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The Safety Profile of Vilazodone: A Study on Post-Marketing Surveillance

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Abstract : Background and Aim: Vilazodone was approved in 2011 as an antidepressant to treat the major depressive disorder. As a relatively new drug, it is not clear if all adverse effects have been identified. The aim of this study was to review the adverse effects reported to the WHO Programme for International Drug Monitoring (PIDM) in order to add to the knowledge about the safety profile and adverse effects caused by vilazodone. Method: Data on adverse effects reported for vilazodone was obtained from the database VigiAccess managed by PIDM. Data was extracted from VigiAccess using Excel® and analyzed using descriptive statistics. The data collected was compared to the patient information leaflet (PIL) of Viibryd® and the FDA documents to determine adverse drug reactions reported post-marketing. Results: A total of 9708 adverse events had been recorded on VigiAccess, of which 6054 were not recorded on the PIL and the FDA approval document. Most of the reports were received from the Americas and were for adult women aged 45-64 years (24%, n=1059). The highest number of adverse events reported were for psychiatric events (19%; n=1889), followed by gastro-intestinal effects (18%; n=1839). Specific psychiatric disorders recorded included anxiety (316), depression (208), hallucination (168) and agitation (142). The systematic review confirmed several psychiatric adverse effects associated with the use of vilazodone. The findings of this study suggested that these common psychiatric adverse effects associated with the use of vilazodone were not known during the time of FDA approval of the drug and is not currently recorded in the patient information leaflet (PIL). Conclusions: In summary, this study found several adverse drug reactions not recorded in documents emanating from clinical trials pre-marketing. This highlights the importance of continued post-marketing surveillance of a drug, as well as the need for further studies on the psychiatric adverse events associated with vilazodone in order to improve the safety profile.

Keywords : adverse drug reactions, pharmacovigilance, post-marketing surveillance, vilazodone
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