Post-market device surveillance in the US: the MedWatcher platform

Kathryn Cole and Merry Lee Bain assess new FDA post-market surveillance initiatives for medical devices.

In April, the US Food and Drug Administration published an update containing proposed next steps to strengthen the national strategy for post-market surveillance of medical devices. The report outlined the FDA’s top priorities in five key areas, as well as deadlines for implementation. Although a number of steps, including finalization of the unique device identification (UDI) rule and its incorporation into a publically accessible global UDI database (GUDID) – also still to be developed – had assigned due dates at the end of Q2 2013, the FDA has yet to release any information regarding the status of the majority of these tasks. The deadline for issuing the new UDI rule has lapsed and the FDA has said only that the rule is under administrative review and that it hopes to release it soon.

There has been progress to date on one of the five strategic priorities, namely the mandate to “Modernize adverse event reporting and analysis.” The FDA celebrated the 20th anniversary of MedWatch this year with the 22 April launch of the MedWatcher system for early detection and tracking of adverse events for devices, drugs, and vaccines in the general population. The MedWatcher platform consists of two main components: (1) a data mining module, MedWatcher Social, and (2) a crowdsourcing module, MedWatcher Personal.

MedWatcher Personal is a mobile and web application, or “app,” that allows consumers to easily report suspected or known problems with medical devices, drugs, or vaccines from a smartphone or tablet, or online from the MedWatcher website, www.medwatcher.com. The crowdsourcing application allows users to search a “comprehensive listing of all drugs, vaccines, and medical devices…track the latest reports and news about the drugs, vaccines and devices…[and] report negative side effects to FDA so they can be tracked and linked to other cases.” The online database on the MedWatcher website is searchable to consumers by product, with the ability to filter the reports by gender and age range. There is an auto-complete function for product.

MedWatcher Social, by contrast, is a social media monitoring and analytics platform that identifies, aggregates, classifies, and visualizes adverse events for drugs, devices, and vaccines. The data mining component of the MedWatcher program, funded by the Office of Chief Scientist at the FDA, acquires data from social media, including Facebook, Twitter, news, and online patient communities. Adverse events detected in social media are MedDRA coded and exported in E2B format for incorporation into safety databases. MedWatcher Social applies information extraction algorithms to filter and classify the information received, and extracts signals of adverse events. The system can even be programmed to automatically alert users when reports reach frequency or statistical thresholds.

As of June, preliminary implementation results included over 200,000 Facebook posts and 6.5 million tweets for 558 products. Of those, 46,000 were hand-labeled and 4,000 were determined to be adverse events or possible adverse events. Data were collected for 225 drugs (201 with more than 1,000 Twitter hits), 55 devices (7 with more than 1,000 Twitter hits), and 58 vaccines (16 with more than 1,000 Twitter hits).

When reporting events using the “Report a Side Effect” button on the website, the MedWatcher system asks questions of the user, such as whether more than one device was affected by the medical countermeasures (MCM) event, if the device(s) were in use prior to the MCM event, if the device was directly related to the event, what other medications or medical products were in use at the time of the MCM event, and the reason for using the device. Event details recorded include date of event, detailed description of experience, including any other ongoing illness, allergies, relevant birth defect or other medical conditions, and a request for any available lab data, as well as checkboxes for all outcomes attributable to the event (eg non-serious, other serious, hospitalization, disability or permanent damage, birth defect, life threatening, death). Patient age, sex, and identifier, such as initials or medical record number, are also required.

Reports that are available at present on the MedWatcher website cover a spectrum of FDA-regulated products and an assortment of adverse events. Several reports aggregated on the site with event dates between January and February 2013 are provided below as examples of the variety:

- 28 February (MedWatcher App/Site, Medical Device, Female, Age 28): Essure – “Bad cramps, heavy bleeding, blood clots, lower back pain, severe bloating, swelling in feet and face, swollen lymph nodes in neck, panic attacks, body aches”;
- 26 February (MedWatcher App/Site, Drug, Male, Age 52): Lidoderm – “Patch does not stick. Very poor adhesion to skin. It does not work, because it does not stick”;
- 17 February (MedWatcher App/Site, Drug, Male, Age 62): Celexa – “62 year old male committed suicide after being on Celexa for 2 weeks”;
- 6 January (Twitter, Drug, Sex Unknown, Age Unknown): Effexor – “Effexor makes me constipated ((ew)) and I’m not allowed lax. Hate everything.”

Clearly, there is a wide range of variation in the type of adverse events reported, the level of detail provided, and the source of the report. The “Report a Side Effect” form only asks the submitter, “Are you a health professional,” as well as for contact information; however, the lay user viewing the site is unable to tell whether the reporter of the event is a patient, healthcare provider, caretaker, or other.

The degree of vigilance required from the manufacturers of these products in terms of complaint follow-up is not clear at this point, nor is it clear how these data will be used by the FDA to improve the post-market surveillance process. The FDA has said, however, that its investigators will review the complaints received to determine if the medical device or prescription in question actually caused the reported problem.

It is apparent that a significant amount of FDA resources will be required for reviewing, and responding to, the information reported through the MedWatcher system, as reports are to become part of a database for review by an FDA safety evaluator who will determine what steps to take. Based on the number of social media posts and wide variety of information submitted since recent implementation, it will be interesting to see if this initiative indeed supports the FDA objectives of providing a more timely and comprehensive assessment of benefit-risk profiles of medical products, and reducing the burdens and costs of post-market surveillance.

The MedWatcher platform is intended for consumers of FDA-regulated products. Manufacturers and healthcare facilities will continue to be required to report problems through the Medical Devices Reporting System and the Medical Product Safety Network.

A longer version of this article is available online at www.scripregulatoryaffairs.com.

Kathryn Cole is a senior consultant and Merry Lee Bain is vice president of medical devices at Precision for Medicine, a US specialized scientific services company based in Bethesda, Maryland. Email: kathryn.cole@precisionformedicine.com or merrylee.bain@precisionformedicine.com.