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A STUDY ON EFFECTIVE DRUG REGULATION IN INDIA

Shivakumar. A[1] & Mr. CM Selvamuthu[2]

ABSTRACT:

The Constitution of India promises healthy life and a proper health care system Article 21 (1) of it's constitution recognizes Adequate health care under the Constitution of the country it also defines getting the right and Effective medication drugs the laws enacted for this are The Pharmacy Act 1948, The Drugs and Magic Remedies Act 1954 and The Narcotic Drugs and Psychotropic Substances Act 1985, defines the making and selling of quality medicines in the industry of pharmaceutical This research paper aims to find whether the medicines that are made within the Country do it also count for the Different Medicines which are imported from other countries, this study is based on both primary and secondary data. The SPSS analytical Tool was used to The primary data for the study is collected from 210 sample respondents through a well-structured questionnaire by the method of simple random sampling using charts, graphs, percentages, and chi-square tests. The rights of the citizens of Indian society are violative in every circumstance where the medicines are prepared in a shorter time and the findings say that people from rural areas are continuously being affected by improper drug regulation policies and laws aren't effective enough to take necessary actions.

KEYWORDS:

Pharmacy Act 1948, The Drugs and Magic Remedies Act 1954, The Narcotic Drugs and Psychotropic Substances Act 1985, Article 21, Fundamental Rights and Adequate healthcare

INTRODUCTION:

India is considered a developing country where health care and infrastructure are still in a considerable state the citizens of India are entitled to get the right to adequate healthcare with the huge availability of different types of drugs and redies for health care within India the regulation of the correct medicines which are approved by the Different authorities of the nation is a persistent issue concerning the wellbeing of the citizens and the development of the

[1] The author is a student at Saveetha School of Law, Saveetha Institute of Medical and Technical Sciences, Chennai.
[2] The Co-author is an assistant professor of law at Saveetha School of Law, Saveetha Institute of Medical and Technical Sciences, Chennai.

country on compared to the USA where the most medication errors are made in the world, India doesn't have any critical issue for medication errors still there is a high chance of availability of fake or unapproved in major metropolitan cities of India like Chennai, Delhi, and Mumbai, etc. There is a high alert in the market and availability of untested and unapproved drugs easily available to the citizens of the country which is due to many causes like the price of the medicines, affordability of citizens, Corrupt officials, improper legislation and control and power of politicians which leads to the circulation and consumption of improper and ineffective drugs within the city and also the citizens of India are mostly people who are illiterates, some are only qualified till school education which is also one of the factors that cause Disturbances in the Distribution of proper and approved drugs. This research paper aims to find out the main causes of the available legislation and other causes why there is a high availability of improper drugs in the pharmaceutical market and other factors which cause the same.

OBJECTIVES :

- To Analyse the causes of the Supply of Improper or unapproved Drugs
- To Explore the Causes of Sale and Manufacturing of Improper Drugs
- To Examine the Remedies for the Effective Drug Regulation
- To Find out the Development of Legislation related to Drug Regulation

REVIEW OF LITERATURE:

Roger Bate et al., *Pilot study of essential drug quality in two major cities in India*, 4 PloS one e6003 (2009), http://dx.doi.org/10.1371/journal.pone.0006003

India is an increasingly influential player in the global pharmaceutical market. Key parts of the drug regulatory system are controlled by the states, each of which applies its standards for enforcement, not always consistent with others. A pilot study was conducted in two major cities in India, Delhi and Chennai, to explore the question/hypothesis/extent of substandard and counterfeit drugs available in the market and to discuss how the Indian state and federal

governments could improve drug regulation and more importantly regulatory enforcement to combat these drugs.

Y. Balarajan et al., *Health care and equity in India,* 377 The Lancet 505–515 (2011), http://dx.doi.org/10.1016/S0140-6736(10)61894-6

In India, despite improvements in access to health care, inequalities are related to socioeconomic status, geography, and gender, and are compounded by high out-of-pocket expenditures, with more than three-quarters of the increasing financial burden of health care being met by households. Health-care expenditures exacerbate poverty, with about 39 million additional people falling into poverty every year as a result of such expenditures. We identify key challenges for the achievement of equity in service provision, and equity in financing and financial risk protection in India. These challenges include an imbalance in resource allocation, inadequate physical access to high-quality health services and human resources for health, high out-of-pocket health expenditures, inflation in health spending, and behavioral factors that affect the demand for appropriate health care.

Mohammed Imran et al., *Clinical research regulation in India-history, development, initiatives, challenges and controversies: Still long way to go*, 5 Journal of pharmacy & bioallied sciences 2–9 (2013), http://dx.doi.org/10.4103/0975-7406.106553

India's Parliamentary Standing Committee on Health and Family Welfare has highlighted the lax standards followed by the regulatory authorities in India. The Central Drugs Standard Control Organisation and its chairman Drug Controller General of India are endowed to protect the citizens from the marketing of unsafe medication. Many controversial groups of medicines; unauthorized and irrational FDCs not relevant to India's medical needs, are available and not sold in any of the countries with matured regulatory bodies.

Rituparna Maiti et al., *Essential Medicines: An Indian Perspective,* 40 Indian journal of community medicine: official publication of Indian Association of Preventive & Social Medicine 223–232 (2015), http://dx.doi.org/10.4103/0970-0218.164382

The concept of defining essential medicines and establishing a list of them was aimed to improve the availability of affordable drugs for the world's poor. Access to essential medicines is a significant determinant of health outcomes. Several countries have made substantial

progress towards increasing access to essential medicines, but access to essential medicines in developing countries like India is not adequate. In this review, we have tried to present the Indian scenario concerning the availability and accessibility of essential drugs over the last decade. To enhance the credibility of the Indian healthcare system, procurement and delivery systems of essential drugs have to be strengthened through government commitment, careful selection, adequate public sector financing, efficient distribution systems, control of taxes and duties, and inculcation of a culture of rational use of medicines in current and future prescribers.

Thakur & Reddy, *A report on fixing India's broken drug regulatory framework*, URl: https://spicyip. com/wp-content/uploads (2016), https://dineshthakur.com/wp-content/uploads/2016/06/CDSCO-Reform.pdf

This report on the drug regulatory framework in India is based on extensive research undertaken by the authors. The main source for the data reported in this study is the responses from public authorities to requests for information filed by the authors under the Right to Information Act, 2005. Other important sources of data for this report are the official state reports by Parliamentary Committees, expert committees appointed by the Government of India, and audit reports of the Comptroller & Auditor General (CAG). Based on this extensive research, the authors were able to identify various problems with the current drug regulatory framework. This executive summary provides a snapshot of the issues raised in this report and suggested solutions.

Gillian Porter & Nathan Grills, *Medication misuse in India: a major public health issue in India*, 38 Journal of public health e150–e157 (2016), https://www.jstor.org/stable/48515567

In India, it has been estimated that 50% of family spending on healthcare is on unnecessary medications or investigations. This, combined with the wide availability of medications, has seemingly contributed to increasing rates of antibiotic resistance and further impoverishment. In this literature review, we aim to characterize the extent of misuse and describe underlying factors contributing to the misuse of medication in India. This is one of the most comprehensive reviews of medication misuse in India. It indicates the widespread nature of the problem and so highlights the need for action. This review provides a detailed understanding of the complex interplay of factors that result in medication misuse in India.

Shashank S. Tiwari et al., *Regenerative medicine in India: trends and challenges in innovation and regulation*, 12 Regenerative medicine 875–885 (2017), http://dx.doi.org/10.2217/rme-2017-0094

The government of India has heavily promoted research and development in regenerative medicine together with domestic innovation and business development initiatives. Together, these promise a revolution in healthcare and public empowerment in India. Several national and transnational linkages have emerged to develop innovative capacity, most prominently in stem cell and cord blood banking, as well as in gene therapy, tissue engineering, biomaterials, and 3D printing. However, challenges remain in achieving regulatory oversight, viable outputs, and equitable impacts. Governance of private cord blood banking, nanomaterials, and 3D bioprinting require more attention. A robust social contract is also needed in healthcare more generally so that participation in research and innovation in regenerative medicine is backed up by treatments widely accessible to all.

Saradindu Bhaduri & Thangminlen Kipgen, *"new drugs" approvals in India: An institutional perspective*, 23 Science, Technology & Society 444–462 (2018), https://journals.sagepub.com/doi/abs/10.1177/0971721818762931

The approval mechanism for new drugs in India has been subjected to scrutiny and controversy. Frequent rollbacks in the guidelines have attracted criticism from the industry as well. This article draws upon scholarships on regulatory science and institutional theories to understand the regulatory processes of new drugs approved in India.

Syed Shahzad Hasan et al., *Pharmaceutical Policy Reforms to Regulate Drug Prices in the Asia Pacific Region: The Case of Australia, China, India, Malaysia, New Zealand, and South Korea*, 18 Value in health regional issues 18–23 (2019), http://dx.doi.org/10.1016/j.vhri.2018.08.007

Drug prices affect affordability and access to medicines, particularly in countries where a major portion of pharmaceutical spending is through out-of-pocket payments. We have undertaken a detailed appraisal of the pharmaceutical policy reforms to regulate drug prices in 3 developed (Australia, New Zealand, and South Korea) and emerging (China, India, and Malaysia) economies of the Asia Pacific region. Despite continuous efforts by the authorities in adopting a wide range of reformatory pharmaceutical pricing policies to ensure the affordability of medicines, these policies may not be optimal if drug prices were not lowered as expected. This

review of pharmaceutical pricing reforms reinforces the need for constant monitoring by policymakers in Asia Pacific countries to monitor drug prices.

Rani & Shukla, *Impact of rules for new drug and clinical trial in India*, International journal of drug regulatory affairs (2020), https://www.indianjournals.com/ijor.aspx?target=ijor:ijdra&volume=8&issue=1&article=005
The draft of the New Drugs and Clinical Trials Rules was published in the Gazette of India by the central government on March 19, 2019. Awareness of the changing rules among the stakeholders will ensure good clinical practice. The responsibility of the ethical regulation of clinical trials is a concern of the Drug Controller General of India (DCGI).

Adrienne Y. L. Chan et al., *Access and Unmet Needs of Orphan Drugs in 194 Countries and 6 Areas: A Global Policy Review With Content Analysis*, 23 Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research 1580–1591 (2020), http://dx.doi.org/10.1016/j.jval.2020.06.020
Before undertaking this study, we searched academic databases for all English systematic reviews on global orphan drug policies published before July 2019. Africa, India, Latin America, and Russia were omitted from previous reviews of orphan drug policies. Of the 200 countries or areas examined, 92 had ODPs with a notable increase in non-high-income countries/areas over the last decade. Our findings highlight disparities in ODP establishment and scope in countries with different income levels. No studies attempted an overview of orphan drug policies in all countries with both governmental and academic evidence. Our study presents the most comprehensive review of ODP to date.

Chitra & Kumar, *Pharmaceutical market structure in India & competition concerns*, Shanlax Int J Arts Sci Humanit (2020), https://www.researchgate.net/profile/Muthu-Chitra/publication/342711665_Pharmaceutical_Market_Structure_in_India_Competition_Concerns/links/5f0595a1a6fdcc4ca455dc65/Pharmaceutical-Market-Structure-in-India-Competition-Concerns.pdf
The health Status of any country depends upon its preventive, curative, and promotive measures. The government of India exposed 'Pharma Vision 2020' aimed at making India a global leader in end-to-end drug production. Health Status is a function of health professionals, health infrastructure, inventions, innovations in the health sector, and the nature of government

programs and policies. Too much regulation reduces competition in the pharmaceutical market, says the researcher.

Markan et al., *Indian Medical Device sector-blue print & regulatory policy roadmap*, International journal of high risk behaviors & addiction (2020), https://www.indianjournals.com/ijor.aspx?target=ijor:ijdra&volume=8&issue=2&article=004
In 2015, the Government of India included the medical device sector in its ambitious Make in India program. Since then, there have been various policy initiatives by the Government to address ecosystem requirements. These include rolling out the Medical Device Rules 2017 to regulate devices and introducing of 100% FDI policy to attract foreign investments. The industry has expectations in terms of a policy roadmap for catalyzing this sector and making it self-sustainable.

The Participation of Pharmaceutical Drug Industry in Patent Governance and Law-Making: A Case Study of India and Nigeria, in Nigerian Yearbook of International Law 2018/2019 153–176, https://doi.org/10.1007/978-3-030-69594-1_7
This paper traces the participation of pharmaceutical drug manufacturers in patent governance and law-making in India and Nigeria. It highlights the complex interrelationship between state and private actors involved in IP knowledge governance. The paper finds that various government policies in India enabled the growth of the sector. Conversely, a series of policies by the Nigerian government incapacitated the Nigerian pharmaceutical sector.

Bhavna Sharma et al., *Impact of the Drug Prices Control Order (2013) on the Utilization of Anticancer Medicines in India: An Interrupted Time-Series Analysis*, 14 Cureus e26367 (2022), http://dx.doi.org/10.7759/cureus.26367
The National Pharmaceutical Pricing Authority introduced a series of Drug Prices Control Orders in 1970 to regulate the prices of essential medicines in India. Out of 1556 anticancer drug packs, 22.3% (n= 347) were price-controlled. The policy led to an immediate and long-term decline in the utilization of anticancer medicines in the Indian private sector. We used monthly sales audit data for 2012-15, provided by Intercontinental Medical Statistics (IMS) Health.

Sadhika Chegu & Maddi V. Nagabhushanam, *A comprehensive study on Regulation of herbal*

drugs in India, US and European union, 9 International journal of drug regulatory affairs 78–86 (2021), https://www.indianjournals.com/ijor.aspx?target=ijor:ijdra&volume=9&issue=1&article=009
The current investigation audits the guidelines of herbal medications (Hm's) in India US and Europe. It illuminates issues identified with their clinical preliminaries. Natural medications have been utilized for quite a while in various frameworks of well-being like Ayurveda, Yunani, Sidha, and Homeopathy. The laws and guidelines for natural medications are distinctive in various nations. The WHO has expressed that every nation ought to have a framework to control Hm's medications in their region.

Swami & Abhyankar, *A Scientific Approach and Perception for Clinical Practice in India*, International business review (Oxford, England) (2021), http://jpionline.phcog.interactivedns.com/index.php/ijpi/article/view/1126
The rate and extent of absorption of a drug from its dosage form are referred to as bioavailability. While bioequivalence between two drug products is attained if their extent and rate of absorption do not relatively differ when administered at the same dose. This study is not an experimental study but a form of data analysis and reporting of comparative bioavailability studies.

Umesh & Balmuralidhara, *SPURIOUS DRUGS IN INDIA: COMPARISON WITH EUROPE AND USA, SYSTEMATIC REVIEW*, of Disease and … (2021), https://archives.biciconference.co.in/index.php/JODAGH/article/view/6064
India has a bigger problem of spurious and substandard drugs, which result in life-threatening issues, financial loss of consumers and manufacturers, and loss of trust in the health system. The conversion of credible medication into unsatisfactory medication can cause several adverse effects from mild to direct and severe. To provide information regarding tracking and tracing of spurious drugs in India in comparison with the United States (USA), and Europe (EU).

Veer J. Patel & Dasharath M. Patel, *A comprehensive review on registration requirements for Drug Approval in India, South Africa and US*, 9 International journal of drug regulatory affairs 62–71 (2021), https://www.indianjournals.com/ijor.aspx?target=ijor:ijdra&volume=9&issue=1&article=007
The drug approval process is country-specific. The regulatory framework of all the national regulatory agencies differs from one another in terms of administration and product-specific

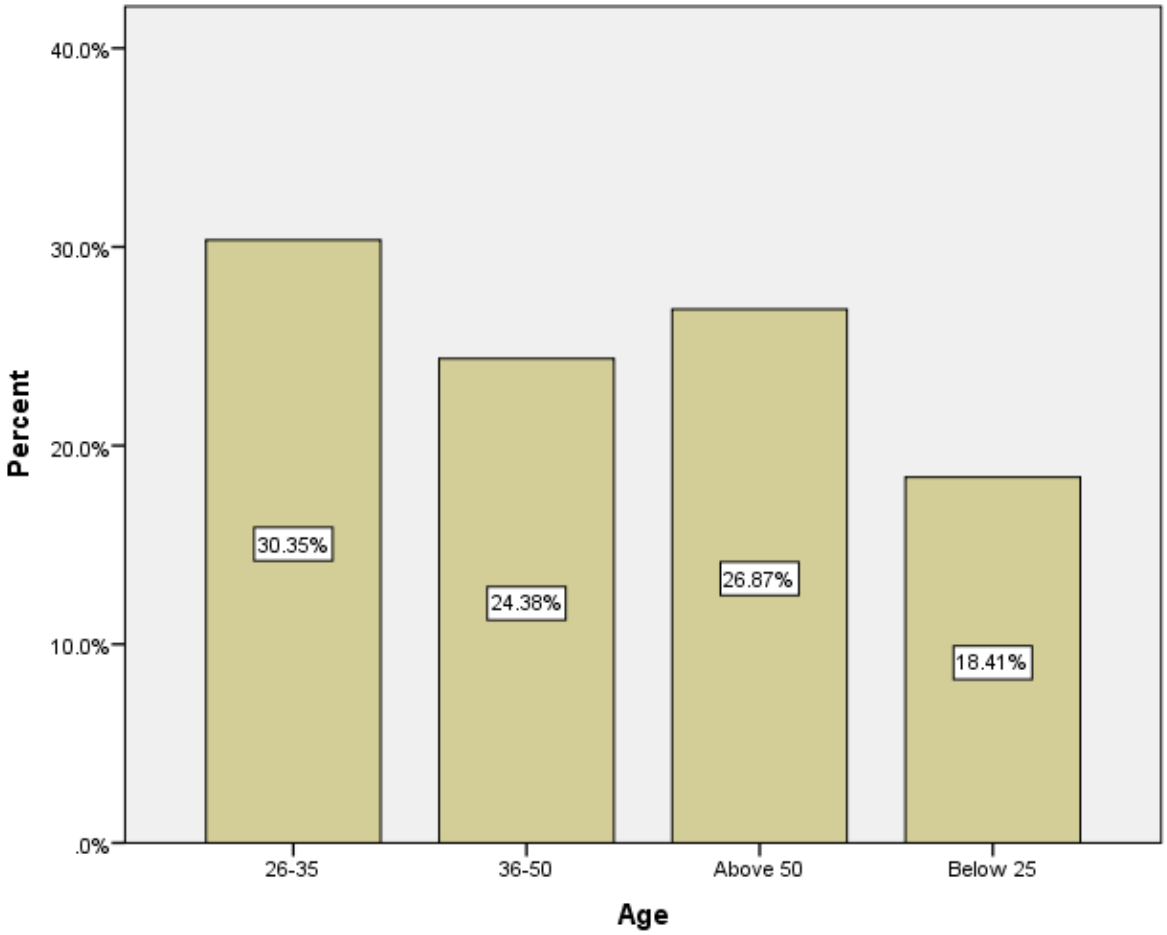
guidelines for the registration of drugs and drug products in a particular country. Every national regulatory authority provides regulatory guidelines for drug or drug product registration and the pharmaceutical industries which rely upon these guidelines prepare drug applications along with all the required administrative, non-clinical, and clinical data in the form of a technical dossier which is known as a Common Technical Document. This Dossier is prepared either in an electronic format or in the paper submission format. This review focuses on the comparative study of the registration requirements for getting drug approval in India, South Africa, and the United States of America. The significant differences between the technical requirements of these three markets have been discussed in detail.

RESEARCH METHODOLOGY AND METHOD :

This research paper aims to find out the main causes of the available legislation and other causes why there is a high availability of improper drugs in the pharmaceutical market and other factors which cause the same. The study deals with empirical research i.e., non-doctrinal study. It deals with both primary as well as secondary sources of data and various secondary sources like books, articles, research papers, etc. were used as references. The study deals with survey methods and the main tool for analyzing the results is SPSS. The method of collecting is through a direct survey method by people's opinions and answers to the questionnaires. The Simple Random sampling method was used for this collection of responses for this study. The total Sample Size is a total of 210 samples collected in this study. The Independent Variables are Age, Gender, Place of Residence, Education qualification, and Income [per month] Occupation Dependent Variables are Do you agree that by effective drug regulation the safety of the general public is assured, On a scale of 1 to 10 how do you rate the efficiency of government policies in drug regulation and According to you What is the main cause for failure of drug regulation

ANALYSIS

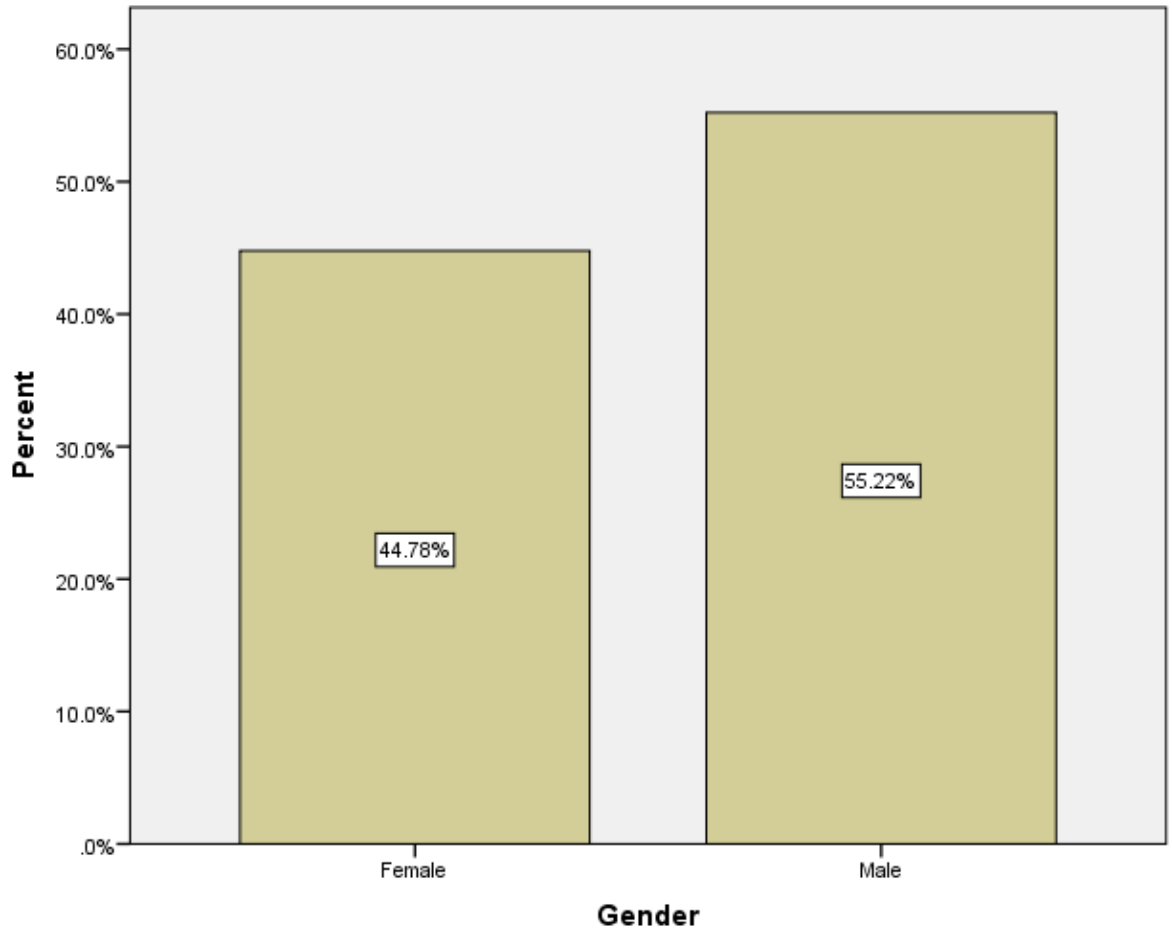
Figure1:



Legend:

Figure 1 Shows the Distribution of the responses for the Independent Variable “Age”

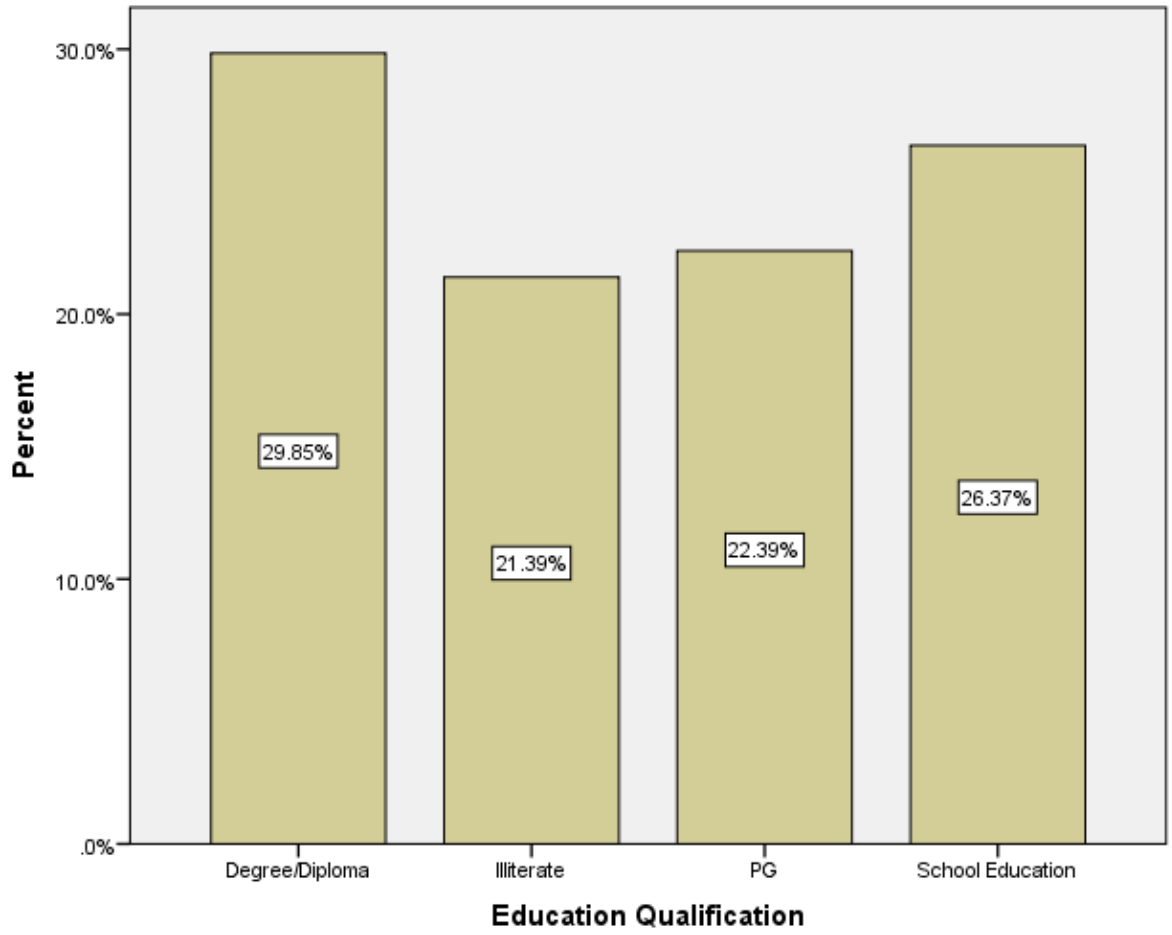
Figure2:



Legend:

Figure 2 Shows the Distribution of the responses for the Independent Variable "Gender"

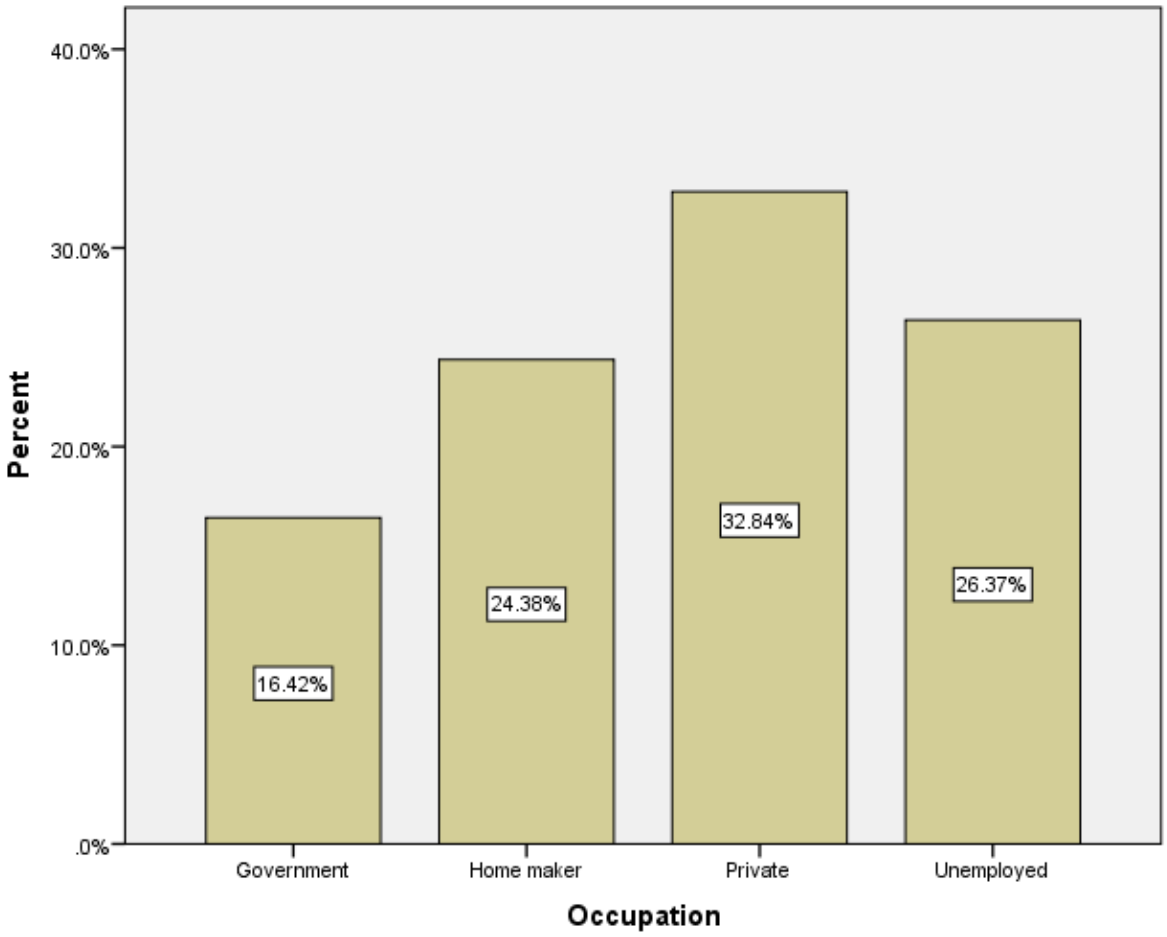
Figure3:



Legend:

Figure 3 Shows the Distribution of the responses for the Independent Variable "Education Qualification"

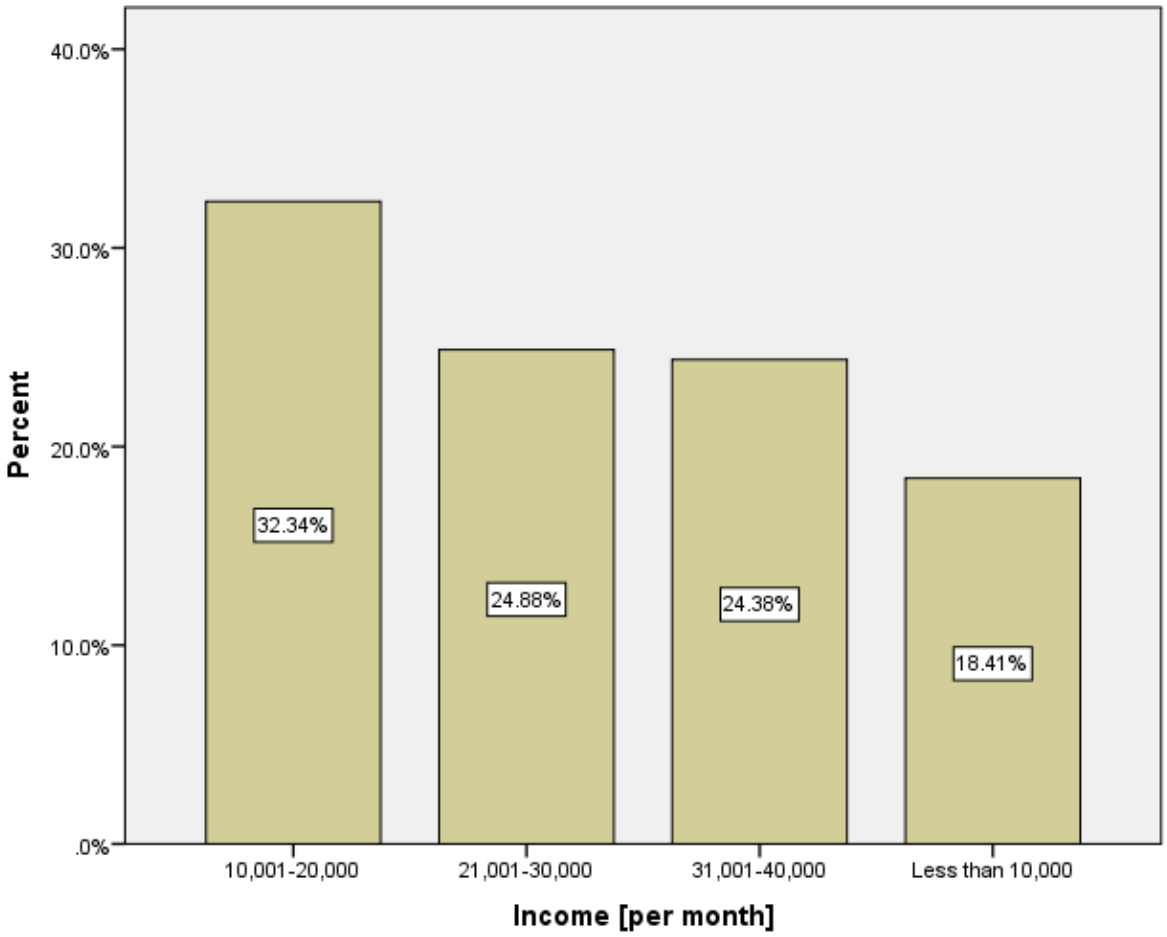
Figure4:



Legend:

Figure 4 Shows the Distribution of the responses for the Independent Variable "Occupation"

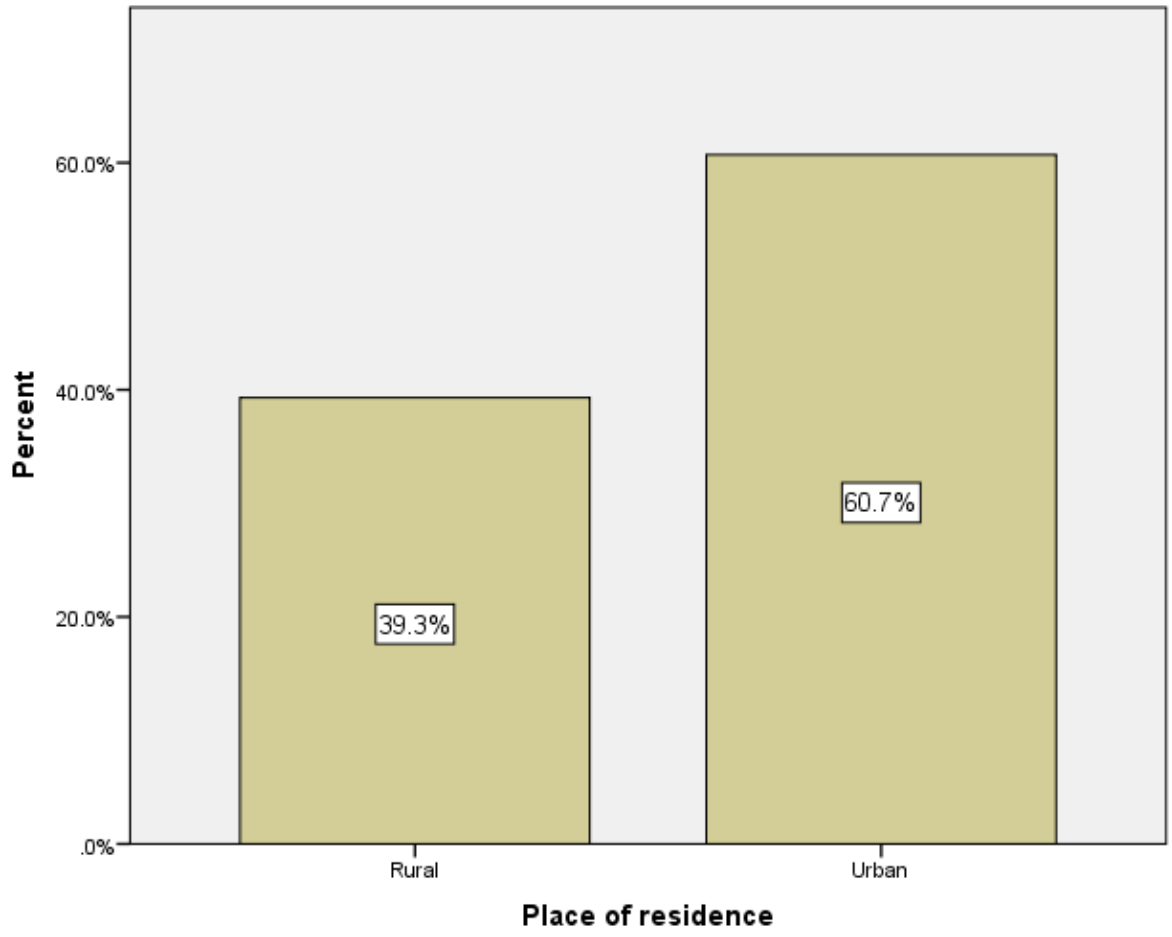
Figure5:



Legend:

Figure 5 Shows the Distribution of the responses for the Independent Variable "Income[Per Month]"

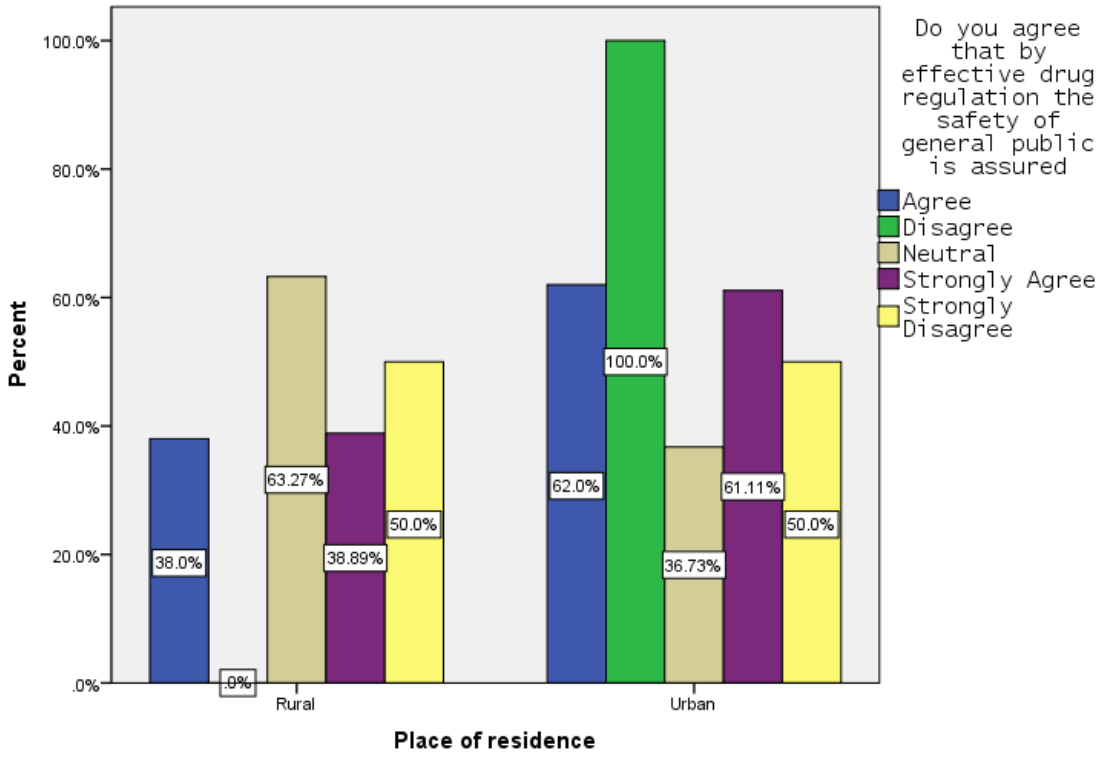
Figure6:



Legend:

Figure 6 Shows the Distribution of the responses to “Place of Residence”

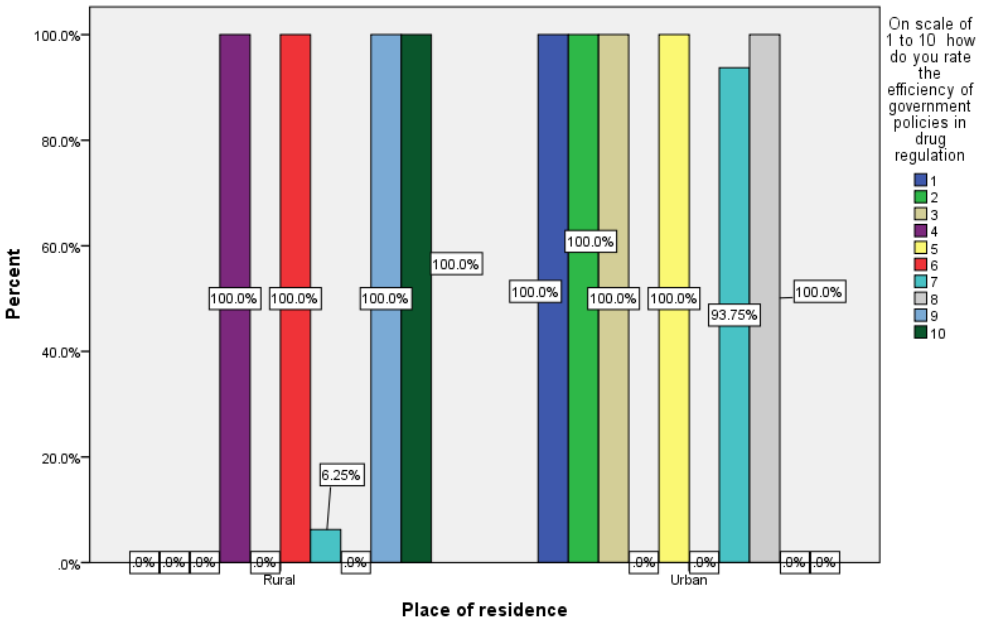
Figure7:



Legend:

Figure 7 Shows the Distribution of the responses to “Place of Residence” and opinions on the Effectiveness of Drug regulation on the health of the General Public

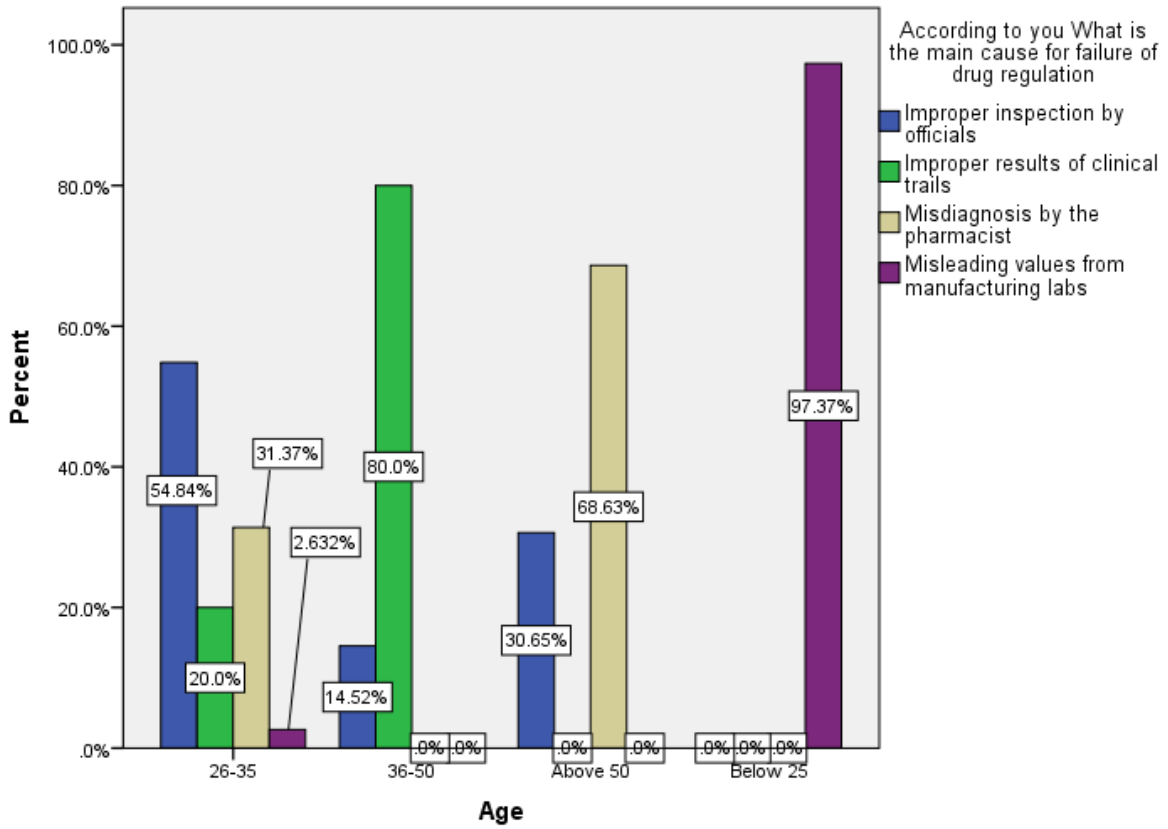
Figure8:



Legend:

Figure 8 Shows the Distribution of the responses of "Place of Residence" and opinions on the Effectiveness of Government policies in the field of Effective Drug Regulation

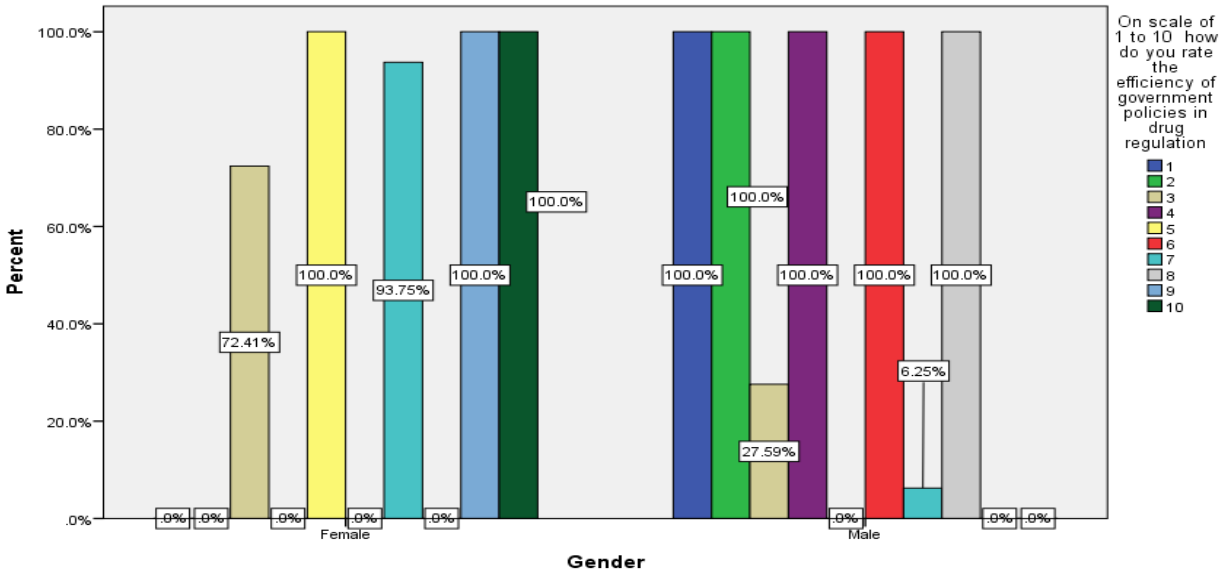
Figure9:



Legend:

Figure 9 Shows the Distribution of the responses of "Age" and opinions on the Causes of Effective Drug Regulation

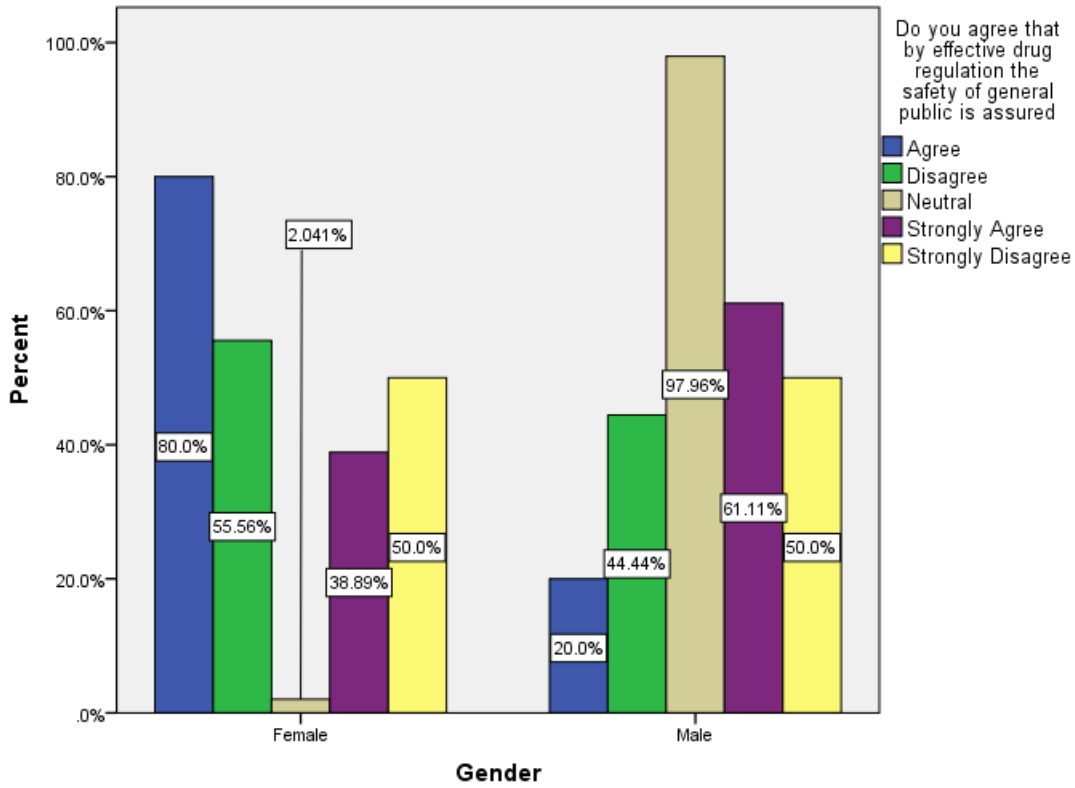
Figure10:



Legend:

Figure 10 Shows the Distribution of the responses of "Gender" and opinions on the Effectiveness of Government policies in the field of Effective Drug Regulation

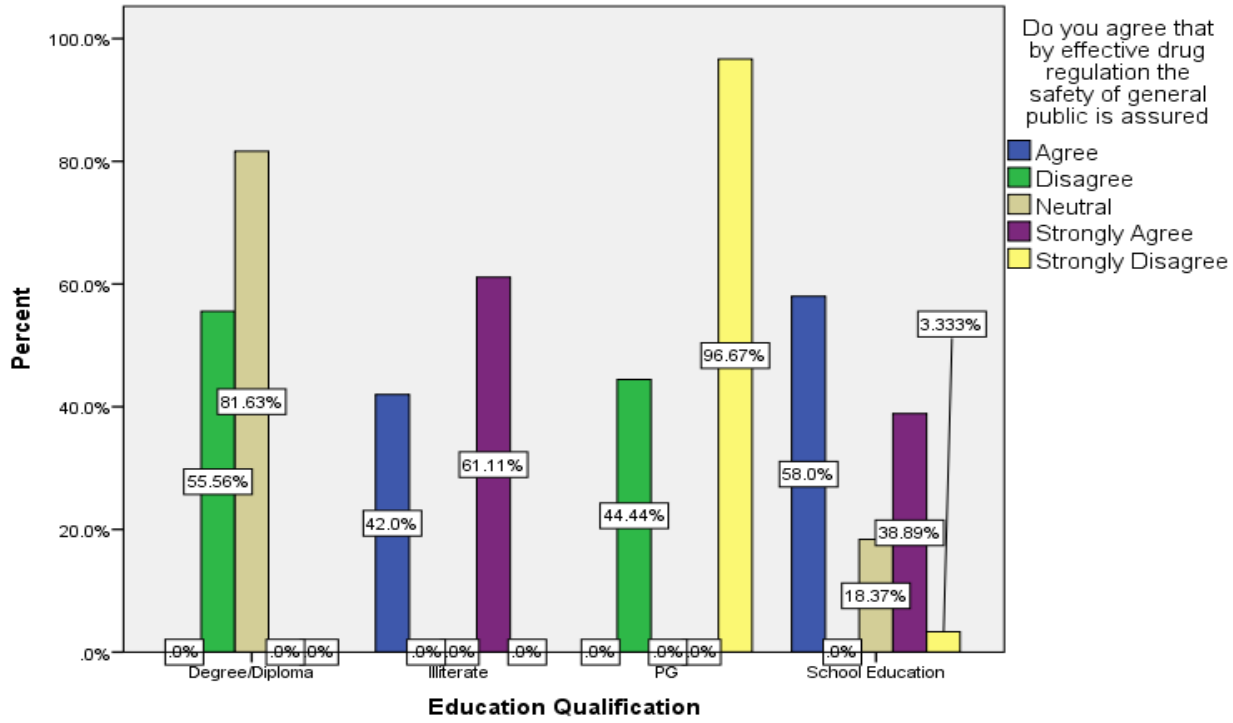
Figure11:



Legend:

Figure 11 Shows the Distribution of the responses of "Income [per month]" and opinions on the Effectiveness of Government policies in the field of Effective Drug Regulation

Figure12:



Legend:

Figure 12 Shows the Distribution of the responses to "Education Qualification" and opinions on the Effectiveness of Drug regulation on the health of the General Public

Figure 13:

Case Processing Summary

	Cases					
	Valid		Missing		Total	
	N	Percent	N	Percent	N	Percent
According to you What is the main cause for failure of drug regulation * Place of residence	201	100.0%	0	0.0%	201	100.0%

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)
Pearson Chi-Square	40.259[a]	3	.000
Likelihood Ratio	48.083	3	.000
N of Valid Cases	201		

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 14.94.

Legend:

Figure 13 shows the chi-square test performed on the locality and causes of failure of drug regulation

RESULTS:

respondents from the age group of 26-35 have responded the most the least respondents are from the age group of below 25 years (figure 1)

Respondents from the male gender group responded the most and respondents from the female age group responded the least (figure 2)

Respondents who have completed a degree/diploma have responded the most Respondents who are illiterate have responded the least (figure 3)

Respondents who work in the private sector have responded the most and the least respondents are from the government sector (figure 4)

Most of the respondents earn 10,000-20,000 per month least respondents earn less than 10,000 (figure 5)

Respondents from the urban area have responded that most respondents from the rural areas are the least responded (figure 6)

Respondents from the rural area mostly responded neutral and least responded agree Respondents from the urban area mostly responded disagree and least responded neutrally (figure 7)

Respondents from the rural area mostly responded neutral and least responded agree Respondents from the urban area mostly responded disagree and least responded neutrally (Figure 8)

Respondents from the rural area mostly responded neutral and least responded agree Respondents from the urban area mostly responded disagree and least responded neutrally (Figure 9)

Respondents from the Female gender have rated 3 the most and the least responses are for the 10 (figure 10)

Respondents from the rural area mostly responded neutral and least responded agree Respondents from the urban area mostly responded disagree and least responded neutrally (figure 11)

Respondents from the rural area mostly responded neutral and least responded agree Respondents from the urban area mostly responded disagree and least responded neutrally (figure 12)

The null hypothesis is rejected as the p-value of the test is below .000 the alternate hypothesis is accepted (figure 13)

DISCUSSION :

The respondents from the age category of 26-35 years have responded to the questionnaire at large. This states that most of the respondents for the questionnaires are from the age category of 26-35 years (Figure1).

The respondents from the gender category of male have responded to the questionnaire at large. This states that most of the respondents for the questionnaires are from the gender category of male (Figure2).

The respondents from the education qualification of Degree/Diploma holders have responded to the questionnaire at large. This states that most of the respondents for the questionnaires are persons of educational qualifications as undergraduates (Figure3).

The respondents from the occupation category of Private sector employees have responded to the questionnaire at large. This states that most of the respondents for the questionnaires are from the occupation category of Private sector employees (Figure4).

The respondents who earn 10,001 -20,000 have responded to the questionnaire at large. This states that most of the respondents for the questionnaires earn 10,001 -20,000(Figure5).

The respondents from the locality of urban areas have responded to the questionnaire at large. This states that most of the respondents for the questionnaires are from the locality of urban areas (Figure6).

The respondents from the different localities category have expressed their views regarding the questionnaire on whether they agree that by effective drug regulation the safety of the general public is assured. In that, the highest respondents from the rural areas neither agree nor disagree the highest respondents from the urban areas disagree This states that the respondents of rural areas are not aware of the effective drug regulation compared to the respondents from the urban areas (Figure 7).

The respondents from the different localities have expressed their views regarding the questionnaire that rate the effectiveness of policies in drug regulation. In that, the highest respondents to the questionnaire from the rural areas responded as 10 out of 10 and the highest respondents to the questionnaire from the urban areas responded that 8 out of 10. This states that the respondents of the rural don't know about the policies compared to the respondents from the urban area (Figure 8).

The respondents of different ages expressed their views regarding the questionnaire about what are the causes of failure of effective drug regulation, the highest number of respondents to the questionnaire those aged below 25 years responded that the leading cause for irregular drug regulation is because due to the misleading values of manufacturing labs This states that the respondents have said to improve proper medicines the labs which manufacture them should give proper details and values (Figure 9).

The respondents from the different gender groups have expressed their views regarding the questionnaire that rate the effectiveness of policies in drug regulation. In that, the highest respondents to the questionnaire from the male gender responded as 10 out of 10 and the highest respondents to the questionnaire from the male gender responded that 8 out of 10. This states that the female respondents don't know about the policies compared to the male respondents (Figure 10).

The respondents from different gender groups expressed their views regarding the questionnaire on whether effective drug regulation ensures the safety of the general public. In that, the highest respondents to the questionnaire from the male gender responded as neutral and the highest respondents from the female gender group responded agree This states that male respondents are more aware of the ineffective policies compared to the female respondents (Figure 11).

The respondents of different Education qualifications expressed their views regarding the questionnaire about whether effective drug regulation ensures the safety of the general public, the highest number of respondents to the questionnaire who completed PG responded strongly

disagree that effective regulation doesn't ensure public safety. This states that the respondents have said drug regulation doesn't ensure public safety(Figure 12).

The respondents from different localities have expressed their views regarding the questionnaire determining causes of failure of drug regulation. In this the p-value is described as 14.97 This states there is no (Figure 13).

From the secondary data, we can get to know about the factors which affect effective drug regulation which are listed as corruption, privatization, politicians, and improper awareness to the public this is considered to be an added cause as India is still in the phase of development and improvement in the existing and available healthcare system within its borders though it also gets some of the medicines from other countries the factor is same for those type of medicines also as the territorial and constitutional laws of India applies once there is a person or any goods.

SUGGESTIONS:

If there are proper authorities who are not corrupt and legislations which are more effective and punish the culprits who supply the improper drug within the nation properly without any influence of the politicians and money influence and with the increase in the awareness campaigns of the nation there will be a decrease in the cases of unethical practices of medicines.

LIMITATIONS:

The sampling method followed in this study is simple random sampling. The study is unable to collect data through random sampling methods due to the reduced geographical arena. Since the study is restricted to the territory within Tamil Nadu and therefore the conclusion derived by average is not perfectly accurate. Since the study collected responses from the general public at large, the findings are mostly based on generalized opinion rather than the legal or scientific background.

CONCLUSION:

India with a diverse availability of medicine the Consumers who lack the tools to confirm the legitimacy or potency of pharmaceuticals must constantly be given the assurance that the medications being made accessible to them are of high quality and secure for usage. Therefore, it is up to other players at different supply chain nodes to offer crucial assurance. Since a participatory approach is used to guarantee the supply of high-quality medication, the problems

associated with it are interrelated and cannot be addressed separately. The definition and application of the manufacturing process's quality standards are one of the main challenges that the business and regulators must overcome. Although they are generally aligned in theory, quality standards vary from country to country (on the one hand), and a more urgent concern inside India arises from the inconsistent interpretation of rules there (on the other hand). Furthermore, the current federal system is complicated by the fact that states have varying regulatory capacities as a result of a lack of testing resources and qualified employees. To address a number of these regulatory bottlenecks, concerted efforts must be made to harmonize the interpretation of legal terminology found in the pertinent act and guidelines, rationalize the workload distribution among regulatory staff, use technological tools to close the information gap for policymakers, and encourage industry self-regulation and voluntary compliance. The great news is that the Indian government and businesses are aware of the issues that need to be prioritized, even though the quality of medications manufactured in India at the moment is being questioned. The cabinet recently approved a plan to enhance the drug regulating system at both the federal and state levels, which is one significant reform step in this direction.