Identification and Evaluation of Pregnancy Safety Signals: SFDA Experience

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Background

Knowledge on the safe use of medication during pregnancy is often sparse. Pregnant women are generally excluded from clinical trials, and post-marketing data is critically important to identify teratogenic medications.

Objectives

This project aims to identify signals of congenital anomaly (CA) related to potentially teratogenic medications use and evaluate these signals based on the available evidence.

Methods

Individual case safety reports (ICSRs) of CA were retrieved from the World Health Organization (WHO) global database of individual case safety reports (VigiBase) using specific keywords, in February 2022. Then, the following exclusion criteria were applied; ICSRs with chromosomal anomaly, skeletal dysplasia, or genetic syndrome were excluded since aetiology is assumed not to be teratogenic; ICSRs with only exposed to (folic acid, minerals and/or vitamins); ICSRs with only exposed to topical medications, or non-locally registered drugs.

After that, a list of drug-CA events was crosschecked in local label and the U.S. Food and Drug Administration, European Medicines label information. Then, identified signals underwent in-depth assessment by conducting a comprehensive safety evaluation using several different evidence sources including literature, global cases retrieved from VigiBase and local cases retrieved from the national pharmacovigilance database at Saudi Food and Drug authority (SFDA) and Periodic Benefit-Risk Evaluation Reports

Results

A total of 181 drug-Congenital anomalies (CA) pairs were subjected to initial assessment. Of these, 151 drug-CA events were labeled in the Saudi product's leaflet; 18 drug-CA events were labled by other stringent regulatory authorities; resulting in a local labeling update for these 18 drugs, and 13 drug-CA events were referred for in-depth assessment. The assessment results were one-drug-CA event was probably related, 11 were possibly related, and one was excluded due to off-label use in pregnancy. Results presented in figure (1).

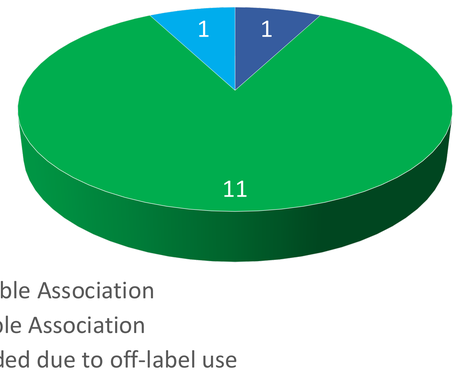

Figure (1) : Drug-Congenital Anomalies Assessment Outcomes

Conclusion

Post marketing data from VigiBase has successfully improved signal detection of CA related to potentially teratogenic medications use. Further studies are needed to detect the potentially teratogenic medications to ensure safe use of medications during pregnancy.