Pharmacovigilance and Spontaneous Reporting Trends of Adverse Drug Reactions in Ghana

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Background; Adverse Drug Reactions (ADRs) cause significant morbidity, mortality and increased healthcare costs. Several studies have shown the impact of ADRs and associated non-reporting of events on healthcare systems. Pharmacovigilance (PV) and ADR reporting activities are decentralised from the national to the regional level through regional PV officers who are linked to Institutional Contact Persons (ICP) in healthcare facilities locally in Ghana. The Food and Drug Authority (FDA) has consistently been reporting below the WHO recommendation of 200 reports per million population despite increased efforts by the FDA to raise awareness and provide training to stakeholders. A safety monitoring unit within the FDA coordinates safety reporting cooperatively with the National Pharmacovigilance Centre (NPC).

Objective; To review and assess the reporting of ADRs by healthcare professionals, Marketing Authorisation Holders and consumers in Ghana.

Method; Empirical literature and reports from the FDA newsletter, the DrugLens, from 2008 to 2020 were reviewed and analysed.

Results; The results showed a decade of the cumulative trajectory of ADR reporting in Ghana, with a sharp increase in reports from 2014 (436) to 2018 (3,729). Since this peak there has been decline of reporting in 2019 (2236) and 2020 (1325). The majority of ADR reports sent to the FDA have been from healthcare professionals (HCPs), followed by marketing authorisation holders and consumers. Among HCPs doctors, nurses and pharmacists were often the HCPs who frequently reported ADR and pharmacists sent the most reports, peaking at 64.4% of reports in 2014. Between 2012 and 2021, the five most commonly reported drugs were anthelmintics and blood pressure medications; Nifedipine (430), Praziquantel (360), Lisinopril (337), Amlodipine (206) and Albendazole (315). Even though it has been more than two decades since Ghana joined the WHO PIDM in Uppsala, Sweden (UMC) ADR reporting is still low. While this may not be generalizable to West Africa it gives an indication for hypothesis formulation and testing to understand further the decline in reporting rates and the factors affecting reporting in Ghana despite increased efforts by the FDA to raise awareness and provide training to stakeholders.