Title:

Drug Safety Status, a comparative analysis of European Union, Arab League, Eurasian Commission & India

Abstract:

Access to medicine has significantly improved during last decade worldwide, thanks to the efforts of global health initiatives and also to the commitment of national governments. Medicines are required to be safe, effective, and of good quality to achieve their intended purpose. However several incidences of harm from poor quality or unsafe products have been recorded. The primary objective of pharmaceutical regulation is to safeguard the public from unsafe medical products. Countries can achieve that by establishing a comprehensive pharmacovigilance (PV) system. While major advancements of the discipline of pharmacovigilance have taken place in the West (US & EU), not much has been achieved in low and middle income countries (LMICs), though several attempts have been taken. However, with more clinical research activities being conducted in these countries, there is an immense need to understand and implement PV. For this to happen, the mind set of people working in regulatory agencies, the Pharmaceutical companies, prescribers and patients/consumers need to change. WHO has a major role in supporting and coordinating these developments.

In the past 20 years, many LMICs have created national PV systems and joined the WHO's global PV network. However, very few of them have fully functional systems. Legislation and regulatory framework as well as financial support to build sustainable PV systems are needed. Public health programs need to integrate PV to monitor new vaccines and medicines introduced through these programs. Signal analysis should focus on high-burden preventable adverse drug problems.