

General information on signals in WHO Pharmaceuticals Newsletter

A signal is defined by WHO 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.

The signals in the newsletter are based on information derived from reports of suspected adverse drug reactions available in Vigibase, the WHO global database of individual case safety reports (ICSRs). The database contains reports of suspected adverse drug reactions, submitted by national pharmacovigilance centres participating in the WHO Programme for International Drug Monitoring. Vigibase is, on behalf of the WHO, maintained by the Uppsala Monitoring Centre (UMC) and periodic analysis of Vigibase data is performed in accordance with UMC's current routine signal detection process. Signals are communicated to national pharmacovigilance centres through SIGNAL (UMC's newsletter about potential medicines safety issues), before being presented in this newsletter. Signal texts from UMC might be edited to some extent by WHO and may differ from the original version.

More information regarding the ICSRs, their limitations and proper use, is provided in the UMC Caveat document. For information on the UMC Measures of Disproportionate Reporting please refer to WHO Pharmaceuticals Newsletter Issue No. 1, 2012.

UMC, a WHO Collaborating Centre, is an independent foundation and a centre for international service and scientific research within the field of pharmacovigilance. UMC's vision is a world where all patients and health professionals make wise therapeutic decisions in their use of medicines. For more information, visit www.who-umc.org. To leave a comment regarding the signals, please contact: the Uppsala Monitoring Centre, Box 1051, SE-751 40 Uppsala, Sweden. E-mail: signals@who-umc.org