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Advances in Prescription Drug Control: Proposals to Strengthen the Regulation of Psychostimulants, Z-Drugs, and Benzodiazepines in Brazil

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Advances in prescription drug control: proposals to strengthen the regulation of psychostimulants, z-drugs, and benzodiazepines in Brazil

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ABSTRACT

Objective: To analyze the Brazilian National Prescription Control System (SNCR) for controlled medications in light of international electronic prescription monitoring models and to identify opportunities for regulatory and clinical improvement in the control of psychostimulants, benzodiazepines, and Z-drugs.

Methods: A comparative narrative review of international prescription monitoring systems was conducted. Case studies were selected according to predefined criteria, including implementation of electronic monitoring systems for controlled medications, availability of official documentation and scientific literature, relevance to international regulatory debates, and diversity of healthcare systems. Models from the United States, Canada, Australia, and the United Kingdom were analyzed and compared with the Brazilian SNCR established under RDC No. 873/2024.

Results: The Brazilian SNCR represents an important administrative advance by centralizing prescription numbering nationwide, enabling digital prescriptions, and improving document traceability. However, the system remains primarily focused on sanitary surveillance and administrative oversight, without providing clinicians access to patients' dispensing histories or tools to identify potentially inappropriate prescribing patterns. In contrast, international models incorporate real-time clinical access, prescription monitoring, automated alerts, audit mechanisms, and prescriber

feedback. Evidence from international experiences suggests these systems are associated with reductions in duplicate prescribing, medication misuse, prescribing errors, and adverse drug events.

Conclusions: Although Brazil has advanced in the digitalization of controlled prescriptions, strengthening the SNCR will require a transition toward integrated clinical pharmacovigilance systems. International experiences support the incorporation of interoperability, real-time monitoring, and structured prescriber feedback to improve patient safety and promote the rational use of psychotropic medications.

Keywords: Psychotropic drugs; tranquilizing drugs; benzodiazepine; international health regulations

Introduction

The increasing prescription of potentially harmful substances, such as psychostimulants (methylphenidate and lisdexamfetamine) (1), benzodiazepines (2), and non-benzodiazepine sedative-hypnotic medications (known as Z-drugs, including zolpidem and eszopiclone) (3), poses critical challenges to global public health policies. Brazil ranks second worldwide in absolute methylphenidate consumption, with a 775% increase between 2003 and 2012 (4). National data indicate a high prevalence of benzodiazepine use in Brazil, with lifetime use reaching 9.8% and a 12-month prevalence of 6.1%, particularly among women, middle-aged adults, and residents of urban areas and the South and Central-West regions (5). Prescribing and consumption of zolpidem have also increased substantially over the past decade, with a 246% rise in sales between 2014 and 2021 (6). This growth may be partially explained by the progressive substitution of benzodiazepines with Z-drugs, driven by the mistaken perception that zolpidem is safer and carries a lower risk of dependence. However, zolpidem shares neurobiological mechanisms with benzodiazepines and is also associated with tolerance, withdrawal symptoms, cognitive impairment, and substance use disorder, particularly when used long-term or at high doses. Thus, the marked increase in prescriptions of psychostimulants, benzodiazepines, and Z-drugs—medications associated with potentially severe harms such as dependence—should be recognized as a public health issue that justifies stricter regulatory control by the Brazilian Health Regulatory Agency (Anvisa) (6).

In Brazil, the recent implementation of the National Prescription Control System (Sistema Nacional de Controle de Receituários – SNCR), established by Resolution of the Collegiate Board (RDC) No. 873/2024, has been presented as a milestone in regulatory modernization, as it constitutes a digital tool developed by Anvisa to centralize the generation and control of prescription numbering nationwide (4). Nevertheless, while the digitalization of prescriptions has improved documentary traceability, it may still be complemented by clinically oriented tools with the potential to more effectively reduce the risk of inappropriate use of controlled medications.

In the United States, the Prescription Drug Monitoring Program (PDMP) exemplifies an integrated, clinically oriented electronic monitoring system. Each prescription for controlled substances is recorded and can be consulted in real time by physicians and pharmacists. Integrated databases such as the PDMP allow healthcare professionals to monitor prescribed medications, including dates, doses, and prescribers within a given territory, thereby facilitating the prevention of nonmedical use of high-risk drugs. The PDMP generates automated alerts for risk signals, including doctor shopping (multiple prescriptions obtained from different providers or facilities), high-risk drug combinations such as concurrent benzodiazepine and opioid use, and duplicate prescriptions or multiple dispensations across pharmacies (7). These systems function as integrated health information platforms, linking clinical data within a defined territory and enabling physicians to visualize, in real time, whether a medication was previously prescribed, when it was dispensed, and whether it was retrieved from a pharmacy, as well as other relevant events such as emergency department visits, hospitalizations, and outpatient consultations, as illustrated by provincial platforms such as ConnectingOntario, in Canada (8). U.S. states with active PDMPs have demonstrated significant reductions in duplicate prescribing, substance misuse, and hospitalizations related to adverse drug events (9). A U.S. study conducted across 24 states between 2001 and 2010 investigated the impact of PDMP implementation on opioid and analgesic prescribing. The program was associated with a reduction in the probability of opioid prescribing during pain-related visits from 5.5% to 3.7%, representing a decrease of over 30% in prescribing rates following implementation. This effect was particularly pronounced for higher-risk opioids and was observed immediately after the introduction of the system, remaining sustained over subsequent years. These

findings suggest a lasting change in prescribing behavior, with increased caution in the use of these substances (10).

Within this context, the present study aims to analyze the Brazilian model for controlling prescriptions of controlled medications in light of consolidated international experiences, describing its scope, limitations, and potential pathways for regulatory and clinical improvement.

Method

A comparative narrative review of international models was also performed. Case studies were selected based on four predefined criteria: (1) implementation of electronic prescribing or prescription monitoring systems for controlled or high-risk medications at a national or large subnational scale; (2) availability of official documentation and peer-reviewed literature describing system characteristics and/or outcomes; (3) relevance to the international debate on the safe use of controlled medications; and (4) diversity in health system organization and regulatory frameworks. Based on these criteria, the United States, Canada, and Australia were selected as examples of mature electronic monitoring models, while the United Kingdom was included as a reference case for advanced electronic prescribing infrastructure and regulatory governance of controlled medications. No middle-income country with a sufficiently documented and fully implemented model comparable to the Brazilian context was identified in the reviewed sources.

In the Brazilian context, the implementation of the National Prescription Control System was examined, with emphasis on changes relative to the previous paper-based model. Using a comparative framework—including electronic centralization of prescriptions, clinical access to dispensing histories, monitoring of prescribing patterns, and strategies to prevent potentially harmful use—the Brazilian model was assessed in terms of its scope, limitations, and potential pathways for regulatory and clinical improvement.

Results

The documentary analysis of Resolution No. 873/2024 identified relevant administrative advances in the regulation of controlled medication prescribing in Brazil, including nationwide validity of prescription notifications and the elimination of interstate bureaucratic requirements. However, from a clinical perspective, the

SNCR presents important limitations, as it does not provide prescribers with access to patients' dispensing histories nor enable the identification of multiple prescriptions or potentially inappropriate use patterns. In contrast, the comparative analysis of international electronic prescription monitoring models showed that systems such as the Prescription Drug Monitoring Programs implemented in the United States, Canada, Australia, and the United Kingdom incorporate real-time clinical access to dispensing histories, monitoring of prescribing patterns at both individual and professional levels, as well as audit and prescriber feedback mechanisms.

Discussion

Since July 1, 2025, the SNCR has made the issuance of prescription notifications mandatory. This change introduced clear administrative advances, including nationwide validity for digital prescriptions classified as B (blue form; psychotropic medications), B2 (blue form; anorectic agents), and Special Control prescriptions (white form), as well as the elimination of the requirement for justification or authorization for Prescription Notification A (yellow form; psychostimulants) in other states. These measures aim to facilitate patient access to treatment and to ensure the constitutional right to freedom of movement and continuity of care (9). Nevertheless, the analysis highlights important opportunities for system improvement. Prescribers do not have access to patients' dispensing histories—including previously issued prescriptions, dosages, quantities dispensed, or dispensing pharmacies—limiting the system's ability to detect multiple prescriptions or patterns of non-prescribed use, as observed in international models (7). As currently implemented, the SNCR remains primarily focused on document authentication and administrative control of prescription numbering, without incorporating clinical information that could support safer prescribing decisions at the point of care. Table 1 presents a comparative analysis of the main models for monitoring and prescribing controlled medications in Brazil, highlighting their key characteristics, scope, and limitations.

Table 1. Comparison between the previous (19) and current (20) models for monitoring and prescribing controlled medications in Brazil.

Dimension	**Previous Model (Paper-based)**	**Current Model (SNCR – RDC No. 873/2024)**	**Advances and opportunities for improvement**
Format and issuance	Printed prescription pads (blue and yellow) distributed locally.	Electronic PDF document with SNCR numbering.	Advance: improved document security and immediate nationwide validity.
Distribution and logistics	Printed prescription pads supplied by local health surveillance authorities.	Elimination of mandatory paper prescriptions; electronic numbering centralized by Anvisa.	Advance: reduced logistical costs and greater nationwide standardization.
Prescription numbering and scope	Local, decentralized numbering at the state/municipal level.	Single nationwide numbering (14-digit standard) managed by Anvisa via the SNCR.	Advance: immediate nationwide validity and assurance of the right to mobility and continuity of care.
Dispensing control	Manual process with mandatory physical retention of the prescription at the pharmacy.	Mandatory electronic recording of dispensing in the SNCR.	Advance: increased administrative traceability and centralized commercial oversight.
Reuse and fraud	Possible, particularly with lost or falsified paper prescriptions.	Electronic blocking of the code after the first dispensing at the pharmacy.	Advance: mitigation of fraud and improper reuse of the same document.
Physician access to patient prescription history	Not available.	Not available.	Gap: need for integration of clinical and care-related data.
Purpose of the system	Basic sanitary and document control, decentralized.	Sanitary surveillance, document traceability, and centralized commercial oversight.	**A**dvance: digitalization of workflows, nationwide standardization of numbering,

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			and mitigation of physical fraud. Gap: implementation of active clinical pharmacovigilance and integration of epidemiological data for public health monitoring.
Recording and archiving	Pharmacies retained and physically archived prescriptions.	Pharmacies perform electronic recording and digital archiving in the SNCR.	Advance: elimination of physical storage and improved traceability. Gap: implementation of automated alerts for clinical risks and drug–drug interactions.
Data access	Local health surveillance authorities.	Anvisa and health surveillance agencies (centralized control).	Advance: strengthened centralized regulatory oversight. Gap: interoperable access for physicians and pharmacists across states and private platforms.

Abbreviation: SNCR (National Prescription Control System).

The National Prescription Control System represents a relevant administrative advance; however, it still lacks strategies for active clinical pharmacovigilance and prescriber feedback. While Prescription Drug Monitoring Programs in the United States and Canada provide real-time clinical information, the Brazilian SNCR operates exclusively as a tool for sanitary surveillance and document traceability. In Brazil, physicians remain without access to essential data to support clinical decision-making, including prior prescriptions, and must rely almost exclusively on patient self-report, which introduces uncertainty and additional risks to clinical management and treatment planning. Technical fragmentation further exposes system shortcomings: pharmacies are required to manually adapt the 14-digit SNCR identifier for registration in the National System for the Management of Controlled Products, which retains outdated character limits. This limitation highlights that a higher level of regulatory effectiveness could be achieved through greater emphasis

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on clinical pharmacovigilance rather than solely on commercial or administrative oversight. International organizations recognize that addressing excessive prescribing of controlled substances requires more than formal prescription validation or administrative traceability. The World Health Organization (WHO) and the United Nations Office on Drugs and Crime (UNODC) advocate regulatory models grounded in the rational use of medicines, continuous monitoring of prescribing patterns, and a balanced approach between legitimate therapeutic access and the prevention of harms associated with misuse, particularly for psychotropic medications with dependence potential (11,12).

In this context, countries such as the United States, Canada, and Australia have incorporated electronic prescription monitoring programs as central instruments of public policy. In addition to these structural features, quantitative evidence supports the effectiveness of such interventions. According to WHO reports, electronic tools that provide clinicians with therapeutic guidance, such as drug interaction databases, renal dosing support, and medication review systems, are associated with reductions in patient harm, hospitalizations, and healthcare costs. Patients undergoing structured medication review experienced 16% fewer hospital visits and 47% fewer emergency department visits over one year, and the use of structured review processes reduced preventable adverse events within 30 days after hospital discharge (13). These systems go beyond document control by enabling physicians and pharmacists to access patients' dispensing histories in real time prior to prescribing or renewing controlled substances. In several U.S. jurisdictions, consultation of PDMPs is mandatory, particularly for opioids and benzodiazepines and has been associated with reductions in duplicate prescriptions, high-risk pharmacological combinations, and overdose-related adverse events (7). A study evaluating Prescription Drug Monitoring Programs demonstrated that their implementation was associated with significant annual reductions in benzodiazepine dispensing, estimated at 6.8% (95% CI, 1.6–11.8) among adolescents and 12.5% (95% CI, 9.3–15.5) among young adults (9). These findings reinforce that such systems are associated with measurable improvements in prescribing patterns and medication safety outcomes. Beyond patient-level monitoring, international recommendations emphasize surveillance of prescribing patterns at both population and prescriber levels. Periodic audits, identification of prescribers with atypical patterns ("outliers"), and peer-based comparative feedback within the same specialty

have been described as effective mechanisms to regulate prescribing behavior, fostering data-driven professional self-regulation (14). Supporting this approach, a cluster randomized controlled trial conducted in Malaysia evaluated the impact of prescription review combined with prescriber feedback in primary care settings. A total of 32,200 prescriptions were analyzed, with an initial error rate of 48%, including issues such as incomplete patient or prescriber information, incorrect dosing, inappropriate frequency, polypharmacy, and contraindications. The intervention group, which received structured prescription review, classification tools, and individualized feedback letters, showed a sustained reduction in prescribing errors over an eight-month period, decreasing from 40.7% to 28.4% (14). These findings suggest that non-punitive, confidential, and educational feedback mechanisms can be effective in improving prescribing practices and reducing medication errors.

Accountability for excessive prescribing, when warranted, is described in international experience as proportional and tiered. Initial measures typically include technical guidance and mandatory additional training; in persistent or higher-risk situations, temporary restrictions on prescribing specific substances, mandatory clinical supervision, or administrative sanctions may be implemented. For medications considered to pose very high risk, some countries adopt regulatory strategies such as supervised dispensing or strict limits on dispensed quantities to reduce diversion and patient harm without compromising legitimate therapeutic access (15). For example, in international programs for the treatment of opioid use disorder, medications such as methadone and buprenorphine are often administered under direct supervision during the initial treatment phases to enhance clinical safety and minimize misuse or diversion. As patients demonstrate clinical stability, take-home doses may be gradually authorized based on individualized risk–benefit assessments (10).

In the United Kingdom, guidelines from the National Institute for Health and Care Excellence (NICE) reinforce this approach by establishing clear time limits for the use of benzodiazepines and hypnotics, requiring periodic reassessment of clinical indication, monitoring for dependence, and systematic documentation of risks and benefits (16). Similarly, Canadian guidelines recommend structured risk assessment, therapeutic agreements, and clinical audit in cases of long-term use or high doses, supported by integrated provincial databases that enable continuous surveillance of prescribing (17). These approaches reflect the principle enshrined in

the United Nations International Drug Control Conventions, according to which states must maintain a careful balance between control and access (12). Regulation focused primarily on administrative oversight may produce unintended consequences, such as undertreatment of legitimate clinical conditions, whereas the absence of clinical monitoring facilitates misuse and dependence (13). In this sense, the most effective public policies are not those that rely predominantly on punitive measures, but those that leverage technology, clinical data, and professional governance to inform real-time medical decision-making.

The implementation of clinically oriented prescription monitoring systems, as proposed in this study, involves important legal and technical challenges in the Brazilian context. Health data are classified as sensitive personal data under the Brazilian General Data Protection Law (LGPD; Law No. 13,709/2018), requiring appropriate legal bases for processing and compliance with principles such as purpose limitation, necessity, and security. In this context, it is necessary to distinguish between identifiable clinical data and anonymized or aggregated data used for public health surveillance, as access to individualized information requires robust governance structures, access control mechanisms, and accountability measures. The definition of user profiles, traceability of access, and accountability for data use are essential elements to ensure compliance with legal and ethical requirements. In addition, significant technical barriers related to interoperability remain. The Brazilian health information system is characterized by fragmentation and limited integration between public and private platforms, which hinders the implementation of unified, real-time access to prescription data. Overcoming these challenges requires the adoption of common data standards, improved system integration, and coordinated efforts among institutional stakeholders. Therefore, the implementation of more integrated models should be understood as a gradual process, dependent on regulatory, technological, and data governance advancements (18).

Despite the regulatory and technological advances associated with the digitalization of prescriptions for specially controlled psychotropic medications, the Brazilian model still presents important opportunities for further development, particularly with regard to expanding physicians’ access to patients’ prescription histories, which could strengthen clinical monitoring of psychotropic use. In this

context, Table 2 presents proposals to enhance the control of psychotropic medications in Brazil, drawing on international experiences.

Table 2. Proposals for improving the monitoring of controlled medications in Brazil based on international models.

Proposal	Description	International models
Integration of clinical prescription history into the SNCR.	Enable physicians to access patients' histories of controlled substance prescriptions prior to issuing a new prescription, regardless of whether prescriptions originate from public or private healthcare settings.	In Australia, the National Real-Time Prescription Monitoring system tracks controlled medication prescribing in real time and provides access to both physicians and pharmacists (10).
Prescription monitoring aimed at active clinical pharmacovigilance.	Provide prescribers and pharmacists with access to a clinical interface of the SNCR to assess patterns of controlled medication use.	In the United States, PDMPs allow authorized users to monitor controlled substance use, supporting informed clinical decision-making (16).
Regular epidemiological reports for public health managers and researchers.	Develop periodic reports based on psychotropic prescription data, highlighting usage patterns, regions with higher consumption, and trends in potential misuse.	In the United States and Canada, PDMP databases are already used by health authorities to conduct analyses of population-level prescribing trends (16).
Automated risk alerts.	Implement real-time alerts for high-risk prescribing patterns, including potential drug–drug interactions and indicators of doctor shopping.	PDMP systems have been enhanced to reduce inappropriate prescribing through the use of automated alerts (16).
Interoperable access across states and private platforms.	Promote system interoperability with state-level systems and private electronic prescribing platforms while maintaining a unified national standard.	Several PDMPs already operate on an interstate basis, ensuring comprehensive data coverage for patients who move across jurisdictions (6).

Abbreviation: SNCR (Sistema Nacional de Controle de Receituários); PDMP (Prescription Drug Monitoring Programs).

This study has several limitations. First, there is a potential selection bias in the choice of countries analyzed, as systems with greater data availability and

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relevance to the Brazilian context were prioritized, which may limit the generalizability of the findings. In addition, there may be a data availability bias, as countries with greater scientific production and institutional transparency tend to be more represented in the literature. The study is predominantly based on documentary analysis and data derived from guidelines, institutional reports, and scientific publications, which limits causal inference and the quantification of effects. Furthermore, reliance on normative documents may not fully reflect the real-world implementation of the analyzed systems. The heterogeneity among the evaluated models, particularly regarding regulatory, structural, and technological aspects, also limits direct comparability. Additionally, as discussed above, the practical feasibility of the proposed model represents an important limitation. Legal and technical constraints may hinder the implementation of more integrated prescription monitoring systems, particularly regarding access to patient-level data and real-time information. These challenges are compounded by interoperability issues, given the fragmentation of health information systems in Brazil and the limited integration between public and private platforms, which increases the complexity of operationalizing such systems. Finally, as this is a brief communication with an exploratory approach, the primary aim is to generate hypotheses and contribute to the debate rather than to establish definitive conclusions.

Conclusion

Brazilian public policies have made significant advances; nonetheless, international experience demonstrates that electronic monitoring systems with real-time clinical access, interoperability, and structured prescriber feedback are essential to balance legitimate therapeutic access with harm prevention. In this context, strengthening the Brazilian National Prescription Control System (SNCR) requires a shift from a predominantly administrative and enforcement-oriented model toward an integrated strategy of clinical pharmacovigilance, focused on patient safety and the rational use of psychotropic medications.

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Disclosure of Interests

The authors declare no conflicts of interest.

Author Contributions

A.G.R conducted the investigation, conceptualization, methodology, formal analysis, and manuscript preparation. R.P.P contributed to investigation, conceptualization, methodology, and manuscript preparation. I.N.L.A contributed to investigation, conceptualization, methodology, and manuscript preparation. V.T contributed to investigation, conceptualization, methodology, and manuscript preparation. F.H.P.K contributed to formal analysis and supervision. All authors approved the final manuscript.

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