FDA improves access to information in FAERS database

FDA has launched a new user-friendly, interactive, web-based dashboard search tool for its FDA Adverse Event Reporting System (FAERS) database that may be especially useful to health-system pharmacists. The dashboard improves access to data about adverse drug and therapeutic biologic products reported to FDA. Prior to this dashboard launch, only raw FAERS data (13 million reports going back to 1968) were available, which made searching difficult.

Data organized by select criteria
With the new searchable, user-friendly interface, health-system pharmacists and other users can organize the data on the basis of select criteria, such as drug or biological product, patient age, reporter type (e.g., consumer, health professional), adverse event type, and year. The dashboard then displays the total number of reports within that search criteria.

Currently FDA uses the FAERS database to identify potential safety-issue “signals.” If a signal is identified in FAERS, further evaluation by FDA is performed, which might include reviewing clinical trial information, initiating discussions with clinical experts in the field, testing the drug or biologic in FDA laboratories, using other databases to conduct comparative studies, searching scientific literature, and requesting that the manufacturer conduct a clinical study to evaluate the concern.

On the basis of an evaluation of the potential safety signal, FDA may take regulatory actions to improve product safety, including updating product labeling, restricting use of a drug, distributing safety information or warnings to the public, or, in rare cases, removing a product from the market.

Data limitations of concern
While the new FAERS dashboard is a valuable upgrade for FDA’s ability to ensure transparency and to help pharmacists assist patients with safe use of FDA-approved drugs and biologics, these data still have limitations. For instance, much of the data contained in FAERS have not been evaluated or verified by FDA. Reports can be submitted by anyone and may be missing important information, may not be accurate, may be untimely, may not have been verified medically, or may include biased information. The information in the new public dashboard does not establish a causal relationship between products. Reporting adverse events, product quality problems, and medication errors to FDA is voluntary, and multiple factors influence if an event is reported to FDA. Also, since FAERS continues to be updated quarterly, the data in FAERS can have a lag time, from entry date to appearance, of 3 months. This means that if a patient is looking for information on a report they submitted in the last few days, the information will not be accessible in the FAERS public dashboard.

These and other confounding factors make numerators used to calculate the incidence of adverse events, product quality problems, and medication errors inaccurate. In addition, the new dashboard does not calculate how many individual patients use individual drugs, so it would not help to calculate a denominator for incidence of an event, and therefore comparison of drug safety profiles cannot be made.

Improvements continue
Adverse event reporting helps FDA monitor the safety of drug and biologic products once they reach the market. These reports are one of the tools used to continuously assess marketed drugs and biologics. As the new FAERS dashboard continues to be used by FDA, pharmacists, physicians, and the public, FDA will look for improvements that can be made for querying the data from the millions of included reports. In the meantime, patients should continue to talk to their doctors and pharmacists if they have questions about their prescription medications.

For questions or assistance with navigating the new FAERS dashboard, please contact the Center for Drug Evaluation and Research’s Division of Drug Information at 1-855-543-3784 or druginfo@fda.hhs.gov.

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