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10% of Adverse Drug Events Reported Miss Deadline

According to an article published in *JAMA Internal Medicine*, approximately 10 percent of serious and unexpected adverse events are not reported by drug manufacturers to the U.S. FDA under the 15-day time frame that is set out in federal regulations.

Drug manufacturers are required by law to report serious adverse events including death, life-threatening, hospitalisation, disability and birth defects and unexpected side effects that are not listed in the drug label to the FDA within 15 calendar days of the initial receipt of such information. However, this study which included more than 1.6 million adverse event reports estimates that nearly 9.94 percent of the reports were not received by the FDA within the 15-day period. Their analysis shows that patient death may be associated with this delayed reporting.

“Our analysis provided evidence that drug manufacturers delay reporting of serious AEs [adverse events] to the FDA. Strikingly, AEs with patient death were more likely to be delayed. It is possible that manufacturers spend additional time in verifying reports concerning deaths, but this discretion is outside the scope of the current regulatory regime,” the authors conclude.

In an accompanying editorial, Rita F. Redberg, M.D., M.Sc., editor of JAMA Internal Medicine, also points out that reporting of side effects should not be delayed because this could result in more patients being put at risk to potentially avoidable serious harm, including death. Adverse event reports could be sent directly to the FDA instead of through the manufacturer to avoid such delays because it imperative that both physicians and patients be made aware of the benefits, harms and alternatives for a wide choice of treatments. This is especially true for drugs that have been approved recently and with which there is limited clinical experience.

Source: JAMA

Image Credit: Pixabay

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