

ADB SUPPORT IN
THE HEALTH SECTOR REFORM IN MONGOLIA

SUPPORTING THE REGULATION OF MEDICINES IN MONGOLIA

EXPERIENCES, LESSONS LEARNED,
AND FUTURE DIRECTIONS

Altantuya Jigjidsuren and Bayar Oyun

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ABBREVIATIONS

ADB	-	Asian Development Bank
ADR	-	adverse drug reactions
FHSDP	-	Fourth Health Sector Development Program
GASI	-	General Agency for Specialized Inspection
GMP	-	good manufacturing practices
HDC	-	Health Development Center
HIF	-	Health Insurance Fund
JFPRAP	-	Japan Fund for Prosperous and Resilient Asia and the Pacific
MOH	-	Ministry of Health
NMRA	-	National Medicines Regulatory Authority
RDFs	-	revolving drug funds
SPA	-	State Procurement Agency
TA	-	technical assistance
WHO	-	World Health Organization

CURRENCY EQUIVALENTS

(as of 11 April 2022)

Currency unit – togrog (MNT)

MNT1.00 = \$0.0003314

\$1.00 = MNT3,017.25

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EXECUTIVE SUMMARY

The history of modern pharmaceutical care in Mongolia began in 1923 when the first pharmacy in the country opened its doors. By the end of the 1980s, the pharmaceutical sector in Mongolia had evolved into a system, fully owned and strictly regulated by the state, with a focus on increasing the supply of medicines throughout the country, including every *soum* (sub-province administrative unit). In the early 1990s, a deep economic crisis and recession in Mongolia left the government unable to finance and maintain the operations of the vast pharmaceutical supply chain, leading to severe shortages of even the most essential medicines. The government introduced initial reforms that led to the privatization and liberalization of the pharmaceutical sector, which served the goal of eliminating the acute shortages in the supply of medicines in the 1990s. As a result of these initial reforms, the production and wholesale and retail distribution of medicines and medical devices are now entirely in the hands of the private sector.

The initial reforms laid the foundation for the pharmaceutical sector in Mongolia as it currently stands and is the origin of the longer-term issues that persist in the sector and which undermine the safety and quality of medicines. With support from Asian Development Bank (ADB), the government is making significant progress in addressing these issues, including through (i) establishing a national medicines regulatory authority that consolidates previously fragmented regulatory functions, (ii) upgrading the national medicines safety laboratory to international standards, (iii) instituting good national pharmaceutical practices based on international standards, (iv) developing national strategies on pricing medicines and pharmacovigilance, and (v) introducing a system for the centralized procurement of medicines for public hospitals. These efforts have faced challenges, such as inadequate political support, lack of sustainable financing and investment options, and opposition from some stakeholders.

Mongolia needs to transform the newly established national medicines regulatory authority into a more powerful, independent, evidence-based, and better funded institution that brings together disparate functions of different sectors. Improved regulation of medicines would ensure better quality and increased assurance of safety, covering areas such as pharmaceutical manufacturing, marketing, distribution, and inspection. All efforts to improve regulation of medicines in Mongolia must follow the implementation of a consistent policy, supported by improved coordination and collaboration with all stakeholders, including beneficiaries and, in particular, the private sector.

This paper describes the pharmaceutical sector in Mongolia and ADB's support for pharmaceutical sector reform, including the results of initial and ongoing reforms, challenges that remain, and future actions needed to ensure better regulation of medicines. The experience from ADB's support for the reform of the pharmaceutical sector in Mongolia and the lessons learned will be useful for future programs in Mongolia and other countries.

I. THE PHARMACEUTICAL SECTOR IN MONGOLIA

A. The Pharmaceutical Sector in Mongolia before the 1990s

The history of modern pharmaceutical care in Mongolia dates to 1923 when the first pharmacy opened its doors in the capital city, Ulaanbaatar. In a relatively short while, the pharmaceutical sector in Mongolia evolved dramatically and by the end of the 1980s existed as a system with a regulatory agency, a single national entity for the importation, sale, and distribution of medicines with branches in all *soums* across the country, and one local manufacturer of medicines.¹ All institutions in the sector were exclusively regulated by the state.² Despite significant advances, the pharmaceutical sector lacked a well-articulated long-term policy to ensure the safety and efficacy of medicines and their use.³

The Medicines Supply and Manufacturing Department, under the Ministry of Health (MOH), was responsible for overall regulation and coordination of the pharmaceutical sector, including needs assessment, planning the supply of medicines at the national level, and overseeing operations of all pharmaceutical entities. One entity, Em-Impex, an importer and wholesaler of medicines, was responsible for the importation of medicines mainly from other socialist countries, and the sale and distribution of medicines and medical supplies across the country through its national distribution network that included warehouses in Ulaanbaatar and all *aimag* (province) centers.

Em-Impex was complemented by a network of retail pharmacies, which were established in Ulaanbaatar, all *aimag* centers, and all *soums* to provide access to essential medicines for people living in remote rural areas. Operations of retail pharmacies were controlled by the Pharmacies Coordination Office and its branches in all *aimags*. The Medicines Factory, established in 1955, was the main manufacturer of locally produced medicines and medical supplies and as of 1960 was producing tablets, injectables, tinctures, ointments, wound care materials, and vitamin supplements.⁴ The production of simple oral liquid medicines was carried out through retail pharmacies and hospital inpatient pharmacies that produced sterile intravenous solutions for use in hospitals. The organized planting and collection of local medicinal herbs were conducted under the supervision of a specialized bureau. Herbs were purchased by the Medicines Factory, which processed and packaged them for local use and export to other socialist countries.⁵

The Medicines Supply and Manufacturing Department also oversaw quality control of medicines, supported by the Central Medicines Quality Laboratory. The medicines testing units, supervised by the Pharmacies Coordination Office with branches in all *aimags* ensured control over the safety and quality of liquid medicines and intravenous solutions produced at local retail and hospital pharmacies. There are no available reports on the quality of locally produced medicines before the 1990s. A World Bank report from 2007 determined that the quality of medicines during the socialist period was often questionable due to concerns that they may have had limited potency. This resulted in many people preferring to be

¹ A *soum* is a sub-province administrative unit.

² G. Tsetseglen. 2013. *Development of the Modern Pharmaceutical Care in Mongolia (1923–2013)*. Ulaanbaatar.

³ D. Nyam-Osor, R. Byamba, and B. Munkhdelger. 2003. *Brief Review of the 80 Years of Development of the Pharmaceutical Care*. Article for the single issue of the Journal dedicated to the celebration of the 80th Anniversary of the Pharmaceutical Sector in Mongolia.

⁴ The Medicines Factory produced following quantities of products, as of 1960: tablets 7.4 million packs, injectables 2.0 million ampoules, tinctures 42 tons, ointments 12 tons, wound care wrapping materials 1.5 million meters, and vitamin supplements 28 tons.

⁵ As of 1985, Mongolia exported 300 tons of raw medicinal herbs to the Republic of Bulgaria, the People's Republic of China, Democratic People's Republic of Korea, and Viet Nam.

given medicines by injection or intravenously, rather than by oral administration. Consequently, Mongolia had one of the highest rates of injected medicines usage in the world.⁶

B. Pharmaceutical Sector in Mongolia–Initial Reforms

At the beginning of the 1990s, the collapse of the socialist system and the withdrawal of Soviet assistance led to a deep economic crisis and recession in Mongolia. The government did not have the resources to fund and maintain the extensive operations of the pharmaceutical supply chain or to ensure the provision of even the most essential medicines to the population. The entire pharmaceutical supply chain was disrupted, leading to an acute shortage of medicines. This prompted the government to authorize a temporary tax exemption on the importation of medicines in 1994. People started to bring medicines from other countries and sell them in black markets, raising serious concerns about quality and safety.⁷ Even pharmacies and hospitals were forced to purchase these medicines due to the absence of supplies from the state.

Realizing the urgent need, the government initiated structural reforms in the pharmaceutical sector, including restructuring the government control and regulation system, privatizing state-owned pharmaceutical entities, and permitting the private sector to manufacture, import, and sell medicines. The Medicines Division of the MOH took responsibility for the formulation of state policies and regulations on medicines, and the newly established Medicines and Bioproducts Quality Control Bureau became responsible for inspection and quality control of medicines.⁸ The legal basis for the establishment of private manufacturers and wholesalers of medicines and medical devices and retail pharmacies was established by the new Constitution of Mongolia in 1992, but the initial rules with the minimum requirements for new businesses became available only after the approval of the law on licensing for private businesses in 1999. By 2013, there were already 41 private manufacturers and 128 private medicines wholesalers operating, along with a significant number of private retail pharmacies throughout the country. At the same time, the government initiated the privatization of two major pharmaceutical entities, the Medicines Factory and Em-Impex, and all retail pharmacies across the country. The lengthy process of privatization continued until 2007. Up to that point, both entities were practically non-operational due to severe financial constraints.

Privatization and private sector development in the pharmaceutical sector, however, have not helped improve access to essential medicines for people at the *soum* level. The newly established private sector was not interested in operating retail pharmacies in *soums* as they were not profitable due to their small population. In addition, because of financing difficulties in *soum* hospitals, there were frequent interruptions in the provision of medicines to their patients. Thus, in 1995, to provide access to affordable essential medicines for people at the *soum* level, the government initiated another reform to create community pharmacies in *soums* by creating revolving drug funds (RDF) supported by local communities and development partners. The initial investment in RDFs by donors and the community was made in the form of a seed stock of essential medicines which were continuously replenished through the revenue generated from the sales. It was assumed that RDFs would not operate for profit but would focus on the availability of essential medicines. After the first RDF pharmacies were successful in increasing the availability of essential medicines in pilot *soums*, the scheme was extended to the

⁶ World Bank. 2007. *The Mongolian Health System at Crossroads: An Incomplete Transition to a Post-Semashko Model*. Washington, DC.

⁷ Beside medicines, at that time there was an acute shortage of everyday necessities including basic food, which was rationed, clothing and other items. People were bringing these items (including medicines) in big plastic textile bags wrapped with adhesive tape. These were called “pigs”.

⁸ In 2003, all state inspection functions, including control of medicines, were unified under the General Agency for Specialized Inspection.

whole country. However, from the beginning, it was not made clear how pricing and mark-ups would be regulated. Thus, over the years, in some *aimags*, RDF pharmacies have become ordinary private pharmacies, while in other *aimags* the local government retained its RDF principle and supported them through various means, including with allocations from the local budget.

In general, the government's initial pharmaceutical sector reforms led to the liberalization of the pharmaceutical sector and served the goal of eliminating acute shortages and improving medicines supply in the 1990s, but they also created several problems.

C. Current Status and Issues

These reforms laid the foundation for the pharmaceutical sector as it is today and set the scene for the longer-term issues the sector continues to face which are affecting regulation of medicines, and the quality and safety of medicines.

The pharmaceutical sector of Mongolia is mainly regulated by the Law on Medicines and Medical Devices. The law regulates manufacturing processes as well as importing, exporting, storing, selling, distributing, using, and monitoring the quality of medicines, including traditional medicines, biological medicines, diagnostic test kits, and medical devices, both for human and veterinary use. Previously, the State Policy on Medicines,⁹ now superseded by the State Policy on Health (2017),¹⁰ sets medium-term policy objectives for the entire health sector, including the pharmaceutical sector. The Essential Medicines List, based on World Health Organization (WHO) recommendations, is actively used and frequently updated, with the latest (ninth) version approved in 2020. In total there are about fifty laws, policy documents, regulations and procedures that regulate the pharmaceutical sector.¹¹

Mongolia is one of very few countries without a national medicines regulatory authority (NMRA) that consolidates medicines control under a single entity. The regulation of the pharmaceutical sector and control of medicines in Mongolia is highly fragmented and lacks coordination which creates inefficiencies. The WHO has issued a set of recommendations on core functions that should be unified under an NMRA. In Mongolia, these functions are split among various institutions belonging to different sectors. MOH is responsible for medicines registration, marketing authorization, and licensing manufacturers and wholesalers. The Human Medicines Council and its sub-councils, appointed by the Minister of Health and chaired by the state secretary of MOH, serve as a technical body that reviews applications and makes recommendations for registration and marketing authorization of medicines. The Medicines and Medical Devices Division of the Health Development Center (HDC) serves as the secretariat for MOH in conducting these functions in addition to developing and updating the national pharmacopeia, monitoring adverse reactions, promoting rational and safe use of medicines and medical devices, and providing and monitoring information on medicines. On the other side, local governments, namely the capital city and *aimag* governors' offices and health departments, are responsible for licensing retail pharmacies in their area of jurisdiction. In addition, the General Agency for Specialized Inspection (GASI)¹² is accountable for overall medical and pharmaceutical inspections, operations of the national medicine quality control laboratory,¹³ identification and elimination of substandard, unregistered, and falsified medicines, and investigation of adverse reactions to medicines and incidents with medical

⁹ First adopted in 2000. The latest, developed with support from ADB funded FHSDP in 2014, covered the period from 2014 to 2018.

¹⁰ Government of Mongolia. 2017. *State Policy on Health*. Ulaanbaatar.

¹¹ Government of Mongolia, Ministry of Health. 2018. *Pharmaceutical Sector Indicators*. Ulaanbaatar.

¹² GASI is an independent government agency under the direct supervision of the Deputy Prime Minister that oversees all inspection functions in the country.

¹³ Part of the National Reference Laboratory on Food Safety operated by GASI.

devices. Some core functions are nonexistent or poorly regulated, such as developing and updating clinical guidelines and protocols, regulation and oversight of patient safety in clinical trials of medicines, pharmacovigilance and post-marketing surveillance, price regulation and control, and investigation of sales and retail, including internet sales and collaboration with international best practice networks.

The poorly regulated growth of the private sector resulted in a dramatic increase in the number of manufacturers and wholesalers of medicines and retail pharmacies. There are currently too many pharmaceutical entities for a country with a population of 3.3 million. Most entities are concentrated in the capital city, Ulaanbaatar. Table 1 illustrates the current number and distribution of pharmaceutical entities fully owned by the private sector.

Table 1: Number of Pharmaceutical Entities in Mongolia, 2018

Type of pharmaceutical entity	Ulaanbaatar	Aimags	Total
Manufacturer of medicines and medical devices	47	-	47
Wholesaler	369	68	437
Retail pharmacy	873	587	1,460

Source: Health Development Center. 2018. *Health Indicators 2018*. Ulaanbaatar.

The pharmaceutical supply system in Mongolia is currently fully decentralized. Health departments in the capital city and *aimags* procure medicines and medical devices for general hospitals and *soum* health centers in the capital city or *aimags*, and the state general hospitals and national centers purchase medicines and medical supplies for their own needs. The procurement of medicines and medical devices is regulated by the Law on Public Procurement, like all goods and services procured from the state budget, and procured mainly using an open competitive bidding method. However, due to the small size of procurement by individual public hospitals, bids do not attract sufficiently competitive and qualified bidders, resulting in high costs and low quality of medicines.

The high cost of medicines is also caused by the liberalization of medicine prices and the lack of policies and regulations to control the cost of medicines. For instance, the current pharmaceutical sector is characterized by the absence of mark-up controls in wholesale and retail operations, reference pricing, and any exemption of essential medicines from taxes.

Consumer prices for medicines are among the highest in Asia, up to 2.25–5.56 times higher than international reference prices. In 2012, the median total mark-up in Mongolia was 63.05% (ranging 44.23%–85.68%), which is higher than the median total mark-up of 42.5% (ranging 26.1%–81.8%) in 10 low- and middle-income countries.¹⁴ The pharmaceutical market relies heavily on imported medicines, with only 30% of the domestic market supplied by local medicines manufacturers (Figure 1). Even though some national medicines manufacturers introduced good manufacturing practices (GMP), the majority still do not comply with GMP requirements.¹⁵

The accessibility of affordable medicines is also hampered by the way medicines are funded. The Health Insurance Fund (HIF) covers medicines prescribed to inpatients or people who are hospitalized in public and private hospitals. However, this does not apply to outpatients, where only a few medicines (13 types)¹⁶

¹⁴ HERA, Gerege Partners. 2017. *Technical Report on Medicines Pricing Policy and Pricing System*. Ulaanbaatar.

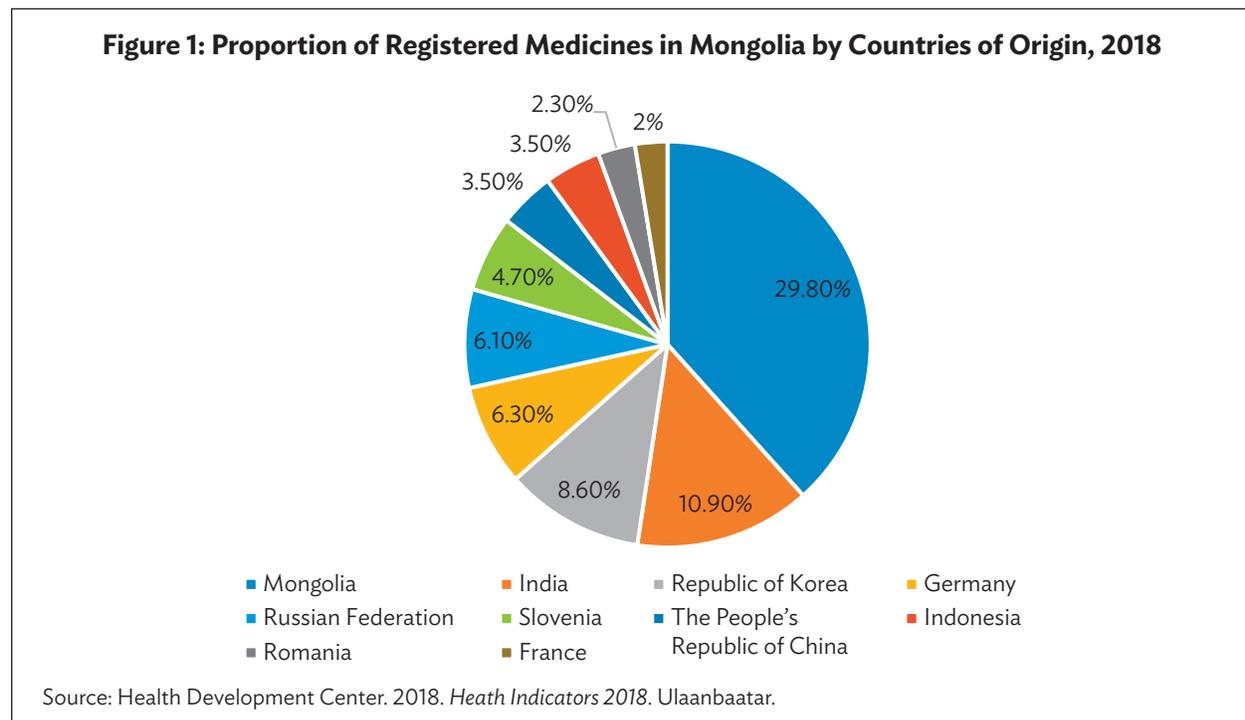
¹⁵ According to the MOH, out of 47 national manufacturers of medicines and medical devices, 6 were GMP certified as of 2020.

¹⁶ Such as insulin for diabetes, human coagulation factors for hemophilia, medicines for prevention of organ transplant rejection etc.

are fully subsidized by the state and distributed free of charge directly to registered patients. Another 141 generic essential medicines are offered with a discount of up to 80% based on prescription by primary care physicians and subsidized by HIF (before November 2020).

However, access to these subsidized medicines is highly limited as the funding allocation for drug subsidies is not based on patients' needs.¹⁷ Other outpatient medicines are paid for directly by patients. The share of out-of-pocket health payments in total household consumption expenditure varies from 4 to 5% and is consistent with other countries in the Asia and Pacific region.¹⁸ However, middle- and low-income families in Mongolia spend 70%–96% of their healthcare expenses on medicines alone.¹⁹

Another issue of the current pharmaceutical system is the low quality of medicines, combined with the irrational use and use of non-essential medicines. Even though the prevalence of substandard, unregistered or falsified medicines is decreasing, it remains high. As reported in 2018, the prevalence of substandard medicines is 10.1%, with a higher prevalence among locally manufactured medicines (18.6%) than among imported products (6.1%). The prevalence of unregistered medicines is 4.3%, and the prevalence of falsified medicines²⁰ is 0.8%.²¹



¹⁷ From 1996 to 2010, the HIF allocated only 2% of its total expenditure for drug discounts. In 2014 it was increased to 6.6% and reached 10% in 2016. However, the allotted budget is sufficient to provide outpatients with discounted medicines for only the first few days of each month, which creates long lines at pharmacies for discounted medicines, and many people cannot get them. Source: Government of Mongolia, MOH. *Health Indicators 2019*.

¹⁸ National Statistical Committee. 2019. *Survey of Households Socioeconomic Status in the 4th Quarter of 2019*. Ulaanbaatar.

¹⁹ Government of Mongolia, MOH. 2011. *Out-of-pocket and Catastrophic Expenditure in Mongolia*. Ulaanbaatar

²⁰ Falsified medical products are those that deliberately misrepresent their identity, composition or source. Falsified medical products may contain no active ingredient, the wrong active ingredient or the wrong amount of the correct active ingredient (WHO).

²¹ Government of Mongolia, MOH and ADB. 2018. *Prevalence of Substandard, Unregistered and Falsified Medicines in Mongolia: Final Report*. Ulaanbaatar.

II. ADB SUPPORT FOR IMPROVING REGULATION OF MEDICINES IN MONGOLIA

A. Fourth Health Sector Development Program 2012–2021

The Fourth Health Sector Development Program (FHSDP) is the first ADB funded program in Mongolia that addressed regulation of medicines and the quality and safety of medicines.²² One of its main components aimed to increase access to safer medicines through assisting the Government of Mongolia to strengthen governance of medicine control functions, establish an NMRA, upgrade the medicines control laboratory to international standards, and support good pharmaceutical practices.²³

The consolidation of medicines regulatory functions is the core action required to improve overall governance, regulation, and safety of medicines. The FHSDP assisted MOH in comprehensively reviewing Mongolia's pharmaceutical sector governance and initiated discussions among key stakeholders to raise and promote the issue of establishing an NMRA. These efforts triggered consultations on the establishment of an NMRA at various levels, including the National Security Council, and led to the incorporation of the NMRA in the National Policy on Medicines (2014)²⁴ and its implementation plan for 2014–2018.²⁵ These policy-level achievements were further supported by developing a concept for establishing an NMRA in Mongolia with several options that included detailed tasks, organograms, and estimated budgets. Staff capacity building in the institutions that might comprise the NMRA was also conducted.²⁶

These positive developments were constrained by several factors such as the resistance of GASI to shift its mandate over inspection and control of medicines to an NMRA and the extended political debate on whether a medicines regulatory authority or a larger scale food and drug authority should be established.²⁷ Due to the economic difficulties at that time, the government did not have room to create any new agencies and was forced to reduce government administrative costs by cutting down the number of civil servants and merging some government agencies.²⁸

The first attempt by MOH to consolidate some regulatory functions under the Medicines Regulatory Division at the Government Implementation Agency, the Department of Health, was discontinued in 2012.²⁹ Important regulatory functions such as the registration of medicines and pharmaceutical organizations and marketing authorization of medicines unified under this division have been transferred back to MOH, which jeopardized autonomy and inevitably led to increased bureaucracy and reduced efficiency. In 2015, MOH re-established the Medicines Regulatory Division at the Health Development

²² Asian Development Bank (ADB). 2010. *Report and Recommendation of the President to the Board of Directors: Proposed Grant to Mongolia for the Fourth Health Sector Development Project*. Manila.

²³ The medicines safety component of the FHSDP was implemented from 2012 to 2015. Other components of the FHSDP are currently ongoing.

²⁴ Parliament of Mongolia. 2014. Resolution No. 57. *About Approving National Policy on Medicines*. Ulaanbaatar.

²⁵ Government of Mongolia, Ministry of Health. 2014. Ministerial Order No. 425. *About Approving the Implementation Plan*. Ulaanbaatar.

²⁶ Trainings were conducted within following four components: good governance of the pharmaceutical sector, regulation of medicines, GMP, and pharmacovigilance.

²⁷ GASI was concerned that other sectors would start lobbying for shifting their respective inspection functions out of the GASI, which would lead to abandoning the concept of the centralized inspection.

²⁸ Several aide-mémoire from FHSDP review missions.

²⁹ In 2011, a Medicines Regulatory Division with 18 staff was established by MOH at the Department of Health, which at that time had the status of a government implementation agency but later downgraded and is currently called the Health Development Center.

Center (HDC).³⁰ Supported by FHSDP, the re-established Medicines Regulatory Division consolidated existing regulatory functions within the health sector, including the registration of medicines and devices, licensing pharmaceutical entities, issuing import and export licenses, promoting rational use of medicines, and developing national pharmacopeia and standards. It also introduced new functions such as monitoring and reporting adverse drug reactions, medicines marketing and advertisement, consolidating information, and releasing annual indicators for the pharmaceutical sector. Overall, even though an NMRA has not yet been established and regulatory functions under the jurisdiction of other sectors have remained the same, the FHSDP has made a valuable contribution in promoting the concept of consolidated control of medicines under a single national regulatory authority.

In addition to its efforts to establish an NMRA, the FHSDP has achieved one of its main outputs in upgrading the national medicines control laboratory. The FHSDP provided technical support to design the laboratory in accordance with international standards, provided the necessary equipment, and supported the development of a strategic business and management plan, standard operating procedures, a quality control system, staff training, and laboratory information management system.³¹ The FHSPD supported the process of acquiring international accreditation that was concluded in its ISO-17025 certification in 2015. As of 2020, the national medicines control laboratory operates sustainably and maintains its compliance with international standards.

The FHSDP aimed to upgrade national GMP standards and procedures to align with WHO guidelines on GMP and support their implementation by the national manufacturers of medicines.³² The project provided technical support to MOH in updating the national GMP standards, regulations, and criteria for GMP certification and conducted hands-on training for regulators and local manufacturers. As a result of these efforts, the national manufacturer of medicines passed the GMP certification for the first time in 2016.³³ However, it was clear that of the many local manufacturers, only a few would become GMP compliant, and the process of transforming existing local manufacturers into GMP-compliant facilities would require significant time, effort, and financial resources. Thus, the medium-term plan includes a road map for the gradual introduction of GMP into the practice of all local medicines manufacturers. This plan was prepared by MOH and the project. Along with GMP, the FHSDP provided additional technical assistance for developing national standards on other good practices, such as distribution, storage, and pharmacy practices based on international experience.

The FHSDP also supported strengthening pharmacovigilance, including post-marketing surveillance and monitoring adverse drug reactions (ADR), developing the national strategy on pharmacovigilance, capacity building efforts at MOH facilities, and increasing the number of hospitals reporting ADR. For the first time, ADR cases were reported to the Vigiflow database of the WHO collaborating Uppsala Monitoring Center, thus beginning cooperation with an international institution that specializes in pharmacovigilance.³⁴ The FHSDP cooperated closely with the WHO country and regional offices on pharmacovigilance and other areas mentioned above, such as developing the state policy on medicines and development of standards on good practices, including GMP, distribution, storage, and pharmacy practices.

³⁰ Later renamed as the Medicines and Medical Equipment Division.

³¹ The drug control laboratory was built with a grant from the Government of the People's Republic of China.

³² GMP is a system for ensuring that products are consistently produced and controlled according to quality standards. GMP covers all aspects of medicine production, from raw materials, premises, and equipment to training and personal hygiene of staff. GMP inspection provides documented proof that correct procedures are consistently followed at each step in the manufacturing process.

³³ IVCO LLC, national manufacturer of intravenous fluids.

³⁴ The Uppsala Monitoring Centre is an independent, non-profit foundation that serves as the WHO collaboration center. It operates the technical and scientific aspects of the WHO's worldwide pharmacovigilance network.

B. Technical Assistance

The technical assistance (TA) project on Improving Access to Affordable Medicines in Public Hospitals of Mongolia implemented actions to improve regulation of medicines.³⁵ The main achievement of the TA was piloting a new centralized system for the procurement of medicines using framework agreements. The pilot involved a wide range of participants including MOH, the Ministry of Finance, the Government Procurement Agency (GPA), the capital city and *aimag* health departments, and public hospitals. The proposed procurement method was based on the WHO operational principles of good pharmaceutical procurement. To prepare for the pilot, the TA provided the necessary regulations and sample bidding documents. The pilot was closely coordinated with the development of an e-procurement module for medicines by the government at the GPA. The advantages of centralized procurement using framework agreements are larger quantities of purchased medicines that attract more competitive bids, reduced workloads for both suppliers and purchasers (fewer tenders and fewer evaluations), the possibility for national suppliers to negotiate better prices for imported medicines with foreign suppliers, and convenience and transparency of using an e-procurement system.

The first pilot was successfully implemented in 2017 and resulted in savings for participating hospitals.³⁶ MOH was responsible for technical tasks, including defining the selection criteria and quantity forecasting of selected medicines, formulating the technical specifications, defining the quality assurance criteria, conducting the market research, and monitoring the quality of medicines and their use. Meanwhile, the GPA was responsible for the actual procurement and operations of the e-procurement module. However, the lack of capacity within MOH for managing procurement remains the main challenge to be addressed. Important recommendations for the government to make the best use of this new procurement system include introducing prequalification of suppliers and providing access to tenders for international suppliers, the extension of the framework agreement, and further improvement of the e-procurement module.³⁷ As of 2020, centralized procurement with the framework agreement is used for an increased number of medicines for public hospitals.

By introducing centralized procurement, the government aimed to decrease the price of commonly used medicines. Another action in the plan was to reorganize pharmacies in public hospitals (previously only available for inpatients), to provide outpatients with cheaper services and medicines. All necessary regulations and technical documents were produced by the TA. However, the implementation was delayed due to the small number of medicines procured under the pilot centralized procurement, which could not support outpatient pharmacies. The concept is currently expected to be implemented with increased centralized procurement and greater autonomy for public hospitals as part of public hospital sector reform.

The TA also contributed to strengthening regulation of medicines through developing medicines pricing policy and a system for monitoring medicine prices, combined with capacity building for government staff. Recommendations include tax exemptions on essential medicines, the introduction of internal and external reference pricing, mark-up control, and the establishment of a medicines pricing observatory to ensure transparent pricing data as part of the single integrated policy. Based on these notes and the concept formulated in the State Policy on Medicines with support from the FHSDP, assistance was

³⁵ ADB. 2015. *Technical Assistance to Mongolia for Improving Access to Affordable Medicines in Public Hospitals*. Manila.

³⁶ In 2017, MOH selected 17 medicines for the first year of the pilot, which were procured under framework agreements and saved MNT222.5 million by reducing the unit price of medicines by 1.3%–38.5% on average. The modest number of items in the first year of the pilot is due to MOH's concern about the risks of potential shortages of essential medicines for public hospitals in case the procurement pilot failed.

³⁷ HERA. Gerege Partners. 2018. *Review of Pilot Medicine Procurement Using Framework Agreement*. Ulaanbaatar.

provided to prepare a draft amendment to the Medicines and Medical Devices Law.³⁸ The TA supported two major studies on the prevalence of substandard, unregistered, and falsified medicines in Mongolia; a market research study on medicine prices and price composition; and an assessment of RDF pharmacies. ADB also supported MOH and the Health Insurance General Office to revise the previously extensive list of medicines for outpatients that are discounted and subsidized from the HIF.³⁹ The current list covers only essential medicines, considering their role in the treatment of the most important causes of morbidity and mortality in the country, and linking them with international evidence-based clinical guidelines (from UpToDate platform), applied in 2020 for national use.⁴⁰

III. RESULTS ACHIEVED WITH ADB SUPPORT IN IMPROVING REGULATION OF MEDICINES

Since the beginning of the 1990s, the pharmaceutical sector in Mongolia evolved dramatically. Currently, manufacturing, wholesale, and retail distribution of medicines and medical devices are fully in the hands of the private sector. Therefore, government regulation and control of medicines are crucial to ensuring the quality, efficacy, safety, and affordability of medicines.

ADB funded FHSDP and TA projects supported the government in the formulation of national policies on medicines, reflecting international practices on regulating medicines and ensuring their quality and safety. They contributed substantially to introducing the concept of consolidated and effective regulation of medicines under an independent and scientific NMRA. The concept was discussed at the national level and the outputs of these discussions were reflected in the national policies on medicines (see section II.A) and current policies on health that cover medicines (see section VI. Future Directions). These efforts also contributed to recent amendments (2020) made to the Law on Medicines and Medical Devices that came into effect on 1 January 2021 and provide the legal basis for the establishment of a single national regulatory authority.

ADB further supported these positive developments and enforced the establishment of the NMRA by including it as a core policy action to improve governance of the health sector within a programmatic policy-based loan (PBL) approved in 2021 to strengthen health security and deepen ADB's support for COVID-19 in Mongolia.⁴¹ The overall aim of the PBL is to strengthen the health sector's response to the COVID-19 pandemic and expedite medium-term reforms that will improve the health system and help Mongolia become better prepared to respond to future health crises. Improving regulation of medicines through establishing the NMRA is defined as one of four main reform areas under the PBL. The critical policy actions under the first subprogram of the PBL include introducing amendments to the laws to establish the NMRA and the actual establishment of the NMRA and approval of its charter. The second subprogram, planned for 2023, will focus on implementing the NMRA, including ensuring that a sufficient budget is allocated for its operations.

³⁸ The Parliament of Mongolia. 2020. *Amendment to the Law on Medicines and Medical Devices*. Ulaanbaatar

³⁹ ADB. 2018. *Technical Assistance to Mongolia for Improving Health Care Financing for Universal Health Coverage*. Manila.

⁴⁰ A total of 132 medicines by generic name and 551 medicines by generic or brand names were included in the final list. The revised list was approved by the National Health Insurance Council on 29 October 2020 and put into use from 1 November 2020.

⁴¹ ADB. 2021. *Report and Recommendation of the President to the Board of Directors: Proposed Programmatic Approach and Policy Based Loan to Mongolia for Strengthening Health Security Program (Subprogram 1)*. Manila.

The government issued a resolution in December 2020 ordering the establishment of the NMRA and affirming its commitment to unify and strengthen the regulation of medicines in the country.⁴² The NMRA was established in 2021, even though its operations are currently at the initial stages and still require capacity building for stable and sustained operations.

Studies conducted on the prices of medicines and prevalence of substandard, unregistered, and falsified medicines contributed to the evidence-based formulation of national policies. The national medicines control laboratory was upgraded to international standards (ISO certification) and plays a crucial role in ensuring the safety of medicines. Considerable support was provided for strengthening regulation of medicines through assisting the development of the national policies and strategies on the pricing of medicines and pharmacovigilance.

The progressive system for centralized procurement of medicines for public hospitals using framework agreements was successfully piloted. The system was institutionalized and expanded by the government.⁴³ It contributes to reducing prices of medicines and medical devices for public hospitals and results in significant savings for hospitals. It is complemented by efforts to introduce outpatient pharmacies at public hospitals intended to supply medicines for patients at lower prices. The concept will be implemented with the expansion of the centralized procurement of medicines for public hospitals.

ADB support was crucial in upgrading national standards on GMP and other good pharmaceutical practices to WHO requirements. Technical support provided to government institutions and national manufacturers of medicines resulted in GMP certification of a national manufacturer of medicines for the first time in the country. The medium-term plan for the gradual introduction of GMP resulted in a greater number of national manufacturers of medicines obtaining national GMP certification.¹⁵ GMP certification has the potential to support the export of nationally produced medicines.

The advances in pharmacovigilance supported by the FHSDP resulted in a higher number of ADR events monitored and reported.

IV. CHALLENGES IN IMPROVING REGULATION OF MEDICINES

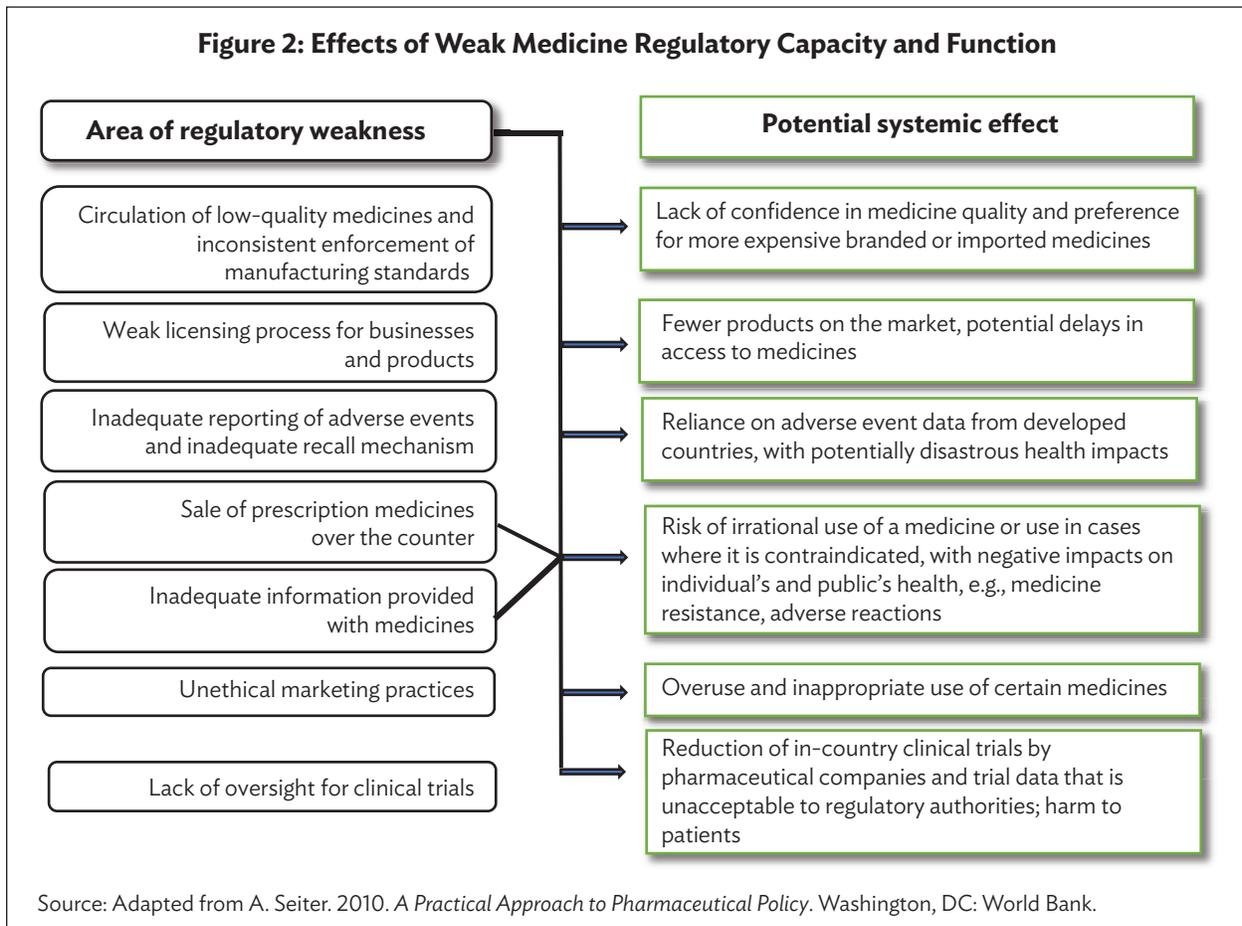
Based on the Law on Medicines and Medical Devices (2020), the government decided (December 2020) to establish the NMRA from January 2021. However, the main challenge for Mongolia in ensuring the safety of medicines remains the same: the fragmentation and the lack of consolidated and coordinated regulation until the new agency can fully fulfill its role. The fragmentation is seen as a major cause of ineffectiveness in enforcement, underdevelopment, poor capacity, and limited access to international expertise, methods, and knowledge.⁴⁴ This negatively affects the whole system for regulation and control of medicines, undermining their quality and safety. It took a long time for the decision to establish an NMRA to be issued, even though ADB funded programs and TA projects initiated consultations to establish an NMRA supported by a comprehensive proposal, options, and estimates for the required investments and recommendations for the necessary changes in legislation. Some of the main factors that affected the unsuccessful result of the initial attempts to establish an MNRA were the lack of sustainable financing

⁴² Government of Mongolia. 16 December 2020. *Resolution No. 222. About Establishing the Agency*. Ulaanbaatar.

⁴³ As of 2020, centralized procurement is used for purchasing 59 medicines and 5 medical devices. Source: MOH.

⁴⁴ MOH.ADB.HLSP.MEC. 2010. TA 7309-MON. Project Preparation Technical Assistance. *Discussion Paper Drug Safety I. Establishing A Single Drug Regulatory Authority*. Ulaanbaatar.

and investment options, inadequate political support, and opposition from some institutions concerned about losing their influence. Countries without an NMRA that coordinate a consolidated and effective system for regulation and control of medicines often encounter the systemic problems illustrated in Figure 2.



International experience indicates that on its establishment, an NMRA needs continuous support for strong and sustained operations. The main external factors that lead to poor functioning of an NMRA are political interference and inadequate political support, lack of independence, and insufficient financing and investment. Additional factors include weak organizational structure and leadership, unclear roles and responsibilities, inadequate capacity building, and lack of effective collaboration with national agencies such as customs and police and international stakeholders.⁴⁵ These challenges need to be addressed to meet the objective of establishing an NMRA that spearheads a well-functioning national medicines regulatory system that controls and ensures the safety of medicines.

⁴⁵ A. Seiter. 2010. *A Practical Approach to Pharmaceutical Policy*. Washington, DC: World Bank.

V. LESSONS LEARNED

ADB assistance for supporting medicines safety in Mongolia produced lessons that should be considered by similar programs and TA projects in the future.

The system reform that requires structural changes involving different sectors and institutions, such as the establishment of an NMRA, needs significant advocacy efforts targeting decision-makers at different levels and considerable time for discussion and debate to change the mindsets of reluctant stakeholders. Even with well-defined policies in place, efforts can be constrained by factors such as deficiencies in a government's technical and financial resources and opposition from influential stakeholders motivated by institutional interests. Similar efforts could focus more on highlighting the economic benefits of better quality and effective and safe medicines that result in the improved health status of the population. Also, a gradual, step by step approach to consolidation of medicine regulatory functions could be considered.

In Mongolia, the private sector acted slowly and opposed the implementation of reforms such as compliance with GMP requirements. This may have been motivated by a number of factors, including financial constraints and a lack of understanding that making poor quality products does not save money in the longer term. In the long run, preventing mistakes saves more money than it costs to correct them. Making, distributing, and using poor quality medicines leads to loss of credibility for everyone, including the medicines manufacturer and seller and the health care facility that uses them. GMP was put in place to prevent mistakes and ensure product quality. Compliance with GMP standards also has the potential to promote exporting of nationally manufactured medicines. Therefore, there is a need to promote the advantages and benefits that reforms such as compliance with GMP could bring in the long term.

Useful recommendations based on international best practices, such as pre-qualification of suppliers for the centralized procurement of medicines, were underutilized despite visible and potential benefits upon implementation.

VI. FUTURE DIRECTIONS

Immediate and medium-term policy objectives for the health sector, including the pharmaceutical sector, are outlined in the State Policy on Health (2017) and the Action Plan for implementing the State Policy on Health (Health Sector Master Plan) 2020–2026 developed with assistance from ADB and the Japan Fund for Prosperous and Resilient Asia and the Pacific.⁴⁶ The following objectives and actions should be considered for possible future ADB assistance in improving the safety of medicines in Mongolia to bring systemic changes into the regulation of medicines and pharmaceutical sectors and build on previous experiences and lessons learned.

The Health Sector Master Plan proposes to improve regulation of medicines through the consolidation of currently fragmented regulatory functions under the NMRA. The government established the NMRA in 2021 to consolidate all the core medicines regulatory functions from relevant sectors and institutions, as recommended by the WHO. It should ensure links with international networks and similar authorities

⁴⁶ Government of Mongolia, Ministry of Health. 2020. *Order of the Minister of Health A/103*. Ulaanbaatar.

in other countries. Strengthening and sustaining the capacity of the national medicines control laboratory is part of the plan to improve the regulation and control of medicines.

The full introduction of GMP to all existing national manufacturers of modern and traditional medicines in the medium term and the immediate application of GMP as a requirement for all new applications for establishing new medicine manufacturing facilities are planned. These efforts would require technical expertise and increased capacities of both regulatory authorities and national manufacturers of medicines.

The Health Sector Master Plan gives special focus to increasing the affordability of medicines through establishing a system for better regulation of prices, further strengthening the centralized procurement and improving the public supply of medicines and medical devices through the hospital outpatient pharmacies. The establishment of a mechanism for procuring medicines and medical devices based on the comparison of clinical efficacy and cost-effectiveness is planned.

There are other objectives and actions outlined in the Health Sector Master Plan that were not specifically addressed by the previous ADB programs and TA projects. They intend to address the safety of medicines in Mongolia and could be considered for ADB support. Intersectoral cooperation is planned to promote the rational use of medicines in the health and agricultural sectors and prevent antimicrobial resistance that has become an issue of global concern. The health sector is expected to implement programs on the prevention and control of antimicrobial resistance at the facility level and introduce international clinical guidelines and protocols for effectively using appropriate medicines. Strengthening of the currently weak post-marketing surveillance and building capacity for regular pharmacovigilance, revision of the national pharmacopeia, and development of the pharmacopeia for Mongolian traditional medicines are planned. Improving regulations and monitoring of advertisement of medicines and biologically active substances are also given a special focus in the Health Sector Master Plan.

VII. CONCLUSIONS

Pharmaceutical products are a fundamental component for the provision of effective and safe health care. The overall goal of the health sector in relation to pharmaceuticals is to increase access to essential, high-quality, safe, effective, and affordable medicines. It is essential that such products are prescribed and used rationally.

Worldwide experiences with the potential negative consequences of weak medicine regulatory capacity and functions underline the need for countries to strengthen their national medicines regulatory systems to achieve this goal.⁴⁴ Mongolia has recently established an NMRA. Leveraging this momentum, Mongolia needs to consolidate functions currently fragmented and distributed across different sectors and create an independent, science-based, well-funded, strong, and reliable NMRA. Improved regulation of medicines would ensure better quality and safety assurances covering all areas such as manufacturing, marketing, distribution, and inspection of pharmaceuticals.

All efforts to improve regulation of medicines in Mongolia must follow a consistent policy and implementation process supported by coordination and collaboration with all stakeholders, including beneficiaries, in particular the private sector.

Supporting the Regulation of Medicines in Mongolia

Experiences, Lessons Learned, and Future Directions

Before the 1990s, Mongolia's pharmaceutical sector was fully owned and strictly regulated by the state. In the early 1990s, the Government of Mongolia started initial socioeconomic reforms as part of a transition to a market economy. This led to the full privatization and liberalization of the pharmaceutical sector, which created challenges that needed further reforms. The government requested the Asian Development Bank to support these reforms. This paper describes the pharmaceutical sector in Mongolia and its reforms, including the results achieved, the challenges that remain, lessons learned, and future directions for ADB support.

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