DRUG SAFETY AND HUMAN RESOURCES SUBSECTORS ANALYSIS

I. Drug Safety Subsector

A. Drug Safety Issues

1. **Lack of coordination.** Drug regulatory functions are undertaken by different organizations which makes coordination difficult and creates inefficiencies. Organizations involved in drug regulation are: (i) the Pharmaceuticals and Medical Devices Division of the Ministry of Health (MOH); (ii) the Drug Registration and Information Department of the Department of Health; and (iii) the General Agency for Specialized Inspection (GASI) in charge of the pharmaceutical inspection, border inspection, and operations of the drug control laboratory.

2. Mongolia is one of the very few countries without a National Regulatory Agency; most other countries—even smaller ones—have followed the recommendations of the World Health Organization to establish a regulatory agency for control of medicinal products and medical supplies. The lack of an agency, with medicine control under one management, using one quality control system and one single information system, seriously weakens the regulatory capacity and effectiveness in Mongolia.

3. **Lack of international links.** Given the population size, the limited budgets, and also the relative small size of the market, some regulatory functions need international connections for reference and backup. This is true for the registration of advanced innovative products (expertise, testing capacity), clinical trials (number of patients, supervision, procedures), inspection (early warnings, international inspections and standards), and for laboratory testing (testing of advanced products, verification tests, proficiency tests). Currently, there are very few international connections.

4. **Poor quality of medicines.** A survey by MOH undertaken by the World Health Organization in 2007 revealed that 26% of all sampled medicines were of insufficient quality. Half of these were counterfeit (illegal imports, or not registered), and half were of substandard quality (less active ingredients). This has serious economic and health consequences.

5. **Weak laboratory capacity.** The drug control laboratory has received very little investments or capacity building since it was brought under the GASI. In 2010, an investment is made in a new facility. It is, however, required to invest in more than a new building; training, guidance with operating procedures, management support, a laboratory information system, and essential equipment are also needed to bring this laboratory to the internationally required ISO 17025 standard. With these investments, this laboratory can make a fresh start and reposition itself as the drug control laboratory for Mongolia. Other laboratories in the public domain are far less developed and equipped. It is necessary to prepare a national laboratory accreditation plan to identify each lab’s functionality and mandate (frequently debated vis-à-vis the current reduced capabilities of the drug control laboratory) and to verify and validate their testing competence on a regular basis.

6. **Deficient pharmaceutical inspection.** The inspection is somewhat disconnected from MOH, although coordination mechanisms are in place; reports are not shared and the inspection policy is determined by SSIA rather than by MOH. Pharmaceutical inspection training has been rudimentary, there is limited specialization (no specialized GMP inspectors) and procedures, and checklists need substantial improvement. In the current situation, both the
pharmaceutical inspectors and the border control inspectors largely work on their personal integrity and opinion, rather than on agreed policies and procedures, which makes each decision a personal endeavour rather than a system decision. Information exchange and access to drug databases would improve the detection rate of counterfeit and illegal imports; fit-for-purpose information should be available to all inspectors and border control points.

B. Pharmaceutical Market

7. Mongolia has switched from a central state-run medicine supply system to a privatized supply system. Now 38 production companies, 200 importers, around 40 specialized wholesalers, and 1,200 retail pharmacies operate in the country, plus over 300 soum-based drug revolving funds and all hospitals and health facilities have their own decentralized procurement mandate and drug budgets. The total market is estimated at $42–45 million (in 2009 at wholesale purchase price), with a forecasted annual growth of 10%–15%. An upgraded and well-managed comprehensive registration, licensing, import/export control, laboratory capacity, and domestic production complying with international standards are an absolute requirement to guarantee that in the private sector lead supply system medicines are of the right quality and safety, and accessible to the entire population.

8. Local drug manufacturing. Several domestic producers have invested in new facilities and international production standards (Good Manufacturing Practice [GMP]). However, the inspection is inadequate and an internationally recognized certificate cannot be issued and there is no legal base. This implies that even the best pharmaceutical companies in Mongolia have serious limitations in exporting their products. The current national standard needs an upgrade to the international GMP standard comparable with neighboring countries. Several companies need investments and upgrades, and guidance is necessary for these companies to make these changes and develop new production lines with good quality and safety standards. As 20%–30% of the domestic market is supplied by Mongolian products, upgrading the quality of the domestic industry will substantially improve the quality of medicines for Mongolian patients. Compliance with international standards will also have a positive economic impact: increased export capacity and a higher domestic market share (import substitution).

C. Key Challenges that Need to be Addressed

9. The key challenges that need to be addressed in the drug regulatory system are:

(i) The need to establish a single drug regulatory authority.

(ii) The need to strengthen the regulatory system. Regardless of the organizational structure, all regulatory functions need strengthening, by defining standard procedures and reporting standards, new dedicated software systems, and by staff training and development. There needs to be more international contact to keep up a professional profile that is comparable with other countries.

(iii) The need to improve the inspection system, including border control activities. The focus of the inspectorate needs to be redefined and the pharmaceutical inspectorate and the border inspection need adequate procedures to ensure consistency and transparency.

(iv) It is necessary to rationalize the drug control laboratory functions. The Drug Control Laboratory should become the certified national control laboratory. Other laboratories can provide additional testing for the Mongolian market or as a backup facility. A laboratory accreditation scheme needs to be developed to
facilitate quality assurance and identify adequate functionality for each laboratory.

(v) It is necessary to upgrade and enforce GMP. The inspection needs to be reformed, standards revised, and certificates must be issued. A training course needs to be developed and run on a continuous basis.

(vi) The current adverse drug reaction monitoring efforts are working, but the functioning of the drug committees in the hospitals needs to be strengthened (better reporting, feedback and effective follow-up activities).

(vii) Finally, the governance of the sector needs to be improved. A reorientation of the Pharmaceuticals and Medical Devices Division in MOH towards increasing the transparency and accountability in drug safety and access to essential drugs through an expanded monitoring and evaluation role is required. Patient and health professional’s participation needs to be structured.

II. Human Resources Subsector

A. Postgraduate Education for Hospital Specialists

10. The Health Sector Strategic Master Plan identifies human resource development as a key area of work and focuses on the need to support the workforce planning and linking policies and planning.

1. Organizational Framework

11. The three main organizations involved in health service human resource planning, development, and training are MOH, the Department of Health (an implementing agency of MOH), and the Health Sciences University of Mongolia. In 2007, an intersectoral Coordinating Committee on Health Sector Human Resources was established under the chairmanship of the Prime Minister to gain high-level support for decision making on health sector human resource development.

12. In 2007, MOH and the Ministry of Education Culture and Science (MECS) signed a contract which resulted in the establishment of a committee (in 2009) chaired by the State Secretary of MECS to evaluate and consider all issues related to the training of health specialists. The committee advises on establishing new training organizations and specialties of different levels, including bachelors, masters, and PhD. The committee sets also the limit on the number of students to be enrolled and trained by health educational institutions, and it is responsible for accrediting health specialist training institutions.

13. MECS is responsible for health worker training. Training institutions do not receive government funding, and must generate their own income through student fees, an incentive to enroll as many students as possible, rather than respond to health sector requirements. The separation of responsibility for health worker production and health worker employment requires close collaboration to avoid problems, and the relationship between MOH and MECS is not sufficiently strong at present to overcome differences in perspective and objectives.

14. Human resource development (HRD) is the responsibility of the MOH Division of Public Administration and Management although some aspects of human resources remain under the responsibility of the Department of Health, including licensing and statistics. The budget allocated for the HRD unit has increased since 2004, enabling the staff to better understand the health human resource situation nationally, and work more effectively to address problems.
The Department of Health is currently the licensing body for health professionals. The licensing system in Mongolia continues to require regular continuing professional development for all professional health workers. Continuing professional development is provided by most large hospitals, regional medical colleges, the Health Sciences University of Mongolia, some private training institutions, and professional associations.

2. Specialist Training

A committee to oversee professional development and postgraduate training of medical specialties was approved in 2009. MOH provides guidelines for the training and for providing specialist degrees for medical postgraduate specialists. MOH guidelines set also the requirements for organizations that conduct postgraduate training.

Currently, postgraduate education is conducted in 23 health organizations including tertiary hospitals, national mono-profile centers, some sanatoriums, some regional diagnostic and treatment centers, the Health Sciences University of Mongolia and its branch colleges, 1 private medical school, 2 professional societies (society to fight female cancer and society for palliative care), and 1 private hospital.

These organizations conduct residency training (postgraduate specialty training) of between 1 to 1.5 years for 23 main specialties. In addition, six-month training is provided for 65 subspecialties. In comparison, in the 25 European Union countries the highest number of recognized specialties is 43 (Italy and Hungary), and the lowest number of recognized specialties is 30 (Germany). Residency trainings in Western European countries are in the average of 5 years and longer for some specialties (e.g., neurosurgery).

It is commonly accepted that the number of specialties recognized in Mongolia is exceptionally high. Consideration should be given to diminish the number of recognized specialties in Mongolia and make specialty training requirements more in accordance with European Union countries, where the residents receive during their training reasonable salaries from the hospitals where they are trained. This facilitates a longer training program than in Mongolia where the residents have to pay (approximately $500 per year) for their residency training.

B. Management Training and Leadership

The need to strengthen health service management capacities in secondary and tertiary hospitals is generally recognized. Weak management at all levels was identified as a priority issue in the key area of work of institutional development in the Health Sector Strategic Master Plan.

1. Organizational Framework

The two main organizations involved in health service management training and development are the Department of Health (DOH) and the School of Public Health of the Health Sciences University of Mongolia (HSUM).
2. Health Services Management Training

22. In the past, the DOH provided a range of short term to midterm management training courses. However, these were discontinued in 2009 because of legal constraints, which have now been lifted. The HSUM’s School of Public Health has a Management Department which was established in 2001. The University runs a postgraduate degree in public administration and a number of short term courses in management (e.g., leadership). A specific course on hospital management is not offered.

23. The strength of the Department of Health is in organizing and coordinating; and the University’s strength is in their teaching and academic approach, training environment, and capacity to undertake research. Professional associations (e.g., Medical Association) were established in Mongolia in the 1990s. They have yet to fully develop their role and do not contribute to the development of the curricula and training regimes, as is usually the case in Western countries.

C. Key Challenges that Need to be Addressed

24. The main challenges include:

(i) The general structure of postgraduate education and development is weak and not clearly delineated and quality driven. The functions of workforce planning, development of guidance on curricula development, production of detailed curricula, development of residency programs, delivery of training, and examination processes need to be undertaken by bodies which have the necessary expertise.

(ii) The quality of postgraduate and continuing education for specialists continues to be an issue of concern. Improving training is identified as a priority issue in the human resource development area of work in the Health Sector Strategic Master Plan. Mongolia is out of kilter with best international practice, with specialists having to pay for their residency training which, as a consequence, is on average only 2 years when international standards would indicate a period of 5 to 6 years is necessary to acquire the necessary skills, knowledge, and behavior in the major specialties.

(iii) Professional medical associations in Mongolia were established in the 1990s. They are relatively new organizations and need to develop their role.

(iv) The ratio of nurses to doctors is low and best use is not made of nurses. Doctors are undertaking functions that could be best performed by nurses. There is an opportunity to increase the role, job satisfaction, and performance of nurses.

(v) Weak management at all levels was identified as a priority issue in the Health Sector Strategic Master Plan. The need to strengthen health service management capacities and governance in secondary and tertiary hospitals is generally recognized.
PROBLEM TREE ANALYSIS

Effects
- Reduced economic growth
  - Loss of productivity
- Increased poverty
  - People are less employable
  - Reduced education attainment

Core Problem
- Poor health status of the population

Causes
- Protection through health insurance is limited
- Health care system, especially hospitals function poorly
- Unsafe drugs harm the health status of people
  - Weak health sector governance and management
- Poor lifestyle and nutrition

- Benefit packages limited and HI coverage insufficient
- Purchasing of health services and payment methods inadequate
  - PHC and hospital sector lack development and investment strategies
- Quality of care is deficient at PHC and hospital level
  - Capacity and attitude of health workers is deficient
  - Drug regulation is ineffective in preventing unsafe drugs to appear in the market
- Weak health sector governance and management
- Poor lifestyle and nutrition

- Government subsidies to health insurance for non-contributor is limited
- Institutional and HR capacity of Health Insurance Fund is deficient
- Lack of vision, commitment, and capacity of decision-makers to reform the sector
- Health workers training, including post-graduate planning, training, and certification are weak
  - Low morale of personnel due to low pay and poor working condition
- Drug regulatory functions are poorly developed and uncoordinated
  - HR management capacity is limited; and planning, monitoring, communication, and inspection systems are deficient
- Rural–urban imbalances favor migration to Ulaanbaatar

HI = health insurance, HR = human resources, PHC = primary health care.
Source: Participatory planning workshops, February–March 2010, Ulaanbaatar
Legend: .................................. Fourth Health Sector Development Project.