



# Technical Assistance Report

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Project Number: 53061-001  
Knowledge and Support Technical Assistance (KSTA)  
December 2020

## Mongolia: Enhancing Medicine Safety for Noncommunicable Disease Control

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Asian Development Bank



## CURRENCY EQUIVALENTS

(as of 23 October 2020)

Currency unit	–	togrog (MNT)
MNT1.00	=	\$0.0004
\$1.00	=	MNT2,832.6400

## ABBREVIATIONS

ADB	–	Asian Development Bank
NCD	–	noncommunicable disease
PHC	–	primary health care
TA	–	technical assistance

## NOTE

In this report, “\$” refers to United States dollars.

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## KNOWLEDGE AND SUPPORT TECHNICAL ASSISTANCE AT A GLANCE

KNOWLEDGE AND SUPPORT TECHNICAL ASSISTANCE AT A GLANCE			
1. Basic Data		Project Number: 53061-001	
Project Name	Enhancing Medicine Safety for Noncommunicable Disease Control	Department/Division	EARD/EASS
Nature of Activity	Research and Development	Executing Agency	Ministry of Health (formerly Ministry of Health and Sports)
Modality	Regular		
Country	Mongolia		
2. Sector		Subsector(s)	
✓ Health	Disease control of non-communicable diseases and other priority programs		ADB Financing (\$ million)
	Health system development		0.47
			0.47
	Total		0.94
3. Operational Priorities		Climate Change Information	
✓ Addressing remaining poverty and reducing inequalities	GHG Reductions (tons per annum)		0
✓ Accelerating progress in gender equality	Climate Change impact on the Project		Low
✓ Strengthening governance and institutional capacity	ADB Financing		
	Adaptation (\$ million)		0.00
	Mitigation (\$ million)		0.00
	Cofinancing		
	Adaptation (\$ million)		0.00
	Mitigation (\$ million)		0.00
Sustainable Development Goals		Gender Equity and Mainstreaming	
SDG 1.4	Some gender elements (SGE)		✓
SDG 3.4, 3.8			
SDG 5.6	Poverty Targeting		
SDG 10.2	General Intervention on Poverty		✓
4. Risk Categorization		Low	
5. Safeguard Categorization		Safeguard Policy Statement does not apply	
6. Financing			
Modality and Sources		Amount (\$ million)	
ADB		0.94	
Knowledge and Support technical assistance: Technical Assistance Special Fund		0.94	
Cofinancing		0.00	
None		0.00	
Counterpart		0.00	
None		0.00	
Total		0.94	
Currency of ADB Financing: US Dollar			





## I. INTRODUCTION

1. The Government of Mongolia has requested support to strengthen the policy environment for noncommunicable disease (NCD) control and pharmaceutical regulation through evidence-based research. The knowledge and support technical assistance (TA) will help the Ministry of Health improve the population's health by (i) strengthening capacity for pharmaceutical regulation, (ii) providing guidance for policies on NCDs, and (iii) expanding awareness for NCDs and medicine safety.

2. The TA is aligned with the country partnership strategy, 2017–2020 of the Asian Development Bank (ADB) for Mongolia. It is also consistent with three operational priorities of ADB's Strategy 2030—(i) addressing remaining poverty and reducing inequalities, (ii) accelerating progress in gender equality, and (iii) strengthening governance and institutional capacity.<sup>1</sup> The TA is included in ADB's country operations business plan, 2020–2021 for Mongolia,<sup>2</sup> and is aligned with Mongolia's State Policy on Health, 2017–2026,<sup>3</sup> which reaffirms the government's sustained commitment to improving health services for the population.

## II. ISSUES

3. Mongolia has made significant progress in improving its health outcomes. Life expectancy at birth increased to 70.19 years in 2018, compared with 69.00 years in 2016. Mongolia achieved its Millennium Development Goal targets in 2015 for maternal and child mortality. It reduced the infant mortality rate from 16 deaths per 1,000 live births in 2015 to 14 deaths per 1,000 live births in 2018, and in the same period also reduced the under-5 mortality rate from 19 to 16 deaths per 1,000 live births. Maternal mortality decreased from 51 (in 2013) to 45 (in 2017) per 100,000 live births. While health outcomes have improved, the country still struggles with systemic issues such as unregulated and substandard medicines, which lead to poor treatment of noncommunicable and communicable diseases and impact the overall efficacy of curative medical care.

4. **Noncommunicable diseases leading cause of death and disability.** Mongolia has experienced a demographic shift from communicable diseases to NCDs, and the burden of NCDs continues to grow. Dietary risk factors, high blood pressure, alcohol abuse, and tobacco use are the leading drivers of death and disability, and directly related to the prevalence of NCDs.<sup>4</sup> Physical inactivity, high stress, and unhealthy diets compound this. Preventing NCDs through behavior change and effective case management remains the most effective way to reduce the disease burden. Mongolia has had an NCD program in place since 2005 for early detection, prevention, and control. The Third National Program on NCD Prevention and Control, 2017–2021 aims to reduce the prevalence of primary and intermediate risk factors, and the morbidity and mortality rates of NCDs.<sup>5</sup> Although the third national program is ongoing, studies suggest that primary health care (PHC) facilities do not have the capacity to provide basic services at minimum

<sup>1</sup> ADB. 2017. *Country Partnership Strategy: Mongolia, 2017–2020—Sustaining Inclusive Growth in a Period of Economic Difficulty*. Manila; ADB. 2019. *Strategy 2030 Operational Plan for Priority 1: Addressing Remaining Poverty and Reducing Inequalities, 2019–2024*. Manila; ADB. 2019. *Strategy 2030 Operational Plan for Priority 2: Accelerating Progress in Gender Equality, 2019–2024*. Manila; and ADB. 2019. *Strategy 2030 Operational Plan for Priority 6: Strengthening Governance and Institutional Capacity, 2019–2024*. Manila. The TA first appeared in the business opportunities section of ADB's website on 5 November 2020.

<sup>2</sup> ADB. 2019. *Country Operations Business Plan: Mongolia, 2020–2021*. Manila. The TA combines two TA projects listed in the country operations business plan (Noncommunicable Disease Prevention and Enhancing Medicines Safety) and streamlines areas of overlapping scope.

<sup>3</sup> Government of Mongolia. 2017. *The State Policy on Health, 2017–2026*. Ulaanbaatar.

<sup>4</sup> Institute of Health Metrics and Evaluation. *Mongolia Health Data* (accessed 17 July 2020).

<sup>5</sup> Government of Mongolia. 2017. *Government Resolution 289: Adoption of the National Program*. Ulaanbaatar.

standards. It is estimated that they are only able to provide 51.7% of the required NCD services.<sup>6</sup> This is quite low and can impair the quality of services, especially since NCD treatment requires curative care with a robust PHC system to manage cases cost-effectively. Underutilization and lack of gatekeeping of PHC also contribute to poor NCD outcomes. Insufficient provision of NCD services, especially in primary care settings, is a notable quality gap that requires strategic investment, better prevention strategies, and management of caseloads. To bridge this gap, the State Policy on Health (footnote 3) proposes to establish public health centers that will deliver NCD prevention services and outreach to communities. However, NCD treatment is also weakened by the poor quality of drugs on the market because proper regulation is lacking.

5. **Substandard drugs and high rates of antibiotic resistance.** The prevalence of substandard (10.1%), unregistered (4.3%), and falsified medicines (0.8%) in Mongolia is one of the highest in the world.<sup>7</sup> Low quality, high cost, and irrational use of medicines are some of the leading issues in the health sector. Pharmaceutical regulation is also highly fragmented; functions such as licensing and registration, pricing, quality, market surveillance and control, inspection and enforcement, integrated regulatory information system, and rational use are implemented by different agencies, rather than by one single drug regulation authority, which leads to poor coordination and increases inefficiencies. Moreover, noncompliance by local drug manufacturers with good manufacturing practices and the absence of an independent national drug regulation authority compromise the safety of medicines in the country.

6. Given the shortcomings of local drug manufacturers, the pharmaceutical market relies primarily on imported medicines. Drug procurement in the public sector is decentralized, however, and every public hospital is required to purchase its medicines directly from private suppliers. This and the absence of price regulation drive up the prices of medicines and also affects the availability of essential medicines in public health facilities. The harmful consequences of unsafe drugs and the incidence of adverse drug events erode public trust in the health system and undermine the use of health services.<sup>8</sup>

7. ADB has already assisted earlier efforts to improve drug safety in Mongolia,<sup>9</sup> and this TA will support the fundamental reforms of the pharmaceutical industry set out in the revised draft Law on Medicines and Medical Devices. They include setting up a single regulatory body responsible for all aspects of pharmaceutical regulation, introducing medicines regulation, and promoting the rational use of medicines. It is imperative to boost capacity and strengthen policies around drug safety in Mongolia to reduce access to expensive and often substandard medicines.

### III. THE TECHNICAL ASSISTANCE

#### A. Impact and Outcome

8. The TA is aligned with the following impact: quality and accessibility of health services increased (footnote 3).<sup>10</sup> The TA will have the following outcome: regulations for NCDs and medicine safety improved.

<sup>6</sup> A. Jigjidsuren et al. 2019. [Free and Universal Access to Primary Healthcare in Mongolia: The Service Availability and Readiness Assessment](#). *BioMed Central Health Services Research*. 19 (129).

<sup>7</sup> Ministry of Health and ADB. 2018. *Final Report: Prevalence of Substandard, Unregistered, and Falsified Medicines in Mongolia*. Ulaanbaatar.

<sup>8</sup> An adverse drug event is characterized as an injury resulting from a medical intervention related to a drug.

<sup>9</sup> ADB. [Mongolia: Fourth Health Sector Development Project](#); and ADB [Mongolia: Improving Access to Affordable Medicines in Public Hospitals](#).

<sup>10</sup> The design and monitoring framework is in Appendix 1.

## B. Outputs, Methods, and Activities

9. **Output 1: Capacity for pharmaceutical regulation enhanced.** The TA team will provide capacity building to policymakers and parliamentarians to keep them abreast of the key reform areas set out in the revised draft Law on Medicines and Medical Devices, and conduct additional analytical work on the expected impact of the law on the pharmaceutical market. The team will (i) organize an international study tour<sup>11</sup> for parliamentarians and policymakers to gain knowledge from other countries on the best practices and key characteristics of an independent drug regulation agency; (ii) carry out extensive domestic training, workshops, and webinars on the changes in the revised draft law, with sufficient female representation; (iii) undertake a financial analysis of the proposed changes to the revised draft law to be used as evidence-based research for policymakers; and (iv) develop draft regulations to facilitate the implementation of the revised law, once passed, in close coordination with multisector stakeholders.

10. **Output 2: Policy guidance for noncommunicable diseases provided.** This output supports the development of key policy documents on NCDs and a set of policy recommendations. The TA team will (i) review and analyze the implementation of the current national program on NCD prevention and control; (ii) identify gaps and generate key recommendations for the next steps; (iii) develop the fourth national program on NCD prevention and control through extensive stakeholder consultations, and identify specific gender needs; (iv) support the establishment of public health centers by defining their organizational structure, job descriptions, and training on NCD screening and detection; and (v) build the capacity of staff in the new public health centers.

11. **Output 3: Awareness of noncommunicable diseases and medicine safety improved.** The TA team will organize two workshops and a final conference for government officials, representatives from professional associations, and international and other research partners to discuss and disseminate the TA findings and policy recommendations. The team will provide policymakers with advocacy material for the revised draft Law on Medicines and Medical Devices, and produce brochures on NCDs; this will be the most effective method of disseminating information.<sup>12</sup> Information on NCD awareness and behavior change will also be disseminated. An economic analysis of the costs and benefits of the revised draft law and the NCD program will be developed.

## C. Cost and Financing

12. The TA is estimated to cost \$987,000, of which \$937,000 will be financed on a grant basis by ADB's Technical Assistance Special Fund (TASF 6). The key expenditure items are listed in Appendix 2.

13. The government will provide counterpart support in the form of office accommodation, venue for meetings, counterpart staff, miscellaneous administration expenses, and other in-kind contributions.

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<sup>11</sup> Study tours will be in ADB developing member countries. If international travel is still restricted because of the global pandemic, virtual tours or a series of webinars will be explored instead.

<sup>12</sup> ADB may print the advocacy materials for policymakers. This is in line with the optional provision for printed external publications of ADB. 2019. *Staff Instruction on Business Processes for Knowledge and Support Technical Assistance* (Attachment 1). Manila.

## D. Implementation Arrangements

14. ADB will administer and manage the TA. The Urban and Social Sectors Division of its East Asia Department will select, supervise, and evaluate consultants; and monitor the quality of their work. The Ministry of Health as the executing agency will oversee and support the consultants to achieve the TA outcome. The ministry's Department of Policy and Planning is the implementing agency, responsible for ensuring the smooth implementation of the TA.

15. Implementation arrangements are summarized in the table.

Implementation Arrangements			
Aspects	Arrangements		
Indicative implementation period	December 2020–November 2022		
Executing agency	Ministry of Health		
Implementing agency	Department of Policy and Planning of the Ministry of Health		
Consultants	To be selected and engaged by ADB		
	Individual selection	Pharmaceutical regulation expert (international, 5 person-months)	\$84,000
	Individual selection	Senior health economist (international, 4 person-months)	\$77,400
	Individual selection	Public health expert and team leader (national, 14 person-months)	\$79,800
	Individual selection	Medicine safety expert (national, 12 person-months)	\$66,000
	Individual selection	Senior NCD expert (national, 12 person-months)	\$66,000
	Individual selection	NCD expert (national, 12 person-months)	\$52,800
	Individual selection	Health economist (national, 6 person-months)	\$33,000
	Individual selection	Project management specialist (national, 10 person-months)	\$44,000
	Individual selection	Finance and administrative specialist (national, 10 person-months)	\$44,000
	Individual selection	Gender expert (national, 6 person-months)	\$35,800
Disbursement	Disbursement of TA resources will follow ADB's <i>Technical Assistance Disbursement Handbook</i> (2020, as amended from time to time).		

ADB = Asian Development Bank, NCD = noncommunicable disease, TA = technical assistance.

Source: ADB.

16. **Consulting services.** ADB will engage the consultants following the ADB Procurement Policy (2017, as amended from time to time) and its associated procurement staff instructions.<sup>13</sup> Individual consultants (international, 9 person-months; national, 82 person-months) will be recruited because the diverse expertise required may not be easily available from a single firm.

<sup>13</sup> Terms of Reference for Consultants (accessible from the list of linked documents in Appendix 3).

#### **IV. THE PRESIDENT'S DECISION**

17. The President, acting under the authority delegated by the Board, has approved the provision of technical assistance not exceeding the equivalent of \$937,000 on a grant basis to the Government of Mongolia for Enhancing Medicine Safety for Noncommunicable Disease Control, and hereby reports this action to the Board.

## DESIGN AND MONITORING FRAMEWORK

Impact the TA is Aligned with			
Quality and accessibility of health services increased (State Policy on Health, 2017–2026) <sup>a</sup>			
Results Chain	Performance Indicators	Data Sources and Reporting Mechanisms	Risks and Critical Assumptions
<b>Outcome</b> Regulations for NCDs and medicine safety improved	<b>By 2022</b> a. Revised draft Law on Medicines and Medical Devices submitted to Parliament for approval (2020 baseline: NA) (OP 6.2.1)  b. Fourth national program on NCD prevention and control, with gender considerations, endorsed by MOH (2020 baseline: NA) (OP 1.1.2)	a.–b. MOH reports	R: Government commitment to pharmaceutical reform is not sustained.  R: Ministries tasked to implement cross-sector NCD actions are unable to coordinate effectively.
<b>Outputs</b> 1. Capacity for pharmaceutical regulation enhanced  2. Policy guidance for NCDs provided  3. Awareness of NCDs and medicine safety improved	<b>By 2022</b> 1a. At least 50 policymakers and/or parliamentarians (at least 40% of them women) report improved understanding of the revised draft Law on Medicines and Medical Devices (2020 baseline: NA) (OP 6.1.1; OP 2.3.1)  1b. Draft regulations for the proposed Law on Medicines and Medical Devices prepared (2020 baseline: no draft regulations)  2a. Fourth national program on NCD prevention and control, with gender considerations, drafted (2020 baseline: NA)  2b. At least 80% of staff in public health centers report improved knowledge on managing NCDs, with specific gender needs identified (2020 baseline: 0)  3a. At least two comprehensive advocacy materials on new pharmaceutical and NCD regulations produced (2020 baseline: 0)  3b. An economic analysis of the cost and benefits of the revised draft Law on Medicines and Medical Devices and the NCD program prepared, with gender considerations highlighted (2020 baseline: not prepared)	1a. Participants' feedback survey and workshop summaries  1b. Semiannual MOH report  2a.–2b. Semiannual MOH report; participants' feedback survey and workshop summaries  3a. Semiannual MOH report  3b. Final TA report	R: Reduced interagency collaboration on NCD prevention

### Key Activities with Milestones

#### 1. Capacity for pharmaceutical regulation enhanced

- 1.1 Engage consultants (Q1 2021)
- 1.2 Identify key parliamentarians and location for international study tour (Q2 2021)
- 1.3 Conduct international study tour of best practice for pharmaceutical regulation (Q3 2021)
- 1.4 Identify staff for domestic training (Q2 2021)
- 1.5 Develop material for domestic training (Q2–Q3 2021)
- 1.6 Conduct domestic training sessions and workshops (Q4 2021–Q3 2022)
- 1.7 Prepare a financial analysis for the revised draft Law on Medicines and Medical Devices (Q3 2021)
- 1.8 Develop draft regulations for the revised draft Law on Medicines and Medical Devices (Q1–Q2 2022)

#### 2. Policy guidance for noncommunicable diseases provided

- 2.1 Engage consultants (Q1 2021)
- 2.2 Conduct survey and NCD assessment (Q2–Q3 2021)
- 2.3 Draft the fourth national program on NCD prevention and control (Q1 2021–Q4 2021)
- 2.4 Develop public health center standards (Q2 2021–Q4 2021)
- 2.5 Define public health center staffing requirements, job descriptions, and operational guidelines (Q3–Q4 2021)
- 2.6 Identify local government participants in capacity building and training of staff in public health centers (Q2 2021)
- 2.7 Build the capacity of staff in public health centers (Q1 2022–Q3 2022)

#### 3. Awareness of noncommunicable diseases and medicine safety improved

- 3.1 Engage consultants (Q1 2021)
- 3.2 Prepare advocacy material on the revised draft Law on Medicines and Medical Devices and NCDs (Q2 2021)
- 3.3 Prepare economic analysis on cost and benefits of improved pharmaceutical regulation (Q3 2021)
- 3.4 Prepare an economic analysis on NCD control (Q1 2022)
- 3.5 Organize inception, midterm, and final workshops to disseminate findings periodically and present implementation status of project (Q2 2021, Q4 2021, Q3 2022)
- 3.6 Produce a publicly available knowledge product on the economic analysis (Q2 2022)

### Inputs

Asian Development Bank: \$937,000 (TASF 6)

Note: The government will provide counterpart support in the form of office accommodation, venue for meetings, counterpart staff, miscellaneous administration expenses, and other in-kind contributions.

MOH = Ministry of Health, NA = not applicable, NCD = noncommunicable disease, OP = operational priority, Q = quarter, R = risk, TA = technical assistance, TASF = Technical Assistance Special Fund.

<sup>a</sup> Government of Mongolia. 2017. *The State Policy on Health, 2017–2026*. Ulaanbaatar.

### Contribution to Strategy 2030 Operational Priorities:

OP 1.1.2 Health services established or improved (number)

OP 2.3.1 Women with strengthened leadership capacities (number)

OP 6.1.1 Government officials with increased capacity to design, implement, monitor, and evaluate relevant measures (number)

OP 6.2.1 Service delivery standards adopted and/or supported in implementation by government and/or private entities (number)

The expected values and methodological details for all OP indicators to which this TA will contribute results are detailed in Contribution to Strategy 2030 Operational Priorities (accessible from the list of linked documents in Appendix 3 of the TA report).

Source: Asian Development Bank.

### COST ESTIMATES AND FINANCING PLAN

(\$'000)

Item	Amount (\$'000)
<b>A. Asian Development Bank<sup>a</sup></b>	
1. Consultants	
a. Remuneration and per diem	
i. International consultants (9 person-months)	161.4
ii. National consultants (82 person-months)	421.4
b. Out-of-pocket expenditures	
i. International and local travel	18.5
ii. Training, seminars, and conferences	25.0
iii. Reports and communications	6.0
2. Printed external publications <sup>b</sup>	15.0
3. Surveys	35.0
4. Training, seminars, workshops, forum, and conferences <sup>c</sup>	158.0
5. Miscellaneous administration and support costs <sup>d</sup>	3.0
6. Contingencies	93.7
<b>Total</b>	<b>937.0</b>

Note: The technical assistance (TA) is estimated to cost \$987,000, of which contributions from the Asian Development Bank (ADB) are presented in the table. The government will provide counterpart support in the form of office accommodation, venue for meetings, counterpart staff, miscellaneous administration expenses, and other in-kind contributions. The value of the government contribution is estimated to account for 5.3% of the total TA cost.

<sup>a</sup> Financed by ADB's Technical Assistance Special Fund (TASF 6).

<sup>b</sup> ADB may print the advocacy material for policymakers since it will be the most effective method of information dissemination. This is in line with the optional provision for printed external publications of ADB. 2019. *Staff Instruction on Business Processes for Knowledge and Support Technical Assistance* (Attachment 1). Manila.

<sup>c</sup> Includes honorarium and travel expenses of resource persons, costs of venue rentals, interpretation and translation, and other international study tour and workshop-related expenses.

<sup>d</sup> Includes translation and editing of knowledge products.

Source: ADB estimates.



### **LIST OF LINKED DOCUMENTS**

<http://www.adb.org/Documents/LinkedDocs/?id=53061-001-TARreport>

1. Terms of Reference for Consultants
2. Contribution to Strategy 2030 Operational Priorities