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 m ore 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"

29-4-2025

Saudi Food and Drug Authority (SFDA) – Safety Signal of Fingolimod and the Risk of Optic Neuritis

*The Saudi Food and Drug Authority (SFDA) recommends all health care professionals to be aware of the safety signal of **Optic neuritis** associated with the use of **Fingolimod**. The signal has been originated as a result of routine pharmacovigilance monitoring activities.*

Introduction

Fingolimod is an immunomodulating medication that work on sphingosine l-phosphate receptor (have important roles in retinal cell death and survival), it used orally to treat relapsing-remitting multiple sclerosis (RRMS).[1] Optic neuritis is a type of neuropathy (nerve disease) that can cause eye pain and vision loss or vision changes. It happens when inflammation affects signals traveling through optic nerve, which connects the eyes and brain. [2] The aim of this review is to evaluate the risk of Optic neuritis associated with the use of Fingolimod and to suggest regulatory recommendations if required.

Methodology

Signal Detection team at SFDA performed a signal review using National Pharmacovigilance Center (NPC) database, and World Health Organization (WHO) database, VigiBase, with literature screening to retrieve all related information to assess the causality between Optic neuritis and Fingolimod use. The search conducted on February 2025.

Results

Case Review: Signal detection team at SFDA have searched Saudi national database and WHO database to find individual case safety reports (ICSRs). The WHO database resulted in 671 global case-reports no case found. The authors used signal detection tool (Vigilyze) to retrieve global cases. [3] Authors also applied WHO-UMC causality assessment criteria on the extracted ICSRs with completeness score 0.9 and above (30 cases). [4] Among them, 22 cases were probably and possibly linked to Fingolimod, while 7 cases assessed as unlikely and the remaining single case were unable to be assessed due to lack of important information.

Datamining: 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. The IC result is (4.2) for this drug/ADR combination which reflects strong positive statistical association. [3]

Literature: The signal team searched the literature to find related publications linking this ADR to Fingolimod. The search showed two published articles linking Optic neuritis to the use of Fingolimod. [5,6]

Conclusion

The weighted cumulative evidence identified from assessed cases, disproportionality analysis and literature might be suggestive for causal association between Fingolimod and Optic neuritis. Health care professionals and health regulators must be aware of the potential risk in drug recipients.

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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2- Optic neuritis: Understanding what it means for you (2024) Cleveland Clinic. Available at: https://my.clevelandclinic.org/health/diseases/14256-optic-neuritis

3- Vigilyze.who-umc.org. 2025. [online] Available at: https://vigilyze.who-umc.org/ .

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6- Bonnan, M., Berthelot, E. and Cabre, P. (2021). Multiple sclerosis-like NMOSD patients suffer severe worsening of status after fingolimod initiation. Multiple Sclerosis and Related Disorders, 52, p.102975. doi:https://doi.org/10.1016/j.msard.2021.102975.