

Expert Workshop: Communicating Findings from Active Medical Product Surveillance

### **Active Medical Product Surveillance – An Overview**

Prior to regulatory approval of a new medical product, data from development programs and the medical literature are reviewed to ensure the product's efficacy and safety. Once products are approved and on the market, additional data about a product become available. These include spontaneous adverse event reports and postmarket studies and trials (which may or may not be mandated by the U.S. Food and Drug Administration (FDA)). Safety data collected through these vehicles accumulate slowly, and safety signals may only emerge after products have been on the market for an extended period of time.

To more rapidly identify and understand potential safety signals, FDA is developing the Sentinel System, which will enable the Agency to conduct safety surveillance of new and already approved medical products using existing databases of electronic health data. Initial active surveillance activities will primarily focus on "signal refinement," a process for evaluating the magnitude and clinical significance of a suspected association between a medical product and an adverse event. Two types of signal refinement evaluations can be envisioned at this time: a one-time evaluation using the entire extent of marketing history; and evaluations at regular time intervals in the postmarket period which rely on accumulating data over time. Once operational, FDA will incorporate results from the Sentinel System into a product's full portfolio of data to inform regulatory decisions.

As part of FDA's mandate to protect public health, the Agency is dedicated to communicating to the public in an effective and transparent manner. This may include information that better conveys the benefit-risk profile of a product or regulatory decisions. Although information that results from an evaluation within the Sentinel System is just one source of information that may contribute to an FDA communication about a product, the FDA is committed to understanding potential approaches for communicating about Sentinel-specific findings. On November 17, 2010, the Engelberg Center for Health Care Reform at Brookings hosted an expert workshop to discuss stakeholder perspectives on communicating information from FDA's medical product safety surveillance activities. This document provides a summary of the workshop's discussion.

### **Challenges in Medical Product Risk Communication**

FDA faces a number of broad challenges in communicating information about a medical product's benefits and risks to the public. A common misperception among patients is the belief that all effects (both those that are beneficial, and also those that are potentially harmful) of a new medical product are known at the time of approval, when, in fact, the product has typically been studied in a very limited number of people compared to those who will take it during marketing, and often in settings and populations that are more limited than those that may be exposed during marketing. Because of this, new information about the safety of the product will be learned and must be communicated to patients and health care professionals in a timely manner to foster not only public health, but also transparency. Achieving these goals without inundating patients with unnecessary (and potentially misleading) information is an important objective for every FDA communication about a medical product.

Communicating findings from active surveillance evaluations, such as those planned to be conducted within the FDA's Sentinel System, introduces a number of additional issues. Within the FDA's current pilot, Mini-Sentinel, which is intended to provide the Agency the opportunity to test approaches to be deployed within the Sentinel System, results from planned evaluations will be posted on the Mini-Sentinel website. These results will provide only one among many sources of information that the Agency is evaluating as it tracks the safety of a product and must be considered in that broader context. Consideration of the entire body of evidence will be necessary for regulatory decision-making.

Attempts by the public to interpret active surveillance results in the absence of all other supporting data create concern and may lead to erroneous conclusions.

### **Communicating to Set Expectations**

The longer a product is on the market, the more information is known about it. It is important that patients be educated about the product risks that are known at the time treatment is initiated and the process for accumulating new risk information. Risk communications that are balanced with benefit information will help set appropriate expectations and lead to informed decision making.

Managing public expectation of Sentinel's capabilities and its place within the Agency's broader medical product safety mandate can help avoid misinterpretation and improper use of Sentinel's findings. During the workshop, experts discussed a number of strategies for ensuring successful active surveillance communications, but highlighted the need to facilitate a robust public understanding of Sentinel's capabilities, limitations, and use of results to underscore Sentinel's role within FDA's broader safety mandate.

### **Roles for Non-FDA Stakeholders in Communicating Risk Information**

Beyond FDA, scientific and medical journals, health care professionals, manufacturers, health plans/systems, and journalists and the media play a role as intermediaries in providing drug safety information to patients and shaping their understanding of these issues. Part of FDA's communication strategy must include clear and consistent information for these parties.

- Scientific and medical journals: FDA's rapid dissemination of active surveillance results does not preclude the peer-review process. Journal editors expressed a willingness to work with FDA to expedite the peer review process for active surveillance findings. A potential model may include swift posting of Mini-Sentinel results onto the Mini-Sentinel website, followed by a formal publication that passes through the peer review process.
- Health care professionals: Health care professionals can provide an important "human interface" for not only conveying information to patients, but also tailoring general communications to suit individual patient needs, accounting for each patient's specific circumstance and alternative options. However, they may also find active surveillance findings confusing, so efforts to educate them on how to properly interpret and apply these findings will be useful. Understanding active surveillance findings could be an area of focus for Continuing Medical Education credits. Although peer review journals are a good resource for health care professionals, they may not be the most effective avenue to communicate with this group due to limited time to read and continually follow the detailed dialogue contained within them. More discussion about effective communication strategies geared towards health care professionals is needed.
- Manufacturers: Manufacturers are most knowledgeable about their products. Therefore, pharmaceutical sales representatives should present both benefits as well as risk information when briefing prescribers. Their visits also provide an opportunity for health care professionals to ask more specific questions.
- Health plans/systems: Health plans/systems can facilitate rapid dissemination of risk information by sending out letters to prescribers within their network. In contrast to more general information from FDA, health plans/systems can provide more pointed guidance in these letters, tailored to each plan's demographics.
- Journalists and the media: The media is an important conduit for patients to obtain information about medication risks, and in some situations, may be their initial source of information. How this information is presented can influence patient perception of risk, and thus, ensuring that journalists have sufficient training to accurately interpret and present active surveillance findings will be important. The National Library of Medicine's education sessions for members

of the media could serve as a potential channel to improve the quality and accuracy of media reporting. Journalists could be educated on issues such as:

- FDA's approval and drug safety monitoring process,
- Nature and complexity of drug safety risks,
- Patient understanding of risk, and
- Introduction to the Sentinel System, activities involved in active surveillance, and how to interpret findings from active surveillance evaluations.

### **Next Steps**

Communicating risks and benefits of medical products is a complex process involving different stakeholders, each of whom plays an important role in ensuring that patients respond appropriately to new evidence as it becomes available. It is important to equip each of these groups with the proper tools to support their roles. Building a successful postmarket active surveillance system depends upon setting appropriate expectations of the Sentinel System's limitations and capabilities, establishing and maintaining credibility of FDA's postmarket surveillance systems, and communicating results rapidly and thoroughly to lay audiences and intermediaries that provide drug safety information to patients.