

# Unveiling the Side Effects of Herbal Remedies in Sub-Saharan Africa: The Need for Enhanced Phytovigilance

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## 1. Introduction

Herbal and traditional medicines (HTMs) are increasingly being recognised as integral to national health systems, with over 70% of the Zambian population benefiting from their use<sup>1,2</sup>. Natural products' perceived safety and availability make HTMs popular among patients, though reports of side effects are often underreported<sup>3,4</sup>.

Concerns about their safety persist due to a lack of comprehensive studies. This prompted an analysis of case safety reports involving HTMs from SADC member countries submitted to the WHO Pharmacovigilance database.

## 3. Results/Findings

202 reports were identified in VigiBase with no clear trend over the last 30 years. Most reports originated from South Africa (Figure 1). The majority of reports were sent by physicians. The active ingredients with highest reports were *Vitis vinifera* leaf (n=24, 11.9%) and *Echinacea purpurea* herb with root (n=12, 5.9%). Common indications were flu symptoms (n=14, 6.9%), abdominal pain and constipation (n=14, 6.9%) loss of weight (n=9, 4.5%), warts (n=6, 2.9%) and HIV and retroviral infections (n=4, 2.0%). Common adverse events were general, gastrointestinal, skin and nervous system side effects (n=177/322, 55% of events). 60 (29.7%) cases were reported as serious, with 12 (5.9%) deaths (three of these patients had renal failure) (Table 1). Of all the cases, 61 (30.2%) had positive dechallenge and 9 (4.5%) had positive rechallenge. The drug-event combinations with positive IC<sub>025</sub> values included Papaver somniferum – Hypersensitivity reaction (IC<sub>025</sub> =1.3) and Cannabis sativa - Psychotic disorder (IC<sub>025</sub> = 0.7) (Table 2).

Table 1. Reported serious cases

Seriousness criteria	n(%)
Death	12 (5.9%)
Life threatening	9 (4.5%)
Caused/prolonged hospitalisation	21 (10.4%)
Congenital anomaly/birth defect	1 (0.5%)
Other medically important condition	23 (11.4%)

## References

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## 2. Methods

We searched VigiBase, the WHO global database of individual case safety reports, on 19 May 2024. We extracted data on reports per country over a period of 30 years, focusing on cases of adverse events reported with any products in the “Unspecified Herbal and Traditional Medicines” ATC class. We also identified the most reported active ingredients and calculated disproportionality measures using Information Component (IC) values, with an IC<sub>025</sub> greater than 0 indicating statistically significant disproportionate reporting<sup>5</sup>.

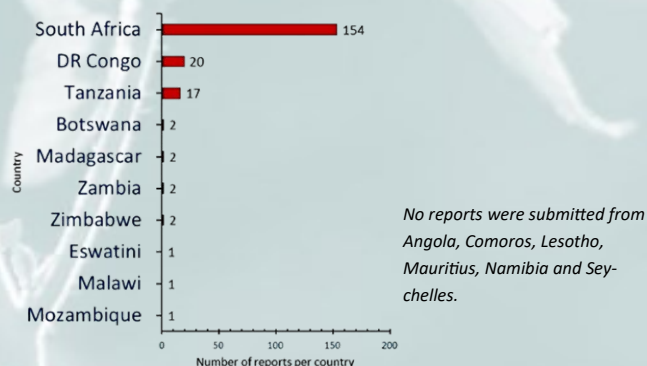


Figure 1. Number of reported cases in VigiBase per country

Table 2. Disproportionately reported events

Active ingredient	Reaction (PT)	IC <sub>025</sub>
Papaver somniferum	Hypersensitivity	1.3
Cannabis sativa	Psychotic disorder	0.7
Echinacea purpurea	Skin discolouration	0.7
Hymenocardia acida	Asthenia	0.5
Vitis vinifera	Haemorrhage	0.5
Vitis vinifera	Muscle spasms	0.4
Papaver somniferum	Rash	0.2

## 4. Conclusions

Safety concerns on HTMs in the SADC region exists. Reports are significantly few in 30 years, yet 12 fatalities were documented. Safety monitoring activities for HTMs should be enhanced. Therefore, consumers and health professionals should report adverse events related to HTMs.

