SFDA SAFETY SIGNAL

"A signal is defined by the SFDA as reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information. A signal is a hypothesis together with data and arguments and it is important to note that a signal is not only uncertain but also preliminary in nature."

26-10-2021

Saudi Food and Drug Authority (SFDA) – Safety Signal of Omalizumab and the Risk of Blurred vision

The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of ***Blurred vision*** *associated with the use of* ***Omalizumab.*** *The signal has been originated through routine pharmacovigilance monitoring activities.*

Introduction

Omalizumab is a recombinant DNA-derived humanized monoclonal antibody that binds to human immunoglobulin E (IgE) selectively [1]. The drug binds to IgE and prevents binding of IgE to FcεRI (high-affinity IgE receptor) on basophils and mast cells, thereby reducing the amount of free IgE that is available to trigger the allergic cascade in asthma [1]. Blurred vision is characterized by inability to see fine detail of objectives [2]. Objective of this review is to evaluate the risk of Blurred vision associated with the use of Omalizumab and suggest regulatory recommendations if required.

Methodology

Signal Detection team at the National Pharmacovigilance Center (NPC) of Saudi Food and Drug Authority (SFDA) performed a comprehensive signal review using its national database as well as the World Health Organization (WHO) database (VigiBase), to retrieve related information for assessing the causality between Omalizumab and the risk of Blurred vision [3]. We used the WHO-Uppsala Monitoring Centre (UMC) criteria as standard for assessing the causality of the reported cases [4].

Results

Case Review: The number of resulted cases for the combined drug/adverse drug reaction are 188 global individual case safety reports (ICSRs) as of March 2021 [3]. The reviewers have selected and assessed the causality for top quality reported cases (14 ICSRs). Out of 14 cases, 11 cases supported the association with two positive dechallenge reactions.

Data Mining: The disproportionality of the observed and the expected reporting rate for drug/adverse drug reaction pair is estimated using information component (IC), a tool developed by WHO-UMC to

measure the reporting ratio. Positive IC reflects higher statistical association while negative values indicates less statistical association, considering the null value equal to zero. The results of (IC= 0.0) means the combination of Omalizumab and Blurred vision has been observed the same as expected when compared with other medications in WHO database [3].

Literature

A 67-year-old Caucasian female presented in August 2019 with multiple symptoms including blurred vision after three years of Omalizumab use for Asthma. After clinical assessment, the patient has been diagnosed with eosinophilic granulomatosis with polyangiitis (EGPA) following omalizumab use. However, there were no more related information about resolution of blurred vision have been stated in the case report [5].

Another article which raises this signal, visual disorders were mentioned as reported adverse drug reactions following the use of Omalizumab [6].

Conclusion

The weighted cumulative evidence identified from causality assessment of the reported cases, and literature are sufficient to support a causal association between Omalizumab and the risk of Blurred vision. Health regulators and health care professionals must be aware of this potential risk and it is advisable to monitor any signs or symptoms in treated patients.

Report Adverse Drug Events (ADRs) to the SFDA

The SFDA urges both healthcare professionals and patients to continue reporting adverse drug reactions (ADRs) resulted from using any medications to the SFDA either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance Center (NPC)
Saudi Food and Drug Authority-Drug sector
4904 northern ring branch rd
Hittin District
Riyadh 13513 – 7148
Kingdom of Saudi Arabia
Toll free number: 19999
Email: NPC.Drug@sfda.gov.sa

References:

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