Pharmacovigilance Of Cannabis-Based Products In Brazil

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Background

In recent years, the **use of cannabis-based products for medical purposes** has grown in **Brazil**, especially after their regulation by the Brazilian Health Regulatory Agency (ANVISA) in **2015**. As with any other medicine, cannabis products are subject to **pharmacovigilance**, and **adverse drug reactions (ADRs)** must be reported to the National Health Surveillance System.

This study aimed to describe **ADRs potentially related to cannabis-based products** recorded in the **Brazilian pharmacovigilance database (VigiMed)**.

Methods

This was a **descriptive quantitative study** using open data from **ANVISA's passive pharmacovigilance system**. All ADR reports involving cannabis-based products between **June 2020 and June 2024** were included.

ADRs were classified according to the **System Organ Class (SOC)** of the **Medical Dictionary for Regulatory Activities (MedDRA)**. Descriptive analyses were conducted using R software.

Results

A total of **157 reports involving cannabis-based products** were identified, comprising **772 reported ADRs**.

Figure 1 - Distribution of notifications involving cannabis products during the period, Brazil, 2020-2024 (n=157)

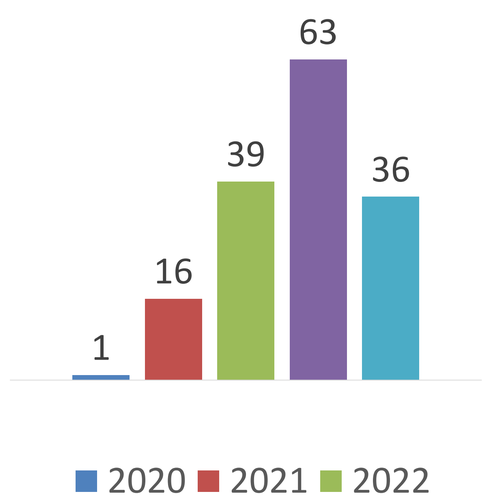

Figure 2 - Classification of suspected adverse events involving cannabis products by severity, Brazil, 2020-2024 (n=772)

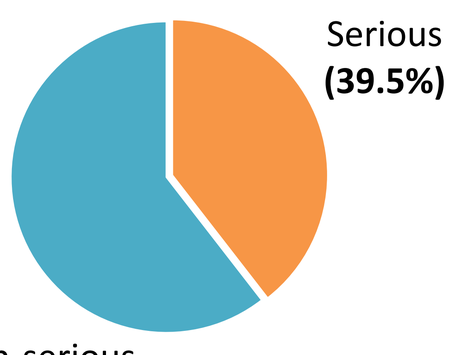

Table 1 - Classification of suspected adverse events by System Organ Class (MedDRA), Brazil, 2020 to 2024 (n=772)

System Organ Class (SOC) (MedDRA)	n (%)
Nervous system disorders	138 (17.9%)
General disorders and administration site conditions	104 (13.5%)
Psychiatric disorders	92 (11.9%)
Injury, poisoning and procedural complications	84 (10.1%)
Gastrointestinal disorders	65 (8.4%)
Skin and subcutaneous tissue disorders	37 (4.8%)
Respiratory, thoracic and mediastinal disorders	36 (4.7%)
Infections and infestations	35 (4.5%)
Investigations	29 (3.8%)
Musculoskeletal and connective tissue disorders	28 (3.6%)
Eye disorders	17 (2.2%)
Cardiac disorders	17 (2.2%)
Immune system disorders	14 (1.8%)
Product issues	12 (1.5%)
Vascular disorders	12 (1.5%)
Others	52 (6.9%)

Conclusion

A **significant number of serious ADRs** were associated with the use of cannabis-based products, which may compromise patient safety, adherence to treatment, and health outcomes, as well as impact healthcare services. These findings underscore the importance of **continuous monitoring** of the safety profile of these products, including **active pharmacovigilance strategies** and **therapeutic follow-up** of users in the Brazilian context.