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Diverticulitis Associated with BaricitinibUse:Adverse Events- Signal Review

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ABSTRACT

Baricitinib is antirheumatic drug that belongs to diseasemodifying antirheumatic drugs (DMARD). Diverticular disease (diverticulosis, diverticulitis) is a broad term that refer to the presence of diverticula. It is a small pouches in the large intestinal (colonic) wall. A signal of Baricitinib and diverticulitis was retrieved from Pharmacovigilance Risk Assessment Committee (PRAC) new signals. Saudi Food and Drug authority (SFDA) has conducted this safety review based on that. The purpose of this review is to evaluate the risk of diverticulitis in association with Baricitinib use. Methods: Signal Detection team at SFDA have retrospectively searched World Health Organization (WHO) database (Vigibase) and the National Pharmacovigilance Center (NPC) database to retrieve all reported cases of Baricitinib and diverticulitis. Local Cases: The search in the National Pharmacovigilance Center (NPC) database resulted in zero cases.On March 25th, 2020, a search in the World Health Organization (WHO) database (Vigibase) was conducted to retrieve all reported cases between 2017 and 2020 via signal detection tool (Vigilyze). The search resulted in 23 Individualized Case Safety Reports (ICSRs). One report was excluded due to duplication.

<u>Biography</u>Roaa works as a Medication Safety Specialist at National Pharmacovigilance and Drug Safety Center at Saudi Food and Drug Authority, Her professional experience has focused on detecting and assessing potential signals that arise from different recourses



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