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Eritrean Pharmacovigilance System: Key Strategies, Success Stories, Challenges and Lessons Learned

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Establishment of a mature pharmacovigilance system in low-income countries is a challenge. Nevertheless, Eritrea, one of the low-income countries, was able to achieve a full-fledged pharmacovigilance system in a period of almost nine years. The Eritrean pharmacovigilance centre (EPC) has managed to submit, cumulatively, 646 individual case safety reports (ICSRs) per million inhabitants per year to the WHO global database of ICSRs, with an average completeness score of 91%. As a result, the center has been rated among the top reporting countries in Africa. It detected about 30 safety signals, achieved maturity level three on the WHO rapid benchmarking assessment, and gained huge political commitment. As part of monitoring product quality through pharmacovigilance systems, in the last few years, the National Medicines and Food Administrationrecalled about 55 medical products from the Eritrean market that were found to be eithersubstandard or falsified. The aim of this presentation is to share Eritrea's success stories, key strategies for success, challenges encountered, and lessons learned with the international pharmacovigilance community and beyond. When pharmacovigilance (PV) first developed as a consequence of the thalidomide tragedy in the 1960s, the focus was on studying adverse drug reactions (ADRs) to medicines after they have been authorized for use. The mostcommonly used classification of these adverse effects are augmented (Type A) or bizarre (Type B) reactions, primarily distinguishing between pharmacological effects and hypersensitivity reactions. Research on medicine-related hospitalizations carried out over the past 35 years has demonstrated that approximately 50% of medicine-related patient harms leading to hospitalization are preventable, that is, are associated not with the intrinsic properties of the medical product itself, but with the way it has been prescribed, dispensed, administered or used .

Thus, current PV methods take a much broader overview of PV focusing thereby on safety surveillance through the entire lifecycle of a medicinal product. In the 1990s, counterfeited medicines emerged as a major threat to public health and confidence in healthcare systems, particularly in resource-limited countries . WHO defines PV as the 'science and activities related to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems. Thus, the WHO definition alludes to all harms associated with a medicine including harms due to poor quality manifesting, for example, as absence of expected effect. In other words, there is scope within PV operations to trace and detect the presence of substandard and poor quality medicines, particularly when these products would lead to adverse events in patients.