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Adverse Drug Reactions Monitoring in the Northern Region of Zambia

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Abstract : The Copperbelt University Health Services (CBUHS) was designated by the Zambia Medicines Regulatory Authority (ZAMRA), formally the Pharmaceutical Regulatory Authority (PRA) as a regional pharmacovigilance centre to carryout activities of drug safety monitoring in four provinces in Zambia. CBUHS’s mandate included stimulating the reporting of adverse drug reactions (ADRs), as well as collecting and collating ADR reports from health institutions in the four provinces. This report covers the researchers’ experiences from May 2008 to September, 2016. The main objectives are 1) to monitor ADRs in the Zambian population, 2) to disseminate information to all health professionals in the region advising that the CBU health was a centre for reporting ADRs in the region, 3) to monitor polypharmacy as well as the benefit-risk profile of medicines, 4) to generate independent, evidence based recommendations on the safety of medicines, 5) to support ZAMRA in formulating safety related regulatory decisions for medicines, and 6) to communicate findings with all key stakeholders. The methodology involved monthly visits, beginning in early May 2008 to September, 2016, by the CBUHS to health institutions in the programme areas. Activities included holding discussions with health workers, distribution of ADR forms and collection of ADRs reports. These reports, once collected, were documented and assessed at the CBUHS. A report was then prepared for ZAMRA on quarterly basis. At ZAMRA, serious ADRs were noted and recommendations made to the Ministry of Health of the Republic of Zambia. The results show that 2,600 ADRs reports were received at the pharmacovigilance regional centre. Most of the ADRs reports that received were due to antiretroviral drugs, as well as a few from anti-malarial drugs like Artemether/Lumefantrine – Coartem®. Three hundred and twelve ADRs were entered in the Uppsala Monitoring Centre WHO Vigiflow for further analysis. It was concluded that in general, 2008-16 were exciting years for the pharmacovigilance group at CBUHS. From a very tentative beginning, a lot of strides were made and contacts established with healthcare facilities in the region. The researchers were encouraged by the support received from the Copperbelt University management, the motivation provided by ZAMRA and most importantly the enthusiasm of health workers in all the health care facilities visited. As a centre for drug safety in Zambia, the results show it achieves its objectives for monitoring ADRs, Pharmacovigilance (drug safety monitoring), and activities of monitoring ADRs as well as preventing them. However, the centre faces critical challenges caused by erratic funding that prevents the smooth running of the programme.

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