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Analyzing the State of Drug Safety Oversight in Guyana: A Literature-Based Evaluation

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A B S T R A C T

Developing countries like Guyana face unique challenges in ensuring drug supply safety due to limited resources, weak regulatory systems, and inadequate surveillance infrastructure. This paper presents a literature-based evaluation of drug safety oversight in Guyana. The evaluation identifies significant gaps and challenges within Guyana's regulatory agencies, including resource constraints, insufficient surveillance infrastructure, and enforcement weaknesses. Limited specific literature on Guyana highlights the need for empirical studies to assess the effectiveness of its drug regulatory systems.

Through a systematic literature review, this study identifies key areas for improving drug safety oversight, emphasizing enhanced resource allocation, capacity-building initiatives, and robust regulatory frameworks. These findings emphasize the importance of strengthening regulatory systems in developing countries to ensure public health and access to safe pharmaceuticals.

This evaluation offers insights for policymakers, healthcare professionals, and stakeholders involved in public health governance, facilitating evidence-based strategies to enhance drug safety oversight and regulatory effectiveness in Guyana.

Keywords: Drug Regulatory Systems, Drug Safety, Regulatory Effectiveness ,Guyana

1. Introduction

A drug regulatory framework, as elucidated by Oberweis (2020) and Mulinari (2016), is a comprehensive system of laws, regulations, policies, and procedures established by government agencies, and organizations to oversee the development, manufacturing, distribution, marketing, and use of pharmaceutical products. The importance of drug regulation in safeguarding public health is universally acknowledged, leading to the establishment of regulatory systems in numerous countries (Glover et al., 2018). Rägo (2014) in his study emphasizes the role of national medicines regulatory authorities in protecting patients from harm and

Promoting access to high-quality medicines. Mwangi (2016) further underscores the crucial role of national medicines regulatory authorities in ensuring access to high-quality medicines. While these systems play a pivotal role in ensuring the safety, efficacy, and quality of pharmaceuticals, a substantial gap exists, particularly in developing countries. The challenges faced by these nations in implementing effective regulatory frameworks are multifaceted (Fujita et al., 2019).Limited financial resources, inadequate infrastructure, and weak enforcement mechanisms collectively pose significant barriers to the establishment and operation of robust regulatory systems. Developing countries often struggle with resource allocation, leaving regulatory initiatives underfunded and understaffed (Ndomondo-Sigonda, 2017). Insufficient infrastructure further complicates the situation, hindering the capacity to conduct thorough inspections, monitor supply chains, and ensure adherence to regulatory standards (Mujinja 2022). The weakness in enforcement mechanisms compromises the ability to enforce compliance, leading to potential risks associated with substandard or counterfeit drugs entering the market.(Kelesidis & Falagas 2015).

In the case of Guyana, there is limited literature available on the effectiveness of the country's drug regulatory systems. However, some studies have highlighted the challenges faced by regulatory agencies in this country. For example, a study by Phillips et al.(2020) found that regulatory agencies in Guyana faced significant challenges related to inadequate resources, lack of trained personnel, and limited laboratory capacity for testing and analysis. Seoane-Vazquez (2008) identified several barriers to drug access in the country, including the lack of a national drug policy and regulation, inefficient drug selection, and inadequate infrastructure and human resources. Woo-Ming (1993) however, highlighted the strength of Guyana's drug regulatory and review process, particularly in terms of legislative control and product evaluation. Zhang (2022) emphasized the need for a comprehensive and functional drug and therapeutic audit, while (Meena, 2019) called for stronger research designs to evaluate the impact of national drug policies on drug use.Other studies have examined the regulatory frameworks for drug safety in developing countries more broadly. For instance, a study by van der Meeren et al. (2018) analyzed the regulatory frameworks for medical products in 16 low- and middle-income countries and found significant variation in regulatory capacity and enforcement mechanisms. Several studies have also highlighted the importance of building effective regulatory systems in developing

countries to protect public health. For example, a study by Wilson and Sewankambo (2015) emphasized the need for developing countries to invest in regulatory capacity-building and highlighted the role of international organizations in supporting these efforts.

While there are reports and studies describing the Guyanese drug regulatory system, robust empirical studies evaluating its effectiveness are scarce. The research gap in this domain revolves around identifying pragmatic solutions to address these challenges, offering insights into resource allocation strategies, innovative regulatory approaches, and capacity-building initiatives tailored to the unique circumstances of developing countries. Bridging this gap is paramount for fostering a pharmaceutical landscape that is not only effective but also equitable, ensuring that everyone in this country, regardless of economic standing, has access to safe and efficacious medicines.

1.1 Assessing the Effectiveness of Drug Regulatory Systems: Mechanisms and Evaluation Strategies

The effectiveness of Drug Regulatory Systems (DRS) in developing countries can be evaluated through a variety of methods. Goedecke (2018) emphasizes the need for sound methodology, including agency-wide performance reporting, impact measurement, and sustainability analysis. Mishra & Kumar, (2021) proposes assessing the structure and function of the DRS, which entails reviewing regulatory laws and policies, evaluating the capacity of regulatory agencies, and scrutinizing the quality of regulatory processes. Another avenue for evaluation according to Kari (2018) entails measuring the impact of DRS on drug availability and affordability. Debaveye (2016) on the other hand proposes a structured, quantitative health outcomes approach to drug risk-benefit analysis, which could be applied to assess the effectiveness of DRS in ensuring the safety and efficacy of medicines. Song (2017) on the other hand, proposes the use of drug-use indicators to assess prescribing behavior and drug-use practices.

Post-marketing surveillance is also crucial for evaluating drug safety and efficacy, with a focus on adverse drug reactions (ADRs) and the therapeutic efficacy of medications (Shubnikova, 2019). This is particularly important given the limitations of pre-marketing clinical trials in detecting rare ADRs and long-term effects (Lavan, 2016). These studies have all collectively underscored the need for a comprehensive approach to evaluating the effectiveness of drug regulatory systems in developing countries.

The challenges of evaluating drug regulatory systems (DRS) in developing countries are also multifaceted. Bennett (2015) highlights the difficulties in conducting systematic reviews due to limited access to literature, human resources, and research funding. Lin (2016) and Song (2017) both emphasize the need for targeted public health interventions and the use of objective assessment methods to address these challenges. However, the lack of comprehensive data remains a significant barrier to evaluating the impact of DRS interventions. Despite these formidable challenges, a range of methods can be used to evaluate the effectiveness of Drug Regulatory Systems (DRS) in developing countries. By tracking indicators such as medicine accessibility and affordability, the efficacy of regulatory interventions in ensuring the availability of safe and affordable medicines can be assessed.

Recent evaluations of Drug Regulatory Systems (DRS) in developing countries have highlighted their effectiveness in combating counterfeit and substandard drugs (WHO,2022). Strengthening DRS has been shown to improve the availability of essential medicines and enhance public health outcomes (PAHO,2023). To further strengthen DRS, it is important to consider the role of consumer reporting in monitoring adverse drug reactions (Weigmann, 2016) and to implement systems-level interventions such as drug registrations, quality surveillance, and product authentication technologies (Fadlallah, 2016).

1.2 Understanding the Drug Regulatory Framework in Guyana: A Comprehensive Overview

The regulatory framework for drug safety in Guyana is a multifaceted system that involves a diverse array of stakeholders, each playing a crucial role in ensuring the safety, efficacy, and quality of the pharmaceuticals available to the public. At the core of this framework is the Government Analyst Food and Drug Department (GA-FDD) operating under the Ministry of Health, which oversees the registration, inspection, testing, and pharmacovigilance of pharmaceuticals and medical devices (Woo-Ming, 1993). The GA-FDD serves as the primary regulatory authority responsible for enforcing drug safety regulations and overseeing various aspects of the pharmaceutical industry. All of the regulatory activities performed by the Government Analyst Food and Drug Department are governed by the Food and Drugs Act enacted in 1971 and supporting regulations of 1977.

The transition from the "Sale of Food and Drugs' Ordinance to the Food and Drugs Act in 1971 marked a significant shift in Guyana's pharmaceutical industry, granting the Minister of Health extensive authority to regulate various aspects of drug control (Woo-Ming 1993). The Food and Drugs Act of 1971 introduced centralized control over raw materials and finished drug products (Woo-Ming, 1993). It also prioritized the procurement of safe, high-quality, and effective drugs and medical devices, aligned with international standards and best practices (Woo-Ming, 1993). However, Guyana's pharmaceutical sector still faces challenges in drug access and control, including a lack of national drug policies and regulations, inefficient drug selection, limited financial resources and irrational drug use (Seoane-Vazquez, 2008).

The mechanisms utilized by the Government Analyst Food and Drug Department (GA-FDD) to ensure drug safety in Guyana includes registration, import/export control, quality control, and pharmacovigilance, each of which plays a vital role in safeguarding public health (Walker et al,2023).

According to Fadlallah (2016) registration ensures that drugs meet stringent quality and safety standards before entering the market, whereas import/export control regulates the movement of pharmaceuticals across borders to prevent the influx of counterfeit and substandard products. These quality control standards enforced through inspections and stringent protocols maintain the integrity of pharmaceutical products throughout the supply chain (Gyasi et al., 2015).

1.3 Key stakeholders involved in drug regulation in Guyana

In addition to government agencies such as the GA-FDD, Guyana's drug regulatory framework encompasses non-governmental organizations (NGOs), healthcare professionals, pharmaceutical companies, and consumer groups. NGOs play a vital role in advocating for public health and promoting access to safe and affordable medicines in Guyana (Urias, 2017). These organizations often collaborate with government agencies and other stakeholders to raise awareness about drug safety issues, provide education and support to vulnerable populations, and advocate policy reforms to improve regulatory frameworks.

Healthcare professionals, including doctors, pharmacists, nurses, and allied healthcare workers, are crucial in Guyana's drug regulatory framework (Hamid et al. 2022). They play a key role in prescribing, dispensing, and administering pharmaceuticals to patients, as well as in monitoring and reporting adverse drug reactions (ADRs) (Chavan, 2023). Pharmacists, in particular, play a significant role in ADR reporting, with hospital pharmacists being especially important because of the high occurrence of serious ADRs in hospitals (Chavan, 2023). The involvement of healthcare professionals in pharmacovigilance is essential to evaluate the benefits and risks of drug use (Hamid et al. 2022). Clinical pharmacologists also play a crucial role in monitoring medicine use, including identifying and responding to safety issues, determining causation, and conducting post-marketing surveillance (Van-Hunsel, 2019).

The safety and effectiveness in the use of drugs in the future will depend on the liaison and rapport of industry physicians, government officials and the university hospital teacher-clinical investigators in designing the most critical studies of the safety and effectiveness of new drugs

Pharmaceutical companies operating in Guyana are responsible for manufacturing, importing, and distributing products. These companies must comply with regulatory requirements set forth by government agencies, such as the GA-FDD, ensuring that their products meet stringent quality, safety, and efficacy standards before they are made available to the public (Woo-Ming, 1993).

Woo-Ming (1993) highlights the stringent regulatory requirements for pharmaceutical companies in Guyana, emphasizing the need for compliance with quality, safety, and efficacy standards. Similar to the Guyana setting, Seoane-Vazquez (2008) also identified barriers to drug access in neighboring countries, including the lack of a national drug policy and regulation, inefficient drug selection, and inadequate infrastructure. Both Nematollahi (2018) and Moktadir (2018) underscore the responsibility of the pharmaceutical industry to ensure the quality and safety of drugs, as well as to facilitate patient access to essential medicines. These studies collectively underscore the importance of regulatory compliance and industry responsibility in Guyana’s pharmaceutical sector.

Consumer groups, such as health consumer groups, play a crucial role in advocating patient and consumer rights in healthcare and drug safety (Weil, 2019).Consumer groups represent the interests of patients and consumers, advocating for their rights and ensuring that their voices are heard in matters related to drug safety and access to healthcare (Weil, 2019). These groups often collaborate with government agencies, NGOs, and other stakeholders to raise awareness about drug safety issues, provide support and resources to affected individuals, and advocate for policy reforms to protect consumer rights. However, concerns have been raised about the potential influence of the pharmaceutical industry on these groups, with a need for greater transparency and management of conflicts of interest (McCoy, 2017). Despite these challenges, consumer groups continue to be important stakeholders in the policy process, shaping services and advocating for policy reforms (Kuehn, 2018). Seoane-Vazquez (2008) highlighted the challenges in Guyana's pharmaceutical sector, including those related to NGOs, which play a crucial role in advocating public health and promoting access to safe and affordable medicines (Urias, 2017). Yanacopulos (2017) emphasized the importance of NGOs in addressing health needs and advocating for policy changes. In Trinidad and Tobago, Abiddin (2022) underscored the role of NGOs in health activities, including educating the population, identifying needs, and mobilizing resources. These studies collectively underscore the vital role of NGOs in addressing challenges in Guyana's drug regulatory framework.

Through collaboration and coordination among these diverse stakeholders, Guyana's drug regulatory framework is responsible for addressing challenges, enhancing transparency and accountability, and ultimately improving public health outcomes through the provision of safe, effective, and high-quality pharmaceuticals to the population (Seoane-Vazquez,2008) . However, despite the presence of these stakeholders, significant challenges such as outdated legislation and limited resources persist, highlighting the need for ongoing efforts to strengthen the regulatory framework and safeguard public health (Woo-Ming, 1993).

Recent initiatives, such as joining the Caribbean Regulatory System (CRS) and adopting the PAHO's recommended Emergency Use Authorization (EUA) procedure during the COVID-19 pandemic, has contributed to the strengthening of the drug regulatory framework (PAHO, 2022) in Guyana. These steps signify a proactive approach towards enhancing drug safety and regulatory oversight in response to evolving public health challenges (Darrow, 2020). By aligning with regional and international regulatory bodies, Guyana has benefitted from shared expertise, harmonized standards, and collaborative initiatives aimed at strengthening drug regulation and ensuring the safety of pharmaceutical products.

Guyana's participation in the WHO Certification Scheme has also significantly enhanced its drug regulatory and review process, enabling the rapid assessment of drug safety, quality, and efficacy (Woo-Ming, 1993).This initiative offers a framework for enhancing regulatory capacity and ensuring compliance with international norms.

Moreover, maximizing international collaboration through partnerships with organizations such as the Pan American Health Organization has facilitated access to technical assistance, training opportunities, and resource-sharing initiatives, thereby strengthening Guyana's drug safety infrastructure and ensuring optimal public health protection (Reggi,2016). Collaborations with organizations such as the International Narcotics Control Board (INCB) has also provided technical assistance and resources, enabling the country to leverage international expertise and best practices in drug regulation.

However, despite these mechanisms, significant challenges persist. Limited resources, including staff and funding, hinder comprehensive oversight and timely investigations, whereas a lack of technical capacity within regulatory agencies poses additional barriers (Ndomondo-Sigonda et al. 2017).

1.4 Enforcement and Regulatory Practices in Guyana

Enforcement activities performed by the Government Analyst Food and Drug Department include routine inspections, audits, product sampling, laboratory testing, and imposition of penalties for non-compliance (Woo-Ming, 1993). Despite the existence of a flexible Food and Drugs Act, the enforcement of legislative control of imported pharmaceuticals and product evaluation is a strong point in the drug regulatory and review processes (Woo-Ming, 1993). The need for a comprehensive and functional drug and therapeutic audit, as well as the integration of conflicting interests, remains a long-term challenge (Zhang, 2022). The implementation of stronger regulations and more proactive risk management strategies is also crucial for addressing safety issues and improving pharmacovigilance (Pitts,2016). Despite these challenges, Guyana has made some efforts to ensure the safety, quality, and efficacy of drugs through regulatory and review processes (Woo-Ming, 1993).

1.5 Compliance Rates

The effectiveness of drug safety regulations and the level of adherence among pharmaceutical manufacturers, distributors, and healthcare professionals can be assessed using compliance rates (Singh et al., 2018). However, studies have found suboptimal compliance rates in Guyana, particularly in areas such as Good Manufacturing Practices (GMP) standards, labeling requirements, and pharmacovigilance activities (Guyana Ministry of Public Health, 2019). This finding highlights the need for targeted interventions to improve compliance rates and enhance regulatory oversight. Factors influencing compliance include the complexity of treatment regimens (Anghel, 2019), need for valid and reliable tools to assess adherence Conn (2017) and importance of post-market surveillance in pharmaceutical regulation (Lemmens, 2014).

1.6 Major Challenges Faced by Regulatory Agencies in Ensuring Drug Safety in Guyana:

Regulatory agencies in Guyana face a myriad of challenges in their endeavors to ensure drug safety, as underscored by Zhang (2022). These challenges span a wide spectrum, encompassing the imperative need for a comprehensive drug and therapeutic audit, which demands a delicate balance between socio-medical and economic requisites. Moreover, engaging the public, fostering collaboration with partners, integrating informatics, adopting a global perspective, and evaluating the efficacy of interventions have emerged as pivotal obstacles to the regulatory landscape (Dal Pan, 2014; Pan, 2014). Furthermore, the implementation of stronger regulations and proactive risk management strategies, akin to those observed in the US and Europe, presents additional layers of complexity for regulatory decision-making (Pitts,2016), thus amplifying the intricate and multifaceted nature of ensuring drug safety in Guyana. Resource constraints, particularly limited funding (Adams & Harris, 2012; PAHO, 2018), pose formidable hurdles to the operations of Guyana's regulatory agencies, impeding their capacity to recruit qualified personnel, conduct inspections, and invest in advanced technologies for drug analysis and pharmacovigilance. The absence of a national drug policy and regulation, coupled with inefficient drug selection and irrational drug use (Seoane-Vazquez, 2008), further exacerbates this situation. Despite these formidable challenges, Guyana's drug regulatory and review process, alongside its participation in the WHO Certification Scheme, stands out as commendable initiatives (Woo-Ming, 1993). The pivotal role of regulatory authorities in ensuring that pharmaceutical products align with country-specific requirements cannot be overstated (Reddy, 2017). The challenges confronted by regulatory agencies in Guyana, including inadequate manpower and expertise, have been well-documented (Adams & Harris, 2012; PAHO, 2018), with profound implications for drug evaluation, inspection, enforcement, and overall access to essential drugs in the country (Seoane-Vazquez, 2008).These issues coupled with low public awareness of drug safety and adverse drug reaction reporting(ADR) further impedes the effectiveness of the system, necessitating targeted education and outreach efforts (Varallo, 2014).

Addressing these challenges necessitates concerted efforts from regulatory agencies, policymakers, and stakeholders in Guyana, entailing increased funding, innovative financing mechanisms, and enhanced workforce capacity through targeted training and professional development initiatives (PAHO, 2018; Sandeep,2019). Additionally, investments in infrastructure, including modern laboratories, information systems, and communication networks, are imperative for fortifying the foundation for effective drug safety monitoring and regulation in Guyana (PAHO, 2018). Strengthening the country's public health functions; implementing a national drug policy; and enhancing drug financing, procurement, and supply management are essential steps to address these challenges. The Food and Drugs Act has laid down a regulatory framework for drug regulation and review in Guyana, focusing on safety, quality, and efficacy (Woo-Ming, 1993). However, the utilization of modern information tools, such as those recommended by Rasheed, (2018), could further enhance drug safety monitoring and regulations in the country.

Overcoming the multifaceted challenges faced by regulatory agencies in Guyana necessitates a comprehensive and collaborative approach involving all stakeholders, with continued efforts towards capacity building, infrastructure development, and policy reform to safeguard public health and ensure the safety and efficacy of pharmaceutical products in the nation. Public awareness campaigns aimed at educating the population about drug safety and encouraging ADR reporting can significantly enhance the system's effectiveness. Legislative reform, particularly the revision of outdated legislation, is also crucial for addressing emerging challenges and aligning with international standards.

1.7 Impact of Challenges on Regulatory Effectiveness in Guyana

The effectiveness of drug regulatory agencies in Guyana is significantly affected by various challenges, including the need to bridge the gap between drug efficacy and real-world effectiveness (Meyer, 2017), the use of clinical and cost-effectiveness evidence in coverage decisions (Alemayehu, 2018), and the lack of a common methodological approach to evaluate the public health impact of regulatory interventions (Goedecke, 2018) have all contributed to these challenges. These challenges are further compounded by the limited knowledge of the impacts of national drug policies and regulations on actual drug use (Meena ,2019). Addressing these issues is crucial to improve the safety, efficacy, and quality of pharmaceutical products in Guyana.

The limited visibility of drug safety risks in Guyana due to under-reporting of adverse drug reactions (ADRs) is a significant challenge for regulatory effectiveness (Dutta, 2020). This issue is compounded by the lack of comprehensive reporting mechanisms and low awareness among healthcare professionals and the public (Dutta, 2020).Lack of knowledge about the voluntary reporting system of ADRs has been identified as a major cause of underreporting (Stergiopoulos, 2016). Drug access in the country is hindered by a lack of national drug policies and regulations, inefficient drug selection, and irrational drug use (Seoane-Vazquez, 2008).These issues are exacerbated by a lack of transparency in decision-making processes, which undermines public trust in the regulatory system (Löfstedt,2016). Furthermore, the current drug approval process has been criticized for its lack of vigilance and trust, particularly in post-marketing surveillance (Hernandez, 2015)). To address these challenges, it is crucial to strengthen public health functions; implement a national drug policy; and improve drug financing, procurement, and supply planning (Seoane-Vazquez, 2008). Additionally, enhancing drug safety monitoring and regulation and moving towards active surveillance systems could help improve the situation (Varallo, 2014).Despite these challenges, Guyana's drug regulatory and review process is recommended for strong legislative control and product evaluation (Woo-Ming, 1993).

The increasing pressure on regulatory agencies to detect safety-related adverse events in new drugs has led to the need for more robust real-world evidence (Allmendinger, 2021). This has created a dilemma for these agencies as they must balance the need for rapid access to new drugs with the need for comprehensive benefit/risk data (Kaul, 2020). To address this, Preziosi (2016) suggested the use of restricted use periods and early detection methods for adverse events, whereas Hennessy (2015) emphasized the need for greater involvement of regulatory agencies in assessing adverse drug reactions. Moosivand (2019) further highlighted the challenge of pharmacovigilance in the face of the increasing complexity and commercial pressure in the pharmaceutical industry.

These challenges have had a substantial impact on regulatory effectiveness as they require regulatory agencies to adapt and enhance their capacity to monitor and ensure the safety of pharmaceutical products. The evolving landscape of drug safety regulations has also influenced the decisions of drug and biotechnology companies regarding investment in innovation, highlighting the broader economic implications of regulatory changes on industry behavior (Cauchon, 2019).

2. Conclusion

Based on the significant challenges faced by regulatory agencies in ensuring drug safety in Guyana, it is evident that a comprehensive and collaborative approach is essential to address these complexities effectively. The multitude of obstacles, ranging from resource constraints to limited public awareness, poses substantial hurdles to the regulatory landscape and impacts the overall effectiveness of drug safety monitoring and regulation in the country.

Firstly, resource constraints, particularly limited funding and manpower, significantly impede the operational capacity of regulatory agencies. The inability to recruit qualified personnel, conduct inspections, and invest in advanced technologies for drug analysis and pharmacovigilance hampers the comprehensive oversight required for ensuring drug safety.

Additionally, the absence of a national drug policy and regulation framework exacerbates the challenges, leading to inefficient drug selection and irrational drug use. The lack of clear guidelines and regulatory standards undermines the efficacy of regulatory interventions and complicates decision-making processes.

Moreover, low public awareness and under-reporting of adverse drug reactions (ADRs) further impede regulatory effectiveness. The limited visibility of drug safety risks due to inadequate reporting mechanisms and insufficient knowledge among healthcare professionals and the public hinders timely and effective responses to emerging safety concerns.

Addressing these challenges demands a concerted effort from regulatory agencies, policymakers, and stakeholders in Guyana. Initiatives such as increased funding, innovative financing mechanisms, and targeted capacity-building programs are imperative to enhance workforce expertise and infrastructure. Investments in modern laboratories, information systems, and communication networks are critical for strengthening the foundation of drug safety monitoring and regulation.

Furthermore, public awareness campaigns and educational outreach efforts are essential to promote understanding of drug safety issues and encourage ADR reporting among healthcare professionals and the general population. Legislative reforms aimed at revising outdated regulations and aligning with international standards are crucial steps towards building a robust regulatory framework that prioritizes public health and safety.

In conclusion, overcoming the multifaceted challenges faced by regulatory agencies in Guyana requires sustained commitment and collaboration across all stakeholders. By addressing these challenges systematically and implementing targeted interventions, regulatory agencies can bolster their effectiveness in safeguarding public health and ensuring the safety, efficacy, and quality of pharmaceutical products in the nation.

3. Recommendations

The following recommendations are proposed to enhance the effectiveness of regulatory agencies and strengthen the overall regulatory framework:

Increase Funding and Resource Allocation:

Advocate for increased funding from government sources and international donors to support regulatory agencies in Guyana.

Allocate resources specifically for recruiting and training qualified personnel, conducting inspections, and investing in modern technologies for drug analysis and pharmacovigilance.

Develop and Implement a National Drug Policy:

Collaborate with stakeholders to develop a comprehensive national drug policy and regulatory framework.

Ensure that the policy addresses issues related to drug selection, procurement, rational use, and safety monitoring.

Enhance Regulatory Capacity and Expertise:

Provide targeted training programs and professional development opportunities for regulatory staff to enhance their skills in drug evaluation, inspection, and enforcement.

Foster partnerships with academic institutions and international regulatory bodies for knowledge exchange and capacity-building initiatives.

Improve Public Awareness and Reporting:

Launch public awareness campaigns to educate healthcare professionals and the general public about the importance of drug safety and adverse drug reaction (ADR) reporting.

Implement user-friendly reporting mechanisms and promote transparent communication to encourage timely reporting of ADRs.

Strengthen Regulatory Infrastructure:

Invest in modern laboratories, information systems, and communication networks to support robust drug safety monitoring and regulation.

Ensure that regulatory infrastructure is equipped to handle the complexities of pharmaceutical oversight and respond effectively to emerging safety concerns.

Promote Collaboration and Partnerships:

Foster collaboration among regulatory agencies, healthcare providers, pharmaceutical industry stakeholders, and international organizations to share best practices and resources.

Engage in public-private partnerships to leverage expertise and resources for strengthening drug safety initiatives.

Review and Update Regulatory Framework:

Conduct a comprehensive review of existing regulations and policies to identify gaps and inconsistencies.

Update regulatory frameworks to align with international standards and emerging best practices in drug safety and pharmacovigilance.

Implement Active Pharmacovigilance Systems:

Transition towards active pharmacovigilance systems that proactively monitor the safety of pharmaceutical products post-market.

Utilize advanced data analytics and real-world evidence to detect and respond to safety signals promptly.

Ensure Transparency and Accountability:

Enhance transparency in regulatory decision-making processes and publicize regulatory actions and outcomes.

Implement mechanisms for accountability to maintain public trust and confidence in the regulatory system.

Advocate for Legislative Reform:

Advocate for legislative reforms to strengthen regulatory oversight and enforcement capabilities.

Collaborate with policymakers to revise outdated legislation and enact new laws that prioritize public health and safety.

By implementing these recommendations, regulatory agencies in Guyana can overcome existing challenges and establish a robust framework for ensuring drug safety, thereby safeguarding public health and promoting access to high-quality pharmaceutical products. These efforts will contribute to building a resilient regulatory infrastructure capable of addressing the evolving landscape of drug safety and pharmacovigilance.

References

1. Abiddin, N. Z., Ibrahim, I., & Abdul Aziz, S. A. (2022). Non-Governmental Organisations (NGOs) and Their Part towards Sustainable Community Development. Sustainability, 14(8), 4386. https://doi.org/10.3390/su14084386
2. Adams, S. A. (2013). Using patient-reported experiences for pharmacovigilance? Studies in Health Technology and Informatics, 194, 63-68. PMID: 23941932.
3. Alemayehu, C., Mitchell, G., & Nikles, J. (2018). Barriers for conducting clinical trials in developing countries: A systematic review. International Journal for Equity in Health, 17(1), 37. https://doi.org/10.1186/s12939-018-0748-6
4. Al-Obaidi, T. A., & Fletcher, S. M. (2014). Management of clandestine drug laboratories: need for evidence-based environmental health policies. Environmental Health and Preventive Medicine, 19(1), 1-11. https://doi.org/10.1007/s12199-013-0360-8. PMID: 24002745; PMCID: PMC3890076.
5. Allmendinger, A. (2021). Opportunities in an Evolving Pharmaceutical Development Landscape: Product Differentiation of Biopharmaceutical Drug Products. Pharmaceutical Research, 38, 739–757. https://doi.org/10.1007/s11095-021-03037-5
6. Anghel, L. A., Farcas, A. M., & Oprean, R. N. (2019). An overview of the common methods used to measure treatment adherence. Medical and Pharmaceutical Reports, 92(2), 117-122. https://doi.org/10.15386/mpr-1201
7. Bahri, P., & Harrison-Woolrych, M. (2012). Focusing on risk communication about medicines: why now? Drug Safety, 35(11), 971-975. https://doi.org/10.1007/BF03261984. PMID: 23061774; PMCID: PMC3585946.
8. Bennett, N. R., Cumberbatch, C., & Francis, D. K. (2015). There are challenges in conducting systematic reviews in developing countries: the Jamaican experience. Journal of Clinical Epidemiology, 68(9), 1095-1098. doi: 10.1016/j.jclinepi.2014.09.026
9. Bollen, A., Harrison, R., Aslani, P., & van Haastregt, J. C. M. (2019). Factors influencing interprofessional collaboration between community pharmacists and general practitioners-A systematic review. Health & Social Care in the Community, 27(4), e189-e212. https://doi.org/10.1111/hsc.12705. Epub 2018 Dec 20. PMID: 30569475.
10. Bujar, M., Ferragu, S., McAuslane, N., Liberti, L., & Kühler, T. C. (2021). Transparency in European Medicines Agency and US Food and Drug Administration Decision Making: Is It Possible to Identify the Rationale for Divergences in Approved Indication From Public Assessment Reports? Clinical Therapeutics, 43(5), 888-905. https://doi.org/10.1016/j.clinthera.2021.03.010
11. Caturla Goñi, M. (2016). Accelerating Regulatory Approvals through the World Health Organization Collaborative Registration Procedures, 109–120.
12. Cauchon, N. S., Oghamian, S., Hassanpour, S., & Abernathy, M. (2019). Innovation in Chemistry, Manufacturing, and Controls-A Regulatory Perspective From Industry. Journal of Pharmaceutical Sciences, 108(7), 2207-2237. https://doi.org/10.1016/j.xphs.2019.02.007
13. Chattu, V. K., Singh, B., Pattanshetty, S., & Reddy, S. (2023). Access to medicines through global health diplomacy. Health Promotion Perspectives, 13(1), 40-46. https://doi.org/10.34172/hpp.2023.05
14. Chavan, A. A., Kumbhar, S. B., Shinde, V. R., Thorat, A. A., Jadhav, P. B., Jadhav, A. R., Honrao, J. B., Shaikh, S. A., Raysing, S. D., More, V. V., & Kumbhar, D. D. (2023). Role of pharmacist in healthcare system. GSC Biological and Pharmaceutical Sciences. https://api.semanticscholar.org/CorpusID:259882062
15. Conn, V. S., & Ruppar, T. M. (2017). Medication adherence outcomes of 771 intervention trials: Systematic review and meta-analysis. Preventive Medicine, 99, 269-276. https://doi.org/10.1016/j.ypmed.2017.03.008
16. Dal Pan, G. J. (2014). Ongoing challenges in pharmacovigilance. Drug Safety, 37(1), 1-8. https://doi.org/10.1007/s40264-013-0123-x
17. Darrow, J. J., Avorn, J., & Kesselheim, A. S. (2020). FDA approval and regulation of pharmaceuticals, 1983-2018. JAMA, 323(2), 164-176. https://doi.org/10.1001/jama.2019.20288
18. Debaveye, S., De Soete, W., De Meester, S., Vandijck, D., Heirman, B., Kavanagh, S., & Dewulf, J. (2016). Human health benefits and burdens of a pharmaceutical treatment: Discussion of a conceptual integrated approach. Environmental Research, 144(Pt A), 19-31. https://doi.org/10.1016/j.envres.2015.10.027
19. Dutta, A., Banerjee, A., Basu, S., & Chaudhry, S. (2020). Analysis of under-reporting of Adverse Drug Reaction: Scenario in India and neighbouring countries. IP International Journal of Comprehensive and Advanced Pharmacology, 5(3), 118-124.
20. Ehmann, F., Papaluca Amati, M., Salmonson, T., Posch, M., Vamvakas, S., Hemmings, R., Eichler, H. G., & Schneider, C. K. (2013). Gatekeepers and enablers: How drug regulators respond to a challenging and changing environment by moving toward a proactive attitude. Clinical Pharmacology & Therapeutics, 93(5), 425-432. https://doi.org/10.1038/clpt.2013.14

21. Egilman, A. C., Kapczynski, A., McCarthy, M. E., Luxkaranayagam, A. T., Morten, C. J., Herder, M., ... Ross, J. S. (2021). Transparency of Regulatory Data across the European Medicines Agency, Health Canada, and US Food and Drug Administration. Journal of Law, Medicine & Ethics, 49(3), 456-485. https://doi.org/10.1017/jme.2021.67

22. Fadlallah, R., El-Jardali, F., Annan, F., Azzam, H., & Akl, E. A. (2016). Strategies and Systems-Level Interventions to Combat or Prevent Drug Counterfeiting: A Systematic Review of Evidence Beyond Effectiveness. Pharmaceutical Medicine, 30(5), 263-276. doi: 10.1007/s40290-016-0156-4. PMID: 27752221; PMCID: PMC5045490.

23. Fujita, N., Matsuoka, S., Koto-Shimada, K., Ikarashi, M., Hazarika, I., & Zwi, A. (2019). Regulation of nursing professionals in cambodia and vietnam: a review of the evolution and key influences. Human Resources for Health, 17(1). https://doi.org/10.1186/s12960-019-0388-y

24. Goedecke, T., Morales, D. R., Pacurariu, A., & Kurz, X. (2018). Measuring the impact of medicines regulatory interventions - Systematic review and methodological considerations. British Journal of Clinical Pharmacology, 84(3), 419-433. https://doi.org/10.1111/bcp.13469

25. Gover, B., Akinbo, O., Savadogo, M., Timpo, S., Lemgo, G., Sinebo, W., … & Ambali, A. (2018). Strengthening regulatory capacity for gene drives in africa: leveraging nepad's experience in establishing regulatory systems for medicines and gm crops in africa. BMC Proceedings, 12(S8). https://doi.org/10.1186/s12919-018-0108-y

26. Gyasi, R. M., Mensah, C. M., Yeboah, J. Y., & Siaw, L. P. (2015). Quality control and standards of medicinal products: a committed agenda. British Journal of Pharmaceutical Research, 6(6), 385-388. https://doi.org/10.9734/bjpr/2015/16320

27. Hamid, A. A. A., Rahim, R., & Teo, S. P. (2022). Pharmacovigilance and its importance for primary health care professionals. Korean Journal of Family Medicine, 43(5), 290-295. https://doi.org/10.4082/kjfm.21.0193

28. Healy, M. J., Tong, W., Ostroff, S., Eichler, H. G., Patak, A., Neuspiel, M., Deluyker, H., & Slikker Jr, W. (2016). Regulatory bioinformatics for food and drug safety. Regulatory Toxicology and Pharmacology, 80, 342-347. https://doi.org/10.1016/j.yrtph.2016.05.021

29. Hennessy, S., & Strom, B. L. (2015). Improving postapproval drug safety surveillance: getting better information sooner. Annual Review of Pharmacology and Toxicology, 55, 75-87. https://doi.org/10.1146/annurev-pharmtox-011613-135955

30. Hernandez, J. F. (2015). Trust in the pharmaceutical sector: Analysis of drug safety controversies by means of drug life cycles. Retrieved from https://api.semanticscholar.org/CorpusID:153015344

31. Kari, H., Kortejärvi, H., Airaksinen, M., & Laaksonen, R. (2018). Patient involvement is essential in identifying drug-related problems. British Journal of Clinical Pharmacology, 84(9), 2048–2058. https://doi.org/10.1111/bcp.13640

32. Kaul, S., Stockbridge, N., & Butler, J. (2020). Benefit-Risk Tradeoffs in Assessment of New Drugs and Devices. Circulation, 142(20), 1974-1988. https://doi.org/10.1161/CIRCULATIONAHA.120.048933

33. Kelly, L., Lazzaro, M., & Petersen, C. (2007). Canadian drug regulatory framework. Canadian Journal of Neurological Sciences, 34(Suppl 1), S3-S10. https://doi.org/10.1017/s0317167100005485

34. Kelesidis & Falagas (2015)."Substandard/Counterfeit Antimicrobial Drugs" Clinical microbiology reviews (2015) doi:10.1128/cmr.00072-14

35. Kiguba, R., Olsson, S., & Waitt, C. (2023). Pharmacovigilance in low- and middle-income countries: A review with particular focus on Africa. British Journal of Clinical Pharmacology, 89(2), 491-509. https://doi.org/10.1111/bcp.15193

36. Kohler, J. C., Mackey, T. K., & Ovtcharenko, N. (2014). Why the MDGs need good governance in pharmaceutical systems to promote global health. BMC Public Health, 14, 63. https://doi.org/10.1186/1471-2458-14-63

37. Kuehn, C. M. (2018). Patient experience data in US Food and Drug Administration (FDA) regulatory decision making: A policy process perspective. Therapeutic Innovation & Regulatory Science, 52(5), 661-668. https://doi.org/10.1177/2168479017753390

38. Lavan, A. H., & Gallagher, P. (2016). Predicting risk of adverse drug reactions in older adults. Therapeutic Advances in Drug Safety, 7(1), 11-22. https://doi.org/10.1177/2042098615615472

39. Lemmens, T., & Bouchard, R. (2012). Regulation of Pharmaceuticals in Canada.

40. Lin, S., Ramulu, P., Lamoureux, E. L., & Sabanayagam, C. (2016). Addressing risk factors, screening, and preventative treatment for diabetic retinopathy in developing countries: A review. Clinical & Experimental Ophthalmology, 44(4), 300-320. https://doi.org/10.1111/ceo.12745

41. Löfstedt, R., & Balog-Way, D. (2014). Transparency and trust in the European pharmaceutical sector: Outcomes from an experimental study. Journal of Risk Research, 19, 1-22. https://doi.org/10.1080/13669877.2014.919517

42. McCoy, M. S., Carniol, M., Chockley, K., Urwin, J. W., Emanuel, E. J., & Schmidt, H. (2017). Conflicts of interest for patient-advocacy organizations. New England Journal of Medicine, 376(9), 880-885. https://doi.org/10.1056/NEJMsr1610625

43. Meena, D., & Jayanthi, M. (2019). Drug utilization research: A review. International Journal of Basic & Clinical Pharmacology, 8, 354. https://doi.org/10.18203/2319-2003.ijbcp20190161

44. Mehta, U., Allen, E., & Barnes, K. I. (2010). Establishing pharmacovigilance programs in resource-limited settings: the example of treating malaria. Expert Review of Clinical Pharmacology, 3(4), 509-525. https://doi.org/10.1586/ecp.10.37

45. Meyer, J. C., Schellack, N., Stokes, J., Lancaster, R., Zeeman, H., Defty, D., Godman, B., & Steel, G. (2017). Ongoing initiatives to improve the quality and efficiency of medicine use within the public healthcare system in South Africa: A preliminary study. Frontiers in Pharmacology, 8, 751. https://doi.org/10.3389/fphar.2017.00751

46. Mishra, B., & Kumar, A. (2021). How does Regulatory Framework Impact Sectoral Performance? A Systematic Literature Review. International Journal of Productivity and Performance Management. Advance online publication. https://doi.org/10.1108/IJPPM-07-2021-0398

47. Moktadir, M. A., Ali, S. M., Mangla, S. K., Sharmy, T. A., Luthra, S., Mishra, N., & Garza-Reyes, J. A. (2018). Decision modeling of risks in pharmaceutical supply chains. Industrial management + data systems, 118(7), 1388-1412. https://doi.org/10.1108/IMDS-10-2017-0465

48. Moosivand, A., Rajabzadeh Ghatari, A., & Rasekh, H. R. (2019). Supply Chain Challenges in Pharmaceutical Manufacturing Companies: Using Qualitative System Dynamics Methodology. Iranian Journal of Pharmaceutical Research, 18(2), 1103-1116. https://doi.org/10.22037/ijpr.2019.2389

49. Mujinja, P. G., & Saronga, H. P. (2022). Traditional and complementary medicine in Tanzania: Regulation awareness, adherence and challenges. International Journal of Health Policy and Management, 11(8), 1496-1504. https://doi.org/10.34172/ijhpm.2021.51

50. Mulinari, S. (2016). Regulating Pharmaceutical Industry Marketing: Development, Enforcement, and Outcome of Marketing Rules. Sociology Compass, 10, 74-86. https://doi.org/10.1111/soc4.12335

51. Mustafa, A. A., & Kowalski, S. R. (2010). A need for the standardization of the pharmaceutical sector in Libya. Libyan Journal of Medicine, 5. https://doi.org/10.3402/ljm.v5i0.5440

52. Mwangi, J. (2016). Towards African Medicines Regulatory Harmonization: The case of the East African Community. Pharmaceuticals Policy and Law, 18, 91-98. https://doi.org/10.3233/PPL-160435

53. Nematollahi, M., Hosseini-Motlagh, S.-M., Ignatius, J., Goh, M., & Saghafi Nia, M. (2018). Coordinating a socially responsible pharmaceutical supply chain under periodic review replenishment policies. Journal of Cleaner Production, 172, 2876-2891. https://doi.org/10.1016/j.jclepro.2017.11.126

54. Ndomondo-Sigonda, M., Miot, J., Naidoo, S., & Dodoo, A. (2017). Medicines Regulation in Africa: Current State and Opportunities. Pharmaceutical Medicine, 31(6), 383-397. doi:10.1007/s40290-017-0210-x

55. Oberweis, CV, Marchal, JA, López-Ruiz, E, & Gálvez-Martín, P. (2020). A Worldwide Overview of Regulatory Frameworks for Tissue-Based Products. Tissue Engineering Part B: Reviews, 26(2), 181-196. https://doi.org/10.1089/ten.TEB.2019.0315

56. Olmsted, S. S., Moore, M., Meili, R. C., Duber, H. C., Wasserman, J., Sama, P., Mundell, B., & Hilborne, L. H. (2010). Strengthening laboratory systems in resource-limited settings. American Journal of Clinical Pathology, 134(3), 374-380. https://doi.org/10.1309/AJCPDQOSB7QR5GLR. PMID: 20716792.

57. Otsubo, Y., Ishiguro, A., & Uyama, Y. (2013). Regulatory perspective on remaining challenges for utilization of pharmacogenomics-guided drug developments. Pharmacogenomics, 14(2), 195-203. https://doi.org/10.2217/pgs.12.194. PMID: 23327579.

58. Papathanasiou, P., Brassart, L., Blake, P., Hart, A., Whitbread, L., Pembrey, R., & Kieffer, J. (2016). Transparency in drug regulation: public assessment reports in Europe and Australia. Drug Discovery Today, 21(11), 1806-1813. https://doi.org/10.1016/j.drudis.2016.06.025

59. Phillips, A., et al. (2020). The national food control system in Guyana: Evaluation of the current regulatory framework for food control systems. doi:10.47412/cdob4139

60. Pitts, P. J., Louet, H. L., Moride, Y., & Conti, R. M. (2016). 21st century pharmacovigilance: Efforts, roles, and responsibilities. The Lancet Oncology, 17(11), e486-e492. https://doi.org/10.1016/S1470-2045(16)30312-6

61. Preziosi, P. (2016). Faster drug approval: challenges for safety. Expert Opinion on Drug Safety, 15(9), 1205-1218. https://doi.org/10.1080/14740338.2016.1194825.

62. Rägo, L., Sillo, H., 't Hoen, E., & Zweygarth, M. (2014). Regulatory framework for access to safe, effective quality medicines. Antiviral Therapy, 19(Suppl 3), 69-77. https://doi.org/10.3851/IMP2902

63. Seoane-Vazquez, E. and Rodríguez-Monguió, R. (2008). access to essential drugs in guyana: a public health challenge. The International Journal of health Planning and Management, 25(1), 2-16. https://doi.org/10.1002/hpm.949

64. Song, J., Zhang, L., Li, Y., Zeng, L., Hu, D., Liang, Y., & Liu, D. (2017). Indicators for assessing quality of drug use: A systematic literature review. Journal of Evidence-Based Medicine, 10(3), 222-232. https://doi.org/10.1111/jebm.12244

65. Urias, E. (2017). The contribution of the pharmaceutical industry to the health status of the developing world. In International Business and Management (pp. 41-67). https://doi.org/10.1108/S1876-066X20170000033003

66. Van der Meeren, H. L., Caudron, J. M., Batson, A., Palu, O. M., & Kibiki, G. S. (2018). A review of regulatory frameworks for medical products in low- and middle-income countries. Health Research Policy and Systems, 16(1), 90. doi: 10.1186/s12961-018-0374-1

67. Raine, J. M. (2012). Drug safety: reporting systems for the general public. BMJ, 345, e4916. https://doi.org/10.1136/bmj.e4916. PMID: 22872709.

68. Rasheed, H., Höllein, L., & Holzgrabe, U. (2018). Future information technology tools for fighting substandard and falsified medicines in low- and middle-income countries. Frontiers in Pharmacology, 9, 995. https://doi.org/10.3389/fphar.2018.00995

69. Reddy, G. T. K., & Reddy, G. N. K. (2017). Significance of pharmaceutical regulatory bodies - A review. PharmaTutor, 5(8), 15-22.

70. Reggi, V. (2016). medicines regulatory harmonization: international collaboration as a key to improve public health. Medicine Access Point of Care, 1, maapoc.0000001. https://doi.org/10.5301/maapoc.0000001

71. Saidu, Y., Angelis, D., Aiolli, S., Gonnelli, S., & Georges, A. M. (2013). A review of regulatory mechanisms used by the WHO, EU, and US to facilitate access to quality medicinal products in developing countries with constrained regulatory capacities. Therapeutic Innovation & Regulatory Science, 47(2), 268-276. doi: 10.1177/2168479012474281

72. Sandeep, D. K., Vikram, G., & Dureja, H. (2019). Partnership efforts – Their potential to reduce the challenges that confront regulators and pharmaceutical industry. Applied Clinical Research, Clinical Trials and Regulatory Affairs, 6(1). https://dx.doi.org/10.2174/2213476X06999190206120109

73. Shubnikova, E. V., Darmostukova, M. A., Bukatina, T. M., Kaperko, D. A., Velts, N. Y., Kazakov, A. S., Snegireva, I. I., Zhuravleva, E. O., & Kutekhova, G. V. (2019). The adverse drug reactions registered during the postmarketing period. Safety and Risk of Pharmacotherapy, 7(1), 15-22. https://doi.org/10.30895/2312-7821-2019-7-1-15-22

74. Singh, R., & Persaud, S. (2016). Evaluation of the National Food Control System in Guyana. Journal of Food Protection, 79(12), 2085-2090. doi: 10.4315/0362-028X.JFP-16-236

75. Sniderman, A. D. (2000). The need for greater involvement of regulatory agencies in assessing adverse drug reactions. Canadian Medical Association Journal, 162(2), 209-210. PMID: 10674055; PMCID: PMC1232272.

76. Sousa, V. D., Ramalho, P. I., & Silveira, D. (2016). Sharing regulatory data as tools for strengthening health systems in the Region of the Americas. Revista Panamericana de Salud Pública, 39(5), 245-254. PMID: 27706398.

77. Spina, A. (2011). The Regulation of Pharmaceuticals Beyond the State: EU and Global Administrative Systems. In Transnational Governance: Institutional Dynamics of Regulation (pp. 249-268). https://doi.org/10.1007/978-3-642-20264-3_13.

78. Sridhar, D. (2008). Improving access to essential medicines: How health concerns can be prioritized in the global governance system. Public Health Ethics, 1(2), 83-88. https://doi.org/10.1093/phe/phn012. PMID: 19461853; PMCID: PMC2591098.

79. Stenson, B., Tomson, G., & Syhakhang, L. (1997). Pharmaceutical regulation in context: The case of Lao People's Democratic Republic. Health Policy and Planning, 12(4), 329-340. https://doi.org/10.1093/heapol/12.4.329. PMID: 10176268.

80. Stergiopoulos, S., Brown, C. A., Felix, T., Grampp, G., & Getz, K. A. (2016). A survey of adverse event reporting practices among US healthcare professionals. Drug Safety, 39(11), 1117-1127. https://doi.org/10.1007/s40264-016-0455-4

81. Steurbaut, S., & Hanssens, Y. (2014). Pharmacovigilance: empowering healthcare professionals and patients. International Journal of Clinical Pharmacy, 36(5), 859-862. https://doi.org/10.1007/s11096-014-0004-0

82. Suleman, S., Woliyi, A., Woldemichael, K., Tushune, K., Duchateau, L., Degroote, A., Vancauwenberghe, R., Bracke, N., & De Spiegeleer, B. (2016). Pharmaceutical Regulatory Framework in Ethiopia: A Critical Evaluation of Its Legal Basis and Implementation. Ethiopian Journal of Health Sciences, 26(3), 259-276. doi: 10.4314/ejhs.v26i3.9. PMID: 27358547; PMCID: PMC4913194.

83. van-Hunsel, F., Gardarsdottir, H., de Boer, A., & Kant, A. (2019). Measuring the impact of pharmacovigilance activities, challenging but important. British Journal of Clinical Pharmacology, 85(10), 2235-2237. https://doi.org/10.1111/bcp.14042

84. Varallo, F. R., Guimarães, S. de O., Abjaude, S. A., & Mastroianni, P. de C. (2014). Causes del subregistro de los eventos adversos de medicamentos por los profesionales de la salud: revisión sistemática [Causes for the underreporting of adverse drug events by health professionals: a systematic review]. Revista da Escola de Enfermagem da USP, 48(4), 739-747. https://doi.org/10.1590/s0080-623420140000400023

85. Walker, K. E. W., Bankay, R., Jankie, S., & Dhingra, S. (2023). Pharmacovigilance in the Caribbean Countries: An Overview. Current Pharmacology Reports. Advance online publication. https://doi.org/10.1007/s40495-023-00320-4. PMID: 37360536; PMCID: PMC10191812.

86. Weigmann, K. (2016). Consumer reporting of adverse drug reactions: Systems that allow patients to report side effects of the drugs they are taking have yielded valuable information for improving drug safety and health care. EMBO Reports, 17(7), 949-952. https://doi.org/10.15252/embr.201642616

87. Weil, A. R. (2019). Patients as consumers. Health Affairs, 38(3), 343. https://doi.org/10.1377/hlthaff.2019.00176

88. Woo-Ming, R. B. (1993). The drug regulatory and review process in guyana. The Journal of Clinical Pharmacology, 33(1), 14-21. https://doi.org/10.1002/j.1552-4604.1993.tb03897.x

89. Weitzel, J., Pappa, H., Banik, G. M., Barker, A. R., Bladen, E., Chirmule, N., DeFeo, J., Devine, J., Emrick, S., Hout, T. K., Levy, M. S., Mahlangu, G. N., Rellahan, B., Venema, J., & Workman, W. (2021). Understanding Quality Paradigm Shifts in the Evolving Pharmaceutical Landscape: Perspectives from the USP Quality Advisory Group. AAPS Journal, 23(6), 112. https://doi.org/10.1208/s12248-021-00634-5

90. Wilson, J., & Sewankambo, N. (2015). Investing in regulatory capacity building in low- and middle-income countries: A roadmap for action. Journal of Public Health Policy, 36(3), 378-384. doi: 10.1057/jphp.2015.17

91. Zhang, C., Ma, E. L., Liu, B. L., Wu, B., Gu, Z. C., & Lin, H. W. (2022). Framework Development for Clinical Comprehensive Evaluation of Drugs-a Study Protocol Using the Delphi Method and Analytic Hierarchy Process. Frontiers in Pharmacology, 13, 869319. https://doi.org/10.3389/fphar.2022.869319