EDITORIAL
https://doi.org/10.22239/2317-269x.02602

# Post-marketing surveillance – Monitoring, technovigilance, and pharmacovigilance

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This section of the Visa em Debate Journal will present evidence to support of regulated technologies, such as drugs, foods, and medical devices (equipment, healthcare supplies, and *in vitro* diagnostics), based on the results of strategic studies produced through cooperation between the Oswaldo Cruz Foundation in Brasília (Fiocruz Brasília) and the National Health Surveillance Agency (Anvisa). This cooperation[1] aims to produce evidence that can inform the regulatory decision-making process, and as an educational and research institution, Fiocruz Brasília has an interest in disseminating the results of these studies.

In Brazil, Anvisa operates throughout the entire regulatory cycle—from development to obsolescence—for a range of products, including medicines and medical devices. Health surveillance is also responsible for conducting post-marketing surveillance activities through the monitoring of regulated products. Within the scope of health regulation, "monitoring [...] is an organized and ongoing process of collecting data on adverse events (AE) and technical complaints (TC) and other information regarding the performance of products and services [...] during their lifecycle on the market"[1].

Post-market surveillance of medical devices is referred to as technovigilance. Its purpose is to monitor adverse events and technical complaints related to equipment under surveillance, medical devices, and *in vitro* diagnostic medical devices, ensuring that these products maintain appropriate performance and safety standards throughout their entire lifecycle as declared during the regulatory approval stage [2].

In the field of drug monitoring, pharmacovigilance involves the identification and evaluation of adverse drug reactions, monitoring the risks of drug therapy in patients exposed to specific treatments during the post-marketing period.

Regulatory authorities must constantly review and evaluate the regulatory frameworks and requirements for product approval at all stages—from preclinical and clinical research through post-marketing—as well as for good manufacturing practices, storage, transportation, and distribution of products. In this regard, the regulatory review process is a key working mechanism, both for its transparency and its predictability. All products regulated by Anvisa must comply with legal requirements when proposing or revising a regulatory instrument, from the public announcement of the issue to the development of a potential intervention strategy, incorporating data and information from various sources that can support the regulatory proposal. To address these issues, regulatory authorities have adopted the systematic use of evidence, technical committees composed of experts in the field, and scientific advice to analyze and compare regulatory alternatives[3].

The cancellation of registration and the withdrawal from the market of certain medications, such as selective cyclooxygenase-2 inhibitor anti-inflammatory drugs, due to the emergence of serious adverse reactions, have highlighted the risks associated with the development of new health technologies. These events, which occurred during the post-marketing phase, were not identified during clinical trials, reinforcing the importance of monitoring, given that the research model is not always capable of replicating real-world product use.

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According to a published study, the drugs with the highest failure rates in their development during the clinical trial phase are in the field of oncology (32%), central nervous system (CNS) (17%), musculoskeletal diseases (13%), cardiovascular diseases (7%), dietary disorders (7%), metabolic disorders (6%), and infectious diseases (5%). The higher proportion of failures in the development of new drugs in oncology or neurology may be related to the greater number of clinical trials focused on these areas, which allows for the review of therapeutic protocols[4].

Scientific evidence and data-driven monitoring[5] provide important insights into product safety and performance by identifying complaints, quality deviations, and adverse events for post-marketing regulation and monitoring of product behavior, technovigilance, and pharmacovigilance, with the aim of ensuring patient safety.

## REFERENCES


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