Increasing Transparency and Good Governance in the Pharmaceutical Sector: Mongolia a Country Case Study

A successful joint Mongolia WHO Good Governance in Medicines Programme

Background

Situated in Central Asia, Mongolia is a landlocked country between the Russian Federation to the north and the People’s Republic of China to the south. It is the fifth largest country in Asia with a total area of 1,565 million square kilometres. The population of Mongolia is 2.68 million where 61% lives in the urban areas and the remaining 39% lives in rural areas. The overall population density in 2008 was 228.1 persons per square km in Ulaanbaatar making it the least densely populated country in the world.

The population is predominantly young. Children and youth under 15 years of age account for 29% of the population, while people aged 65 years and over account for only 4% of the population. The remaining 67% is between 15 to 64 years of age. Males comprise 49% and females 51% of the total population. The adult literacy rate is reported as 98% (NCHD, 2008).

In recent years, the total revenue and grants of the general government budget increased as seen in Table 1. According to the Word Bank, the Gross Domestic Product (GDP) in 2008 was 1649 US$ per capita.

<table>
<thead>
<tr>
<th>Indicators</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
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<tbody>
<tr>
<td>Annual change of GDP, %</td>
<td>7.3</td>
<td>8.6</td>
<td>10.2</td>
<td>8.9</td>
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<tr>
<td>GDP per capita, thous. MNT</td>
<td>1 091.0</td>
<td>1 170.2</td>
<td>1 271.9</td>
<td>1 361.5</td>
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<tr>
<td>GDP per capita, USD</td>
<td>801</td>
<td>998</td>
<td>1294</td>
<td>1649</td>
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<tr>
<td>Inflation rate, annual average %</td>
<td>4.3</td>
<td>9.6</td>
<td>28.0</td>
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<tr>
<td>General government revenue, mln. MNT</td>
<td>837 858.3</td>
<td>1 360 409.8</td>
<td>1 880 488.9</td>
<td>2 156 382.6</td>
</tr>
<tr>
<td>Exchange rates, annual average, MNT/USD</td>
<td>1 205.27</td>
<td>1 179.55</td>
<td>1 170.43</td>
<td>1 169.26</td>
</tr>
<tr>
<td>Exchange rates, annual average, MNT/EUR</td>
<td>1 501.39</td>
<td>1 481.44</td>
<td>1 603.20</td>
<td>1 728.53</td>
</tr>
<tr>
<td>Exports, mln.USD</td>
<td>1 063.9</td>
<td>1 542.0</td>
<td>1 947.5</td>
<td>2 534.5</td>
</tr>
<tr>
<td>Imports, mln.USD</td>
<td>1 177.3</td>
<td>1 435.0</td>
<td>2 061.8</td>
<td>3 244.5</td>
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Since 1990 Mongolia has made a rapid transition to democracy and a more open market. This change has required the health sector to move in this direction as well. The health care system in

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Mongolia is characterized by three levels of care, and its prevailing principle is to deliver equitable, accessible and quality health care services for every person.

- **Primary care level**: family hospitals in Ulaanbaatar and aimag4 centers, soum5 and inter soum hospitals in aimags
- **Secondary care level**: districts hospitals in Ulaanbaatar, aimags and rural general hospitals in aimags
- **Tertiary care level**: tertiary level hospitals and centers in Ulaanbaatar, regional diagnosis and treatment centers in aimags

The most recent data on the health sector of Mongolia (2008) indicates that there are 15 tertiary level hospitals and centers, 3 regional diagnostic and treatment centers, 18 aimags (Mongolia is divided into 21 aimags), 9 districts general hospitals, 6 rural general hospitals, 289 soum5 hospitals, 35 intersoum hospitals, 228 family hospitals and 1063 private hospitals delivering health care services to a population of more than 2.635 million.6 To date, 22 local manufacturers, 130 wholesalers of drugs and more than 1000 pharmacies are already registered.7 A total of 37952 employees are engaged in the public health sector with the following distribution: 8912 nurses, 7584 physicians, 2480 feldshers8 and 1514 high graduated staff, 1899 pharmacy assistants and 1088 pharmacists, 836 laboratory technicians, 693 midwives, 368 disinfectionists, 518 other assistants, 165 dental technicians and 11721 other workers.9 Estimating the workforce, there are 28 physicians and 60 mid-level medical personnel per 10 000 population.

Health financing consists of four main sources: state budget, health insurance fund, paid service and other incomes. Health care costs, including pharmaceuticals, in Mongolia are relatively high owing to the low population density and high dependency on imported pharmaceuticals, medical equipment and supplies. In 2008, the government allocated 10% of the GDP to the health sector, which showed an increase of 1.6 times compared to previous years (see table 2 below).10 Of this amount, 8-10% was spent in pharmaceuticals and medical devices and a total of 2% for reimbursed drugs. According to various studies, more public awareness and improvement in the prescribing patterns amongst physicians and consumers is required.11 12 13 14 Also, more awareness raising activities about the impact of corruption is needed as these large amounts of money are attractive targets for abuse, vulnerability to corruption and unethical practices.

<table>
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<tr>
<th>Table 2 Drug expenditure</th>
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<tr>
<td>Expenditure</td>
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<tr>
<td>Health expenditure, MNT</td>
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<tr>
<td>Drugs and medical devices, MNT</td>
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<tr>
<td>Reimbursement for Essential Drugs, discounted, MNT (14.19%)</td>
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Source: Health Indicators of Mongolia, 2008, Health Department

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4 Aimag is an administrative unit equivalent to province
5 Soum is an administrative unit equivalent to district outside Ulaanbaatar
7 Annual report, Ministry of Health 2009
8 Feldsher is village health workers with limited formal training generally funded by the collective farm
Since 2006, the Mongolian pharmaceutical procurement sector is 100% privatized. The drug procurement can be provided through three organizations, such as drug wholesaler, manufacturers and pharmacies. The wholesalers can import and procure medicines with an approval, which is a special permission issued by the Ministry of Health. This infrastructure causes definite barriers in organizing and implementing some tasks.

The Aimag Health Departments and tertiary-level health facilities have their own tendering committee, whereas the MoH has two separate tender committees: one for the procurement of medical devices, and the other for the procurement of pharmaceuticals. The pharmaceuticals and medical devices in the rural areas are provided by the health departments at each aimag.

As of 2009, there were 199 procurement organizations registered to supply drugs, medical devices, reagents for laboratories, dental materials, bioactive and disinfection compounds, of which 67 imported medicines.\(^{15}\)

Medicines in the government health sector are funded on a mix of government own source funds (tax), social health insurance payments, private-out-of-pocket payments (co-payments) and donor funds.

**Structure of Mongolian Pharmaceutical Regulatory Authorities**

The Mongolian pharmaceutical sector has a complex structure and existing system. The Division of Pharmaceuticals and Medical Devices, MoH is responsible for the development of the drug policy, law and regulation affairs that provide pharmaceutical care to the population. The Health Department is responsible for health statistics and takes charge of medicines registration. The Health and Education Division of the Professional Inspection Agency is responsible for the inspection of drug manufacturers, suppliers, private and public pharmacies. The Agency of Standardization, Government Regulatory Agency, authorizes all national standards through the Standardization Committee and evaluates the standards developed by the MoH. The Human Drug Council and Special Permission Committee of the Ministry of Health, Division of the Drug Registration at the Health Department- Implementing Agency of Government of Mongolia, and the Health and Education Division of the Professional Inspection Agency, Regulatory Agency of the Government of Mongolia are responsible for the implementation of the concerning regulations, rules and legislations, and quality assurance of pharmaceuticals and medical devices in Mongolia.

The Drug Law of Mongolia was approved in 1998 and the National Drug Policy of Mongolia (NDPM) was approved in December, 2002 by the State Great Khural of Mongolia. The NDPM provides health organizations, veterinary hospitals and people with highly effective, qualified, accurate medicines.\(^{15}\)

\(^ {15}\) MoH. Annual report of Ministry of Health of Mongolia. Ulaambaatar: Ministry of Health of Mongolia; 2009
registered drugs and medical equipment continually, sufficiently and equally. It also introduces and promotes the appropriate use of drugs. The Parliament approved the amendments of the Drug Law including articles on the Drug Regulatory Agency (DRA) in April 2010. It is expected that the DRA will be established as government agency reporting to the MoH.

Mongolian Government has been taking action against corruption, since 1996 with the approval of the anticorruption law (1996) and its national programme to fight corruption. Mongolia joined the United Nations Anti-Corruption Convention (UNCAC) in 2005. The first Mongolian Independent Anticorruption Agency was established in 2007. And, in 2009 the MoH of Mongolia announced that the same year was to be dedicated to the improvement of ethical issues, accountability and the fight against corruption in the health sector, as a top government priority. But, despite these efforts, corruption has increased and is more deeply rooted within the Mongolian society.

That is why the Good Governance for Medicines program with its’ 3 phases has become a very important contribution to decreasing corruption. This case study will describe the process of implementation of the 3 phases of GGM in Mongolia, the main results, successes, challenges and lessons learned.

Good Governance for Medicines Programme in Mongolia

The Mongolian National GGM programme follows the WHO model, seen below, and it was launched with the aim of increasing awareness about the potential for corruption in the pharmaceutical sector and its impact on the health system amongst stakeholders. It also wanted to enhance transparency and accountability in the medicines regulatory authorities supply a management system and develop the national capacity for Good Governance in the medicines regulation system of Mongolia.

The Good Governance for Medicines (GGM) program in Mongolia was introduced in 2005 with the Measuring Transparency Assessment Tool for Phase I. This assessment was conducted during a 2.5 month period in 5 areas of the pharmaceutical sector: registration, promotion, inspection, selection and procurement of medicines. Both the private and public sectors were included in this assessment which resulted in significant findings that showed the existing problems and crucial requirements for further actions. The transparency of each of the surveyed functions was rated on the basis of 10 points as recommended by the WHO instrument, where 1 is the most vulnerable to corruption and 10 the least vulnerable to corruption. The registration, inspection and procurement functions showed a marginal vulnerability to corruption with ratings above 6. The selection and promotion functions showed a moderate vulnerability with

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16 Transparency Assessment in the Mongolian pharmaceutical system (registration, control of medicine promotion, inspection of establishment, selection of essential medicines, and procurement of medicines) 2006 and Progress Report July 21 2008 by Prof. S. Tsetsegmaa, Health Sciences University of Mongolia (Good Governance and monitoring)

17 Measuring transparency to improve good governance in the public pharmaceutical sector: A comparative analyses of five country assessment studies (Bolivia, Cambodia, Indonesia, Mongolia, Papua New Guinea). WHO
ratings between 4-6. As a whole, the pharmaceutical system of the country showed a marginal vulnerability to corruption with a 6.2 rating.

The transparency assessment revealed that registration, promotion, inspection, selection and procurement of medicines in Mongolia are conducted according to specific rules and legal acts. But the violators of legal provisions are not properly punished even though the legal acts provide necessary provisions. Also, there is no system for enabling the public to have equal and accessible information on the relevant legal acts, regulations and rules. The availability and accessibility of the instructions for the members of the drug registration, selection and tendering committees are insufficient, and the policy for the declaration of conflicts of interest (COI) is not available.

The key recommendations provided by national assessors were:

1. Develop an ethical code of conduct for pharmacists with its’ corresponding accountability system
2. Create a national ethical framework for medicine regulation and procurement
3. Make publicly available transparency regulations and laws
4. Provide that all procedures related to tendering of medicines are available and open within the legal frameworks
5. Develop a transparent system to control and inform about the executions of tendering programs
6. Update laws and procedures for the committees
7. Have a standardized conflict of interest form that is mandatory for the members of the committees and public officials
8. Develop written procedures to prevent capture between inspectors and manufacturers or distributors.

During Phase II of the GGM Programme, the WHO Model Framework for Good Governance in the Pharmaceutical Sector was used as a main instruction manual and included activities based on the results for the Phase I transparency assessment. It was also adapted to the local context through national and provincial consultative workshops with key actors during 2006. The process was guided by the GGM Task Force members who are from various institutions, such as, the Ministry of Health, the Professional Inspection Agency- the Regulatory Agency of the Government of Mongolia, the Health Sciences University and from the Professional Pharmaceutical Association of Mongolia. The final document is similar to the WHO model framework with the exception that the ethical principles have an added subcomponent called national loyalty, patriotic initiative in the pharmaceutical sector of Mongolia.

The GGM programme is currently in its’ Phase III in Mongolia and is being implemented by the GGM task force and the National Ethical Committee of Mongolia, that is part of the Ministry of Health. The Ethical Committee and GGM task force members were officially renewed by the Health Minister’s Order #167, dated June 4th 2009.
Using the Mongolian GGM Framework, developed during Phase II, as a guide and taking into account the recommendations of the Transparency Assessment for Phase I, many concrete actions have already been implemented during Phase III of the GGM programme in Mongolia, such as:

- Code of conduct for pharmacists adopted during the 1st Assembly of the Mongolian pharmacists in 2006.
- Several Mongolian National Standards (MNS) were revised and approved by Agency of Standardization and Measurement of Government of Mongolia during last two years: Drug prescription and prescribing, General principles for pharmacy and General principles for drug wholesale agencies.
- Ethical Committee of MoH was approved by the Minister’s order No. 146 in 2007 and is renewed every 2 years. This committee is responsible for the GGM programme.
- Results of the National Transparency Assessment were officially published in 2008.
- Registration of a special permission to conduct professional activities in the medical field and the licensing to import medical equipments and pharmaceuticals can be completed by using the Licemed website since 2008. This project is expanding with the aim of including pictures of registered medicines in the country for the benefit of the Drug Inspectors, Customs and making it more accessible to the public.
- Information about drug registration and the organizations conducting activities in the medical field are publicly available.
- Interaction between licensing to import, special permission and drug registration are improved. Procedures for the licensing to import are more transparent and hierarchical. Applicants have an access from both remote and rural areas of Mongolia.
- Elements of the National Ethical Infraestructure (NEI) were introduced to the new pharmacy curriculum of the School of Pharmacy, Health Sciences University of Mongolia (HSUM) in 2008.
- WHO’s “A Guide for promoting an ethical infrastructure for good governance in the pharmaceutical sector” translated into Mongolian was published in 2009 and is used as a training guide.
- Declaration of conflict of interests form for external experts of drug registration in the Health Department was developed and is being implemented since 2009.
- Activities undertaken by the GGM program in Mongolia were socialized during national and regional meetings/workshops in 2009 and 2010. During these meetings the collaborative GGM activities with other active anticorruption institutions, such as, the Mongolian Independent Anticorruption Agency, were identified and first steps taken.
- The Government of Mongolia has publicized the Anti-Corruption Agency of Mongolia as main implementing organization for the project “Support to integrity and transparency efforts in Mongolia till 2013” with collaboration of Ministry of Health, State Specialized Supervision Agency of Mongolia. The GGM team has joined the project and it is working to strengthen and improve the “Code of conduct for pharmacists”.
- Workshop for GGM Ethical committee, and Drug Council Members took place during June, 2009.
Seminar on “Enhancing the participation of the private organizations in the promotion of good governance for medicines programme and transparency in the health sector” took place on January, 2010 with the objective of enhancing knowledge and awareness about the GGM programme among private pharmaceutical organizations in order to increase their participation and collaboration and to increase moral leadership capabilities among directors, managers and executives of the pharmaceutical companies.

Amendment to the Drug Law was approved by the Parliament of Mongolia in April 2010 and incorporates the COI declaration forms for the members of the Drug Committees.

A training entitled “Capacity Building Training in Procurement under GPRHCS” took place in 2010 with support from UNFPA in Ulaanbaatar, Mongolia. This training consists of 12 modules and module 2 was on Ethics in Pharmaceutical Procurement, Good Governance (WHO). This module was introduced by GGM team members.

FUNDING

The implementation of the national GGM programme is mainly financed by WHO. It has the technical support of WHO and the MoH of Mongolia. The website http://www.moh.mn/licemed for the registration of a special permission to conduct professional activities in the medical field was established initially under the Project for Promoting Ethics, Justice, and Good Governance in the Health Sector, supported by UNDP /2006-2007/.

LESSONS LEARNED

Key Barriers:

-Political Instability and changes in government: Due to this, considerable time was lost for the establishment of the GGM committee with high level authorized individuals and the official development/adoption of the national GGM program.

-MoH Prioritized Other programmes: Various programmes and emergency situations, such as the outbreak of swine flu in 2009, were constantly prioritized, causing certain difficulties due to the rescheduling of planned activities and others.

-Structural issues and delays between official appointments of GGM committee and action: The new Ethical Committee of MoH was approved by the Minister’s order No. 146 in 2007 but they only started to implement the GGM program in Mongolia since April, 2008. The inspection of the GGM is under the supervision of the Prime Minister of Mongolia and the tendering procedures are under the control of the Ministry of Finance. Therefore, the implementation in these areas is insufficient and further actions should be undertaken for improvement.

-Low Compliance with Regulations in certain areas of the Medicines Chain: Local manufacturing companies do not comply with GMP requirements causing low quality products, and insufficient quality control laboratories in Mongolia. Inadequate stock management in health facilities, especially in rural areas are also to be emphasized. There are issues related with human resources, public and health personnel resulting in irrational use of medicines. The absence of post marketing surveillance of imported and local products may also be a basis for ongoing adverse drug reactions, side effects.\(^\text{18}\)

Key successes:

During the five years that GGM has been in Mongolia there have been many successes in the pharmaceutical and health sectors:

\(^{18}\)Pharmaceutical Situational Analysis of Mongolia 2009. Ministry of Health of Mongolia, World Health Organization, Health Sciences University of Mongolia
- Increase in availability of key medicines in public and private health facilities and lower costs of acquiring medicines in urban areas

- Compliance with laws and regulations in procurement and dispensing

- Increase in Awareness about the need for Good Governance, Transparency and Accountability in the Health Sector: The government officially published the Good Governance for Medicines National Transparency Assessment results (2008) in the official language of Mongolia which provided the opportunity for stakeholders to understand the need for GGM and to promote the implementation of the programme. Various national and regional workshops have taken place since 2009 to promote transparency and accountability in the public and private health sectors.

- Increase in the Transparency and Accountability of Processes in Pharmaceutical Legislation: pharmaceutical laws and regulations in different areas of the medicines’ chain and the EML were reviewed and updated (2007-2009), an online system was created to facilitate the registration of special permissions to conduct professional activities in the medical field and to acquire the necessary licensing to import medical equipment and pharmaceuticals (2008), a Conflict of Interest (COI) form for external experts of drug registration was developed and approved by the Health Department of Mongolia (2008). The government has approved the law for tenders and all hospitals and other institutions procuring medicines must follow the specific tender documents. The public sector procurement is based on, but not limited to, the EML. And it is estimated that generally about 80% of procured medicines are on the EML. The amendment of the revised Law on Drugs and Medical Devices in Parliament was incorporated within the COI declaration in the drug committees and was integrated in the newly approved law in 2010.

- Increase in the Transparency and Accountability of the Ministerial structure for GGM: GGM Task Force members from the Ministry of Health, Professional Inspection Agency- the Regulatory Agency of the Government of Mongolia, Health Sciences University of Mongolia and Professional Pharmaceutical Association of Mongolia and the Ethical Committee of Mongolia, from the Ministry of Health, assume the responsibility for implementing the GGM Programme. The Parliament approved the amendments of the Drug Law including articles on the Drug Regulatory Agency (DRA) in April 2010. It is expected that the DRA will be established as government agency reporting to the MoH.

- Increase in Public Awareness due to Information being more readily available: Websites, online registrations in different areas, public communications including media, and the topic of “good governance” has been added to the curriculum of the new pharmacy curriculum of the School of Pharmacy, HSUM.

FUTURE DIRECTIONS

An official approval of the national GGM program with complete edition is required. More anticorruption collaboration initiatives between the different stakeholders such as NGOs, anticorruption agencies, donors and community are recommended. The special tools and indicators for monitoring and evaluating the GGM program are required, as well as, trained human

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19 Draft of Drug Law which is being discussed by Parliament of Mongolia, 2009
resources for a sustainable implementation of the GGM program in Mongolia.