FDA Announces Medwatcher—A Mobile App to Submit Device Problems

U.S. Food & Drug Administration

MedWatcher is a mobile application (app) that allows individuals to submit voluntary reports of serious medical device problems to the FDA using a smart phone or tablet. The app makes it easier and faster for healthcare professionals, patients and caregivers to send voluntary reports of medical device problems to the FDA, compared to the traditional reporting methods - mail, phone or online.

The MedWatcher app allows users to upload photographs of medical devices, which can help identify visible problems with the device, such as breakage or corrosion. App users can also choose to automatically receive MedWatch Safety alerts, FDA safety communications, recall information, relevant articles and other information on specific medical products of interest.

MedWatcher is not intended to fulfill mandatory reporting requirements [1] for manufacturers and facilities.

The FDA relies on reports of serious problems with medical devices and other products as one important way to help identify and better understand the risks associated with these products. Receiving higher quality reports more quickly helps the FDA identify and respond to safety signals and public health emergencies more efficiently and effectively. These reports, along with data from other sources, can provide critical information that can lead to improved patient safety.

The FDA encourages healthcare professionals, patients and caregivers to report the following types of problems, even when they are not certain that the device caused the problem:

- Serious adverse events that might be associated with a medical device, especially events that are not listed in the product labeling. "Serious" means fatalities, hospitalizations, and medically significant events.
- Therapeutic failures where the device failed to work as it should.
- Use errors with devices, including situations where the error may have been due to poor communication, or to ambiguities in product names, directions for use, or packaging.
- Product quality issues, such as suspected counterfeit products, defective components, potential contamination, device malfunctions and poor packaging.

Download the MedWatcher Mobile App

- iTunes Store: MedWatcher App Download [2]
- Google Play Store: MedWatcher App Download [3]

Confidentiality
Confidentiality is important in all of our reporting mechanisms. We have taken steps to build a strong firewall for incoming reports, so that information contained in the report is not vulnerable to unauthorized access after we have received it.

The MedWatcher app does not store personal information from the user's mobile device, nor does it store adverse event reports once they have been submitted. This prevents personal medical information collected by the app and sent to the FDA from being stored on the phone after the report has been submitted to the FDA.

Similar to the MedWatch 3500 voluntary reporting form, a government form used for mail and e-mail submissions, MedWatcher form asks for the reporter's name and contact information. This enables the FDA to contact the reporter to get more information about the event, if necessary. As with other forms of voluntary reporting, the reporter's identity may be shared with the device manufacturer to allow for timely follow-up in serious cases, unless the reporter specifies that he does not want his identity disclosed. If you are a facility or manufacturer, you must continue to comply with the Medical Device Reporting (MDR) regulations [1].

The MedWatcher app does not change or interfere with the personal privacy settings set by the mobile device user. Using the MedWatcher mobile app carries the same risk as using any other mobile app that transmits sensitive data, such as banking apps or apps that allow users to make purchases on mobile devices. Neither the FDA nor the MedWatcher app can control personal privacy settings on individual mobile devices.

Links:
[1] http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/default.htm
[2] https://itunes.apple.com/us/app/medwatcher-for-drugs-vaccines/id391767048?mt=8
[3] https://play.google.com/store/apps/details?id=org.medwatcher&hl=en