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REVIEW

Control and inspection of prescription drugs, narcotic drugs, psychotropic substances and others with similar effects

Control y fiscalización de drogas de prescripción, estupefacientes, sustancias psicotrópicas y otras de efectos semejantes

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ABSTRACT

Introduction: the appropriate use of medications has emerged as a crucial public health issue, given that misuse can have serious repercussions on people's health and finances. This phenomenon requires a multidisciplinary approach involving sectors such as education, economics, and social communication, due to associated risk factors such as work-related stress and anxiety.
Objective: to describe the control and oversight of prescription drugs, narcotics, psychotropic substances, and other substances with similar effects.
Development: the paper highlights the need for a solid legal framework and ongoing training for health professionals in best practices. Collaboration between government agencies, health institutions, and community organizations is essential to address the problem of substance abuse. Furthermore, the paper emphasizes the importance of evidence-based protocols and guidelines to guide prescribers in making appropriate decisions.
Conclusions: despite efforts, significant challenges persist in the regulation and oversight of medications. It is essential to promote education and ethics in prescribing, as well as to establish pharmacy and therapeutics committees to improve the quality of health care. The availability of reliable information is key to ensuring safe and effective use of medications.

Keywords: Control; Supervision; Medications.

RESUMEN

Introducción: el uso adecuado de medicamentos ha emergido como un tema crucial en salud pública, dado que el uso indebido puede tener graves repercusiones en la salud y economía de las personas. Este fenómeno requiere un enfoque multidisciplinario que involucre sectores como educación, economía y comunicación social, debido a los factores de riesgo asociados, como el estrés laboral y la ansiedad.
Objetivo: describir el control y fiscalización de drogas de prescripción, estupefacientes, sustancias psicotrópicas y otras de efectos semejantes.
Desarrollo: se destaca la necesidad de un marco legal sólido y la capacitación continua de los profesionales de la salud en mejores prácticas. La colaboración entre organismos gubernamentales, instituciones de salud y organizaciones comunitarias es esencial para abordar el problema del abuso de sustancias. Además, se enfatiza la importancia de protocolos y pautas basadas en evidencia para guiar a los prescriptores en la toma de decisiones adecuadas.

Conclusiones: a pesar de los esfuerzos realizados, persisten desafíos significativos en la regulación y fiscalización de medicamentos. Es fundamental promover la educación y la ética en la prescripción, así como establecer comités de farmacia y terapéutica para mejorar la calidad de atención en salud. La disponibilidad de información confiable es clave para garantizar un uso seguro y efectivo de los medicamentos.

Palabras clave: Control; Fiscalización; Medicamentos.

INTRODUCTION

In recent years, the correct use of medication has become one of the most debated and, at the same time, interesting issues in the health field, becoming a relevant aspect of public health.[1]

Medication misuse has significant repercussions for individuals and society, with consequences for health and the economy. Its complexity requires implementing strategies that transcend the health sector and involve many other sectors, such as education, the economy, industry, commerce, community, and social communication.[1]

The risk factors related to drug abuse include work-related stress, depression, anxiety, and easy access to these drugs, especially propofol, which does not require a unique prescription. Cases of drug abuse have serious consequences for both the individual and the patients in their care.[2]

According to a study carried out by Serebrenic et al.[2], the majority of cases of abuse of narcotics, psychotropics, and intravenous anesthetics begin during residency, and the mortality rate in these cases can reach 37 %.

In practice, the term narcotic applies to pharmaceutical specialties that contain active ingredients that act on and modify the central nervous system and to magisterial formulas with the same active ingredients. Narcotics require an official prescription for their prescription and dispensation; they must also be accounted for in the official narcotics ledger. Some narcotics only require prescription and dispensation on an official narcotics prescription when they exceed the dosages or do not comply with the stated combination conditions, in which case they are also recorded in the official ledger for these drugs.[3]

During the negotiations of the Convention on Psychotropic Substances of 1971, the pressure exerted by the large pharmaceutical industry in Europe and the United States became evident, as they feared that their products would be subjected to the rigorous controls of the Single Convention. The need for a new treaty was based on a highly questionable distinction between narcotics or narcotic drugs controlled by the 1961 Convention and so-called psychotropic substances. Compared to the strict controls established by the schedules of the Single Convention on drugs derived from plants, the 1971 treaty imposed a less rigid control structure for the prescription of these drugs.[3]

In Cuba, Resolution 335, dated October 17, 2005, of the Minister of Public Health, approved the list of substances considered to have a similar effect to drugs, narcotics, and psychotropics subject to national control, and Instruction 6, dated July 1, 2011, of the Vice-Minister for Medical and Social Assistance of the organization, established the procedure for the prescription and control of these substances, which must be annulled to incorporate new drugs into the list that produce effects similar to the drugs themselves or in combination with others, and to establish new regulations for the prescription and control of the dispensation of these substances in community and hospital pharmacies as appropriate.[4]

On March 24, 2022, in the extraordinary Official Gazette No. 22 of the Republic of Cuba, a new protocol was issued for the prescription and dispensing of drugs with drug-like effects, which establishes that" substances with a similar effect to drugs are considered to be those of natural or synthetic origin that have a pharmacological activity on the individual's central nervous system, similar to the impact caused by narcotic and psychotropic substances, and can be subject to misuse, and are therefore subject to national control.[4]

The importance of the subject and the lack of information available in the national and international literature on the subject were the main motivations for carrying out this research, which aimed to describe the control and regulation of prescription drugs, narcotics, psychotropic substances, and others with similar effects.

DEVELOPMENT

National laws and regulations in Cuba governing the prescription and control of narcotics and psychotropic substances are aligned with international guidelines established by the World Health Organization (WHO) and the International Narcotics Control Board. These guidelines seek to ensure the availability of opioids for medical and scientific treatment at the same time.[5]

In Cuba, the Medicines Act and other legal provisions strictly regulate the prescription of narcotics and psychotropic drugs. Doctors must follow specific procedures for prescribing, including the use of special prescriptions and limitations on the quantity and duration of treatment. These regulations are designed to

prevent abuse and ensure that medicines are used safely and effectively.[5]

The legal framework was established at the international level by the Single Convention on Narcotic Drugs of 1961 and the Convention on Psychotropic Substances of 1971, both overseen by the INCB. These conventions require countries to implement control systems for the production, distribution, and use of narcotics and psychotropic substances, ensuring that they are available to doctors and scientists but not to the general public.[5]

The WHO also provides guidelines on the appropriate use of opioids for pain management, especially in the context of cancer. These guidelines emphasize the need to balance adequate access to pain medications with control measures to prevent abuse.[5]

In Cuba, the availability of opioids for pain management has historically been limited, in part due to strict regulations and a lack of resources. However, efforts have been made to improve access to these essential medicines, following WHO recommendations.[6]

Regulatory barriers, such as the need for special prescriptions and restrictions on the quantity of medicines that can be prescribed, are common in many countries in the Americas. These barriers can make it difficult for patients who need opioids to access them.[6]

Doctors in Cuba must be well informed about the regulations and follow the proper procedures for prescribing these medications. This includes using official prescriptions, complying with quantity and duration restrictions, and properly documenting the prescription.

In addition, education and ongoing training of healthcare professionals are essential to improve pain management and safe use. This includes understanding the principles of the WHO and the INCB on the availability and control of these drugs.[5]

The research team considers that laws and regulations in Cuba and internationally are designed to ensure that narcotics and psychotropics are available to doctors and scientists, and the effective implementation of these regulations will require the cooperation of health professionals, regulatory authorities, and international organizations.

Regulations on the control of narcotic and psychotropic substances vary significantly between different countries, reflecting cultural and political differences. In East and Southeast Asia, countries such as Japan, China, Singapore, South Korea, Malaysia, and Taiwan have adopted a combination of legislative mechanisms to control new psychoactive substances (NPS), including the specific listing of individual substances, generic control of a family of substances and control of analogs of similar substances. Japan is particularly proactive in regulating NPS, with 41 %.[7,8]

Portugal and the UK have specific legal responses to NPS and focus on harm reduction strategies, while Sweden pursues a drug-free society objective without particular regulation. The lack of harmonization in national drug policies in the EU reflects cultural values and national political interests, with a predominant focus on law enforcement and strategies.[9]

In Switzerland, some federal requirements, such as reporting the off-label use of controlled drugs, have fallen into disuse, and paper prescriptions are not actively used to monitor the market. In addition, the conditions for authorizing treatment with opioid agonists differ between cantons, with some requiring additional training for doctors.[11]

In the international context, UN drug control treaties, such as the 1971 Convention on Psychotropic Substances, prohibit the non-medical use of amphetamines, cannabis, cocaine, and heroin. However, the legalization of cannabis use in Uruguay, eight US states, and Canada has called into question the future of these treaties. It is argued that the legalization of cannabis could promote intensive use and increase harm from a weakly regulated industry.[12]

In the Czech Republic, a new legislative framework has been introduced for the control of psychomodulatory substances, which are psychoactive substances with low risk to health and society. This innovative approach suggests strict rules for commercialization, security, and prevention of sales to minors to eliminate illicit markets, protect vulnerable populations, and promote controlled use.[13]

Regulations on narcotic and psychotropic substances vary widely between countries and are influenced by cultural, political, and legal factors. International collaboration and implementing adaptive legislative approaches are essential to address the challenges of NPS and other controlled substances effectively.

The classification of prescription drugs, narcotics, and psychotropic substances worldwide is based on international conventions and national regulations. Globally, classification is governed primarily by three United Nations treaties: the 1961 Single Convention on Narcotic Drugs, the 1971 Convention on Psychotropic Substances, and the Convention against Illicit Traffic in Narcotic Drugs. These treaties established a system of “lists” or “schedules” that classify substances according to their potential for abuse, risk to health, and therapeutic value.[13]

In the context of the United States, the Controlled Substances Act (CSA) classifies substances into five categories (Schedules IV) based on their potential for abuse and accepted medical use. For example, substances

such as heroin and LSD are in Schedule I due to their high potential for abuse and lack of accepted medical use, while medications such as diazepam are in Schedule IV due to their lower potential for abuse.[14]

In Cuba, regulating these substances follows a similar scheme influenced by the conventions. The Cuban Ministry of Public Health is the entity responsible for regulation and control. Substances are classified and controlled according to their potential for abuse and therapeutic use, following international guidelines and local adaptations to ensure adequate access to essential medicines while preventing abuse.[6]

Both globally and in Cuba, the classification of prescription drugs, narcotics, and psychotropic substances is based on international treaties and national regulations that consider the potential for abuse, the risk to health, and the value. This is why healthcare professionals play a crucial role in regulating these drugs. Their responsibility includes appropriately and safely prescribing these drugs, educating patients about the risks and benefits, and complying with laws and regulations.

First, doctors must follow the prescribing guidelines established by entities such as the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA).[15]

In addition, healthcare professionals should use prescription drug monitoring programs (PDMPs) to track the dispensing of controlled substances and detect risk patterns. These programs allow prescribers to verify a patient's previous prescriptions and make informed decisions.[16]

Continuing education is another essential component. Clinicians should participate in pain management and addiction education programs to stay current on best practices.[17]

Finally, healthcare professionals should collaborate with pharmacists and other entities to ensure a comprehensive approach to prescription management. Pharmacists, for example, act as an additional check in the prescription chain, helping to identify and prevent opioid misuse.[18]

The research team believes that healthcare professionals should regulate the use of narcotic and psychotropic substances through adherence to prevent further harm to patients in need.

Technological innovations also have a significant influence on the regulation of narcotics and psychotropic drugs. The assessment of the abuse potential of psychedelic drugs, such as psilocybin, LSD, and MDMA, is an example of how technology impacts regulation. In countries around the world, the Controlled Substances Act (CSA) and the Food and Drug Administration (FDA) require potential abuse studies to reprogram these substances, which involves using advanced technologies to assess their effects.[14]

In Europe, the response to new psychoactive substances (NPS) has been facilitated by early warning systems and risk assessments, which use monitoring and data analysis technologies to detect and respond quickly to threats to public health.[19]

The European Medicines Agency (EMA) and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) have implemented innovative measures to control these substances, including the use of digital surveillance tools.

In addition, the pharmaceutical industry has developed drug delivery technologies with abuse-deterrent properties, such as physical and chemical barriers, antagonists, and aversive agents.] These technologies seek to minimize the abuse of opioids and other narcotics, optimizing the safety and efficacy of the drugs.[20]

Therefore, in the team's view, technological innovations, from abuse potential studies to early warning systems and drug delivery technologies, play a crucial role in the regulation of narcotics and psychotropic drugs, improving the capacity of regulators. That is why strategies must be devised to achieve optimal prescribing.

The WHO recommends developing pharmacotherapy courses based on specific topics in the curricula of medical schools and other health sciences, as these topics can significantly affect the quality of prescriptions.[21]

Prescribers have a moral obligation to guarantee the best quality of healthcare, so it is essential to emphasize the transmission of technical knowledge and ethical and social values implemented in an efficient, timely, responsible, and human way.[21]

The availability of reliable information makes it possible to make the right decision. Prescribing should be based on scientific details acquired through developing skills that determine valid, objective, independent, and up-to-date information.[21]

Organizations such as universities, international organizations, NGOs, and health organizations that provide scientific and technical information should facilitate access to such information—the promotion of appropriate advertising and medicines by the pharmaceutical industry. Recognizing the benefits that the pharmaceutical industry brings to humanity, prescribers should be encouraged to take a critical and responsible attitude towards advertising strategies and the promotion of various medicines and to make everyday use of the Guidelines and Schemes issued by the General Directorate of Medicines, Supplies, and Drugs of the Ministry of Health.[21]

The protocols include procedures and guidelines developed systematically to help prescribers decide the most appropriate treatment for specific medical conditions. Evidence-based treatment guidelines are essential to encourage the rational use of medicines. The prescriber's participation is sought for implementation and updating, which helps to guarantee the prescriber's credibility and acceptance. Establishing dissemination,

adoption, evaluation, and feedback strategies is also necessary.[21]

Promoting the formation and functioning of pharmacy and therapeutics committees in healthcare organizations and care networks. The Pharmacy and Therapeutics Committees are technical bodies with advisory and executive functions, adopting different configurations within the public healthcare network. This strategy can be replicated in private healthcare organizations. Disseminate the legal provisions on the prescription of medicines.[21]

The medical team must cooperate with health regulators to comply with the laws and regulations relevant to their profession and through scientific or professional bodies in the public and private sectors. It provides a comprehensive understanding of the prescribing practice, its powers, and limitations, and its primary purpose is to achieve the best and most effective therapy with the best cost-benefit ratio.[21]

Certain practices in the prescription of medicines should be avoided, such as not using the drug in unsolicited medical circumstances, not dispensing with non-pharmacological measures if appropriate, avoiding the use of pharmaceutical products with unclear efficiency and/or safety or their unjustified linking, as well as avoiding the incorrect selection of drug(s) for the diagnosed condition of the patients.[22]

Other practices that should be avoided are over-prescribing or over-the-counter prescribing of "polypharmacy" when the dose, route of administration, and/or time of treatment are not available. It is also a mistake to ignore the notable particularities of patients or the cultural barrier to modifying therapies and to omit the adequate or complete explanation of aspects of the prescription to the patient. Likewise, it is a mistake to prescribe expensive drugs when there are less costly, equally effective, and safe alternatives and to believe that generic drugs are inferior to brand-name drugs.[22]

Poor control of drug therapy can hinder early detection of treatment failure and/or adverse drug reactions, as can writing prescriptions and giving instructions to the patient in handwriting that is difficult to read. Inadequate medical practices also include poorly documented instructions to patients and unclear and imprecise details of dosage and non-pharmacological measures.[22]

CONCLUSIONS

The regulation and control of prescription drugs, narcotics, and psychotropic substances is a complex challenge that requires a comprehensive and multidisciplinary approach. A sound legal framework is essential to prevent abuse and ensure the safe use of these substances. This implies continuously training health professionals in best practices and legal guidelines. Collaboration between government agencies, health institutions, and community organizations is essential to address the problem of substance abuse effectively. Despite the efforts, significant challenges persist, such as the lack of resources and variability in applying laws, which hurt public health.

Technological innovation can offer practical solutions, such as monitoring systems and shared databases, which facilitate the identification of abuse patterns. Furthermore, fostering a culture of responsibility among prescribers and patients and promoting therapeutic alternatives whenever possible is crucial. Continuous research into the use and effects of these substances will inform effective policies and evidence-based clinical practices.

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