Pharmacovigilance needed for rheumatology patients

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(HealthDay)—Recommendations have been developed for

pharmacovigilance in rheumatology, emphasizing the need for continued monitoring of new drugs, according to a position statement issued by the American College of Rheumatology (ACR).

Researchers from the ACR developed a position statement relating to pharmacovigilance with respect to rheumatology treatment.

According to the statement, the ACR supports robust pharmacovigilance to ensure the safety of all rheumatology medications. In addition, the ACR supports continued development of the Sentinel System by the U.S. Food and Drug Administration; this system relies on information from existing databases to monitor adverse events in real time. In order to actively monitor patients for adverse events, the ACR recognizes the role of health care providers, with reporting of any serious adverse events through MedWatch. The ACR encourages reporting of full product information, including biosimilar suffix, lot information, and indication for drug use when reporting adverse events related to biologics. Given the current partial reliance on patients for spontaneous reporting of adverse events, pharmacovigilance systems should be readily available and easy for patients to use.

"This statement puts us on record of supporting prompt reporting of new and unexpected side effects to the FDA and advocating for more comprehensive systems to observe drug safety in practice," Donald R. Miller, Pharm.D., member of the ACR's Committee on Rheumatologic Care, said in a statement.

More information: ACR Position Statement

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