of the specific disease state
- Epidemiology of the disease state or clinical entity (provides context)
- Relevant company clinical study information
- Relevant information from published medical literature
- Relevant information from other data sources, e.g., disproportionality analyses of the Adverse Event reporting System (AERS)
- Review of spontaneous cases or case series, including (as appropriate):
  - Summary of cases (e.g., #/% serious vs. non-serious, age, gender, ethnicity)
  - Aggregate analyses of cases (e.g., reporting rates vs. background rates; number of positive dechallenges or positive rechallenges; etc.)
  - Brief narrative summaries of selected individual cases
  - Benefit-risk assessment
  - Conclusions

MIA with consultation from Medical and Global Patient Safety will determine appropriate information to include in SARD based on these considerations

Challenges to Providing Accurate and Timely Communications

- 24 hour notice of FDA posting
- Requires cross-functional coordination
- Requires partnership with FDA to maintain accuracy and consistency
- Information on the internet is transmitted instantly across the globe, which could generate questions from multiple countries

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Opportunities: FDA and Pharma Partner to…

- Increase transparency in Safety Surveillance
- Improve awareness on Pharmacovigilance
- Improve Content of Risk Communication
- Use a Consistent Approach across the Industry
- Embrace New Technology

Ensure Patient Safety

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BACK-UP

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Links to web pages viewed in TDIs and IDIs

- http://www.fda.gov/Safety/MedWatch/default.htm
- http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm091428.htm
- http://pfizer.com/responsibility/medicine_safety/medicine_safety_education.jsp
- http://astrazeneca.com/responsibility/safety-of-medicines/?itemId=4809492

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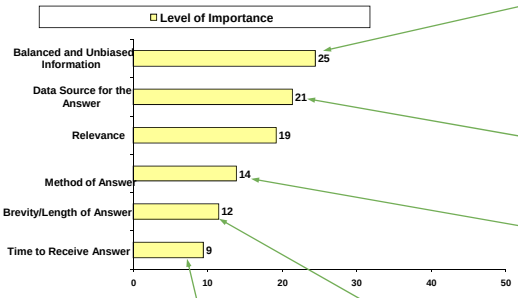
Physician Priorities

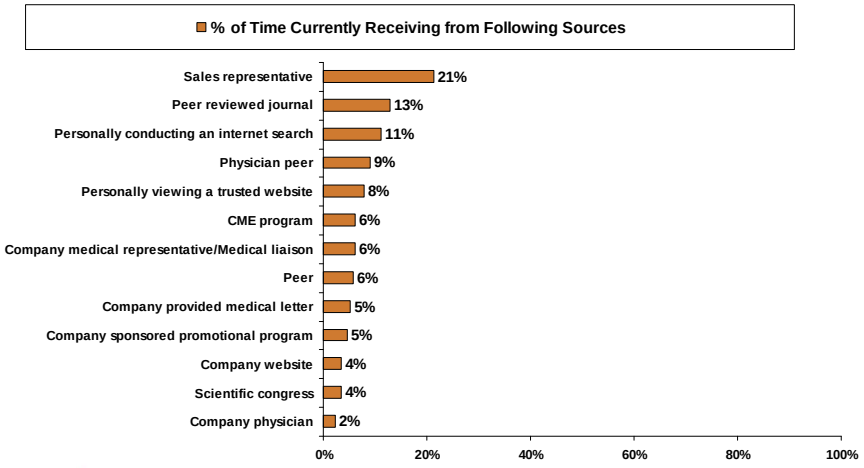
Q601 Regarding your general product-related questions, please distribute 100 points among the following attributes, based upon their level of importance



	n
Total sample size	952
PCP	235
Psychiatry	107
Obstetrics & Gynecology	103
Oncology	99
Endocrinology	102
Urology	103
Pain Specialist/Neurologist	102
Cardiology	101

- Nearly 70% of respondents selected Top 2 box responses for "Info on Safety and Tolerability", "Supportive Information", and "Info on All Studies". Nearly 60% chose Top 2 responses for comparative information about other products/therapies
- Respondents prefer non-company data (especially when peer reviewed) as data source for answers
- Within current environment, respondents prefer to receive answers to Off-Label questions via methods not directly controlled by the company: Peer Reviewed Journals, Thought Leaders (not necessarily programs) and Scientific Congress. Responses from Sales Reps were not among the Top 5 most highly ranked methods
- Respondents generally prefer answers within 24 hours, but will accept wait times of up to one week – especially for off label questions
- Respondents prefer verbal responses to be one minute or less and for written responses to be one page or less. Specialists may tolerate longer responses to Off label questions

Current Sources of Receiving Answer



Q870 Over the past 6 months when you have had a product-related question, what percent of the time did you get your answer from each of the following sources?

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U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

- Today, physicians rarely utilize the FDA site as a resource.
- They are aware that the FDA has a site, but they have very low awareness of the content of the site and are likely to visit only if a link from another site or article takes them to it.
- It is not that physicians have been turned away from the FDA site due to lack of content or poor navigation; there is low awareness of the content on the site, and they simply do not think of it as a resource to use.
- There are varying opinions about the FDA
  - Too conservative – delay approval of much needed medications or remove medications even though patients were benefiting
  - Overworked and understaffed
  - Typical inefficient government agency
  - In "bed" with pharmaceutical companies – conflict of interest

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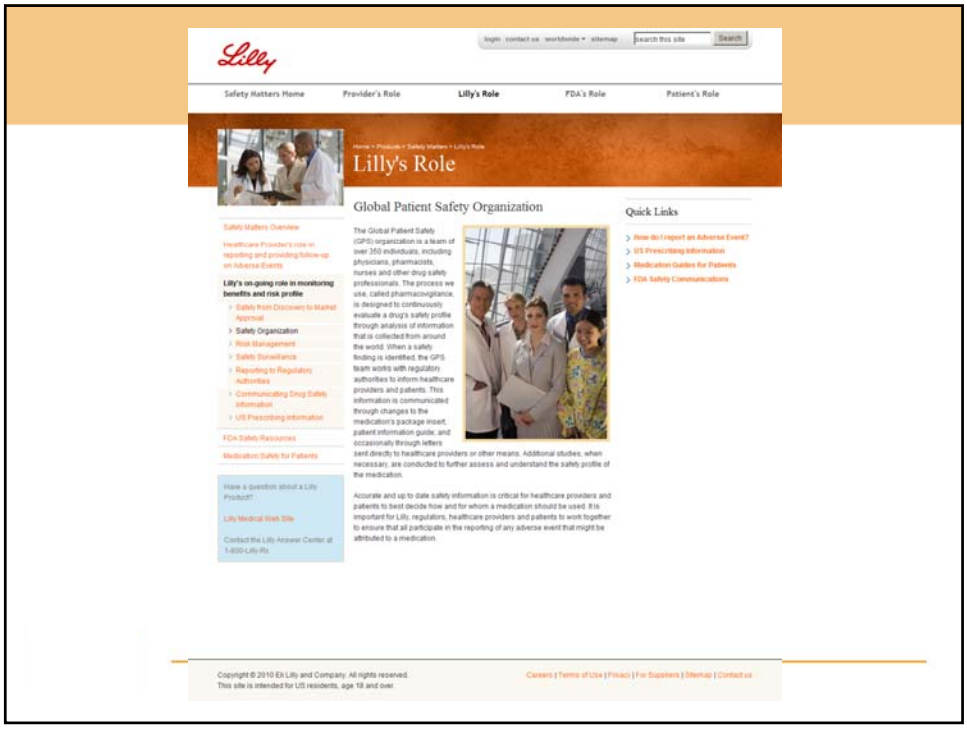
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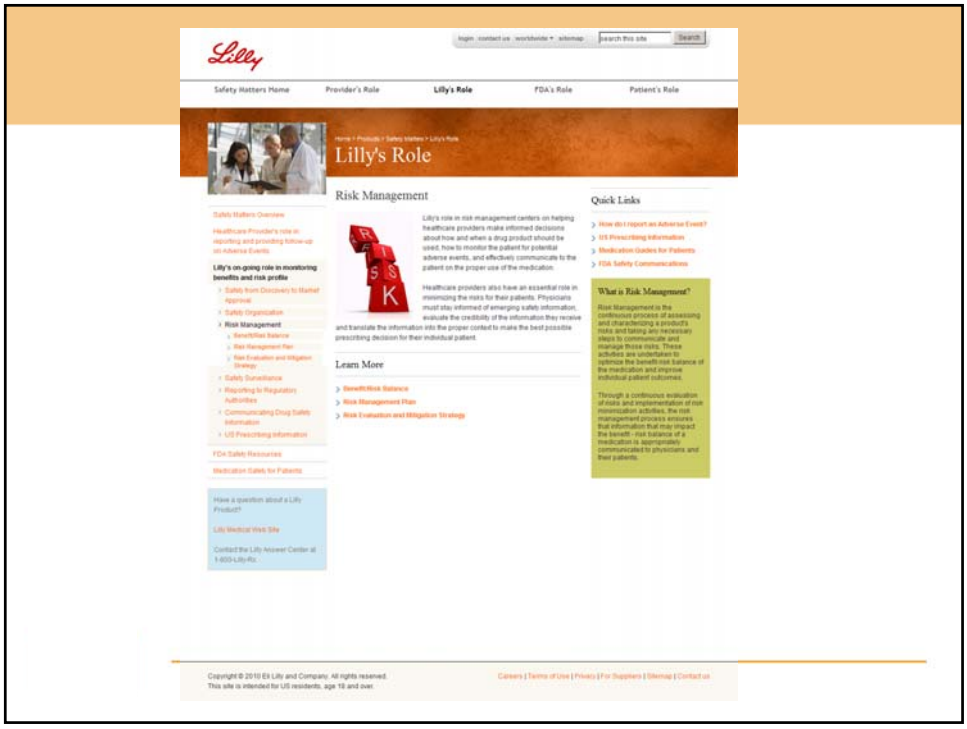
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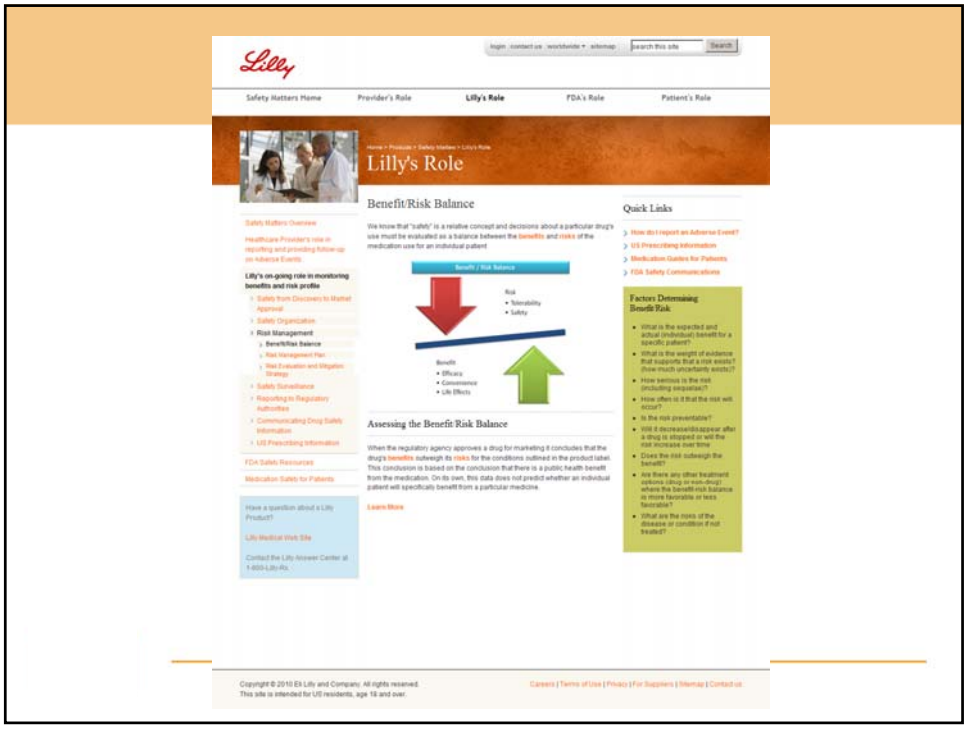
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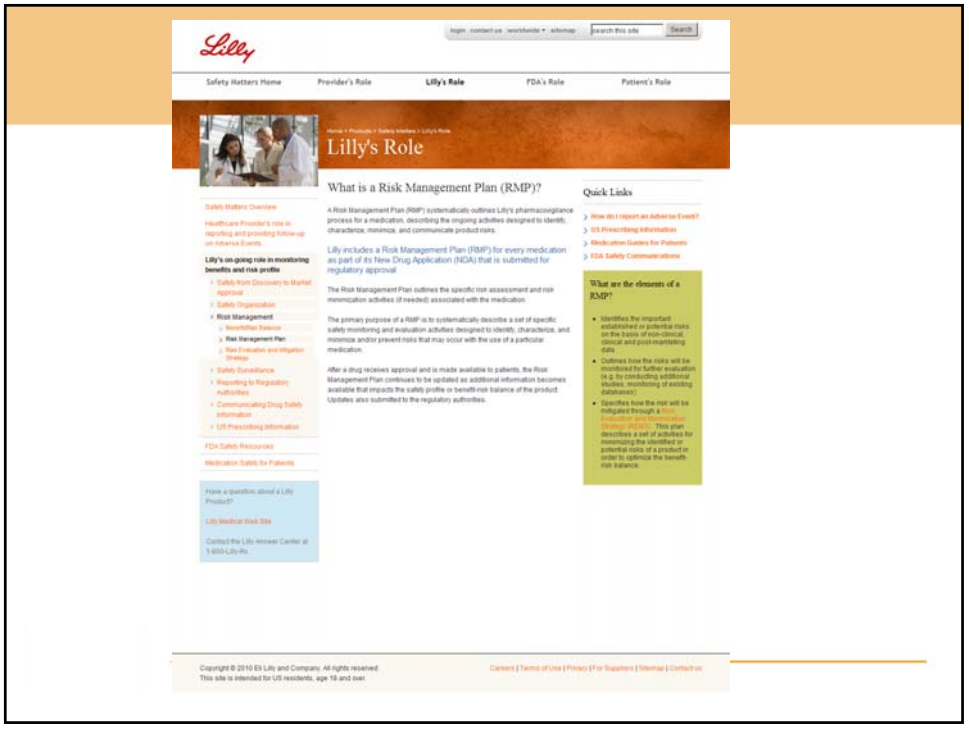
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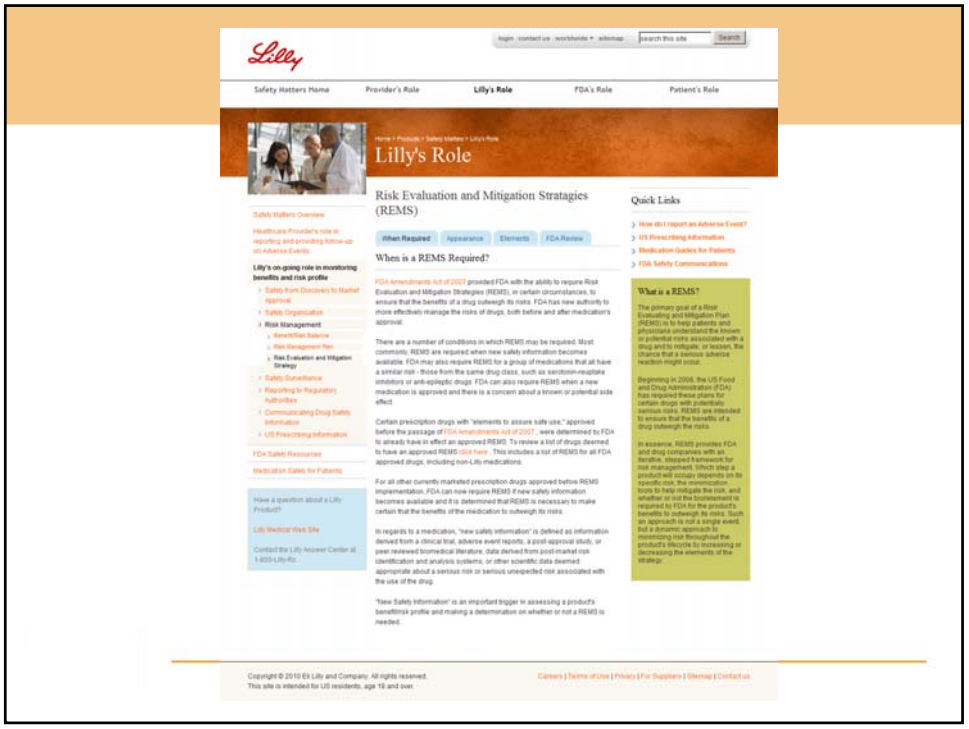
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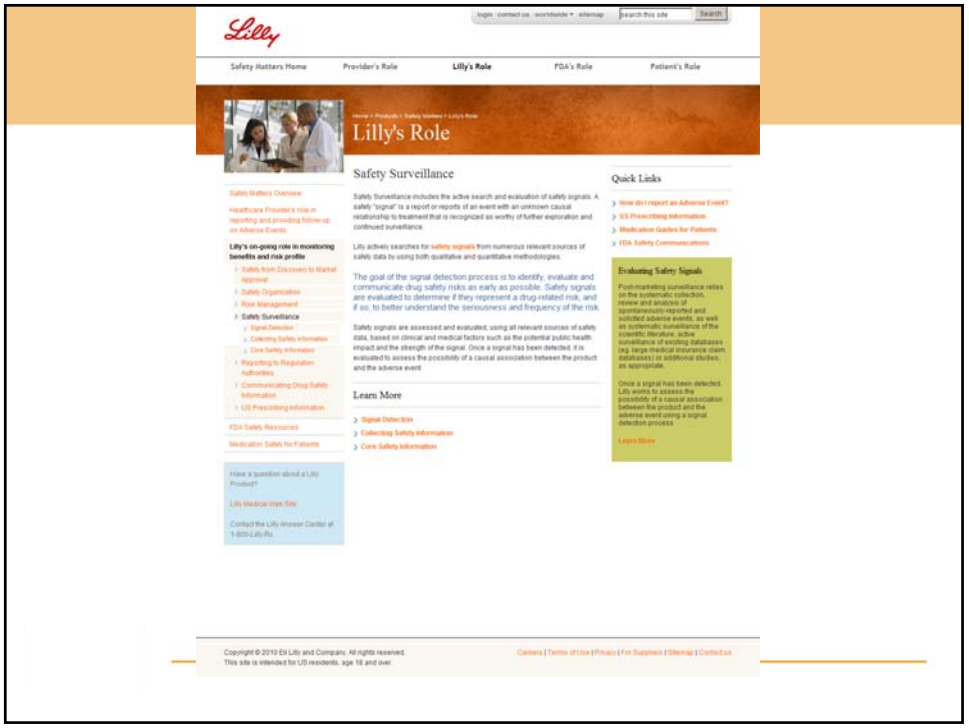
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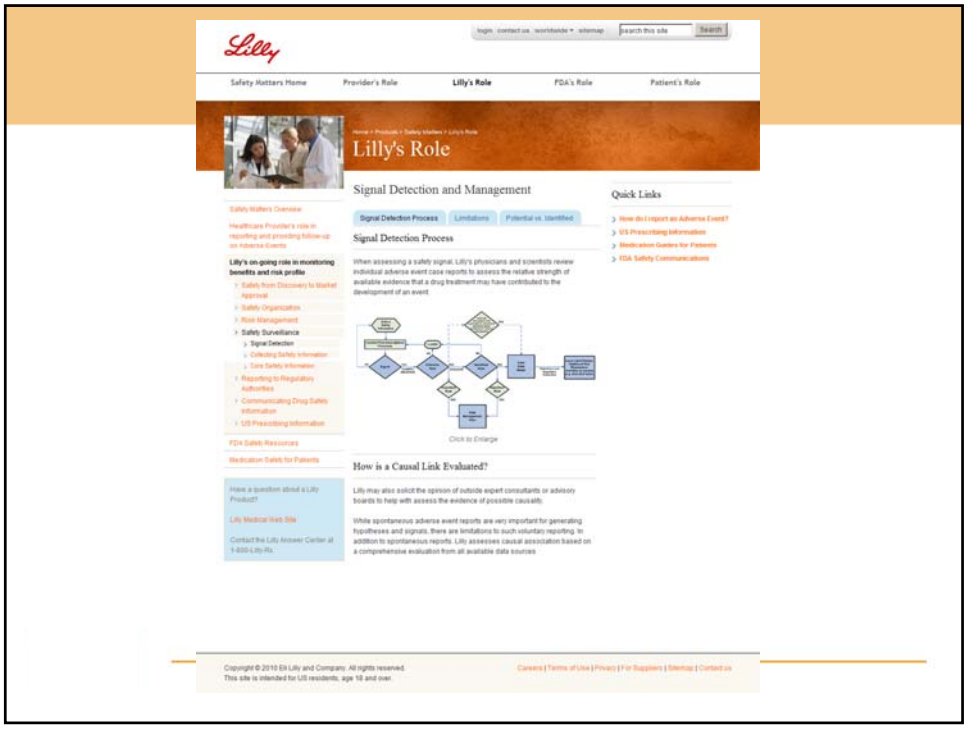
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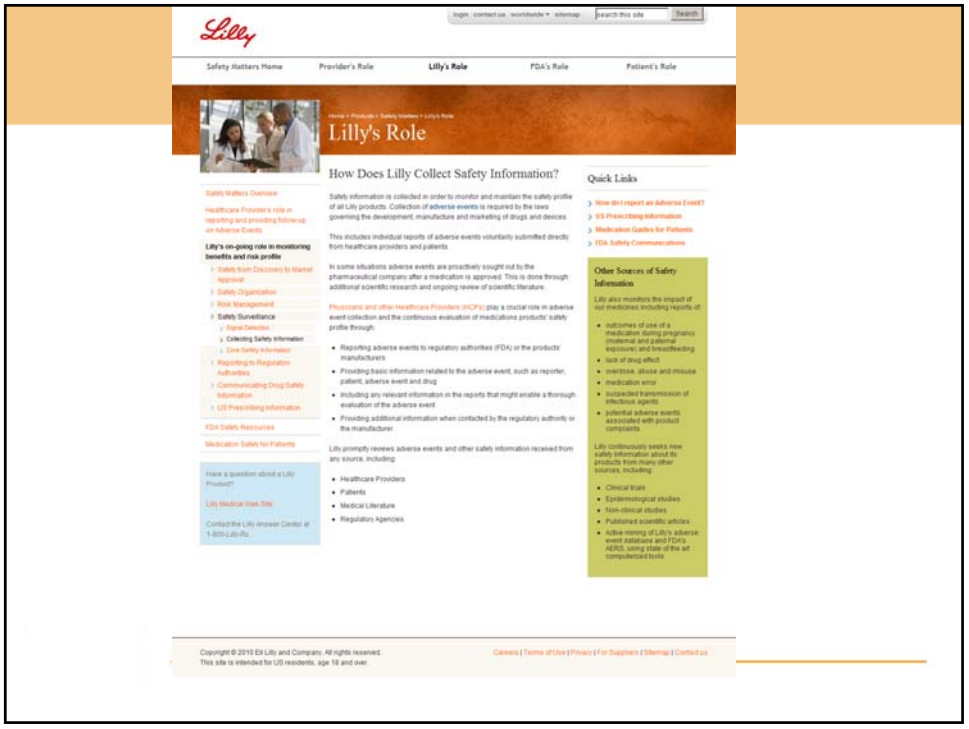
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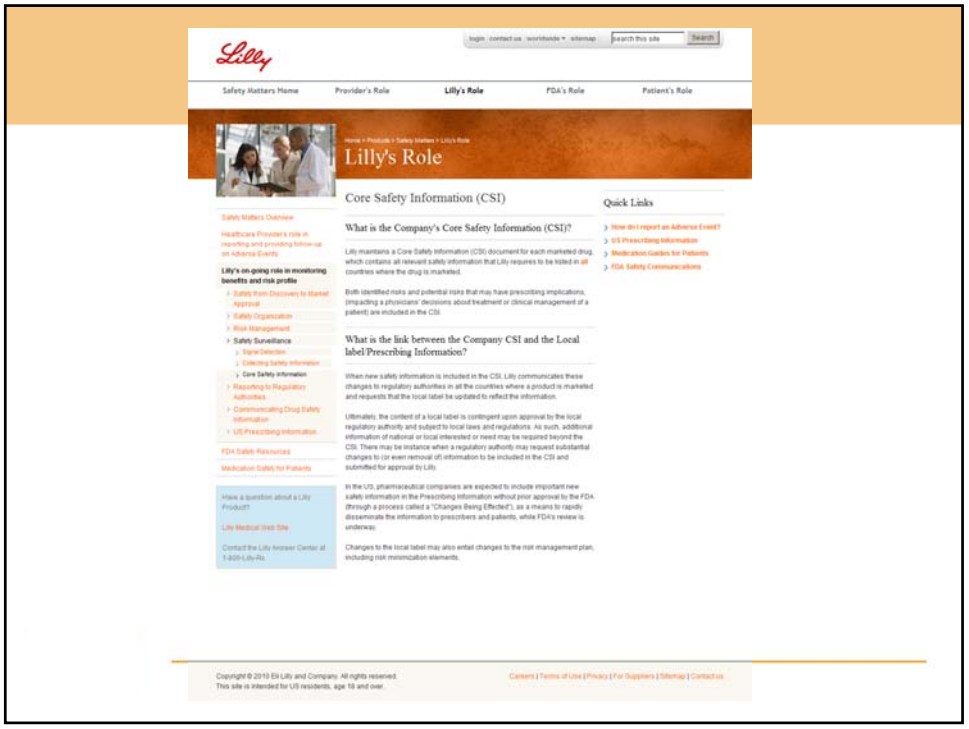
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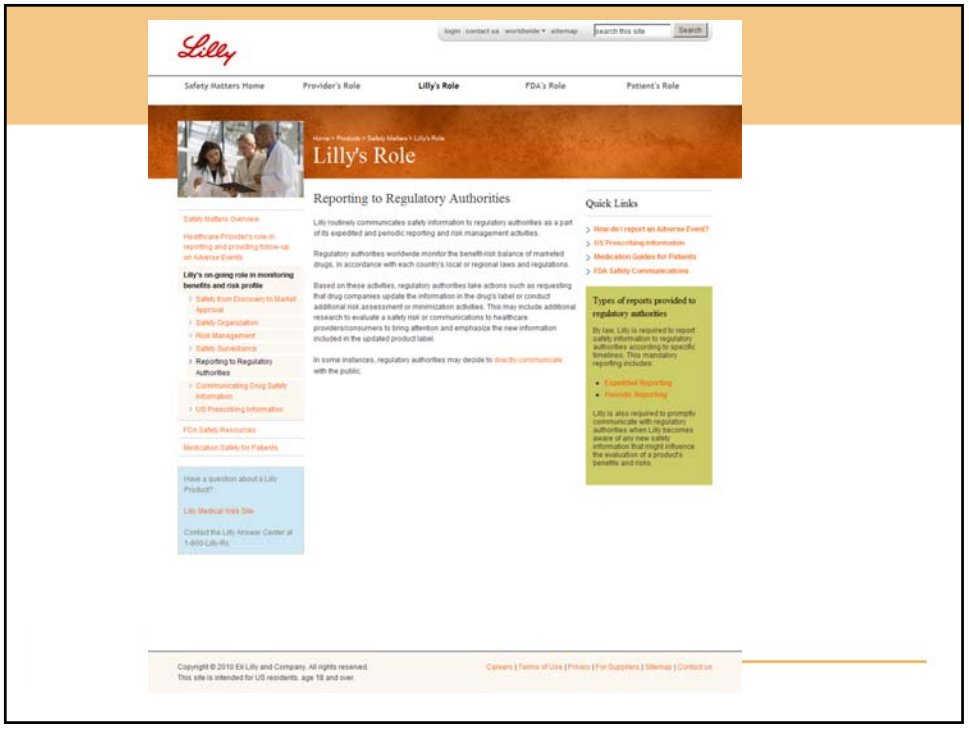
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Types of reports provided to regulatory authorities
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Physicians know very little about how to report an adverse event .

- There is very low awareness of MedWatch, and there is little to no connection between MedWatch, reporting AEs, and the FDA.
- Those who have reported adverse events indicate that they have delegated this to a nurse, hospital pharmacist or other staff member, or they have reported it to the manufacturer's rep.
- They also do not fully understand how AE reports are used in the overall safety surveillance process or what other sources are used to gather adverse event data.
- Overall, physicians do not appreciate that they are a critical part of the safety surveillance process.

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Physicians believe they make a benefit/risk assessment before prescribing any medication.

- Physicians express a belief that there are risks associated with any medication or medical product – prescription, OTC, herbal/alternative.
- They also believe that patients expect all the benefit without any risk.
  - This places physicians on the defensive when safety issues are discovered after a product has launched.
- There is very little understanding of how safety surveillance is conducted after a product is approved by the FDA, but there is an assumption that it is being done.

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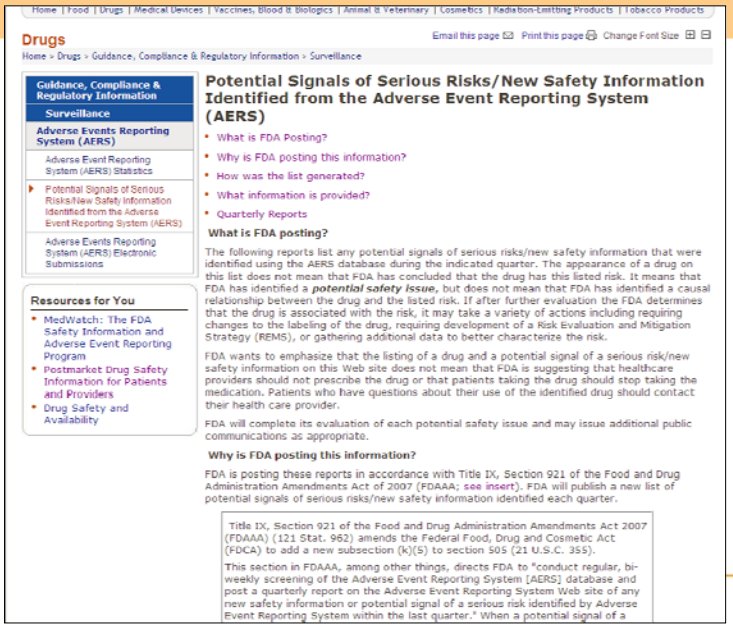
FDA Communication Methods

Types of communication	Content	Target audience
Public Health Advisory and Drug Safety Podcasts	Information and advice regarding an emerging issue	General Public
Patient Information Sheet	Concise summary in plain language of the most important information about a particular drug. Includes an Alert when appropriate.	Patients and/or consumers, lay caregivers, and interested members of the general public
Healthcare Professional Sheet	Concise summary of an important, and often emerging, drug safety issue, with background information about the detection of the issue and points to consider for clinical decision making	Healthcare professionals
Alerts on Patient Information and Healthcare Professional Sheets	Summary of an important, and often emerging, drug safety issue. Alerts are tailored to the needs of the primary target audience for each type of information sheet.	Healthcare professionals, patients and/or consumers, lay caregivers, and interested members of the general public.
Potential Signals of Serious Risks	Quarterly reports of certain drugs under evaluation for potential safety issues based upon reports in FDA's Adverse Event Reporting System.	General Public
Quarterly Drug Safety Newsletter	Communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional AE reports.	Healthcare professionals
Index to Drug Specific Information	Web links to safety sheets, press announcements, dear health care professional letters, and other fact sheets.	General Public

Example FDA Communications



Drugs

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Guidance, Compliance & Regulatory Information
Surveillance
Adverse Events Reporting System (AERS)
- Adverse Event Reporting System (AERS) Statistics
- Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)
- Adverse Events Reporting System (AERS) Electronic Submissions

Resources for You
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- Postmarket Drug Safety Information for Patients and Providers
- Drug Safety and Availability

Potential Signals of Serious Risks/New Safety Information Identified from the Adverse Event Reporting System (AERS)

- What is FDA Posting?
- Why is FDA posting this information?
- How was the list generated?
- What information is provided?
- Quarterly Reports

What is FDA posting?

The following reports list any potential signals of serious risks/new safety information that were identified using the AERS database during the indicated quarter. The appearance of a drug on this list does not mean that FDA has concluded that the drug has this listed risk. It means that FDA has identified a ***potential safety issue***, but does not mean that FDA has identified a causal relationship between the drug and the listed risk. If after further evaluation the FDA determines that the drug is associated with the risk, it may take a variety of actions including requiring changes to the labeling of the drug, requiring development of a Risk Evaluation and Mitigation Strategy (REMS), or gathering additional data to better characterize the risk.

FDA wants to emphasize that the listing of a drug and a potential signal of a serious risk/new safety information on this Web site does not mean that FDA is suggesting that healthcare providers should not prescribe the drug or that patients taking the drug should stop taking the medication. Patients who have questions about their use of the identified drug should contact their health care provider.

FDA will complete its evaluation of each potential safety issue and may issue additional public communications as appropriate.

Why is FDA posting this information?

FDA is posting these reports in accordance with Title IX, Section 921 of the Food and Drug Administration Amendments Act of 2007 (FDAAA; see insert). FDA will publish a new list of potential signals of serious risks/new safety information identified each quarter.

Title IX, Section 921 of the Food and Drug Administration Amendments Act 2007 (FDAAA) (121 Stat. 962) amends the Federal Food, Drug and Cosmetic Act (FDCA) to add a new subsection (k)(5) to section 505 (21 U.S.C. 355).

This section in FDAAA, among other things, directs FDA to "conduct regular, bi-weekly screening of the Adverse Event Reporting System [AERS] database and post a quarterly report on the Adverse Event Reporting System Web site of any new safety information or potential signal of a serious risk identified by Adverse Event Reporting System within the last quarter." When a potential signal of a

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Drugs

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- FDA Drug Safety Newsletter
- FDA Drug Safety Newsletter Issues
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Resources for You
- MedWatch: The FDA Safety Information and Adverse Event Reporting Program
- 2009 Safety Alerts for Human Medical Products
- Submit a Medical Product Adverse Event Report Online
- FDA Patient Safety News Video Broadcasts

FDA Drug Safety Newsletter

This publication provides postmarketing information to healthcare professionals to enhance communication of new drug safety information, raise awareness of reported adverse events, and stimulate additional adverse event reporting.

Current Issue:

Volume 2, Number 2, 2009 HTML | PDF

Previous Issues

FDA Drug Safety Newsletter

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Silver Spring, MD 20993
Phone: 1-888-INFO-FDA (1-888-463-6332)

Health professionals report to:
1-800-FDA-1088
1 800 FDA 0178 (FAX)
MedWatch Online

Editorial Staff
Renan A. Bonnel, PharmD, MPH
Gregory D. Busse, PhD

Suggestions?
We value your comments and please let us know by reaching us at Comments

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