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Original Research Article

A Study on the Legal Environment of Medical Devices and Enhancing the Regulatory System

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ABSTRACT

The regulation of medical devices is governed by the Law on Health, the Law on Medicines and Medical Devices, and the Law on Metrology. While these laws provide definitions of key terms, they lack detailed regulations. The Law on Health addresses issues related to special licenses, while the Law on Metrology covers metrological inspections. According to the "Methodology for Assessing the Consequences of the Implementation of Legislation", as approved by Appendix 6 of Government Resolution No. 59 of 2016, the implementation of these laws, including the Law on Medicines and Medical Devices, the Law on Health, and the Law on Metrology, has not fully aligned with reality. This misalignment has failed to regulate certain essential relationships, leading to negative societal impacts. Consequently, we assessed the implementation and consequences of these laws, considering the lag between social changes and legal developments. Additionally, comparing medical device regulations with the standard regulations of countries around the world revealed several differences, starting from the definitions of key terms. We concluded that there is a need to improve the legal and regulatory environment to establish unified policies and regulations for registration, quality, safety, optimal asset planning, and maintenance management, particularly for medical equipment.

Keywords—*Specialists, Consequences, Equipment, Medical devices, Medical supplies, Regulation.*

INTRODUCTION

The medical device market in Mongolia is small, which limits the potential for major manufacturers to establish businesses in the country. Mongolia does not produce any medical devices, except for disposable syringes and a few other minor items. As a result, nearly all medical devices are imported from various countries and manufacturers. This situation leads to many unregistered medical devices of uncertain quality. Supplying government hospitals with modern, high-quality, safe, and reliable equipment and ensuring regular preventive maintenance and repair services has been one of the biggest challenges in the Mongolian healthcare sector.

State budget investments in medical equipment have varied over the years: in 2019, USD 2.4 million were allocated; in 2020, USD 11.2 million; in 2021, USD 32.7 million; in 2022, USD 4.3 million; and in 2023, USD 3.5 million. Before 2017, the budget for medical equipment maintenance was included in the organization's operational expenditure. However, starting in 2018, the maintenance and service costs for major technologies, such as magnetic resonance imaging (MRI) scanners, computed tomography (CT) scanners, and angiography machines, were separately allocated within the state budget. In 2018, USD 0.7 million were dedicated to this purpose, followed by USD 0.8 million in 2019, USD 1.1 million in 2020, and USD 1.6 million in 2021. From 2022 onward, due to performance-based financing, a separate budget for these services is no longer allocated.[1]

Many developing countries today face similar challenges with medical devices due to their complex nature, as they combine mechanical, electronic, software, and chemical components. This complexity necessitates a higher level of safety and an improved regulatory system. Medical devices play a crucial role in diagnosing, preventing, monitoring, and treating diseases. Unlike drugs or biologics, medical devices can range from simple devices that pose little or no risk to the user (e.g., a suction pump) to life-sustaining devices (e.g., a pacemaker). The solution to these challenges lies in developing a comprehensive regulatory system for medical devices.

Regulatory systems for medical devices are generally less developed than those for other health products such as medicines or vaccines. A desk survey conducted in 2015–2016 revealed that 58% of World Health Organization (WHO) member states had some form of regulation for medical devices, even if limited.[2] Many governments, including Mongolia, that have drafted medical device regulations have made limited progress in implementing them.

In Mongolia, medical device regulatory systems are less developed than in other countries. Having an appropriate and comprehensive policy that guides medical equipment selection, procurement, and maintenance in compliance with international standards. While Mongolia has some ministerial orders and policy documents related to medical devices and health technology, there is still a need for improvement. Additional regulatory systems are required, including import control, product registration, classification, packaging and labeling, advertising, use, and disposal.

METHODOLOGY

We assessed the implementation of laws and regulations related to medical device regulation to identify areas for improving the regulatory system. We reviewed relevant articles, audit and evaluation reports, and other documents from authorized organizations to analyze the practical compliance of laws and regulations with their provisions and compare them with the most significant and influential international standards. Additionally, recommendations, documents, and standards from the WHO and international regulatory organizations were analyzed. Comparative studies were conducted on the regulations of other countries in relation to Mongolia's legal environment. Data collection involved meetings, discussions, and feedback exchanges using the following methods.

The descriptive study included audit, monitoring, assessment reports, news from authorized organizations, and recommendations, documents, standards, and regulations from the WHO and international regulatory organizations. Additionally, three focus group interviews were conducted, involving 26 participants divided into three groups: 9 medical equipment engineers from local healthcare facilities, 8 university faculties, and 9 medical equipment engineers from the private sector. The focus group interviews were analyzed using the content

analysis method to assess the implementation of legal documents related to medical equipment, the quality and accessibility of equipment, the capacity and adequacy of human resources, and the challenges encountered while implementing the laws.

RESULTS

The WHO defines "medical devices" as a broad category encompassing items ranging from small medical instruments and supplies to large diagnostic and therapeutic equipment.[3]

The International Medical Device Regulators Forum (IMDRF)/GHTF also defines "medical devices" as encompassing a wide range of products, from relatively simple non-implantable devices, such as tongue depressors, thermometers, blood pressure monitors, stethoscopes, scales, disposable gloves, wound dressings, hospital beds, and crutches, to highly advanced imaging diagnostic devices and implants. They recommend classifying medical devices to patients and medical professionals based on their risk level, with appropriate regulations tailored to each category.[4,5]

The IMDRF is a voluntary coalition of regulatory authorities that fosters international collaboration in regulating medical devices.

Established in 2011 as a part of the Global Harmonization Task Force (GHTF), the IMDRF aims to harmonize and enhance the global regulation of medical devices.

In the countries of the WHO Western Pacific Region, including Australia, Japan, Korea, China, and the Philippines, medical devices are classified based on the risk they pose to patients and medical professionals. These classifications include Categories A, B, C, and D, and Classes I, II A, II B, and III. Regulations are tailored to these classifications, with high-risk devices, such as those in Categories C, D, or Classes II B, and III, requiring registration, while lower-risk devices are listed separately.[6–10]

These classifications align with the "Global Model Regulatory Framework for Medical Devices" issued by WHO[11] and the general regulatory models provided by IMDRF.

In terms of the legislation in Mongolia, the regulation of medical devices is as follows: The Law on Health provides definitions of four terms: 3.1.13 "medical equipment", 3.1.14 "medical instrument", 3.1.15 "accessories for medical equipment", and 3.1.16 "prosthesis", and Article 19 of the law includes a group of provisions related to licenses to engage in healthcare activities. The Law on Medicines and Medical Devices defines two terms: 3.1.4 "diagnostic device" and 3.1.5 "medical device", and Article 8.1.1 of the Law on Metrology regulates them separately.

According to the descriptive study, within the framework of the above legislation, the following standards have been approved: Structure and Operation Standards-7, Medical Equipment Standards-16, Order of the Deputy Prime Minister of Mongolia-1, Order of the Minister of Health-14, and Order of the Director of the Mongolian Agency for Standard Metrology-2.

In a survey on implementing laws and regulations related to medical equipment, 86.1% of respondents said that a state inspection and regulatory system for medical equipment had not been established. 91.7% indicated that a legal framework for regulating medical equipment was absent. 91.9% reported no legal framework for ensuring the quality and safety of medical equipment. 91.7% said a legal framework for the optimal planning and regulation of medical equipment assets was not established. 97.3% indicated a legal framework for regulating medical equipment maintenance and service management was not in place. 75% of respondents said that a state inspection and regulatory system for medical equipment had been established, while 25% disagreed. A total of 25.7% felt that regulating medical equipment licenses was sufficient, while 74.3% believed it was insufficient.

Implementation of Legal Documents and Reflection of Stakeholders' Feedback

There is limited regulation related to medical equipment in sectoral laws, and existing regulations are scattered across individual laws. Although healthcare facilities follow Ministerial Order No. 439 of 2006, the implementation of this order varies depending on the hierarchy of healthcare facilities, with local areas facing particular challenges. It

is emphasized that human resources and room requirements are insufficient in these areas. In private healthcare facilities, regulations are created based on the internal rules and regulations of the institution, which prioritize customer requests. Since the rules and regulations concerning equipment regulation are separate, there is a recognized need for an integrated legal framework. This would involve consolidating and updating the existing regulations, including Ministerial Order No. 439 of 2006, Ministerial Order No. 404 of 2006, and MNS5097:2017 General Hospital Structure and Operation Standards.

Ministerial Order No. 439 of 2006 states that there should be 1 engineer for every 100 pieces of equipment. However, it is necessary to define which types of equipment should be included in the 100-piece count. Additionally, it should be clarified that one engineer should specifically be assigned to high-cost equipment, and there needs to be clear criteria for identifying what qualifies as high-cost equipment. Overall, an integrated legal regulation is needed, rather than relying solely on Ministerial Order No. 439 of 2006." (Engineer of the medical equipment, Healthcare facility)

"In the MNS5097:2017 standard, equipment is evaluated as either present or absent. For example, a hospital bed is considered 'present' even if it is broken. We would like to change this evaluation to a numerical system, where the condition of the equipment is assessed with plus or minus signs, rather than simply being counted as present or absent. A numerical evaluation would provide a more realistic assessment of the equipment's status." (Engineer of the medical equipment, Healthcare facility)

"It would be beneficial to include criteria for buildings, rooms, and human resources in the accreditation standards, so that these aspects can be properly evaluated." (Engineer of the medical equipment, Healthcare facility)

"In the future, the regulations should require the medical equipment manuals in a simplified format with two categories: user and engineering." (Engineer of the medical equipment, Pharmaceutical supply organization)[1]

Representatives from faculties and researchers have recently been involved in developing policy documents. However, representatives of engineers and technicians are not always included, and it is emphasized that the participation of other professionals is also crucial.

Equipment Quality, Availability, and Regular Maintenance

Investment and supply of medical equipment have improved due to the coronavirus pandemic. However, the lack of routine maintenance, inadequate funding planning, and the pressure to operate in high-demand conditions contribute to increased equipment damage.

While performance financing and management privatization have positively impacted equipment supply, some hospitals are forced to cut their maintenance budgets to remain profitable

"A hospital can only attract customers if it has both good equipment and skilled specialists." (Engineer of the medical equipment, Healthcare facility)

"Our hospital has a budget of USD 0.6 million for normal operations, covering everything from vehicles and buildings to computers. However, only about USD 500-600 are allocated for hospital equipment, which is insufficient even to cover the spare parts for a single device." (Engineer of the medical equipment, Healthcare facility)

"There is no stock of spare parts for the equipment, and availability is always uncertain. The order is constantly dependent on someone else. After the equipment is installed, if a failure occurs later, the spare parts may already be outdated, or the equipment may no longer be produced. As a result, we engineers are left with no choice but to resort to a 'Mongolian way' of handling it." (Engineer of the medical equipment, Supply organization)[1]

Medical equipment purchases are often organized by unqualified individuals without obtaining quotes based on technical specifications. As a result, the manufacturer is often unknown, and expensive, substandard equipment is frequently purchased.

"There was an instance where a company selling toys in the market won the tender to supply CPAP machines for infants, claiming there were no professionals available for the local tender. When the equipment was delivered, two salesmen—who were not professionals at all—came

to hand it over." (Engineer of the medical equipment, Healthcare facility)

"It is difficult to obtain spare parts for expensive equipment, and it would be beneficial if a certain percentage of the budget received from insurance were allocated specifically for spare parts." (Engineer of the medical equipment, Healthcare facility)[1]

It is believed that the equipment registration system needs to be updated.

Human Resource Capacity and Accessibility

Four universities train medical equipment engineers and technicians, with an employment rate of 95%. However, the high workload, part-time work, low salaries and benefits (which are set for non-medical professionals), and the lack of opportunities for postgraduate training and specialization contribute to a shortage of human resources, particularly in public hospitals and rural areas.

"There should be one engineer for every 100 pieces of medical equipment, but in reality, one engineer is responsible for 200–300 pieces of medical equipment." (University professor)

"Our hospital has over 600 pieces of medical equipment, and we have one engineer and two technicians working here. However, there are no engineers specifically responsible for CT, hemodialysis, and oxygen equipment, so three people are handling these tasks. Additionally, there is extra work related to Occupational Safety and Hygiene (OSH)." (Engineer of the medical equipment, Healthcare facility)

"We are performing tasks similar to surgeries, such as assisting with hemodialysis, and working with CT, yet we are paid at the Government Service (GS) level. Therefore, we want to be included in the GS of the Health Sector." (Engineer of the medical equipment, Healthcare facility)

"There are many people who don't fully understand the responsibilities of a medical equipment engineer or what their role should entail. They assign tasks to engineers simply because the work is related or similar." (Engineer of the medical equipment, Healthcare facility)

"We want to hire new specialists, but they are not coming to local areas. Students graduating from private universities are entering engineering fields, not medical technology. Additionally, graduates often lack the ability to distinguish between different types of equipment. Therefore, we need to focus on improving the quality of training." (Engineer of the medical equipment, Healthcare facility)[1]

Medical equipment engineers often have to take on various additional tasks due to the ambiguity of their responsibilities and are frequently employed as OSH staff. Medical equipment engineers can be compensated through the Health Sector Government Service (GS).

DISCUSSION

Based on the recommendations from the WHO and international regulatory bodies, as well as the legal frameworks related to the regulation of medical devices and other products in various countries, a wide range of products, from small medical instruments to large diagnostic and therapeutic equipment, are defined as "medical devices". These devices are then classified as A, B, C, and D, or Class I, Class II A, Class II B, and Class III, based on the level of risk they pose to patients and medical professionals. Regulations are being developed according to these categories, including the registration of high-risk products, such as those in categories C, D, or Class II B, and Class III, while other products are listed separately in the remaining categories.

The survey, conducted among medical equipment engineers, technicians, representatives of supply organizations, and faculties regarding the implementation of legislation, included 35–37 participants in each group. The findings indicate that the legal and regulatory framework concerning medical equipment is insufficiently developed, and state inspection and regulation are weak.

When comparing the regulations on medical equipment and other products included in major healthcare sector laws in our country with the standard regulations on "medical devices" in countries around the world, differences are evident, starting with the definition of the term. Establishing a legal framework for integrated policies and regulations covering medical equipment registration,

quality, safety, rational asset planning, and maintenance management is essential.

CONCLUSION

When comparing the regulations related to medical devices in Mongolia, particularly those concerning medical equipment, with the WHO recommendations, the IMDRF general regulatory models, and the regulations of countries such as Australia, Japan, Korea, China, and the Philippines significant differences emerge. These include discrepancies in the definitions of terms, the absence of a classification system for medical devices, a lack of post-market quality surveillance, and no regulations regarding packaging, labeling, advertising, or proper disposal. However, the regulations for importing medical devices through licensed suppliers are in line with the medical device regulations of the aforementioned countries and WHO recommendations.

AUTHOR CONTRIBUTIONS

Conceptualization, A.D., M-E.L., G-O.N. ;Methodology, A.D., M-E.L.; Formal Analysis, A.D., G-O.N.; Writing – Original Draft Preparation, G-O.N.; Writing – Review & Editing, A.D., M-E.L.; Supervision, A.D.; Project Administration, M-E.L.; Funding Acquisition, G-O.N.

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DATA AVAILABILITY STATEMENT

Not applicable.

CONFLICTS OF INTEREST

The authors declare they have no competing interests.

ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study methodology was reviewed and approved by the Research Ethics and Monitoring Committee of the Mongolian National University of Medical Sciences during its meeting on January 21, 2022 (Approval No. 2022/3-01).

CONSENT FOR PUBLICATION

Not applicable.

FURTHER DISCLOSURE

Part of the findings from this study, titled "Assessment of the Implementation of Medical Equipment Policy in Mongolia", authored by Gerelt-Od Namdag, Munkh-Erdene Luvsan, and Amarsaikhan Dashtseren, was presented at the 5th International Clinical Engineering and Health Technology Management Congress (ICEHTMC), held from November 11 to 23, 2023.

Additionally, the abstract of this study was published in the Global Clinical Engineering Journal (GCEJ) Special Issue 5.

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