Ensuring Pharmaceutical Integrity: The Impact of India's Drugs and Cosmetics Act Relating to Spurious Drugs on Public Health

Abstract:

The Drugs and Cosmetics Act, 1940, plays a vital role in regulating drugs and cosmetics in India. It encompasses various chapters, each addressing specific aspects of quality, safety, and effectiveness. Notably, the Act defines spurious drugs explicitly in different contexts, with stringent penalties for violations. These provisions are designed to protect public health by ensuring the authenticity and quality of pharmaceutical and cosmetic products, thus preventing the distribution of counterfeit or adulterated items.

Over the years, the Act has undergone several amendments to adapt to changing needs and advancements in the pharmaceutical and cosmetic industries. These amendments have strengthened the regulatory framework and addressed emerging challenges.

A case study from the Rajasthan High Court in 2012 illustrates the Act's practical application. In this case, an individual was accused of manufacturing and distributing fake life-saving injections. The court's decision to reject bail emphasized the gravity of the accusations and the importance of considering the nature of the offense. The Drugs and Cosmetics Act, 1940, with its amendments, is a cornerstone of pharmaceutical and cosmetic regulation in India, prioritizing public health and product quality.

KEY WORDS:

Drugs and Cosmetics Act, Pharmaceutical regulation, Spurious drugs, Public health, Amendments, Regulatory framework, Drug quality, Counterfeit drugs, India, Pharmaceutical integrity.

Introduction:

The Drugs and Cosmetics Act, 1940, is a vital Indian law that governs drugs and cosmetics. It covers various chapters, addressing specific aspects of regulation. It provides definitions for key terms and creates essential bodies. Chapter III regulates the import of drugs and cosmetics, emphasizing "standard quality" and public safety. Chapter IV focuses on manufacturing, sales, and distribution, setting quality standards and enforcing regulations. The Act aims to ensure product quality, safety, and effectiveness, emphasizing compliance with standards and penalties for violations, all in the interest of public health.

In the Drugs and Cosmetics Act, 1940, several sections explicitly define what constitutes a spurious drug within different contexts. Section 9B(2) of the Act outlines that a drug is considered spurious if it is imported and sold under a name that belongs to another drug, imitates or serves as a substitute for another drug in a manner likely to deceive consumers, bears a fictitious manufacturer's name on the label or container, has been partly or wholly substituted by another drug or substance, or falsely claims to be the product of a manufacturer to which it has no true connection. Similarly, Section 17B provides parallel definitions for spurious drugs, emphasizing the importance of clearly marking products to reveal their true character and lack of identity with other drugs, along with penalties for violations.(3)

In Section 33EEA(4), which is specific to Ayurvedic, Siddha, or Unani drugs, spurious drugs are defined as those sold under another drug's name, imitate or substitute for another drug in a deceptive manner, bear a fictitious manufacturer's name on the label or container, have been partly or wholly replaced by any other drug or substance, or falsely claim to be the product of a particular manufacturer. These stringent definitions and regulations are critical components of the Act, aimed at safeguarding public health by ensuring the authenticity and quality of drugs and cosmetics in India while preventing the distribution of counterfeit or adulterated products.(5)

Material and methods:

1. Data Collection:

Legislative Analysis: The study involved an extensive review and analysis of India's Drugs and Cosmetics Act, 1940, including its various amendments up to [specific date or version].

Case Study: Information about the Rajasthan High Court case of Rajesh Purohit (Bholiya) vs State on 15 December, 2012 was obtained from the court records, legal documents, and available public reports.

2. Research Approach:

Literature Review: A comprehensive literature review was conducted to gather information on the historical context, evolution, and impact of India's Drugs and Cosmetics Act, as well as the definitions and implications of spurious drugs in the pharmaceutical industry.

3. Data Analysis:

Content Analysis: The content of the Drugs and Cosmetics Act, along with its amendments, was meticulously examined to identify key sections defining spurious drugs, penalties for violations, and the evolution of regulatory provisions.

Case Study Analysis: Details of the Rajasthan High Court case were analyzed to understand the practical application of the Act in a real-world scenario, emphasizing its implications on public health and legal proceedings.

4. Ethical Considerations:

Ethical Review: As the study involved the analysis of publicly available legal documents and publicly reported case information, ethical considerations primarily revolved around ensuring accurate interpretation and representation of the legal facts and proceedings without biases or misinterpretation.

4.Limitations:

Scope Limitations: The study's scope was limited to the available information in publicly accessible legal records and documented reports. The analysis is based on the accuracy and completeness of these sources.

Tailor these sections to describe how the information was gathered, the methods of analysis employed, any ethical considerations, and the limitations of the study. Adjust the specifics to align with the actual approach taken in the research.

Results & Discussion:

Amendments:

The act has been amended several times. The following are a list of amending acts:

1955's Drug (Amendment) Act(8)

4.2. 35 of 1960, The Drugs (Amendment) Act

4.3. 1962's Drugs (Amendment) Act (21 of 1962)

4.4. Act of 1964 (13 of 1964) amending drugs and cosmetics

4.5. 1982's Drugs and Cosmetics (Amendment) Act (68 of 1982)

4.6. Act of 1986 to Modify Drugs and Cosmetics

4.7. Act of 1995 (71 of 1995) to Modify Drugs and Cosmetics

4.8. Act of 2008 to Modify Drugs and Cosmetics (26 of 2008)

4.9. Act of 2016 to Modify Drugs and Cosmetics

4.1. 1955's Drug (Amendment) Act:(9)

The Drugs (Amendment) Act, 1955, made several changes to the Drugs Act, 1940, in India. It expanded the definition of "drug" to include medicines for humans and animals, substances for disease treatment and prevention, and substances affecting human body functions. It clarified the term "manufacture" and defined "prescribed." The Act also amended the composition of the DTAB, empowered inspectors to enforce the Act's provisions, and introduced penalties for repeat offenses. It provided for the publication of offenders' details and allowed magistrates to impose sentences exceeding their usual powers. The Act also protected individuals acting in good faith under its provisions. Lastly, it made changes to the Schedule, specifying standards for various substances

35 of 1960, The Drugs (Amendment) Act:(10)

The Drugs (Amendment) Act, 1960, introduced changes to the Drugs Act, 1940, in India. Some key amendments included defining the roles of Government Analysts and Inspectors, empowering them to ensure drug quality, and setting penalties for violations. It also allowed for the seizure of evidence related to drug offenses and streamlined the process for rule-making and parliamentary oversight. Additionally, the Central Government gained the authority to provide directions to State Governments for effective implementation of the Act. These amendments aimed to enhance drug regulation and public safety.

1962's Drugs (Amendment) Act (21 of 1962):(11)

The Drugs (Amendment) Act of 1962 expanded the Drugs Act of 1940 in India to include cosmetics. It defined cosmetics and established standards for their quality. The act introduced penalties for manufacturing or selling misbranded cosmetics and allowed for confiscation of non-compliant products. Repeat offenders faced stricter penalties. The government could make rules for cosmetics, subject to parliamentary oversight. The act also empowered the Central Government to issue directions to states for consistent implementation. In summary, this amendment aimed to regulate cosmetics, prioritize consumer safety, and maintain product integrity.

Act of 1964 (13 of 1964) amending drugs and cosmetics:(12)

This amendment, known as the D&C (Amendment) Act, introduced changes to the Indian D&C Act of 1940. It applied certain provisions, including penalties, to Ayurvedic, Siddha, and Unani drugs. The Act specified the books for reference in the Ayurvedic and Unani systems and established standards for these medicines. It allowed for the confiscation of contraband drugs and required that rules be laid before Parliament. Additionally, it set standards for imported drugs and certain substances, including vaccines, vitamins, and hormones. Until the constitution of the DTAB, the existing board was deemed to continue functioning.

4.5. 1982's Drugs and Cosmetics (Amendment) Act (68 of 1982):(13)

The D&C (Amendment) Bill of 1982 aimed to enhance drug regulation and quality control in India due to concerns about spurious and substandard drugs. Key issues included the need for a robust regulatory system, prevention of unauthorized drug imports, and addressing shortages of trained personnel in the drug control administration. The bill also focused on raising public awareness about penalties for selling spurious drugs and introducing summary trials for drug-related offenses. However, concerns were raised about potential misuse of Section 34AA against drug inspectors. The legislation aimed to strike a balance between enforcement and safeguards for inspectors.

4.6. Act of 1986 to Modify Drugs and Cosmetics:(14)

The D&C (Amendment) Act, 1986, is a legal amendment in India that modifies the Drugs and Cosmetics Act, 1940. It allows recognized consumer associations to take legal action against violations of the Act. This amendment also defines a recognized consumer association as one in compliance with the Companies Act of 1956 or another applicable laws. Additionally, it empowers individuals and these associations to file complaints regarding violations. This amendment came into force on a date specified by the Central Government through an official notification.

4.7. Act of 1995 (71 of 1995) to Modify Drugs and Cosmetics:(15)

The D&C Act aims to regulate drugs and cosmetics in India to maintain high medical standards. It covers medicines for humans and animals, as well as substances used for diagnosis, treatment, or prevention of diseases. The government has the authority to create rules, appoint inspectors, and control standards. Violators can face imprisonment and fines. The D&C Rules

of 1995 list drugs requiring licenses for manufacture, import, and export. Recently, in vitro diagnostic devices for blood groups and diseases like HIV were added to the list for quality control.

4.8. Act of 2008 to Modify Drugs and Cosmetics (26 of 2008):(16)

The D&C (Amendment) Act, 2008 introduced significant changes to the Drugs and Cosmetics Act, 1940, in India. One key aspect of this amendment was the establishment of Special Courts to exclusively handle cases related to adulterated or spurious drugs. These Special Courts were designated by the Central or State Government and had jurisdiction over specific drug-related offenses. Furthermore, the Act made certain drug-related offenses cognizable, meaning they could be investigated and charged without requiring a warrant. It also imposed stricter bail provisions for individuals accused of these offenses. To facilitate legal proceedings in these Special Courts, the Act extended the provisions of the Code of Criminal Procedure, 1973, treating these courts as Courts of Session. Additionally, the Act allowed for the appointment of Public Prosecutors or Special Public Prosecutors for these cases. Moreover, the High Court was granted the authority to exercise powers of revision and appeal over cases handled by Special Courts. These amendments were aimed at enhancing the legal framework for drug and cosmetic regulation, particularly in cases involving adulteration and spurious products, and streamlining the legal processes associated with them.

4.9. Act of 2016 to Modify Drugs and Cosmetics:(17)

The D&C (Amendment) Bill, 2016, proposed changes to the D&C Act, 1940, in India. The bill aimed to enhance the expertise within the Drugs Technical Advisory Board by including a scientist with knowledge and expertise in non-animal alternatives to experimentation. This addition was seen as crucial to avoid redundant animal testing, align with global practices, and meet the requirements of Indian law that emphasize the avoidance of experiments on animals when possible. The bill sought to address the need for more contemporary and humane testing methods in India's regulatory framework.

DISCUSSION:

5.1 CASE STUDY:
Rajasthan High Court - Jodhpur
Rajesh Purohit @ Bholiya vs State on 15 December, 2012(18)

5.2 BRIEF FACTS OF THE CASE:

In 2012, Rajesh Purohit (Bholiya) sought bail in the Rajasthan High Court. He was accused of manufacturing and distributing fake life-saving injections. The police had raided several medical stores, seizing spurious drugs. Purohit was charged with making counterfeit labels, boxes, and distributing fake drugs. His bail plea was rejected due to the serious nature of the accusations and potential harm caused. The court emphasized that bail should consider the gravity of the offense.

5.3 PROCEDURE:

The case pertains to a bail application filed in the Rajasthan High Court in 2012. The petitioner, Rajesh Purohit (also known as Bholiya), had been arrested in connection with a criminal case involving offenses under various sections of the Indian Penal Code, Trade Marks Act, and the Drugs & Cosmetics Act.

The key points from the order are as follows:

5.3.1. Accusations: Rajesh Purohit was accused of being involved in a racket that manufactured and distributed spurious drugs, specifically spurious Mero-CD and Merosul injections. These injections were found to be fake and spurious after analysis, and they were identified as life-saving drugs.

5.3.2. Investigation: The case was initiated based on information received by the Senior Head Officer of the Khanda Falsa Police Station and the Drug Control Officer of Jodhpur. Several medical stores were raided, and spurious injections were seized. The accused were allegedly involved in manufacturing, distributing, and selling these spurious drugs.

5.3.3 Charges: Rajesh Purohit was charged under various sections of the Indian Penal Code (such as cheating and criminal conspiracy), the Trade Marks Act (related to trademark violations), and the Drugs & Cosmetics Act (specifically sections 17-B and 27, related to spurious drugs).

5.3.4. Evidence: The prosecution presented evidence that the accused Rajesh Purohit was allegedly responsible for manufacturing the spurious drugs, printing counterfeit labels and boxes, and distributing these fake drugs to various medical stores.

5.3.5. Bail Application: Rajesh Purohit filed a bail application under Section 439 of the Code of Criminal Procedure, seeking release from judicial custody.

5.3.6. Arguments: The petitioner's counsel argued that the petitioner had been falsely implicated and that the recovery of counterfeit labels and boxes did not conclusively prove his involvement in dealing with spurious medicines. They also contended that similar allegations against a co-accused had resulted in bail being granted to that individual.

5.3.7. Prosecution's Opposition: The prosecution opposed the bail application, asserting that the petitioner was the mastermind behind the racket involving the manufacture and supply of spurious drugs, which had resulted in loss of lives.

5.3.8. Court's Decision: The court rejected the petitioner's bail application, considering the nature and gravity of the accusations against him. The court noted that the accused was allegedly responsible for manufacturing, distributing, and selling spurious drugs, which affected the lives of innocent people. Given the seriousness of the offense, the court concluded that the accused did not deserve to be granted bail.

In the end, the court emphasized that while bail is generally granted as a matter of course, it should be considered in light of the nature of the offense and the gravity of the allegations. The court also discussed relevant legal provisions related to bail and the prosecution of offenses under the Drugs & Cosmetics Act.

TABLE NO:1 OFFENCES AND PENALITIES:

OFFENCES	PENALITIES
6.1 Imports of spurious drugs or cosmetic unsafe for use(19)	Punishable by imprisonment for up to three years, a fine of up to five thousand dollars, or both upon the first conviction. imprisonment for up to five years, a fine of up to ten thousand dollars, or both upon the second.
6.2 **Manufacture of a spurious medication likely to result in death or severe bodily harm in accordance with IPC Section 320.**(19)	2 years in prison for life and a minimum fine of Rs. 10,000.
6.3 Sale stocking, display, or distribution of Spurious pharmaceuticals(7)	3-5 years in prison and not less than a fine of Rs. 5,000 for a first offense, and 6–10 years in prison and not less than a fine of Rs. 10,000 for a second offense
6.4 Sale, stocking, exhibition, or offer for sale of drugs that are likely to cause death or serious injury in accordance with Section 320(20)	5 years life in prison and a fine of at least 10,000 rupees. sale, stocking, display, or offer to sell a contaminated medicine 1-3 years in jail and a fine of at least Rs. 5,000 for a first offense, and 2–6 years in prison and a fine of at least Rs. 10,000 for a second offense.

CONCLUSION**:**

India's Drugs and Cosmetics Act, 1940, is a comprehensive and dynamic legal framework that plays a vital role in regulating pharmaceuticals and cosmetics, ensuring their quality, safety, and effectiveness. The Act defines spurious drugs explicitly and enforces stringent penalties for violations, aiming to protect public health by preventing the distribution of counterfeit or adulterated products.

Through a series of amendments, the Act has evolved to meet the evolving needs and challenges of the pharmaceutical and cosmetic industries. These amendments have strengthened regulatory mechanisms, enhanced accountability, and adapted to contemporary issues.

A noteworthy case study from the Rajasthan High Court in 2012 demonstrated the practical application of the Act, emphasizing the seriousness with which it treats offenses related to spurious drugs, especially when they jeopardize public health.

The Drugs and Cosmetics Act, 1940, and its amendments remain a cornerstone of pharmaceutical and cosmetic regulation in India. They prioritize public health, product quality, and consumer safety, reflecting the nation's commitment to maintaining pharmaceutical integrity and safeguarding its citizens' well-being.

References:

1. Agrawal P, Kushwaha V, Sahu A, Kumar P. SPURIOUS DRUGS (A BRIEF REVIEW). Certified Journal | Kushwaha et al World Journal of Pharmaceutical Research [Internet]. 2023;12(2). Available from: www.wjpr.net

2. Section 9B in the Drugs and Cosmetics Act, 1940 [Internet]. [cited 2023 Oct 16]. Available from: https://indiankanoon.org/doc/499171/

3. Swaminath G. Faking it - I The Menace of Counterfeit Drugs. Indian J Psychiatry [Internet]. 2008 [cited 2023 Oct 16];50(4):238. Available from: /pmc/articles/PMC2755136/

4. Section 33EEA in the Drugs and Cosmetics Act, 1940 [Internet]. [cited 2023 Oct 16]. Available from: https://indiankanoon.org/doc/1551098/

5. Das S, Bhakta T. A Survey to the Extent of Spurious Drugs in the Market of India. Research Journal of Pharmacognosy and Phytochemistry. 2018;10(3):233.

6. Yadav S, Rawal G. Counterfeit drugs: problem of developing and developed countries. International journal of Pharmaceutical Chemistry and Analysis. 2(1):46–50.

7. Section 17B - The Drugs and Cosmetics Act | LAWGIST [Internet]. [cited 2023 Oct 16]. Available from: https://lawgist.in/drugs-and-cosmetics-act/17B

8. THE DRUGS AND COSMETICS ACT, 1940 [Internet]. [cited 2023 Oct 16]. Available from: https://wipolex-res.wipo.int/edocs/lexdocs/laws/en/in/in021en.html

9. A1955-11.

10. A1960-35.

11. A1962-21.

12. A1964-13.

13. Act 068 of 1982 : Drugs and Cosmetics (Amendment) Act, 1982 | CaseMine [Internet]. [cited 2023 Oct 16]. Available from: https://www.casemine.com/act/in/5a979db54a93263ca60b72d0

14. A1986-71.

15. (Beta version)National Institute of Health & Family Welfare [Internet]. [cited 2023 Oct 16]. Available from: http://www.nihfw.org/Legislations/THEDRUGSANDCOSMETICS.html

16. the-drugs-and-cosmetics-(amendment)-act,-2008.

17. Drug and Cosmetics Act 1940 & Rule 1945 (Amended 2016) | ChemLinked [Internet]. [cited 2023 Oct 16]. Available from: https://cosmetic.chemlinked.com/database/view/236

18. Rajesh Purohit @ Bholiya vs State on 15 December, 2012 [Internet]. [cited 2023 Oct 16]. Available from: https://indiankanoon.org/doc/16213971/

19. THE DRUGS TECHNICAL ADVISORY BOARD, THE CENTRAL DRUGS LABORATORY AND THE DRUGS CONSULTATIVE COMMITTEE.

20. CrPC Section 320 - Compounding of offences | Devgan.in [Internet]. [cited 2023 Oct 16]. Available from: https://devgan.in/crpc/section/320/

Abbreviations:

1. DTAB: Drug Technical Advisory Board.
2. D&C Act: Drug and Cosmetics Act.
3. HIV: Human Immunodeficiency Virus.