Commentary

Drugs Act 1978 of Nepal: A Critical Analysis

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Abstract

Background: With the enactment of the Drug Act in 1978, through the establishment of different bodies under the act, drug-related activities have been regulated and controlled in Nepal so as to provide safe and efficacious drugs of standard quality to the general public. However, with the overgrowing use of drugs, cosmetics, biotechnological products, nutraceuticals, and veterinary products in the present market and the present act failing to include these aspects, this paper tries to critically analyze the Drug Act 1978 of Nepal which will comprise strengths, weaknesses, opportunities, and threats faced in current scenario regarding the act. The regulation of drugs in Nepal was started with the enactment of the Drugs Act in 1978 AD, which is being carried out by the Department of Drug Administration as provisioned in the section 5 of the act. To facilitate the proper implementation of the act, various rules, regulations and guidelines are framed. The objective of this study was to explore the areas to improve in the Drugs Act and help foster the use of safe, efficacious and quality drugs.

Method: The Drugs Act 1978 was critically analyzed focusing on the strengths, weaknesses, opportunities, and threats of the act as of current scenario.

Result: After critically analyzing the drugs act 1978 we found out that there is lack in regulations of use of cosmetics, newer biotechnology products, nutraceuticals, veterinary product, innovative pharmaceutical products as well as the online pharmacy services.

Conclusion: A major amendment and periodic revision is required with the consequence of meeting timely needs and promoting the idea of safety and efficacy in drug related activities.

Keywords: Drugs, Act, DDA, Regulation, Nepal

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Introduction

Among the historical period of Nepal, the Lichchhavi period was a prolific period as the historical development of health care services was initiated during this period. Despite the lack of detailed explanations on the *Aarogyashala* or hospital, mentioned on an ancient document dating back to 604 AD, it still remains as one of the significant evidence of historical data ever to be found in over the period of health and hospital development during the ruling period of the Amshu Verma (605-620 AD).[1]

Nepal being close to the Himalayan civilization the traditional ayurvedic system of medicine flourished and the practices of herbal remedies was much favored by the Hindu priest as they were influenced from Banaras (India) during the period. With this an ayurvedic

medicine production unit was established during Pratap Malla regime (1641-1674 AD) in Hanuman Dhoka Durbar which was later moved to Thapathali in 1846 AD in Singh Durbar Compound by Rana Prime Minister Jung Bahadur Rana. This was later named as Singh Durbar Vaidya Khana and later on with the period of 1906-1955 AD, the provision of distribution of medicines to the general public was made by King Tribhuvan.[2]

The concept of allopathic medicine came into existence with the establishment of a small clinic in the British Residency in 1816 AD, which was established after the Sugauli treaty, for their staff as well as the local public.

After this, with the aim of providing health care services to general people, Bir Hospital was established in 1890 AD.[1,3] The initiation of Royal Drug Research Laboratory (RDRL) (now known as Nepal Medicine Laboratory (NML)) in 1964 AD was the preliminary phase in the development of pharmaceutical field in context of Nepal.

The shops run by the government during the early 1960s to 70s helped in increasing the number of tourists. This was so because the shops were selling hashish. With the aim of enjoying and having pleasure of smoking marijuana, hippies came to Nepal from various parts of the world. However, strict regulations and rules were imposed towards the hippies and tourist during the early 1970s because of their dress codes and appearances and they were sent back to India, as it was an effect of directive from the Government of USA. With this, the hippies felt miserable and their movement phased out in the late 1970s. Taking this into consideration the government of Nepal halted the production, sales and consumption of Narcotic substances in Nepal by promulgating the Narcotic Drugs (Control) Act in 1976 AD.[4]

After the development of Narcotic Drugs (Control) Act, it somehow implemented in the development of the Drugs Act 1978 which was promulgated by the government on 25th October 1978.[3] Drugs Act 1978 was promulgated with the aim of regulating provisions related to medicinal drugs and was amended in 1988 and 2000 AD subsequently. The major aims of Drugs Act are to promote the concept of safety, efficacy and quality of drug product and to prohibit any illegal activities that may negatively impact safe and efficacious use of drugs by the general public in context of Nepal. Drugs Act 1978, act number 21 of the year 1978 is divided into 7 Chapters which consists of 40 sections.[5] (**Table *1*)**

This paper focuses on the critical analysis of the act which discusses on the strengths, weaknesses, opportunities and threat faced by the current act (**Table 2)** and recommendations in order to tackle the problems. With the changing times there needs to be an inclusion of regulations on cosmetics, nutraceuticals, biologics, poison, biotechnology products which is why this study aims to focus on such issues such that it would help strengthen the Drugs Act. Regular review and update of rules and regulation is important to address the emerging systems or technologies and challenges. This analysis will explore the areas to improve in the Drugs Act and helps to foster the use of safe, efficacious and quality drugs.

Analysis of the act

Strength

The Drugs Act has a provision for Drug Advisory Council and Drug Advisory Committee (Chapter 2, Section 3, 4) which establishes a link between the Government and Department of Drug Administration (DDA) to deal with the various aspects namely, theoretical, administrative and technical matters related to regulation of drugs. Furthermore, the act explains on DDA, a separate body, (chapter 3, Section 5) which is responsible for carrying out the function outlined by act which is definitely a strength to be reckoned with. For facilitation of research and quality control of drugs, the act (Chapter 3, Section 6) points out that not only governmental institution should be committed to testing and analysis of drug but any native or foreign person or even institution apart from governmental institution would be approved for testing, analysis and research of drug. The apical body NML is established in reference to this section that focuses on the quality control of drugs. It has opened path for private sectors to participate in drug research and quality control which brings healthy market competition.

The National Drug Policy 1995 speaks on the availability of drugs to general public. So, to achieve this objective of availability of drugs to people, establishing pharmaceutical industries is must. This availability is fulfilled by the Chapter 4 of Drugs Act where it speaks on the establishment of industries and the documentation required for it such as letter of recommendation, product license and product registration. Furthermore, section 9

provided by the act has made it feasible for trans-border trade of drugs and has helped in the transaction market by establishing healthy trading. Along with this sale of registered drug from registered shop establishes safety concerns with public and create environment of trust.

The most important parameter to be considered while manufacturing drugs is its quality and in regards to this the act provides certainty (Chapter 5, Section 12) on the fact that any drug substance which is not of utmost quality and has substandard issues can result in organ damage and casualties which is why the drugs being manufactured for public consumption should be safe, efficacious and of quality standard. Similarly, chapter 5, section 13 also prohibits drug related activities that do not adhere to safety and efficacy parameters. Making the manufacturer company liable to provide compensation in case of death or injury to the public and returning of substandard quality drugs, this act has promoted the manufacturing companies primarily towards the quality production rather than profit orientation. The ability to recall any drug (Chapter 5, Section 14) which is not safe or any sub-standard product ready for consumption which is not of quality, categorization of drugs (Chapter 5, Section 17) in three categories as narcotic and poisonous, antibiotics and hormones and over the counter drugs that helps in distinguishing which drugs can be sold, dispensed by pharmacist or assistant pharmacist based on prescription and prohibiting false or misleading advertisement of drugs (Chapter 5, Section 19) confines anybody not to falsely advertise on any matters relating to drug are the pillars that justifies chapter 5 strongly. The latest recall published on DDA's website is of 14 February 2022 where it issued an information on drug recall, stating that products from different companies didn't specify to quality parameters.[6]

The act has provisioned the systematic approach for enquiry and inspection of places where the activities relating to drugs are being carried out so as to ascertain that these activities comply with the regulation of the act. In order to facilitate the preamble of the act, Chapter 7, Section 25 provides full authority on prohibiting illegal drug related activities ranging from production to consumption when the government deems necessary. Similarly powers to fix price (Chapter 7, Section 26) gives the department an authority to fix price which may be crucial in maintaining affordability and healthy market competition. A perfect example is the price fixing of drug Tocilizumab during the corona virus treatment period.[7] The adulteration of drug and selling of adulterated and date expired drugs which can negatively impact the health of the public has been prohibited by the act as per chapter 7, section 29, 30 respectively. Similarly, section 28 also addresses about the requirement of sufficient human resources for conducting the pharmacy business which results in quality production and services related to drugs.

Clinical trials should be performed on the grounds of ethical requirements and should address the safety of participants which makes such research delicate and should be strictly regulated. By making DDA the body to provide license for the clinical trial of new drugs, the act has regulated the clinical trials in Nepal (Chapter 7, Section 31).

With the aim of controlling abuse and misuse of narcotic and poisonous drugs, section 33 requires clear labelling on narcotic and poisonous drugs along with their safe storage. Along with that a proper documentation of sold or distributed narcotic and poisonous drugs in a standard format must be maintained. With the discovery of different novel drugs in today's context their registration as an Intellectual property right is very significant. With the aim of facilitating the registration of intellectual property rights, the act has preserved the right to register the patent of drug as per section 36. Ultimately the strongest pillar of Drugs Act 1978 is section 40 'Powers to frame Rules'. This section paves a path for supplementing the act with further inclusion of different rules and regulations. Drugs Advisory Council and Drugs Advisory Committee Formation Rules, 2037(1970), Drugs Registration Rules, 2038 (1981), Drug Investigation and Inspection Rules, 2040 (1983), Drugs Category Rules, 2043(1986) all were framed under this section with the aim of proper functioning of different sections of the act.

Weakness

There are numerous weaknesses within the act and in order to find the weakness we need to compare it with an act of other countries that deals with human life in each and every aspect. The Drugs Act 1978 of Nepal doesn't deal with cosmetics, and its usages however Drug and Cosmetic Act 1940 of India (Act 23 of 1940) deals with its regulation. Our market which is so much filled with cosmetics needs a strong vigilance and for that a concrete rule that specifically deals with cosmetics should also be

incorporated within this act. An article in 2012 concluded that various desired lipsticks available in the Nepalese market were found to have very high level of lead. Upon continuous use the amount of lead present was enough to cause different kinds of disabilities and health problems. The study also explained that during the market survey there was no any responsible monitoring body for the quality, sell, import and distribution of cosmetics.[8] Similarly, a study published in 2021 concluded in its findings that the concentration of heavy metals such as cadmium and lead were more than the standard limit which is why a proper assessment of such cosmetics is necessary to ascertain its quality and harmful effects.[9] This finding shows that a strong regulation is in need regarding cosmetics regulations. Unlike the Drug and Cosmetics act of India, the Drugs Act of Nepal haven't addressed on the topic of spurious, misbranded drugs and cosmetics together. However, it addresses on the prohibition of adulteration in drugs and its sales (chapter 4, section 29) only.

A rise in formulation of the biologics control act 1902 was one of the major milestone in the evolution of Good Manufacturing Practice (GMP) within the US which came into existence when a tragic incident involving death of more than 10 children was encountered due to the contamination of diphtheria antitoxin with live tetanus bacilli.[10] The fact that US realized the importance and lethality of biologics back then gives a reference for developing nations like us to realize its importance. No inclusion of Biologics regulation in the current act of 1978 questions on the inspection and regulation of manufacture and sales of biological products. Since the Drugs Act highlights the use of drug for animals or bird too, it does not specify its regulations and safety protocols.

The guideline responsible for regulating the nutraceuticals is Dietary Supplement Guideline 2016 in context of Nepal. With the rampant prescribing of nutraceuticals for financial perks, it has aroused a question regarding its safety and efficacy.[11,12] Drugs Act 1978 and the Dietary supplement guideline 2016 are not concerned with proper prescribing, dispensing and counselling requirements. Therefore, for its proper management within the prescribing field, the act must include criteria and regulations to it.

The Right to Safe Motherhood and Reproductive Health Act, 2075 explains the contraceptives with in the 'Right to reproductive health and Safe motherhood and newborn baby'.[13] However, regarding its production, sale and distribution is not mentioned within the Drugs Act.

Section 17 of Drugs Act includes categorization of drugs but hasn't categorized drugs on the basis of risk during pregnancy. Section 5 of the act explains on the establishment of DDA and the roles conducted by DDA in order to implement different chapters and section. With the nomination of DDA as the National Pharmacovigilance Center by the government of Nepal, it has started collecting reports on adverse drug reactions.[14] Despite this fact the act do not specifically elucidate on Pharmacovigilance and its proper working framework. The content regarding labelling is explained by the Drug category rules 2043 schedule 5 which is framed under section 40 of Drugs Act 'Power to frame rules. The Drug and Cosmetics Act 1940 of India has a provision where it explains that if the drug or a cosmetic is not labelled properly then it comes under misbranded drugs/cosmetics, spurious drugs/cosmetics, however the drugs act 1978 doesn't explain on any of these topics. One of the alarming issue in today's context is medication disposal. The role of pharmacist in safe medication disposal and proper counselling to patient can definitely help in reducing health risk and environmental safety.[15] The inclusion of such thing in the act can improve and help recognize many pharmaceutical field personnel in reducing the medical disposal burden. This demands for an adequate patient counselling on safe disposal of medication which ultimately aims in protecting human health and contributing towards the environment protection.

It's been more than two decades the act has been amended. With the rapidly growing pharmaceutical field and in order to meet contemporary demands amendment is necessary. There has been a global increase in number of online pharmacies in recent times. In India, acts and regulations such as the Drug and Cosmetics Act 1940, Drugs and Cosmetic Rules 1945, Pharmacy Act 1948, the Indian Medical Act of 1956 and the Information Technology Act 2000 are governing online pharmacies. However in India also the laws regulating online business are not properly defined and can be interpreted differently.[16]

Table 1. Drugs Act 1978 Chapters and Sections

Chapter Number and Title	Section Number Included
1. Preliminary	1-2
2. Drugs Advisory Council and Drug Advisory Committee	3-4
3. Research and Control of Drugs	5-6
4. Manufacture, Sale, Distribution, Export and Import of Drugs	7-11
5. Quality Standard of Drugs	12-19
6. Inquiry and Inspection	20- 24
7. Miscellaneous	25-40

Table 2. Analysis of the act

Strength	**Weakness**
➢ Drug Advisory Council and Drug Advisory Committee (Chapter 2, Section 3,4) ➢ Department of Drug Administration (DDA) (Chapter 3, Section 5) ➢ Drug Research Laboratory and other Laboratories (Chapter 3, Section 6) ➢ Safe, efficacious and quality standard drugs for consumption (Chapter 5, Section 12) ➢ Prohibition of drug activities not conforming to safety and efficacy parameters (Chapter 5, Section 13) ➢ Return of drug not conforming to prescribed standards (Chapter 5, Section 14) ➢ Categorization of drugs (Chapter 5, Section 17) ➢ Prohibition on false or misleading advertisement of drugs (Chapter 5, Section 19) ➢ Powers of Government of Nepal to prohibit drug related activities (Chapter 7, Section 25) ➢ Powers to fix Price (Chapter 7, Section 26) ➢ Safe storage of Narcotic and Poisonous drugs (Chapter 7, Section 33) ➢ Powers to frame Rules (Chapter 7, Section 40)	➢ Exclusion of regulation relating to Cosmetology ➢ Lack of explanation of Spurious Drug ➢ Biological Medicines ➢ Veterinary Products ➢ Nutraceuticals ➢ Contraceptives ➢ Drug category for Pregnant women ➢ Pharmacovigilance ➢ Labelling and Advertisement ➢ Weak Penalty Model
Opportunity	
	➢ Growth of Cosmetics ➢ Rise in Nutraceuticals use ➢ Inclusion of regulations regarding contraceptives, biological medicines, veterinary products, poisons ➢ Drug Classification for Pregnant Women ➢ Spurious and Adulterated products
Threat	
	➢ Violation of Drugs Act ➢ Trafficking of Drugs ➢ Impact in quality and efficacy of drugs ➢ Increase counterfeiting of drugs ➢ Misuse and improper marketing of ayurvedic and homeopathic products ➢ Irrational use of nutraceuticals

In context of Nepal, there is no specific regulation governing online pharmacies. There is availability of numerous websites as online pharmacies however their exact data is still unknown due to lack of clear registration regulations. On the ground of possibilities of dissemination of wrong information and increasing illegal sales of medicines from the so called online pharmacies, the Department of Drug Administration of Nepal had issued a notice on 25th March, 2021 to close such pharmacies until further notice.[17] The patient can get easy and fast services from the online pharmacies and considering the increasing number of unregistered online pharmacies that has potential to grow further in Nepal, there seems a necessity of strong regulations to promote and govern online pharmacy in general.

Opportunities

With numerous such weaknesses, the opportunity also arises. The ever-rising use and growth of cosmetics definitely forwards a space for growth of the cosmetics act or inclusion in the act. Regulatory provisions regarding proper prescribing and dispensing of nutraceuticals can govern current rampant use. Inclusion of regulations relating to contraceptives, biological

medicines, veterinary products, and a comprehensive model of classification of drugs including risk drugs for pregnancy category and sections highlighting the topic of spurious and adulterated products and the requirements for labeling and advertisement of drugs, cosmetics, and biotechnological products can further help in improving the current Drugs Act. The application of modern technology in the regulation of drug-related business can facilitate the better implementation of the act. Chapter 7, Section 34 "Penalties" deals with penalties regarding violations of the act. The penalties section has not been updated since the second amendment which makes the penalties weaker as of present which is why it possesses a threat to its violation again and again.

Threats

Since there are open borders between Nepal and India and a lack of proper surveillance due to open borders pose the risk of trafficking of drugs. Trafficking of drugs can include spurious or adulterated drugs that can pose threat to the general public which is why it can be a matter of great concern. Counterfeit of drugs may increase as the act doesn't specifically focus on counterfeit drugs and also because of the weak penalty system. Misuse and improper marketing of ayurvedic and homeopathic products and no detailed information on these products can lead to its misuse and improper marketing as it could lead to serious adverse health outcomes. Finally, a huge impact on the quality and efficacy of drugs can be seen since there are no proper storage condition requirements defined in the act.

Conclusion

As of present, the act seems unable to regulate all the business related to the pharmacy which can pose risk to the health of the public. Analyzing strength-opportunities (maxi-maxi) and weakness-opportunities (mini-maxi) points, a strategy must be laid out by the responsible officials which would pave a path for the formulation of a plan and help for the amendment of the act. With the growth in the use of drugs, cosmetics, and biotechnological products in today's era it is essential for our country to include proper regulation regarding these products in a principal act which would definitely help us to increase our standard in the coming future. Major amendment of the Drugs Act 1978 is recommended along with a periodic revision of the act.

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