

Evolution of Medicines Regulatory System in Bhutan: History, Status and Challenges

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Abstract

Bhutan is a small landlocked Kingdom in the eastern Himalayas, situated between China and India. Health care in Bhutan is provided free by the government, as guaranteed under the Constitution. No proper system for regulation of medicines existed before 2003. The Essential Drugs Program, instituted in 1986, played the role of regulatory authority and issued technical clearances for sale and distribution of medicines. Notable improvements were seen in the procurement, quantification and store management of medicines under the umbrella of the Essential Drugs Program. The path to medicines regulation in Bhutan started with the enactment of The Medicines Act of the Kingdom of Bhutan in 2003. The Drug Regulatory Authority, established under the Ministry of Health in 2004, began to register medicines before they were imported into Bhutan. Premises licensed for manufacture, sale, distribution, storage and dispensing medicines are monitored for regulatory compliance. Systems for pre-marketing and post-marketing control of medicines were initiated. Bhutan's medicines regulatory system has gradually evolved over the last decade. As a new regulatory system, it faces a number of challenges as the scope of regulatory activities continues to expand. However, there is a need to further strengthen the capacity of drug testing laboratories, and the availability and capacity of regulatory human resources should be enhanced and infrastructure improved for effective regulation of medicinal products in the country. As systems evolve and people change over time, institutional memory is lost. It is important to document the steps adopted by Bhutan, so that other small nations can learn from Bhutan's experiences. This article documents the path Bhutan has taken towards strengthening the regulatory system for medicines. The article also addresses the challenges involved and recommends measures to address them.

Keywords: medicines, regulation, evolution, Act, Bhutan

1. Introduction

Bhutan is a small Kingdom situated in the eastern Himalayas and landlocked between China and India. As of May 30, 2017, the total population of Bhutan was 735,553, with a birth rate of 15.5 per 1000 population, while the general fertility rate is 57.3 percent [12]. The gross national income per capita was USD 2640.17 in 2016 [10].

The modern health system in Bhutan began in 1961 with two hospitals, two doctors and two nurses [18]. Today, health services have reached every corner of the country. Health care is provided free by the government as guaranteed under the Constitution [9]. In 2017, 94.8 percent of Bhutanese lived within three hours of the nearest health facility [7]. Medicines and technologies constitute an important building block of the health system. Key concerns in public health are regulation of medicines and making medicines available through proper distribution channels, as medicines make up an important aspect

of health development technology [16]. Bhutan is heavily dependent on the import of pharmaceuticals and, owing to the low volume of demand, a number of procurement challenges exist.

More than 40 years after the establishment of a modern health system in Bhutan, the government enacted a bill regulating medicines, called the Medicines Act of the Kingdom of Bhutan. The Drug Regulatory Authority (DRA) was established in May 2004 to enforce the provisions of the Act. Since then, Bhutan's medicine regulatory system has gradually evolved. However, there is paucity of information related to the medicines and regulatory system in Bhutan. As systems evolve and people change over time, institutional memory is lost. It is important to document how Bhutan built the regulatory system, as many smaller nations still do not have a proper national medicine regulatory system and these countries could learn from Bhutan's experience.

This article documents the history of medicines regulatory practices in Bhutan, highlights the steps and processes adopted to strengthen the system, underlines the challenges and recommends measures to address these challenges. This is the first such article on the subject and can serve as a repository

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of knowledge for future research on this subject in Bhutan. The information was sourced from consultancy reports, review records, records of minutes and proceedings in the bill drafting process, as well as historical narratives of people who worked in the system.

2. Early Medicines Regulation in Bhutan

No proper system of medicines regulation existed in Bhutan prior to 2003. All pharmaceuticals in the country were broadly regulated by a notification called Drug Control Rules of Bhutan, 1974. This notification, however, did not cover all aspects of pharmaceutical regulation [19]. A list of pharmaceutical companies in India was obtained from the Drug Controller of India and, from this list, selected companies were registered as suppliers who could then participate in a tender. The registration process required submission of an application form, along with the World Health Organization (WHO) model Good Manufacturing Practices Certificate.

There was no system for registration of medicines or issuance of import permits for importation of medicines. Starting in the early nineties, few prioritized medicines were sampled and sent for testing in laboratories in neighboring countries like India and Thailand. However, this was constrained by high testing charges and delayed receipt of the results. Only a few private pharmacies were operating in the country at this time. These pharmacies were allowed to import medicines directly from Indian wholesalers, without having to register the medicines or the companies supplying them. During that time, private pharmacies were licensed by the Ministry of Trade and Industry (currently the Ministry of Economic Affairs) in line with the existing rules [6]. Sections 12 and 20 of this Rule are specific for pharmaceuticals.

3. Role of the Essentials Drugs Program

Until 1986, challenges in the drug supply system resulted in poor drug availability, poor quality, irrational prescribing and high expenses of medicines [17]. A government corporation, the State Trading Corporation of Bhutan Limited, procured and supplied medicines to the public health facilities before the institution of the Essential Drugs Program (EDP), and continued to do so until 1998, when the Supplies Management Unit was established to manage the supply of medicines. The EDP functioned as a regulatory body and coordinated the drafting of the National Drug Policy, which provided basis for development of pharmaceutical legislation.

In 1990, a Medical Supplies Unit was established at Phuntsholing and took over the activities of both the Supplies Management Unit and the State Trading Corporation of Bhutan Limited. The Medical Supplies Unit was responsible for selection, quantification, procurement, storage and distribution of medicines in the public sector. Later, the EDP, under the then Drugs, Vaccines and Equipment Division within the Ministry of Health (MoH), was responsible for monitoring the sale and

distribution of medicines in the country. The EDP played a crucial role in the medicines governance system with notable improvements in the procurement, quantification and store management. By 1998, Bhutan's EDP was considered one of the most successful programs in the Southeast Asia Region [17].

4. Drafting of the Medicines Bill

Legal, administrative and technical measures are all essential to ensure the safety, efficacy and quality of medicines, as well as the relevance and accuracy of product information [15]. In 1996, a consultant fielded in by the WHO to study the medicines regulatory system in Bhutan and, as a result, the basic structure of the Bill was developed. However, the draft Bill remained dormant until early 2001.

In order to continue the legislative drafting process, a Drafting Committee, consisting of members from various organizations, was formed to work on the draft Bill. A Review and Translation Committee was then formed to review and translate the Bill into Dzongkha, the national language of Bhutan. The Bill was discussed and reviewed in several consultative meetings before it was presented to the Lhengye Zhungtshog (Cabinet of Ministers) for endorsement. The Bill was finally passed by the National Assembly of Bhutan during its 81st session on August 5, 2003.

5. Establishment of the DRA

In accordance with Section 10 of the Act, the Drug Regulatory Authority was established in May 2004 and was housed under the MoH with the appointment of three staff. The DRA remained under the MoH for almost five years, as there was limited human resources and infrastructure capacity to function as an independent organization. It was granted full autonomy in 2008 via executive order of the Council of Ministers (COM/04/07/121 dated 29 July 2007) to ensure greater independence and efficiency in the enforcement of the Act.

The Bhutan Medicines Board (BMB) was constituted as the highest policy making body in accordance with Section 4 of the Act. The first BMB meeting was convened on June 14, 2004 and suspended the issuance of licenses for pharmacies until a proper system of registration procedures for new pharmacies could be put in place. The BMB also recommended the drafting of the Bhutan Medicines Rules and Regulations (BMRR) and the constitution of the Drug Technical Advisory Committee (DTAC). As per Section 9 of the Act, the DTAC was formed as the highest technical advisory body, designed to support the BMB and DRA in effective medicines regulation. The first DTAC meeting was held on September 28, 2004. Since then, 34 DTAC meetings and 17 BMB meetings have been held.

6. Drafting of the BMRR

Drafting of the BMRR began soon after that first BMB meeting in June of 2004. The meeting involved all relevant agencies and stakeholders in order to ensure a comprehensive

Regulatory Provisions	BMRR ^a 2005	BMRR ^a 2008	BMRR ^a 2012
Route of registration	Full evaluation	Full evaluation	Full and Abridged evaluation
Clause on post registration changes	No	No	Yes
Clause on registration exemption	No	No	Yes
Minimum qualification for Competent Person ^b	Certificate in Pharmacy with at least 5 years experience	Certificate in Pharmacy/Diploma in gSo_ba Rig_pa ^c /Veterinary medicines	Certificate in Pharmacy/Diploma in gSo_ba Rig_pa/Veterinary medicines
Minimum qualification for ADI ^d	Silent	Silent	Certificate in Pharmacy
Doctors ^e dispense medicines at private pharmacies	No	No	Yes
Procedure for storage of first-aid medicines	No	No	Yes
General Sale Lists medicines	No	No	Yes
Penalties for offences	Same penalties for government and private pharmacies	Same penalties for government and private pharmacies	Different penalties for government and private pharmacies

^a Bhutan Medicines Rules and Regulation; ^b Personnel authorized for sale and distribution of medicinal products; ^c Bhutanese Traditional Medicines; ^d Assistant Drug Inspector; ^e Human and Veterinary Doctors.

Table 1: Revision of Bhutan Medicines Rules and Regulations.

discussion about the regulatory provisions. The first edition of BMRR came into force in 2005 and has undergone two revisions so far - one in 2008, and another in 2012 - to align with national policies and international standards. Drug regulation must be dynamic and it is important for the National Regulatory Authorities (NRAs) to function in keeping with the changing environment. The revisions and changes incorporated in each edition of the BMRR are shown in Table 1.

During the revisions, relevant government agencies and private pharmaceutical dealers were consulted and their issues and challenges were considered. Stakeholders were trained and sensitized on the provisions of the BMRR to create awareness and encourage compliance. Public acceptance and compliance with medicines regulation was a challenge initially, but people gradually started to better understand the importance of regulation for quality medicinal products, and compliance improved as a result.

7. Implementation Status, Challenges and Lessons

There have been several achievements in the regulation of medicines since the establishment of the DRA in 2004. Bhutan began registering medicines and issuing import authorizations in accordance with the BMRR. Personnel involved in dispensing of medicines in private pharmacies became certified as competent after clearing the competency exams conducted by the DRA. Today, more than 60% essential medicines are registered and available in public health facilities (draft 12 Five Year Plan of DRA, 2018-2023). Monitoring has been emphasized through pre-marketing and post-marketing control mechanisms. Private and public pharmacies are now aligned with the regulatory provisions, and medicinal products are evaluated for quality, safety and efficacy following defined standards [5]. Product category-specific guidelines have also been developed for evaluation of

vaccines, biotechnology products, health supplements, test kits and veterinary medicines.

In addition, various mechanisms have been adopted to improve access to medicines. Availability has improved through the use of alternate registration processes, such as expedited and abridged routes and exemption system. Bhutan has adopted an abridged registration route from 2012, which allows WHO prequalified products and products registered with any of the identified regulatory authorities to become registered with minimum documentation [4]. On June 30, 2017, Bhutan introduced the expedited registration process, which resulted in registration of over 800 medicinal products in under one year, increasing the availability of medicines to the public, as per the records. Overall, increased governance and transparency in regards to the regulation and procurement of medicines in Bhutan has resulted in the increased availability of safe, quality and efficacious medicines, which has in turn boosted confidence and trust in the public health system.

One study showed that product approvals by regulatory authorities in Saharan Africa took longer than other countries [1]. In Bhutan, the turn-around-time for issuance of a product registration certificate is 45 working days, which is much shorter compared to other countries. Some of the regulatory services can be accessed online from 2018 through the Government to Citizen (G2C) services. The validity of import authorizations for registered products has been extended from one month to one year. The DRA is also exploring online system for dossier submission as studies have reported that digitization of drug regulation is effective in many other countries [15].

Premises licensed for manufacture, sale, distribution, storage and dispensing medicines are inspected for regulatory compliance, which has improved over the years. The number of private pharmacies and manufacturing firms in the country has also increased over the years. The number of private pharmacies and manufacturing firms licensed by the DRA is shown

Types	Numbers	Existing Activities
Retail pharmacies	60	Sale and dispense both human and veterinary medicines
Wholesale pharmacies	30	Import and distribute both human and veterinary medicines
Manufacturing firms	1	Active Pharmaceutical Ingredients firm
	2	Manufactures Medical oxygen
	1	Manufactures veterinary vaccines
	1	Manufactures traditional herbal medicines (gSo-ba-Rig-pa)

Table 2: Number of private pharmacies/manufacturing firms operating in the country.

in Table 2. Pharmacovigilance and drug safety are central to post-marketing surveillance; therefore, Bhutan became a member of the WHO International Drug Monitoring Program in 2014 [3]. Adverse drug reactions reported by healthcare professionals are received and assessed using the pharmacovigilance guideline, and drug safety information is disseminated in the form of newsletters, notifications and control of drug advertisements. Pharmacovigilance and drug safety, while important, are still new concepts in Bhutan and much remains to be done to improve adverse reactions reporting [2].

Medicines regulatory authorities need to balance diverse types of demands, including timely entry into the market of quality, safe and efficacious products, and public safety, which is not easy in resource-limited countries [8]. Bhutan's DRA is also faced with a number of challenges, such as inadequate manpower, scarce financial resources, limited laboratory testing capacity and procurement challenges, which stem from a combination of low volume requirements and poor coordination among the relevant stakeholders. These issues have been mitigated through collaboration with other enforcement agencies and through the outsourcing of drug testing activities. Risk based inspections of pharmaceutical companies and a product defect reporting system has also helped ensure quality. Refresher courses for those working in private pharmacies has proved helpful in aligning pharmacy professionals with regulatory requirements. Drug shortages in Bhutan have been reduced through constant dialogue and consultation with the Department of Medical Supplies and Health Infrastructure, MoH.

7.1. Discussion

The most important lessons learned during the implementation of medicines regulation in Bhutan are included below:

1. Policy and technical support is key to setting the right direction for regulation of medicines. The establishment of the EDP and the development of the National Drug Policy in 1986 are both examples of this kind of support.
2. It is important to establish a central coordinating body to ensure that the Bill drafting process goes smoothly and that all the stakeholders are on board. The EDP played a

crucial central coordinating role in spearheading the development of the draft Bill.

3. Independence of the regulatory body is vital in ensuring efficiency and independence in decision-making. Although the DRA set up the foundation for the regulatory system under the MoH, full implementation of the Act became possible only after it became autonomous in 2008.
4. Collaboration and coordination with other enforcement agencies is necessary for successful implementation of medicines regulation. The DRA in particular benefitted from the continued support of the technical experts and enforcement agencies.
5. It is helpful to implement the Act in phases. There were small glitches during early implementation where medicine shortages were blamed on the medicines registration process. These issues were addressed through the addition of flexibility into the legislative procedures as temporary measures.
6. Legislation for medicines regulation should be developed comprehensively, as it is not easy, nor desirable, to frequently amend the Act. Medical devices and cosmetics are not mentioned in our current Act and there is a need to either include an addition or develop a separate Bill for regulating such products in the near future.
7. Public education and awareness is a must. When new systems for import were introduced in Bhutan, there was media pressure caused by shortages of medicines in the public health facilities. Although there were other coincidental issues in procurement and supply, this problem was said to be caused by regulation by the DRA. Public education and awareness through mass media channels helped improve public perception and acceptance.

8. Conclusion

Bhutan's medicines regulatory system has evolved and expanded since establishment of the DRA in 2004. Several no-

table achievements were made within the span of a decade. The quality, safety and efficacy of medicines are now ensured through enforcement of the Act, thereby promoting the consumer's confidence in the regulatory system. Today, more than 60 percent of essential medicines of the MoH are available in the market. Many important lessons learned during implementation of the Act could be useful in further evolving Bhutan's medicines legislation system. However, the country must focus on areas requiring improvement, including strengthening the Drug Testing Laboratory and pharmacovigilance system. The technical capacity of the officials also needs to be enhanced to ensure efficiency in the enforcement of the Act.

9. Declaration of Conflicting Interest

The authors declare no conflict of interest.

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11. Article Information

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