Study finds less than a third of FDA regulatory actions are backed by research or public assessments

October 5 2022

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Less than a third of regulatory actions taken by the US Food and Drug Administration (FDA) are corroborated by published research findings

or public assessments, finds a study published by *The BMJ* today.

The researchers say their findings, based on analysis of drug safety signals identified by the FDA from 2008 to 2019, suggest that either the FDA is taking regulatory actions based on evidence not made publicly available, or that more comprehensive safety evaluations might be needed when potential safety signals are identified.

Monitoring the safety of a medicine once it is available to patients (known as post-marketing pharmacovigilance) is essential for monitoring drug safety.

The US Food and Drug Administration (FDA) receives more than 2 million adverse event reports annually through its Adverse Event Reporting System (FAERS) and reviews all potential safety signals to determine if regulatory action is needed.

In 2007, the FDA Amendments Act required the FDA to publish quarterly reports of safety signals from FAERS, providing an opportunity to examine them to better understand this pharmacovigilance system.

A team of US researchers therefore decided to analyze safety signals identified within the FAERS database. They investigated how often these signals resulted in regulatory actions and whether they were corroborated by additional research.

They found that from 2008 to 2019, 603 potential safety signals identified from the FAERS were reported by the FDA, of which about 70% were resolved, and nearly 80% led to regulatory action, most often changes to drug labeling.

In a separate in-depth analysis of 82 potential safety signals reported in

2014-15, at least one relevant study was found in the literature for about 75% of the signals, but most of these studies were case reports or case series.

However, less than a third (30%) of regulatory actions were corroborated by at least one relevant published research study, and none of the regulatory actions were corroborated by a public assessment, reported by the Sentinel Initiative.

These are observational findings, and the researchers acknowledge some important limitations. For example, they did not evaluate regulatory actions taken in other countries in response to these safety signals, which might have informed the FDA's actions, nor could they consider unpublished studies or other data accessible to the agency but not publicly available.

Nevertheless, they say these findings "highlight the continued need for rigorous post-market safety studies to strengthen the quality of evidence available at the time of regulatory action, as well as the importance of ongoing efforts to leverage real world data sources to evaluate and resolve signals identified from the FAERS and support FDA regulatory decisions."

In a linked editorial, experts argue that regulators should publish all evidence underlying their responses to drug safety signals to reduce harm and ensure public trust in medicines.

The COVID-19 pandemic has exposed the tension underlying regulatory decisions and the public's right to know about serious risks associated with medical interventions, they write. This same tension exists more broadly in medicine safety.

"Safety signals are an important step, but radical transparency about

available evidence and the basis for regulatory judgments is needed to reduce harm caused by medicines, as is adequate follow-up to ensure safer use," they conclude.

More information: Characterization and corroboration of safety signals identified from the US Food and Drug Administration Adverse Event Reporting System, 2008-19: cross sectional study, *The BMJ* (2022). DOI: 10.1136/bmj-2022-071752

Provided by British Medical Journal