Pharmacovigilance in Low and Middle-Income Countries: A review with particular focus on Africa

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Abstract

Low- and middle-income countries (LMIC) face unique challenges with regard to the establishment of robust pharmacovigilance systems capable of generating data to inform healthcare policy and practice. These include the limited integration and reliance of pharmacovigilance systems across LMIC despite recent efforts to harmonize pharmacovigilance rules and regulations in several regional economic communities; the need to translate reporting tools into numerous local languages; low numbers of healthcare providers relative to number of patients, with very short consultation times; scarcity of well-trained pharmacovigilance personnel with little or no budgetary support for these activities from national governments; high turnover of pharmacovigilance staff whose training involves a substantial amount of resources; little awareness of pharmacovigilance among healthcare workers, decision makers and consumers; very low spontaneous reporting rates with poor quality reports which hinders robust signal detection analyses; little collaboration between public health programmes and national medicines regulatory authorities; limited investment in pharmacovigilance activities especially during mass drug administration for neglected tropical diseases; high uptake of herbal and traditional medication, mostly by self-medication; disruptive political conflicts jeopardizing fragile systems; and little or no access to drug utilization data which makes it difficult to reliably estimate the true safety risks of medicine use. This review summarises the specific challenges and areas of progress in pharmacovigilance in LMIC with special focus on the situation in Africa.

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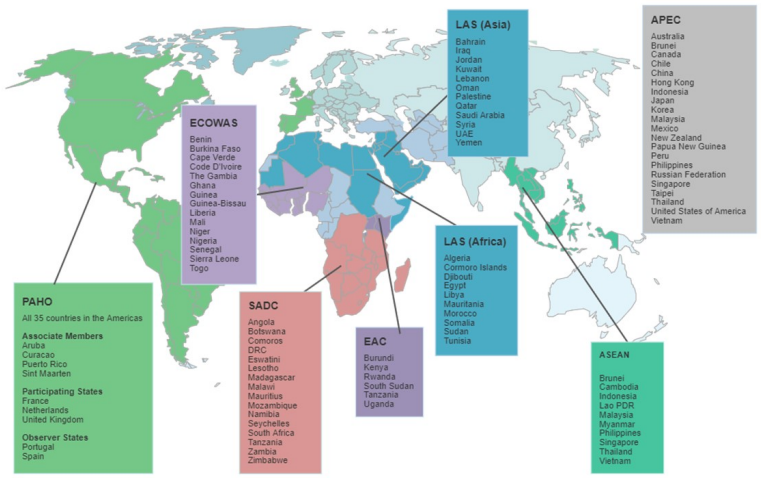

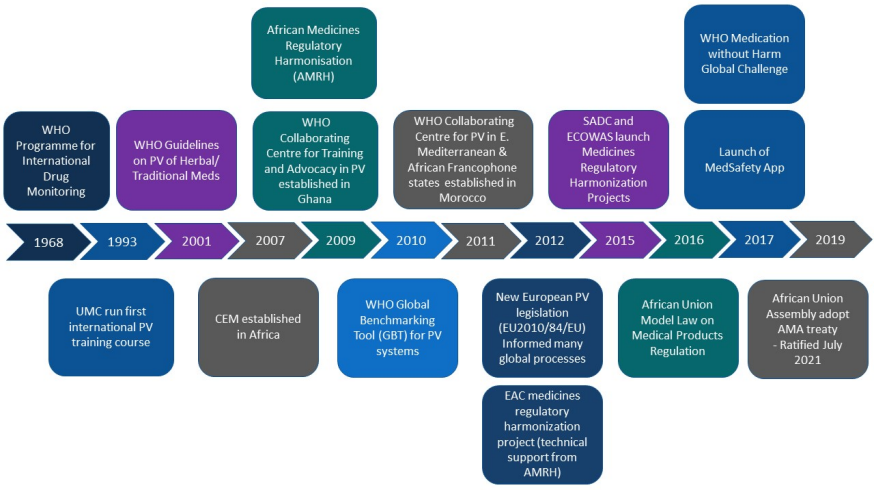

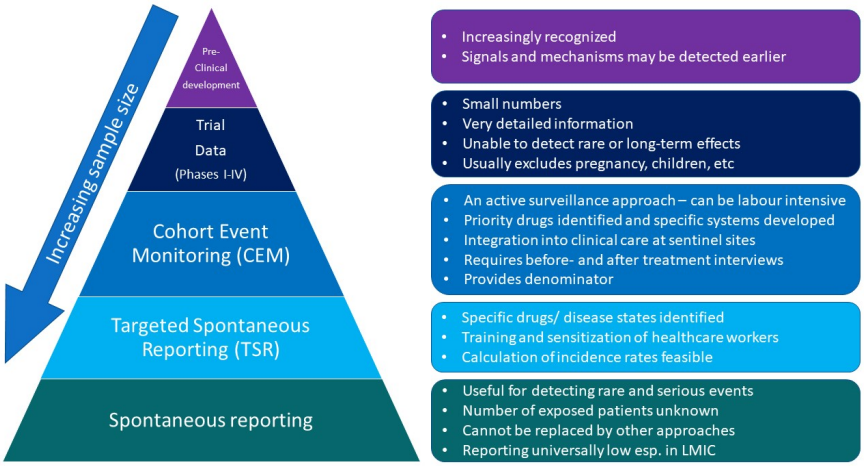

Justice

Fairness in distribution of benefits and burdens

Key questions

- Are there systematic disparities in the medical evidence base for drug safety between different settings (ie HIC and LMIC)?
- What factors affect the fairness/unfairness of excluding or delaying pharmacovigilance research in LMIC?

Non-Maleficence

"First, do no harm": Act to Avoid or Minimize Harms

Key questions

- Do existing laws and regulations suffice to minimize harm?
- Does the lack of evidence put populations at risk of harm?
- What factors make study- related harm a case of wrongful malfeasance vs unfortunate injury?
- Are there harms to individuals in LMIC resulting from PHPs and MDA initiatives not accompanied by appropriate pharmacovigilance?

Autonomy

Opportunity and Capability of Individuals to Make Informed Decisions About Themselves

Key questions

- Does sufficient data exist to support comparably autonomous health choices on the part of LMIC communities vs other groups?
- Does lack of data mean the autonomy of individuals in LMIC is curtailed?
- Should an individual be permitted to choose a higher risk option?
- Should an individual be able to decline a proposed treatment or vaccine?

Beneficence

Act with the Intent & Effect of Providing Benefits

Key questions

- What is the consequence of not establishing pharmacovigilance systems in PHPs and for MDA?
- Are there known risks, to communities or individuals?
- Are there any subgroups of particularly uncertain risk?