FDA Reporting for Safer Medical Devices

Purpose

The course covers who should report various types of safety issues, how to report, and how the FDA uses these reports to resolve issues and get essential safety information back out to the public.

Introduction

After completing this course, you should be able to: describe the purpose, goals and requirements of the FDA's MedWatch and Medical Device Reporting (MDR) systems. Explain the importance of reporting adverse events and other product issues to the FDA and to manufactures. Identify the types of reports that healthcare professionals, manufacturers, user facilities and consumers should submit to the FDA when a problem with a medical product occurs. Access key information, resources and tools within the MedWatch and MDR sections of the FDA website.

Adverse Events

Reporting adverse events, product use errors and quality problems is a critical process through which healthcare providers, manufacturers and consumers can help ensure that medical products are used safely and effectively in the marketplace.

The Role of the FDA

Since it was established over 100 years ago, the FDA's focus has always been on safety. First, the FDA relies on companies to conduct laboratory, animal and human clinical testing of new drugs, biologics or devices in development. Then, it reviews the results to determine if products are safe, effective and ready to be put on the market. Second, the FDA monitors the safety of all products after they go on the market. This role is especially critical because no matter how extensively a product has been tested in clinical trials, the testing process cannot predict all of the potential issues and limitations that a product may exhibit when used by a wide population over a long period of time.

The FDA carefully monitors reports of adverse experiences with products after they are on the market. If this monitoring turns up problems that need to be corrected, the FDA can take timely and appropriate actions. Healthcare providers, consumers, product manufacturers and distributors, all play a key role in helping the FDA monitor the safety of all the medical products that are used or prescribed. To fulfill this role, it is important to understand the guidelines, resources and tools available for reporting adverse events and other problems associated with a product.

The MDR System

Medical Device Reporting (MDR) is the system through which the FDA obtains information about medical device adverse events from manufacturers, importers and user facilities such as hospital and nursing homes. Congress established the MDR system with the goal of increasing the amount of information that both the FDA and device manufacturers receive about problems with medical devices. Yet even though manufacturers of medical devices have been required since 1984 to report all device-related deaths, serious injuries and malfunctions to the FDA, historically, problems have been drastically underreported. In an effort to combat underreporting, the Safe Medical Device Act (SMDA) was passed

in 1990. Under the SMDA and the Food and Drug Administration Modernization Act (FDAMA), device user facilities such as hospitals were required to report all known device-related deaths to the FDA and the manufacturer.

These facilities were also required to report device-related serious injuries to the manufacturer or to the FDA if the manufacturer was not known. In addition to these basic reporting requirements, the SMDA also required that facilities submit an annual report to the FDA summarizing all reports submitted during the time period.

FDA Databases

The Medical Device Reporting section of the FDA website offers a wealth of information for manufacturers and healthcare professionals who work in user facilities such as hospitals and nursing homes. Two databases, the "Manufacturer and User Facility Device Experience" database (MAUDE) and the "Medical Device Reporting" database (MDR), which includes information from an older "Device Experience Network" database, can be used to search for reports of: Adverse events involving medical devices, mandatory manufacturer reports on devices that may have malfunctioned and caused death or serious injury. The site provides a series of documents with detailed guidance on reporting. User facilities can subscribe to a quarterly reporting bulletin that is designed to help them maintain compliance with reporting requirements. The site also offers a series of downloadable files with detailed information for user facilities and manufacturers about how and where to report, including forms, instructions and contact information.

Mandatory Reporting

The FDA's ability to conduct accurate monitoring of adverse events over time depends on reporting by: product manufacturers and distributors, user facilities, healthcare professionals and consumers. As mentioned earlier, reporting adverse events that occur with medical devices is mandatory for manufacturers, distributors and user facilities, and should be done through the MDR system.

Voluntary Reporting

Reporting is voluntary for individual healthcare professionals for all medical products except vaccines. Reporting is also voluntary for consumers. Voluntary reports are generally spontaneous, meaning that an incident is observed during direct patient care and reported by a healthcare professional or patient, either directly to the FDA or to the manufacturer and the to the FDA. The FDA encourages healthcare professionals and patients to report any adverse event that they determine to be significant. Even the suspicion that a medical product might be related to a serious adverse even is an adequate reason to submit a report. Both mandatory and voluntary reporting by all parties is critical because even when a small number of reports are submitted to the FDA, they can reveal serious problems that may indicate the need for a label change or other action mandated by the FDA to improve the safe use of that medical product.

How to Report

The FDA website provides detailed guidance on how and where to report adverse events, product use errors and product quality problems.

Improving Safety

When a suspected problem with a drug, device or other medical product is reported, the FDA will investigate the root cause by evaluating and comparing it with similar reports in their database. Once it is determined that a legitimate safety issue exists, the FDA will work the manufacturer to identify the source of the problem.

Minimizing Risk

The FDA will then take specific steps with the goal of keeping the drug or device on the market while resolving the safety issue and minimizing any risks to patients. Changes to product labeling are the most commonly used strategy. The change might be a boxed warning placed prominently at the top of the prescribing information for a drug, or it could be the addition of precautions or adverse reactions information. Other changes include monitoring recommendations and dosage adjustments. When these changes aren't enough, a more extensive strategy is developed by the FDA and the manufacturer. This might include prescribing or dispensing limits, or tracking all patients who either received a particular drug or who are treated using a specific device.

Postmarket Surveillance

Tracking is not required for many medical devices, so when a problem is reported with one of these, the FDA may order the manufacturer to conduct postmark surveillance of the device. Postmarket surveillance means the active, systematic, scientifically valid collection, analysis, and interpretation of data or other information about a marketed device. The data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

Conclusion

Timely and accurate reporting of adverse events and other safety issues is critical for healthcare organizations, providers, consumers, product manufacturers and distributors alike. By understanding the guidelines, resources and tools available for reporting these issues, we can all work with the FDA to minimize risks and maximize safety.