



February 26, 2010

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2009-N-0441
Response to FDA Call for Comments
***Promotion of Food and Drug Administration-Regulated Medical Products Using
the Internet and Social Media Tools***

Dear Sir or Madam:

AstraZeneca is a global, innovation-driven biopharmaceutical business focused on the discovery, development and commercialization of prescription medicines. As part of this mission, we believe we have an important responsibility to educate and empower patients, caregivers, and prescribers to make informed decisions about our products.

We are pleased to have the opportunity to provide comments in response to the above referenced public notice “**Promotion of Food and Drug Administration-Regulated Medical Products Using the Internet and Social Media Tools**” published in the Federal Register on September 21, 2009.

Our comments are presented in several sections. We begin with some introductory remarks below. We then provide some proposed principles for company participation in social media and a possible framework for regulating social media. That discussion begins on page 3. We follow that with a discussion of our view on the regulation of social media conversations at p. 6. Finally, we present our specific responses to the questions posed beginning on page 7.

Introduction

Like advancements in the discovery and development of medicines, the technology that enables how we communicate and relate to one another continues to develop. The Internet and social media have emerged as one of the most utilized options for individuals seeking and exchanging information on their health and on the role of pharmaceutical products in the prevention and treatment of disease. Online stakeholders are relying much less on seeking out information through company websites and other one-way online tools. People now want dialogues, not monologues, and they want information and answers to their questions in forums like Facebook, YouTube, and Twitter.

As an expert on our approved products and the conditions they address, AstraZeneca believes that we have an obligation to participate in social media and that our responsible participation is in the interests of patients, caregivers, health care providers, and the general public. Our active participation can provide information to help ensure that patients get the appropriate medicine at the right time and that it is taken in the right way. Our engagement will also provide a known, identifiable presence to answer questions and provide accurate information on our medicines and their approved usage.

AstraZeneca engages in this new media today. You can find information on many of our efforts at <http://www.astrazeneca-us.com/about-astrazeneca-us/social-media/>. As you will see, our current participation includes YouTube, blogs, Twitter, and Facebook. Currently, these uses are intentionally quite limited and often involve providing corporate, non-product information.

As discussed extensively at your two-day public meeting, the current lack of specific guidance on the regulatory responsibilities of product sponsors* in social media has had a limiting effect on product sponsor participation in this information channel. Without guidance, our activities are limited in a manner that we believe is not in the best interests of informed health care decision making. In our absence, consumers will turn to information sources that are not regulated and not always well informed.

Therefore, AstraZeneca strongly supports FDA's efforts to provide guidance to the industry that will address questions and concerns regarding the application of existing promotional regulations to the Internet and social media.

Most importantly, we support guidance that will enable AstraZeneca and other product sponsors to engage in real-time, social media conversations as a full participant reflecting our mission, values, and goal to responsibly provide accurate, balanced information on our medicines from a known, identifiable and reliable source. Moreover, due to the dynamic nature of the technology that drives social media, AstraZeneca recommends FDA consider establishing a frequent periodic review of its guidance in this area.

Before we respond to the specific questions set forth in the FDA Call for Comments, AstraZeneca would like to share some key considerations that we have taken into account given the unique nature of social media. In particular, we would like to share our perspective on five principles that we believe should be at the core of any company engagement in social media; a proposed new regulatory framework; and the special considerations at play in the regulation of online conversations.

* For purposes of this comment, we will use the terms "product sponsor", "sponsor", and "company" to mean manufacturers, packers, and distributors of FDA regulated drugs and devices unless the reference is specifically to AstraZeneca.

Social Media Principles and a New Regulatory Framework

Social media presents both opportunities and risks. AstraZeneca believes that responsible product sponsors must address both. Establishing essential principles that should inform social media engagement will be a promising first step. From there, a regulatory framework can provide clearer parameters for appropriate behaviors. Our recommendations for both the Principles and the Regulatory Framework follow.

AstraZeneca Principles

We believe that the FDA should look to the following principles in determining how to regulate participation by product sponsors in online education, communication, digital marketing, research or social media undertaken by United States-based business units with regards to activities directed specifically towards United States residents[♦]:

- To Ensure Truth and Accuracy. Guidance should direct product sponsors to ensure that any content created, developed, or made available by them in social media is truthful, balanced, accurate, and not misleading.
- To Be Respectful. Guidance should encourage product sponsor participation that respects the interests of patients, caregivers, and health care providers, particularly related to matters of privacy and the primacy of the patient/physician relationships.
- To Protect and Advance Patient Health. Guidance should facilitate patient access to quality information that they can use with their physician to improve their health and protect patients through encouraging accurate and timely reporting on medicine safety.
- To Be Transparent. Guidance should require that any product sponsor participation be accomplished in a manner that, at all times, is entirely transparent to other participants as to the role of product sponsors as the participants in online discussion.
- To Respect the Views of Others. Guidance should respect that patients, caregivers, clinicians and others who participate in social media have their own opinions and that, when they differ from those of the product sponsor, it is not the role of a product sponsor to censor or limit these views but to add the product sponsor's own views to the discussion.

Recommended Regulatory Framework

In developing guidance for company participation on the Internet and in social media, AstraZeneca recommends that the FDA adopt a regulatory framework that is specific and

[♦] Internet and social media activities can be and are initiated in many different countries each of which have their own legal and regulatory controls. In the case of websites and social media activities that are designed to be global in their audience and participants, it would be helpful if national regulatory agencies would agree a workable approach to jurisdiction.

appropriate to the unique characteristics of these new media. We especially believe that this framework should, consistent with our recommended principles, respect the special characteristics of social media as an ongoing, real-time conversation, where the audience also serves as author and publisher. As such, social media is distinguished from static forms of product promotion such as print and broadcast advertising, detail pieces, journal advertising and even static Internet pages. Social media involves user created content and an immediate, exchange of views akin to in-person conversation.

We recommend that FDA consider a regulatory framework that defines, distinguishes, and distinctly regulates three types of communications on the Internet and in social media. There are:

- Company-controlled, hosted online communications. Such communications would be defined as communications placed on web sites and other online properties that are under the control of a product sponsor. Controlled sites and properties would be defined as those that the sponsor owns, operates, or where the sponsor retains editorial control. Such communications would include company-owned product information web sites, company controlled disease information sites, company sponsored and controlled content areas on third party web sites such as Facebook. For such communications, the company should be held accountable in a manner that reflects the letter and spirit of FDA's promotional rules for advertising.
- Company-controlled communications. Such communications would be defined as communications that a product sponsor places or provides for use by web sites and other online properties that the sponsor does not control and where such communications are used in the form, manner, and context for which the sponsor provides it. Such communications include company sponsored and created advertisements or banners on third party web sites. They can also include company-provided content such as videos, online tools, or articles. Where these communications include information on the uses of medicines or medical devices, the sponsor would have to ensure that the communication is appropriately balanced and includes information and links to further information on the risks of the medicine or device. The guidance should require the sponsor to provide this information to an extent and in a form that is appropriate to the size or other limitations of the site or forum.
- Real-time, social media participation communications. Such communications would be defined to include company real-time, social media interactions on web sites and online forums that are not company-controlled. Such communications typically occur in chat areas, comment areas or as an integral part of the operation of the web site (for example in pop up or pop over windows created by the web site creator).

Such communications would be considered consistent with law and regulation where they are:

- appropriate to the context and intended audience of the site and the initial interaction that the product sponsor is participating in;
- when examined in that context, as a whole provide an accurate and balanced picture of the risks and benefits of the sponsor's products, and;
- preserved along with its context, where feasible, for review and audit by the product sponsor and, at its discretion, by the FDA.

Please see our comments in the section titled *Regulating Social Media* for a more detailed discussion of this type of communications.

In contrast to these three types of communications, we believe that the FDA should define Independent Communications to include content that a product sponsor does not provide or post or material that was originally provided but that has been altered by others outside the control of the product sponsor. An example of such communication would be Google Sidewiki. Such communications would not trigger obligations from the product sponsor.

In order to effectuate this framework, we urge the agency to adopt guidance that:

1. Clarifies for which communications the FDA will hold a product sponsor accountable. As we propose in our framework, we believe that product sponsors should be responsible only for communications that they control or create and that is used in the form and manner for which they have created it. We believe that such a limit on accountability is an appropriate reading of the concepts of labeling and advertising under the Federal Food, Drug, and Cosmetic Act (FDCA). Specifically, the Act defines labeling to include “all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article” (quoting 21 U.S.C. § 321(m)). It is difficult to interpret such a definition without understanding it to include only material affixed or made accompanying by the product sponsor itself and not anything affixed or made accompanying by others. Similarly, advertising is understood as an act of the product sponsor and not a third party. While others may make statements that have the effect of directing attention to a particular product, the product sponsor, absent some form of control, cannot be said to have caused or created the advertisement.
2. Provides instruction on how to apply promotional rules to space-restricted digital media. The FDA, in issuing its regulations on drug advertising (21 C.F.R. § 202.1) has already recognized that different media for advertising merit different forms of regulation. For example, broadcast advertising have special space (and time) limitations that allow for different ways of providing patients, prescribers, and others with balanced information. Similarly, the agency should recognize the special space limitations of Internet and social media and create common sense, practical guidance that will facilitate Internet and social

media communications while, at the same time, ensuring that participants will have access to balanced information.

3. Clarifies the treatment of social media conversations. As discussed more fully below, we believe that the agency should provide guidance stating that it will treat company participation in real-time, social media participation communications in a manner analogous to how it regulates oral dialogue. However, because of the differences between real-time, social media communications and such oral communications, we make recommendations as to additional requirements for social media preservation.
4. Clarifies how existing requirements for reporting adverse events will be applied to real-time, social media communications. We provide detailed comments on this issue in our answer to the agency's questions.

Regulating Social Media Conversation

Real-time, social media participation communications encompasses the type of online communications that are most often understood as social media. Interactive social media communications are most commonly associated with forum, comment or chat areas of generally accessible sites such as Facebook, YouTube, and Twitter as well as restricted sites such as Sermo and Within3. It is our view that the FDA, in developing its guidance, should view such participation in a manner analogous to its existing regulation of in person and telephonic promotional activities. In that case, the FDA examines not just one part of the conversation but the entire conversation as a whole.

This concept is most clearly seen in the FDA's current policies related to professional discussion of and dissemination of information on uses of medicines and devices that are not approved by the FDA. Such policies permit companies to provide "responsive, nonpromotional, balanced, scientific information, which may include information on unapproved uses, without subjecting their products to regulation based on the information" on the unsolicited request of a health care professional (Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices; Request for Comments, Federal Register, November 18, 1994). Similarly, a company medical professional should be able to provide non-promotional, balanced, scientific information in a real-time, social media conversation with a health care professional in response to an unsolicited request.

It is also worth pointing out that social media real-time participation communications, in contrast to oral communications between company personnel and others, has the advantage of being, in most cases, amenable to preservation and post hoc review. This provides a large degree of regulatory safety that compensates for the fact that, in contrast to private communications, the interactive social media content is available for others to see. We believe that this should argue powerfully for FDA making the maximum efforts to facilitate

responsible product sponsor use of social media for communications with physicians and other prescribers.

Another precedent for regulating social media real-time participation content in context and as a whole is found in the Draft Guidance for Industry, Presenting Risk Information in Prescription Drug and Medical Device Promotion, (May, 2009, access at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM155480.pdf>). In that draft, the agency reported that:

FDA looks not just at specific risk-related statements, but at the net impression – i.e., the message communicated by all elements of the piece as a whole. The purpose of the evaluation is to determine whether the piece as a whole conveys an accurate and non-misleading impression of the benefits and risks of the promoted product.

It is similarly appropriate for the agency to view a social media conversation as a whole and not regulate each and every “post” as if it were, in itself, a promotional piece. We recommend a framework that understands that a conversation may include text, video, sounds, and other elements that are appropriate to consider together.

In order to enable effective, real-time participation in such communications, it is simply not feasible to require a company to review and approve every “post” from an authorized employee or agent prior to its appearance in a social media space. Such prior review, which is possible for advertisements, detail pieces and even for company –controlled, hosted online communications and company- controlled communications (as defined previously), is inconsistent with the real-time, conversational aspects of social media.

Our recommended regulatory approach would recognize that inherent in the nature of real-time, social media participation is the risk that any one individual conversation may not have a “net impression” consistent with regulatory requirements. The FDA should explicitly acknowledge that, in exercising its regulatory enforcement discretion, it will look not only to the individual conversation but place it within the larger framework. Specifically, that the communication, when examined in the context and intended audience of the site and the initial interaction that the product sponsor is participating in, as a whole presents an accurate and balanced picture of the risks and benefits of the sponsor’s medicines

Responses to Questions Posed

AstraZeneca hopes that the preceding comments on an overall regulatory framework are helpful to the agency in developing guidance. Based on our principles and these comments, we will proceed to address the specific questions raised.

1. For what online communications are manufacturers, packers, or distributors accountable?

We believe that the governing law and regulation, as well as their intent and principles of Constitutionally protected commercial speech, argue that the level of accountability should be tied to the amount of control that a sponsor has over the content.

In that regard, we have defined previously four different types of communications:

- Company-controlled, hosted online communications. Such communications would be defined as communications placed on web sites and other online properties that are under the control of a product sponsor. Controlled sites and properties would be defined as those that the sponsor owns, operates, or where the sponsor retains editorial control. Such communications would include company-owned product information web sites, company controlled disease information sites, company sponsored and controlled content areas on third party web sites such as Facebook.
- Company-controlled communications. Such communications would be defined as communications that a product sponsor places or provides for use by web sites and other online properties that the sponsor does not control and where such communications are used in the form, manner, and context for which the sponsor provides it. Such communications include company sponsored and created advertisements or banners on third party web sites. They can also include company-provided content such as videos, online tools, or articles.
- Real-time, social media participation communications. Such communications would be defined to include company real-time, social media interactions on web sites and online forums that are not company –controlled. Such communications typically occur in chat areas, comment areas or as an integral part of the operation of the web site (for example in pop up or pop over windows created by the web site creator).
- Independent Communications. content that a product sponsor does not provide or post or material that was originally provided but that has been altered by others outside the control of the product sponsor. An example of such communication would be Google Sidewiki.

We propose that accountability vary by these categories. The most accountability would come for company-controlled, hosted online communications. These are ones that are fully within the control of a product sponsor. An example of such communication might be those on a “productname.com” sites owned and controlled by the company. For such communications, we believe that it is appropriate to hold the sponsor fully accountable for its content.

To the extent that such communications include social media content, we believe that the product sponsor should be accountable for such content as well. The product sponsor could control such content through the enforcement of terms of use imposed as a condition of participation and that allow for the review of social media content prior to its appearance on the web site. However, we also believe that, in the interests of permitting the free flow of information, product sponsors should have the ability to allow real-time, unedited conversations if they promptly (within perhaps 48 hours) remove any information that does not comply with the established terms of use.

The next level of accountability relates to company-controlled communications. This level would define responsibility over the unaltered content provided by a product sponsor to a web site or other online property that does not meet the definition of company-controlled. In these cases, we believe that the FDA should hold the product sponsor accountable for these communications but not for other communications that may appear with it or be linked to it. This position is based on our view that the FDA should not hold a product sponsors accountable for things that it cannot and, in some cases, should not control or attempt to control. The guidance could condition such treatment on the company not intentionally directing the placement of its company-controlled communications with or near content that the company is aware provides information on its product or diseases for which a product is not indicated. For example, directing placement of otherwise balanced company-controlled communications near communications on off-label uses of its product would trigger product sponsor accountability for such content.

The next level of accountability that we recommend relates to real-time, social media participation communications. We believe that this type of communication merits specifically tailored regulation based on its unique characteristics and its importance in making possible the active, responsible participation of product sponsors in real time, online conversations. It is our view that the FDA, in developing its guidance, should view such participation in a manner analogous to its existing regulation of in person and telephonic promotional activities. In that case, the FDA examines not just one part of the conversation but the entire conversation as a whole.

We recommend that guidance provide that such communications would be considered consistent with law and regulation where they are:

- appropriate to the context and intended audience of the site and the initial interaction that the product sponsor is participating in;
- when examined in that context, as a whole an accurate and balanced picture of the risks and benefits of the sponsor's medicines, and;
- preserved along with its context, where feasible, for review and audit by the product sponsor and, at its discretion, by the FDA.

Finally, we also believe strongly that, consistent with existing FDA rules and guidances, product sponsors should have no legal accountability for independent communications.

1a. What parameters or criteria should be applied to determine when third-party communications occurring on the Internet and through social media technologies are subject to substantive influence by companies that market products related to the communication or discussion? In particular, when should third-party discussions be treated as being performed by, or on behalf of, the companies that market the product, as opposed to being performed independent of the influence of the companies marketing the products?

We recommend that the agency define substantive influence based on the communication origin. Substantive influence would come when the communication originates from someone who is an employee or agent of the product sponsor, including employees, contractors, representatives, and all those who are otherwise under our control with regard to such communications. We do not believe that the existence or magnitude of financial support to the communicator determines control by the product sponsor. This would be especially true when any financial support is not related to product promotion as, for example, when a product sponsor provides financial support to a clinical investigator.

Communications should retain their independent status where the communicator has retained editorial controls of the communication and the communication is not subject to review and change by the product sponsor. This position would maintain the freedom of individuals and groups that receive support from a product sponsor to take positions and express views that may differ from those of the product sponsor. Subjecting a product sponsor to regulatory responsibility for communications by third parties that receive support from a product sponsor would, effectively, preclude providing such support because it would require a product sponsor to condition support on editorial control of communications. In this regard, we urge the agency to consider the same concepts that it has applied to company support for continuing medical education.

1b. How should companies disclose their involvement or influence over discussions or material, particularly discussions or material on third-party sites? Are there different considerations that should be weighed depending on the specific social media platform that is used or based on the intended audience? If so, what are these considerations?

Consistent with the principles set forth above, we believe that companies should be fully transparent as to their creation of communications that are company-controlled, hosted online communications and company-controlled communications (see definitions above). Each communication should include a clear identification of product sponsor control or influence in a manner appropriate to the venue. In the case of real-time, social media participation communications (see definition above), we also believe that company participants should provide clear identification. The form of such identification and whether such identification needs to take place in each “post” as part of an ongoing conversation will have to depend on the form and nature of the real-time, social media participation communications platform. For example, in some situations it may be sufficient for identification to take place within the communication itself. In others, it could come in adjacent identifying areas. In some ongoing conversations, the context may preclude the need to repeat the identification in each “post” where the identity of the communicator is obvious. We do not support the participation of company employees or agents in real-time, social media participation communications where the nature of the platform precludes identification of company control.

1c. With regard to the potential for company communications to be altered by third parties, what is the experience to date with respect to the unauthorized dissemination of modified

product information (originally created by a company) by noncompany users of the Internet?

While we do not have any data to present at this time, we are generally aware that AstraZeneca product information is sometimes presented by a third party – outside of our control – in a manner that may not be fully consistent with the FDA-approved labeling. While we cannot say for sure where third parties may get communications content, it is certainly possible that such content may be based in part on communications originally created by AstraZeneca and presented by AstraZeneca in a manner fully consistent with regulatory requirements. As discussed, we do not believe that we should be held accountable for such altered content. This is consistent with current agency policies related to printed content that is altered.

2. How can manufacturers, packers, or distributors fulfill regulatory requirements (e.g., fair balance, disclosure of indication and risk information, postmarketing submission requirements) in their Internet and social media promotion, particularly when using tools that are associated with space limitations and tools that allow for real-time communications (e.g., microblogs, mobile technology)?

Consistent with our proposed regulatory framework, we believe that, as to company-controlled, hosted online communications (as defined previously), if a product and its indication are mentioned, a product sponsor should provide balance and risk information and Prescribing Information analogous to advertising and labeling rules. An acceptable way to provide such information is to have links to additional information as long as the initial presentation itself is balanced as to risks and benefits. We believe that these same requirements should apply in the case of company-controlled communications (as defined previously).

As discussed previously, we believe the agency should recognize the special space limitations of Internet and social media (including in mobile settings) and, in the absence of existing clearly applicable statutory or regulatory rules, create common sense, practical guidance that will facilitate Internet and social media communications while, at the same time, ensuring that participants will have access to balanced information. The FDA, in issuing its regulations on drug advertising (21 C.F.R. § 202.1) has recognized that different media for advertising merit different forms of regulation. For example, FDA recognizes that broadcast advertising has special space (and time) limitations and therefore it allows for different ways of providing patients, prescribers, and others with balanced information. We believe that suggestions made by PhRMA and others for the use of special signifiers or logos may have particular merit and that the agency should allow product sponsors to try different approaches.

2a. How should product information be presented using various social media tools to ensure that the user has access to a balanced presentation of both risks and benefits of medical products?

As discussed previously, for real-time, social media participation communications (as defined above) we urge the FDA to apply standards and practices that are analogous to those it applies to oral communications. We urge the agency to adopt a flexible approach that considers whether the communication, when examined in the context and intended audience of the site and the initial interaction that the company is participating in, as a whole presents an accurate and balanced picture of the risks and benefits of the sponsor's medicines. This approach would have the agency examine the overall "net impression" of the communication and all of its elements including its individual parts (or "posts") and its use of links and other tools.

As an example, on Twitter or another micro-blogging site, a sponsor might use multiple, simultaneous "posts" to convey information on risks and benefits including using links or other reference marks or symbols. In a comment section of a web page, through multiple comments that appear together or as near as together as the site or format allows, a product sponsor could provide information that is not possible to present in a single "post" or inappropriate to present in the context of a real-time interaction.

2b. Are there data to support conclusions about whether different types or formats of presentations have a positive or negative impact on the public health?

We do not have any such data to present at this time.

2c. Are there proposed solutions that may help address regulatory concerns when using social media tools associated with space limitations or tools that allow for real-time communications to present product information?

Please see our comments in 2a. above.

2d. How should companies address the potential volume of information shared on various social media sites with regard to real-time information that is continuously posted and regulatory requirements to submit promotional materials to FDA as applicable?

AstraZeneca believes that companies should have an obligation to preserve, where feasible, real-time, social media participation communications (as defined previously) along with their context, for review and audit by the FDA at its discretion. These interactions could be seen to be analogous to sales representative/healthcare professional dialogue for which there is no Form 2253 requirement. We believe that, as with these oral communications, there should be no requirement for submission.

3. What parameters should apply to the posting of corrective information on Web sites controlled by third parties?

In general, AstraZeneca does not believe that companies should have any obligation to provide corrective information related to independent communications (as defined above). As to

social media, we believe that the FDA should not require correction for any such communication in which the company does not participate.

Even when a product sponsor chooses to make real-time, social media participation communications (as defined above) by becoming a participant in a social media conversation, we do not believe that correction is the appropriate obligation in all cases. Participants in social media may have their own views and opinions. Respect for such views should preclude an obligation to “correct” them.

While we believe a product sponsor should have no obligation to correct information on third party web sites when it has not otherwise chosen to participate in the social medical conversation, when the sponsor chooses to address information about its products that it believes is not fully consistent with the approved labeling, the guidance should permit the sponsor to direct participants to the approved labeling or product web site. This approach respects freedom of speech and the ability of physicians and other prescribers to exercise their professional judgment.

For example, when a product sponsor chooses to make real-time, social media participation communications by becoming a participant in a social media conversation and believes that other participants have provided information that it believes are incorrect or incomplete, it should state for example that “information presented here may be incomplete or inconsistent with the FDA-approved labeling for [name of product]. For more information on this product, please go to [link to product information].”

This opportunity for providing information comes, in our view, in addition to the obligations discussed above that real-time, social media participation communications, when examined in the context and intended audience of the site and the initial interaction that the product sponsor is participating in, as a whole presents an accurate and balanced picture of the risks and benefits of the sponsor’s medicines

3a . Are there any parameters or criteria that could be used to determine the appropriateness of correcting misinformation and/or scope of information a company can provide when trying to correct misinformation on a Web site outside a company's control?

Please see our answer above.

3b. Should the parameters differentiate with regard to the prominence of the third-party site (i.e., readership), its intended audience (e.g., general public, health care professionals, patients), its intended purpose (e.g., personal diary, encyclopedia-type reference), and/or the author of the information on the site?

We do not recommend that the obligation to provide additional information vary depending on the nature of the site, its audience or purpose.

4. When is the use of links appropriate?

AstraZeneca supports the comments made by the Pharmaceutical Manufacturers of America on this point.

5. Questions specific to Internet adverse event reporting

How are entities with postmarketing reporting responsibilities and other stakeholders using the Internet and social media tools with regard to monitoring adverse event information about their products?

Today, AstraZeneca is reviewing our company sponsored sites for possibly reportable adverse events. Similarly, if we become aware of possibly reportable adverse events on other sites, we review these to determine whether they contain the necessary elements to trigger a reporting requirement. To the extent that the minimum criteria for reporting are absent, we assess our ability to identify a reporter and follow-up for additional information.

How is adverse event information from these sources being received, reviewed, and processed?

We receive information that is identified by company staff or vendors through our call center or company-created web-based forms. We then assess this information based on current FDA regulations and company processes to determine whether we can make a report. Our current policies include follow-up for additional information where such follow-up is possible.

What challenges are presented in handling adverse event information from these sources?

The main challenge is the often found lack of all necessary information elements and a lack of ability to contact the apparent reporter to gain additional information.

What uncertainties are there regarding what should be reported from these sources to meet FDA adverse event reporting obligations?

A key uncertainty is the definition of a valid reporter in an on-line environment. In this environment, there are often anonymous posting or posting using pseudonyms. We propose that, for purposes of the Internet and social media, FDA define a valid reporter as one who has provided an e-mail address or other effective form of contact information (such as a Facebook contact). We also would support a requirement, applicable to company –controlled, hosted online communications (see definition above) that companies include a web-based reporting tool or prominent link to an FDA-hosted web-based reporting tool.

In addition, we believe that there is unnecessary uncertainty over product sponsor investigative responsibilities in the case of anonymous reports that appear on the Internet and in social media. We recommend that FDA clarify that a sponsor does not have any obligation to investigate a report where that report does not itself contain the four minimum criteria.

Another uncertainty is the extent of a sponsor's obligation to monitor for possibly reportable adverse events. We do not believe that it is practical or helpful to attempt to monitor the entire Internet for possibly reportable adverse events. Therefore, we recommend that FDA clarify in guidance that sponsor obligation for monitoring extends only to company-controlled, hosted online communications (see definition above).

We also recommend that the agency provide additional guidance on the definitions of spontaneous versus solicited reports for the Internet and social media. We recommend that solicited reports be limited to those collected from organized data collection systems including any information gathering systems that a sponsor uses. In contrast, we urge to agency to consider any unsolicited reports as spontaneous reports.

AstraZeneca appreciates the opportunity to provide comments for consideration during the development of this important and much needed regulatory guidance on the use of social media tools. Please do not hesitate to contact us should you have any questions.

Sincerely,

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