

THE CURRENT SITUATION AND ANALYSIS OF MEDICAL AND HEALTH SERVICE REGULATION IN CHINA

**Background discussion paper to inform the Regulatory Reform Review of
China**

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The current situation and analysis of medical and health services regulation in China

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INTRODUCTION

In 1997, the Central Committee of the Communist Party of China's (CPC) "Decision on Health Reform and Development" provided preliminarily steps to establish a health system with Chinese characteristics by 2000. It addressed: healthcare services; medical security; supervision of health services administration; achieving the goal of universal access to basic primary care; and further improving the level of national health standards. Supervision of the medical health services, which is a principal form of national management in medical and health affairs and an important part of the socialist legal construction, has been raised to a high level of importance in China. After more than 50 years of development, particularly in the area of reform and opening-up over the recent 30 years, China has already formed a legal and regulatory system for health addressing: socialized public health, services related to health care, medical and health agencies and the regulation of professionals. However, due to the China's rapid economic development, continued progress in the regulatory system for healthcare services is necessary.

1. The current situation of medical and health services in China

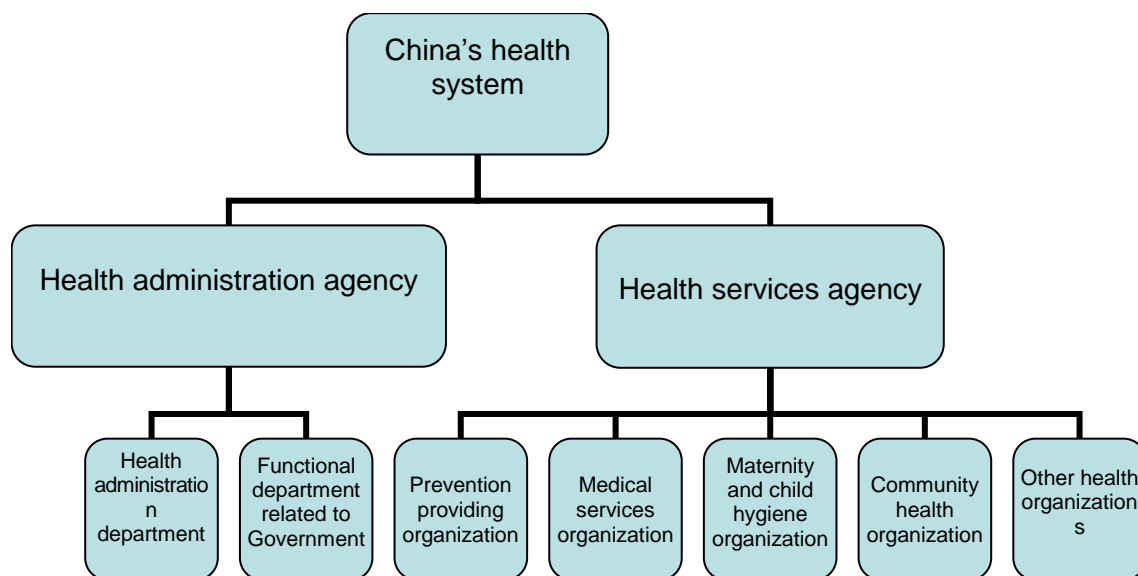
More than 50 years following the founding of the new China, the medical and health services infrastructure in China is approaching a high level of development. The medical and health agencies are taking shape and the basic medical and health services system has been formed. Domestic medical and health technology is also advancing rapidly. Meanwhile, the level of health within the population has seen remarkable improvement. The average lifespan of Chinese citizens has increased from 35 years before the foundation of new China to 70 years today.

1.1. *The structure of the medical health system in China*

The medical and health system in China consists of various subsystems including prevention, health protection, medical services, rehabilitation services, implementation and enforcement of health regulations, service organizations in medical scientific education and research, as well as governmental health administrations for monitoring different health services organizations. Figure 1 illustrates the regulatory framework for healthcare in China.

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Figure 1. Regulatory framework for healthcare in China



Medical and health administrations in China

National medical and health administration

Ministry of Public Health (MoPH) of People's Republic of China (PRC) is charged with governing domestic health. It is overseeing a new era of medical services policy: with an emphasis on the rural region, giving priority to prevention, paying equal attention to Chinese and western medicine, relying on technology and education, mobilizing the participation of the entire society, and serving the people's health through socialist modernization. Having implemented two reforms since 1998, the MoPH is currently composed of a: general office, personnel department, financial planning department, health administration regulation department, health emergency office (emergency control central of sudden occurrences in public health), country health management department, health supervision bureau, maternity and child healthcare and community health department, medicine administration department, disease control and prevention bureau (National patriotic public health campaign office), technology and education department, international cooperation department, healthcare bureau, 13 functional departments (department, general office and office) and the Party committee. In addition, the national Traditional Chinese Medicine Administration is also a health administration regulating the practice of Traditional Chinese Medicine.

Regional medical and health administrations

According to the scheme of the national medical and health administration, every province, city, autonomous region, and municipality that is directly under the central government together with regional cities, counties and villages that are under their authority, must establish regional medical and health administration institutions (offices or sections). In the regional health administration institutions, Traditional Chinese Medicine offices (or sections) have been established to govern the practice of Traditional Chinese Medicine within the region.

Functional departments related to national and regional governments. As medical and health services are related to many departments, apart from medical and health administrations, many other governmental departments are involved in regulating and managing this sector, which extends vertically to the departments related to regional governments. For instance, along with the development of the market economy, private medical facilities now operate in China. To date, the Ministry of Civil Affairs has been in

charge of regulating approvals for the entry of private medical facilities. Under the planned economy, many large and medium sized state-owned enterprises had established medical systems for their own employees, some of these have remained, and many administration and supervision functions related to these medical institutions by their parent organizations including those under the Ministry of Commerce (MOFCOM), the same as the Ministry of Education (see Fig 2).

Medical and healthcare system in China

China's medical and healthcare system comprises institutions to administrate medical services, prevention, health care, rehabilitation services, family planning, health education and medical research in order to meet the current health needs of people both in urban and rural areas. The general definition of the medical and healthcare system in China includes institutions providing public health services, medical services and enforcement of health regulations across the entire society. This definition includes not only healthcare agencies in narrow sense, including the institutions providing medical services, preventative medicine, healthcare and medical research, but also the bureau of blood and blood products, the bureau of biological products, pharmaceutical manufacturers, manufacturers of health materials and medical appliances, and the bureau of drug-testing in broad sense. Also included in this definition are non-governmental organizations and public health academic agencies (academy, association, seminar and foundation) and agency organizations (committee for the evaluation of medical technology and appraisal of accidents), and so on.

According to the information provided by the MoPH, there were a total of 299 thousand national health institutions at the end of 2005. These included 290 thousand registered medical institutions (not including village clinics). Of these, 132 thousand were non-profit medical institutions and 156 thousand were commercial. There are 18 703 thousand hospitals, 17 thousand community health services centers (stations) and 41 thousand rural townships clinics.

Table 1. Number of national health facilities and beds from 2001 to 2005

| | 2001 | 2002 | 2003 | 2004 | 2005 |
|---|-----------|-----------|-----------|-----------|-----------|
| Numbers of health facilities in total | 330 348 | 306 038 | 291 323 | 297 540 | 298 997 |
| Hospital subtotal | 16 781 | 17 844 | 17 764 | 18 393 | 18 703 |
| Hospitals of health ministries | 7 676 | 8 940 | 9 126 | 9 146 | 9 139 |
| Clinics | 48 643 | 46 014 | 45 204 | 42 471 | 41 694 |
| Rural county clinics | 48 090 | 44 992 | 44 279 | 41 626 | 40 907 |
| Outpatients department | 3 716 | 7 019 | 6 152 | 6 148 | 5 895 |
| Clinics, infirmaries, health centers | 244 345 | 212 888 | 198 316 | 202 646 | 201 509 |
| Private clinics | 136 561 | 131 817 | 127 072 | 132 162 | 133 132 |
| Sanatorium | 461 | 365 | 305 | 292 | 274 |
| Community health services centre (stations) | ... | 8 211 | 10 101 | 14 153 | 17 129 |
| Maternity and child care centre (bureau, station) | 2 548 | 3 067 | 3 033 | 2 998 | 3 021 |
| Specialist prevention centers (bureau, station) | 1 783 | 1 839 | 1 749 | 1 583 | 1 502 |
| Disease control and prevention centre | 3 813 | 3 580 | 3 584 | 3 588 | 3 585 |
| Health supervision centre | ... | 571 | 838 | 1284 | 1702 |
| Medical technology and research institutions | 397 | 298 | 284 | 276 | 263 |
| Number of beds of medical institutions (pieces) | 31 55 558 | 3 113 165 | 3 144 235 | 3 250 938 | 3 350 810 |
| In hospitals | 2 229 601 | 2 221 753 | 2 269 505 | 2 363 464 | 2 445 012 |
| In clinics | 746 499 | 685 400 | 685 655 | 682 383 | 689 918 |
| Beds per 1 000 persons in hospitals and clinics | 2.39 | 2.32 | 2.34 | 2.40 | 2.45 |

Source: "Statistical bulletin of development of health services in China" (2005), Statistics and Information Centre of the MoPH.

By the end of 2005, China had established 3585 national disease control and prevention centers (anti-epidemic — including 145 prevention and health care centers). Other health facilities include 1702 national supervision bureaus for health of which 31 were at the provincial level, 318 were at the city or prefectural

level (representing 96% coverage of all cities and prefectures), and 1318 at the county level (representing 46% coverage of all counties, county level cities and municipal districts — see Table 1).

Hospitals are the main component of the medical system and are comprised of 3 grades: there are 946 hospitals at the level of Grade III (of which 594 hospitals are at the level of Grade III A), 5156 hospitals at the level of Grade II, 2714 hospitals at the level of Grade I, and 9887 hospitals are ungraded. In terms of hospital beds per hospital, there are presently: 11 156 hospitals with fewer than 100 beds, 3746 hospitals with between 100 and 199 beds, 2777 hospitals with between 200 and 499 beds, 740 hospitals with between 500 and 799 beds, and 284 hospitals with more than 800 beds.

Additionally, there were 5.427 million medical health professionals in China in 2005, of which 4.46 million were health technology personnel, 226 thousand were other technical personnel, 313 thousand were management personnel, and 428 thousand were support service personnel. There were totally 1.938 million practicing physicians and physician's assistants (of which are there 1.556 million were practicing physicians), as well as 1.35 million registered nurses.

Among the medical and health personnel, there were 5.093 million health personnel in medical institutions, of which 4.221 million were health technical personnel, including 1.81 million practicing physicians and practicing physicians assistants and 1.331 million registered nurses; there were 206 thousand health personnel in disease control and prevention centers (health and quarantine stations), of which 158 thousand were health technical personnel, including 92 thousand practicing physicians and physicians assistants; there were 48 thousand health personnel in health supervision centers, of which 35 thousand were health technical personnel.

2. The current situation of medical and health services regulations in China

The medical and health services regulatory system is an administrative legal system by which the government regulates and manages the practice of medical and health services via political, economic, legal and other measures. These measures are precisely applied in the health sector to address "normative constraints" and "demand management" with a view to achieving desired social policy goals based on the conduct and activities of an administrative legal system. It comprises not only the external regulatory system concerning health services, but also the institutional regulatory system for departments and institutions; it includes not only the spectrum of professional controls and regulations in broad sense, but also the supervision of law-enforcements in narrow sense.

2.1. The contents and means of medical and health services regulation in China

2.1.1. The contents of medical and health services regulation in China

The constitution of medical and health services regulation in China is abroad, and new measures are continually added along with the development of medical and health services.

From static view, medical and health services regulation includes public health, security of health products, medical institutions and professional personnel, national environmental hygiene and family planning. It is comprised of four categories:

Firstly, public health regulations: supervision of control and prevention of infectious diseases, and occupational diseases, supervision of radiological health, supervision of health in public places and supervision of health in schools.

Secondly, regulation of products related to health: it includes the health regulation of food, cosmetics, domestic and drinking water and disinfectant products.

Thirdly, regulation of health institutions and professional personnel: it includes regulation of medical institutions, maternal and child healthcare institutions, blood collection and supply institutions, physicians and other health professional personnel, Traditional Chinese Medicines, medical safety and medical waste.

Fourthly, regulation of national environmental hygiene, medicines, population and family planning: it includes regulation of environmental hygiene, medicines, medical facilities, population and family planning.

From a dynamic perspective, the regulatory system for medicine and health covers the entry of providers, services standards, product quality standards, pricing and practices of medical services institutions, professional personnel, medicines and so on.

2.1.2. The main modes of medical and health regulation in China

Generally speaking, the means of health regulation consist of two parts, one addresses the capacity of the subjects of health regulation, and the other deals with improving practices in the process of health regulation. The first refers to the conditions of being the facilities and institutions subject to health regulation. The second refers to the categories of the administrative practices, as well as the functional scope and methods of the subjects of health regulation. Current regulations mainly consist of administrative regulation and law-enforcement regulation. For example, the “Regulations on Practicing Physicians of People’s Republic of China and Procedures for Nurses” regulates standards on the practice of technical health professionals. The MoPH’s “Procedures for Health Supervision of Domestic and Drinking Water and Regulations on Domestic and Drinking Water” regulates standards for products related to water. The Central Committee of the CPC’s “Regulations on Supervision of The Health of Cosmetics and the Implementation Details” regulates standards for cosmetics. The MoPH’s “Regulations on Health of Food of People’s Republic of China and its Rules, Provisions and Standards” regulates standards for food. China has implemented a hygienic licensing system for public places, which governs site selection and the design of projects for construction as well as the improvement and expansion of public places. The measures normally employed in regulating health services encompass administrative regulations, supervision, inspection, sanctions and law-enforcement.

Health administration permission

Health administration permission refers to the legal qualifications and rights lawfully established by the subjects of health regulations to counterparts through granting permits and licenses for their operation. It is an important measure for governing public health affairs. It is also an administrative practice conducted by the subjects of health regulation to the counterpart. It aims to regulate the preparation of activities and products related to the health of the population, to maintain a sound healthcare social order and thus to protect public health.

Health administration confirmation

Health administration confirmation refers to regulatory activities related to examining, confirming or approving the counterpart’s legal status, legal relations and legal facts according to the law. It is different from the health administration permission. It is only a confirmation of legal status, legal relations and legal facts, but cannot grant any rights or qualifications. However, as the preconditions of health administrative permission and arbitration, health administrative confirmation is always associated with health administrative permission and arbitration. Administrative confirmation is always conferred before granting permission and completion.

Health supervision and inspection

Health supervision and inspection refers to regulatory activities related to inspecting, assessing and influencing the counterpart to comply with the law, regulations and rules. Health supervision and inspection are the most universal health supervision activities in health administration, law-enforcement and management. It is also an indispensable area of administrative functions governing the subjects of health regulation. It aims to prevent and adjust illegal practices in the healthcare sector and to ensure the implementation of laws related to health. Health supervision and inspection is a professional occupation comprising preventive health supervision and routine health supervision. It can also be divided into all-around health supervision and inspection, and key health supervision and inspection, or general health supervision and inspection, and particular health supervision and inspection.

Health administration law-enforcement

Health administration law-enforcement refers to regulatory activities related to influencing the counterparts to perform their obligations or the activities of taking any urgent or immediate measures to fulfill the goal of health regulation and to protect the interests of public health, the health of the population and security. The majority of administrative law-enforcement activities focus on the area of administrating preventive measures. The health administration's preventive measures are compulsory measures, as well as being special powers and functions guaranteed under laws and regulations. The subjects of health regulation and their personnel lawfully implement measures to deal with activities, articles, or any specific places that endanger or likely to endanger the health of the population and social interests. They aim to prevent and address activities or events endangering public health.

Health administration sanctions

Health administration sanction refers to regulatory activities related to implementing disciplinary measures to citizens, corporations or other agencies that do not constitute criminal penalties according to the law, regulation and rules. To the subjects of health regulation, it is a lawfully administrative practice, but to the counterparts, it is a legal result of offending the rules of administrative management.

Health administration arbitrament

Health administration arbitrament refers to regulating procedures concerning inspecting and arbitrating specific civil disputes, which are closely related to administrative activities concerning two equal parties. It is different from the concept of administration arbitrary. Administration arbitrament is a progress of carrying out administrative functions. It is a regulatory procedure in the area of healthcare, which has power of execution and confirmation upon the counterpart. Under these procedures a counterpart can apply for administrative reconsideration or bring an administrative suit.

Health administration guidance

Health administration guidance refers to regulatory activities addressing the counterpart of regulation within the scope of functions and duties and according to the requirements of health regulation. The regulatory subjects carry out the guidance with authorization or assistance from the counterpart. The health regulatory subjects undertake flexible and non-compulsory measures in accordance with health regulations to guide and assist the counterpart in the healthcare and healthcare legal field in order to improve their performance in meeting the requirements of the healthcare laws and regulations. Attention to administrative guidance in the healthcare field has been a characteristic of healthcare regulation over several years in China. It is also an experiment in health regulation services.

Health administrative mediation

Health regulatory subjects, on a voluntary basis as two equal parties under health legal relations, mediate civil disputes between them in accordance with laws and regulations. It assists the parties to the dispute to settle them through equal consultation and voluntary agreement. In accordance with the “Medical Accident Ordinance” implemented on 1 September 2002, patients and physicians can request the health administrative agencies to mediate and settle disputes about medical accidents. The two parties should fulfill the resulting agreement once reached following mediation.

Health administration award

Health administration award is a concrete practice in health supervision, through which the health regulatory subjects, in accordance with the legal conditions, give material or moral awards to those units or individuals who have outstanding performance or make great contributions to national or social health services or health supervision. It aims to honor the advanced and to encourage the backward, to boost the people’s morale and creativity. The main means for award include granting bonuses and prizes; awarding legal honors or titles; and promotion or salary increases.

Aside from those measures mentioned above, other regulatory measures in health services exist including: the formulation of regulations on health inspection technologies; the formulation, implementation, administration and inspection of health standard programs; and work concerning the inspection or guidance of health services at the national level.

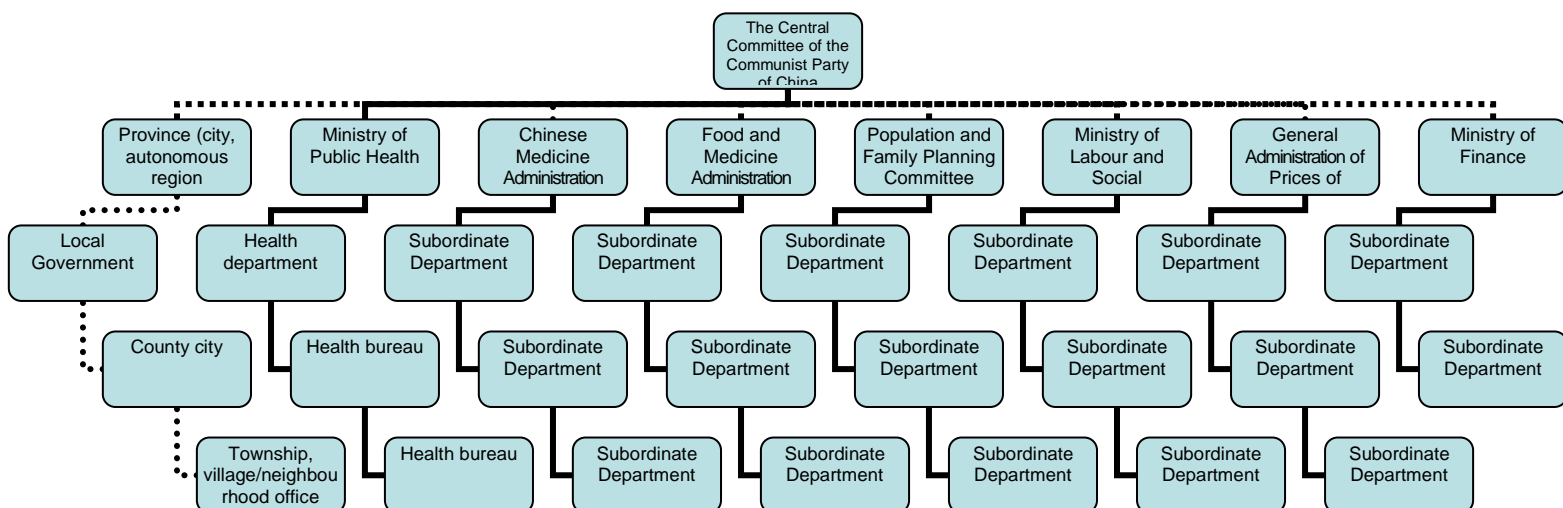
2.2. *The framework of medical and regulatory system for health in China*

As indicated in Figure 2, the framework of the medical and regulatory system for health in China is large and complicated, and many aspects of it have special Chinese characteristics.

The health and medical regulatory system is a top to bottom vertical administrative system. It has relevant supervisory agencies in each department from the Central Committee down to the level of local government, which is characteristic of the administrative system in China.

The fields of medical and health services regulations encompass many relevant departments, which clearly reflect Chinese characteristics. Aside from the MoPH, the main supervisory agencies also include the National Traditional Chinese Medicine Administration and the National Food and Medicine Administration. Apart from these main regulatory agencies, many other agencies also are involved in the governance of market entry, delivery and distribution of medical health. These include the Ministry of Finance, National Development and Reform Commission (NDRC), National Price of Commodities’ General Administration, Ministry of Labor and Social Protection, Committee of Population and Planning, National General Administration of Quality Supervision, Inspection and Quarantine, National Administration for Industry and Commerce, Ministry of Civil Affairs, National Economic and Trade Commission, National General Administration of Customs, Ministry of Agriculture, Ministry of Education, Ministry of Railways, Ministry of Post Telephone and Telegraph and Ministry of Broadcast, Film and Television. Indeed, the relevant government agencies of each province, city, autonomous region and the local cities, townships and villages below them are involved in or intervene the provision of local medical and health services.

Figure 2. Health administration agencies in China



Note: Dotted lines in the chart refer to subordinated relations and unbroken lines refer to the relevant professional guidance and management relations.

2.3. *Urban and rural regulatory models in China*

China has differing health services regulatory systems in urban and rural regions. China is still a society with dual economic structure, with 60% of the population living in rural areas. Furthermore, rural areas are the key emphasis of health services in China; and the health regulatory system in rural areas is different from that in urban areas.

Differing departments and administrative authorities oversee the regulatory system in urban areas. Horizontally, it is a system under which every functional governmental department works together. Vertically, each government has independent health institutions and its own systems. Although both belong to the Ministry of Health's medical and health institutions, local governments at all levels have their own health institutions, and differing systems of medical and health organization exist. The MoPH and Traditional Chinese Medicine Administration have hospitals and Traditional Chinese Medicine hospitals under direct authority across 11 provinces of the country. Local governments, such as provinces, cities, counties and districts, also have health services institutions under their direct authority, which make up the urban-rural health services system including province-city-county, township and village; of which they have their own vertical system at the city (local) level. This includes city, district and some streets. Hospitals, sanitation and anti-epidemic stations, and maternity and child healthcare centers will always be present at the city and district levels. Some of them also have specialized prevention stations like anti-tuberculosis stations. At the national level, there are county hospitals, Traditional Chinese Medicine hospitals, health and quarantine stations, maternity and child healthcare institutions, and some of them also have the specialized prevention institutions.

Meanwhile, relevant National Ministries and Commissions, universities and colleges, armies, armed police forces, public security departments and large institutions also have their subordinate hospitals and clinics, as well as the vertically administrated health services institutions. For instance, there were 4809 such hospitals established or operating as of 2004. This is the reason for non-health administration government institutions such as the Ministry of Education and Economic and Trade Committee to have become included under medical and health regulation.

The health supervision system operates under a multi-level management system in rural regions. Taking each county's health institutions as basic unit, rural regions have a three level (county, township, village) administration system. It divides the three different health institutions (ownership by the state, collective and individual) into different areas (medical services, epidemic prevention, maternity and child healthcare, Traditional Chinese Medicine). Aside from the medical and health institutions under direct control of the county, there are also specialized prevention institutions. Normally there are 6-9 health institutions allocated per county including central healthcare stations at the township level, and clinics at the village level. The administrative system is a mixed system with multiple levels and systematic management of health departments in multiple fields.

2.4. *The main health supervision institutions and their functions in China*

As illustrated indicated above, medical and health regulation covers many subjects in China. But the most important components are MoPH, National Traditional Chinese Medicine Administration and National Food and Medicine Supervision and Administration. These three institutions play an essential role in regulating and formulating regulations concerning medical and health services, public health management, medical institutions, professional licensing, medical services and the quality of medicines.

MoPH of People's Republic of China

The MoPH is the key institution in the health services sector. It is the most essential and important institution for governing and regulating medical and health services in China. There are four departments under the MoPH that fulfill its governance and regulatory functions.

- The Health Policy and Regulation Department is in charge of formulating national planning for health legislation development; guiding local health legislation development; and institutionizing health standards and administration. It is responsible for health administrative reviews and responding to administrative actions.
- The Medical Administration Department is mainly responsible for services in the medical field. It supervises the health services in detail. It examines and implements the laws, regulations and orders concerning the: licensing of medical and blood collection and supply institutions; licensing medical professionals; and regulating the use of clinical technologies. It examines the administering regulations and norms of medical and blood collection and supply institutions in relevant treatments, nursing and rehabilitation, as well as organizing and guiding their implementation. It participates in the research and examination of the regulations, rules and policies applicable to the clinical management of medicine and medical instruments, as well as organizing and guiding their implementation. It studies the supervisory regulations concerning the evaluation of quality control in the field of services of medical and blood collection and supply institutions, as well as organizing and guiding their implementation. It also coordinates and organizes the urban medical team to support the services in rural regions and to assist urgent medical services in case of heavy casualties

- The Rural Health Management Department is responsible for the reform and development planning of rural health services, and the formulation of relevant policies. It engages the examination of laws, regulations and rules related to rural health services. It examines the planning of rural primary health care, as well as coordinating and guiding their implementation, organization and evaluation. It is in charge of the general management of a new cooperative medical care system in rural areas, researching and reviewing the policy for the new system as well as coordinating, organizing and guiding their implementation. It researches, plans and guides the formation of rural health services system. It also collects and analyses relevant information about rural health and coordinates and guides local governments in fulfilling national policy on rural health. It lawfully guides the local government to develop procedures for licensing and registration of rural physicians and other relevant administrative functions. It cooperates with relevant departments and bureaus to formulate and implement programming for rural public health, basic medical services and training of personnel.
- The Health Supervision and Law-enforcement Department is in charge of public health field. It participates in the review of relevant draft laws and regulations, standards, policy advice, programming, regulations and systems in health supervision field in compliance with its functions and duties. It regulates food, cosmetic, schools, environment, radiation and occupational health. It administers the supervision and inspection of medical and blood collection and supply institutions. It improves and standardizes the medical services market. It lawfully organizes and develops the supervision and inspection activities on the prevention and treatment of infectious and local diseases. It organizes, coordinates, regulates and examines relevant big or important health cases. It regulates and guides the work of local health regulation.

National Traditional Chinese Medicine Administration

National Traditional Chinese Medicine Administration is probably the most typical medical and health regulation institution with Chinese characteristics. Its responsibilities include promoting Traditional Chinese Medicine. It formulates policy on the development of Traditional Chinese Medicine based on relevant policies, law and regulations of health and medicine. It plans, guides and coordinates improvements to Traditional Chinese Medical treatments, research, administrative structures and operational mechanisms of educational organs. It reviews different Traditional Chinese Medical or healthcare institutions, regulations and technology standards, and regulates their implementation. It reviews the standards for evaluating professional credentials and practicing qualifications for those professionals practicing Traditional Chinese Medical treatment, health care, Traditional Chinese Medicine and nursing, and regulates their implementation. It participates in formulating the *National Basic Medicine Catalogue* and standards for practicing Chinese herbalists.

National Food and Medicine Administration

National Food and Medicine Administration is a professional regulatory institution. It oversees the safety of food, health foods, cosmetics and medicines. It is responsible for administrative and technical supervision of research, production, circulation, use of medicine (e.g. Traditional Chinese Medicinal material, Traditional Chinese Medicines prepared in ready to use form, patented Traditional Chinese Medicines, chemical medicinal materials and their preparation, antibiotics, biochemicals, biological products, diagnostic medicines, radiopharmaceuticals, narcotics, toxic medicines, psychotropic substances, medical instruments, health materials, medicinal packaging materials, and so on), food, health foods and cosmetics. It coordinates the investigation of major accidents and is also responsible for the examination and approval of health care products.

Box 1. Advantages and disadvantages of Good Manufacturing Practice

In 1982, China formulated Good Manufacturing Practice (GMP — trial version) and it was tried out in some pharmaceutical enterprises. In 1998 it was developed and revised as Good Quality of Manufacture Practice (the previous acronym was retained), and it came into force in August 1998. It took 14 years from its issue to generally compulsory implementation. By 30 June 2004, more than 1700 enterprises that did not meet the GMP standard were ordered to stop production and at the same time, more than 800 enterprises were eliminated. Most of the GMP Enterprises became automated, so that the general quality levels of pharmaceutical enterprises in China improved. China currently has almost 6000 pharmaceutical enterprises.

Still, the high cost of implementing GMP in combination with price controls maintained on medicines by the MoPH, of the NDRC, and of Ministry of Labor and Social Protection, many pharmaceutical enterprises currently face heavy debts and difficulties in operation.

National General Administration of Quality Supervision, Inspection and Quarantine

National General Administration of Quality Supervision, Inspection and Quarantine is responsible for the regulation of public health in international harbors. The "Frontier Health and Quarantine Law" prescribes that state border health and quarantine institutions should be established in international harbors and airports of People's Republic of China, as well as at land borders and river ports of national borders. This institution carries out the quarantine, inspection and health regulation of infectious diseases according to the law.

National Population and Family Planning Committee

The Population and Family Planning Committee, which is established by National Population and Family Planning Committee and local governments at various levels, is an administrative institution for population and family planning. It is responsible for leading, guiding, regulating and lawfully implementing national policies and regulations related to population and family planning. It is also charged with addressing transgressions of population and family planning policy or regulation.

- The National Industrial and Commercial Administration is responsible for examining and approving the admission of private medical institutions and their taxation.
- The National Price Control Administration regulates the prices of medical and health services.
- The NDRC formulates and controls the factory price and retail price for pharmaceuticals.
- The Ministry of Labor and Social Protection regulates medical services provided at the appointed hospitals of the socialized medical and insurance system, as well as prices for medicines.
- Other departments' health regulation institutions. Based to current national conditions in China, some other health institutions also belong to the health regulatory system. The National Economic and Trade Committee is in charge of enterprise medical institutions, and supervises their operation, restructuring and transformation. Ministry of Railways and Ministry of Transportation also established health regulation institutions authorized by law or regulations. Still under the MoPH, it regulates health services provided within its system. These health supervision institutions are also an integral part of the health monitoring system.

2.5. *The current condition of the public health law-enforcement system*

Health law enforcement is the key element in the field of health regulation. Health regulatory institutions developed from health and quarantine stations into the health regulatory administration. An independent health and law enforcement system is, however, far from complete.

Health and quarantine stations

The contribution of the health and quarantine station system should not be neglected when considering public health regulation. Health administrative departments always assign health services institutions to implement regulation and law-enforcement in accordance with health law and regulations. As institutional units, health and quarantine stations are entrusted at different levels by health administrative agencies and have historically carrying out numerous regulatory and law-enforcement activities beyond health services. Health and quarantine stations have become a most important institution for health regulation.

In the 1950's, health and quarantine stations were established in various places (there is no central administration for health and quarantine stations in China, and it is not a top down administrative system). It is a public health organization linking both administration and technology. They naturally carried out the task of health regulation. After the economic reforms implemented throughout China in the 1980s, health and quarantine stations began to charge fees for health and medical services due to cutbacks in public funding, thus introducing a change in their previous practice of providing essentially free basic health services.

Health Oversight Board

After 1995, the subject of health regulation and law-enforcement in China transformed from health and quarantine stations to the health administrative departments. In 2000, MoPH issued the "Advisory on the Reform of Health Regulatory System" which set, as a goal for the future, the establishment of a new health supervision system reform characterized by: smooth operations, reasonable structure, efficiency, coordinated operations, a strong code of conduct, clear procedures and effective enforcement. In accordance with this document, each province was to establish an institutional unit under the health administrative department — of the Health Oversight Board. By 2005, 31 health supervision institutions at provincial level have been officially established; 313 (representing 95.4% coverage) health regulation institutions were established in 351 cities (provinces, autonomous regions, prefectures, municipalities), 1824 (representing 73.4% coverage) health supervision institutions at county (city, district) level operated in 2909 counties (cities, districts). The MoPH's Advisory on the Reform of Health Regulatory System is a symbolic mark of the transformation of public health supervision function from health and quarantine stations to health administrative departments. This reform separated the regulatory role from that of financing and service provision.

2.6. *Divisions of subjects in medical services regulation*

The most important component work-stream of the department of medical and health services is that of regulating services. The main areas of medical and health regulation in China are found in the present regulatory situations: firstly, the key points of regulation are the quality and price of medical and health services. As can be observed in Figure 3, these fields have more regulatory subjects. Secondly, different medical and health institutions have different regulatory subjects due to differing ownership structures. MoPH regulates the state-owned medical institutions. Privately owned medical services institutions are divided into non-profit and commercial medical institutions. The Ministry of Civil Affairs and MOFTEC regulate market entry and pricing policies of non-public health services providers; medical services

institutions such as those contained within the Ministry of Economy and Trade or the Ministry of Transportation are regulated under them. The inevitable overlapping regulatory competencies remain to be clarified.

Table 2. Overlapping regulatory institutions for medical services (the central committee level)

| Regulatory functions | Types of medical institutions | Regulatory subjects |
|------------------------------------|---------------------------------|--|
| Regulating market entry | Public non-profit | MoPH, National Food and Medicine Supervision Administration, Traditional Chinese Medicine Administration, National Commission Office for Public Sector Reform, The Ministry of Personnel |
| | Private non-profit | MoPH, Ministry of Civil Affairs |
| | Commercial medical institutions | MoPH, Industry and Commerce departments |
| Price supervision | Public non-profit | MoPH, National Food and Medicine Supervision Administration, NDRC (Price Sector) |
| | Private non-profit | MoPH, NDRC (Price Sector), National Food and Medicine Supervision Administration |
| | Commercial medical institutions | Industry and Commerce departments, Price departments |
| Quality regulation | All medical institutions | MoPH, National Food and Medicine Supervision Administration |
| Public allowance | Public non-profit | MoPH, Ministry of Finance |
| Regulation of non-profit providers | Public non-profit | MoPH, Ministry of Finance, NDRC |
| | Private non-profit | MoPH, Ministry of Civil Affairs |

Sources: Gao Shiji, Zhang An, XU Lanfei (2006), Enforcing the Formation of a Regulatory System to Develop and Reform the Medical Services System, January 24. See online at www.chinado.cn.

Box 2. The National Development and Reform Commission regulates the price of medicine and medical services

Arrangements to reform and regulate order in the economy, imposed by the NDRC in June 2006, strengthened price regulation for medicines and medical services and fully regulated the charges and pricing behavior of hospitals and pharmaceutical enterprises. The main measures carried out by NDRC include those to address: disorderly pricing for medical instruments; extreme price increases by market intermediaries; the establishment of a system for regulating pricing by medical facilities; and the publication of domestic and international price information for key health products and services — in order to support more efficient pricing by enterprises. Also included were measures implemented to limit rates of price mark-ups and to facilitate the development of distribution links in fields where the distribution price differentials are too high or the profits of intermediaries are excessive. The objective was to reduce retail prices charged by large medical facilities for examinations and treatments.

Domestic policy must prevent medical institutions from applying arbitrary charges or double charges by creating or segmenting treatments without authorization. Domestic policy must also improve social regulation, and build up the price credit history of pharmaceutical enterprises, business and medical institutions.

Other measures applied by the NDRC include those to: encourage the production and utilization of standard medicines under pricing restraints; strengthen price supervision for the market prices of regulated medicines; improve the transparency of price formation by strengthening the entire regulatory system's capacity to address the pricing of regulated medicines, in accordance with the Law of Price; intervening when the price of medicines are extreme or rising at excessive rates, by carrying out the measures such as requiring price declarations, recording price adjustments, restricting the ratio of price differentials or profit ratios; and gradually bring non-price regulated prescription drugs within the scope of government regulation through revisions to the government medicine pricing catalogue.

2.7. *The regulatory system for the distribution of medicines*

Regulating for quality and pricing in the distribution of medicine is not only a key aspect of medical and health regulation in China, but also the most difficult — especially regulating pricing for medicines. Rapid increases in the prices for medicines is the main reason that it has become “too expensive to see a doctor” in recent years. After the transformation from total government control to a relaxation of controls, medicine prices in China have been returned under partial government control. According to the “Law on Price Regulation for Medicine” and its implementation regulations, the government’s general approach to regulating price controls on medicines is to combine macro-controls with regulation by market forces. Three forms of medicine prices exist in China including: the guiding price, the government fixed price and the market price. The government guiding price or government fixed price applies for the medicines listed in *National Basic Medical and Insurance Medicine Catalogue*, and a few medicines whose production and distribution are monopolistic and special such as: narcotics, Level I psychotropic substances, medicines for family planning and immunization which represent roughly 40% of the market. The market established the price of prices of the remaining medicines.

Box 3. The example of price controls on medicine

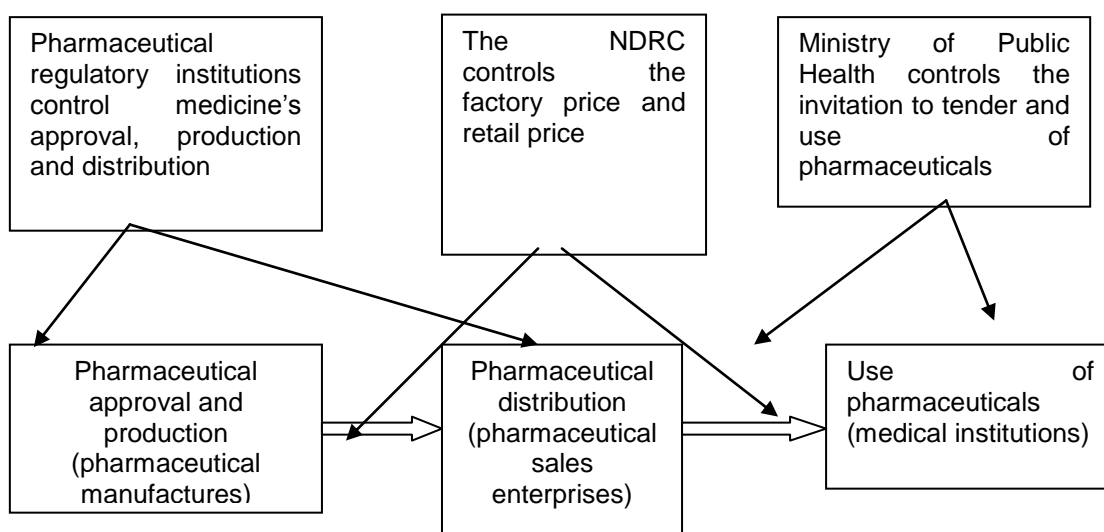
Before 1998, pharmaceutical manufactures made large profits while quality was low due to low drug approval requirements. Following the general implementation of the Regulations on Medicine Quality in 1998, the quality of medicines improved but rapid price increases caused concern among the public. From 1998 to June 2007, relevant departments have made 17 requests for reductions in pharmaceuticals pricing, but the results have been unsatisfactory and consumers have not benefited from this policy. Two main reasons explain this situation, one is that the compensation mechanism reliant on “supporting physicians by the sale of medicine” has not been reformed, thus physicians and hospitals have disincentives to use cheap medicines. The second is that the distribution system for pharmaceuticals has not been reformed

The medicine quality and price regulation system includes several components: firstly, the Food and Drug Administration must certify the quality of new drugs before they are produced and sold. Secondly, NDRC formulates and sets the factory and retail price of the drug. Thirdly, the drugs pass from pharmaceutical companies through wholesale and retail sales channels comprising multiple intermediate stages. Fourthly, health administrative departments set and administer activities such as inviting tender, sales and purchases. Then the medical institutions will select and purchase medicines based on variety, quantity, specifications, requirements related to transport and storage, distribution, and those requiring prescriptions. Finally, patients are able to purchase the medicines. There are thus four components involved between a drug’s production, distribution and consumption by patients. They are comprised of institutions including: production, distribution, provision of medical services and insurance, as well as regulation. (see Fig 3)

3. **The main problems of medical and health services regulations in China**

Although medical and health system in China has succeeded in many areas since its establishment and continues to develop progressively, we are going to discuss the aspects where we need to make more effort.

Figure 3. Flow chart of pharmaceutical production, distribution, consumption and regulation



3.1. The protracted process of legislating medical and health regulations

The time-consuming process of legislating medical and health regulation is one of the shortcomings in the legal architecture of medical and health services. Over the last thirty years, China has experienced transformation from a planned to a market based economic system, as well as continuous and rapid economic growth. Accordingly, many large changes have occurred in the structure and governance of the medical and health services sector, as well as in the population's demand and the supply of medical services. However, the sluggishness of the legislative process concerning medical and health services and their regulation has resulted in many legal ambiguities within the system that now constitute blind spots within the national regulatory framework for health.

The reform of medical institutions for example provides a sense of how slow the legislative process is. The 1994 "Regulations for Medical Institutions" (hereinafter referred to as the "Regulations") has been in operation for 11 years, but it cannot because of its incompleteness meet the demands of current developments. It contains legal "gaps" and defects because of its limited content and coverage. These "gaps" and defects include: (1) "gaps" in regulation and blind spots in the categories and titles of medical institutions and services. The new institutions or services such as medical associations, blood stations, medical healthcare enterprises, pediluvium, health massage, Traditional Chinese Massage and physical therapy are not included within the scope of the Regulations. (2) Supervision and management related defects exist within the Regulations. Article 40 of Chapter 5 of the Regulations contain only four programmatic subjects. This article does not cover fields such as medical administrative health regulation and legal responsibilities. It has brought "no legal standard" to the difficulties facing medical administrative regulation. (3) Penalties are too "soft" in the Regulations. Article 47 of Chapter 6 in the Regulations prescribes that medical institutions whose medical activities exceed the Regulations' scope will be fined a maximum of RMB 3000. This figure is too low based on the current level of economic development. This level of fines is too small, "rigid", weak and is insufficient. (4) There are many standard applications "defects" in the approval process for medical institutions. In the "Fundamental Standards of Medical Institutions" (trial) promulgated by the MoPH in 1994, regulations exist only for personnel, departments and offices, basic facilities, registration capital, but none exist for the administrative systems of medical institutions, functional zones for establishment, allocation and procedures for medical

departments, institutional management and supervision, management and reporting systems for infectious diseases, establishment and management of intensive care units (ICUs), or disposal of medical wastes. Thus, the institutional capacity in terms of administrative management and systems for infectious diseases is incomplete, and outbreaks of infectious diseases have occurred from time to time. This system will be unable to guarantee public safety.

From the point of view of health regulation, many problems such as incomplete laws and rules of regulation, an unsound regulatory system, limited regulatory powers, and the lack of self-regulation within the industry, has resulted in no regulation, wrong regulation and over regulation in the approval of health services pricing and quality, and in non-profit field. For instance, a standard for “public non-profit institution” managements systems has not been established despite great advances in the operation independence of medical institutions. Medical institutions now follow a policy of increasing profit and maximizing revenue. The supply and demand for medical services has diversified, but the cost of care falls on individuals. The healthcare system now largely relies on medical payments at the expense of individuals. These factors have led to high costs, low effectiveness, the provision of unqualified services and deteriorating physician-patient relationships in the medical services field.

From a point of view of jurisprudence, regulatory institutions for health are equivalent to public security bureaus under the judicial system. Its responsibilities are to investigate, obtain evidence, and then transfer such information to a court or the Procuratorate (health administrative department) with recommendations for disciplinary action

The current regulatory mechanism for food security is a typical regulatory institution in which various departments regulate horizontally from differing fields. For example, agricultural products involve nearly ten departments including agriculture, quality control, health, industry and commerce which participate in regulating from farm to table. However, it is not easy to divide clearly between the links of production, distribution and consumption. The slowness apparent in the legal development and the lack of a “Law of Food Security” results from the phenomenon known as “more profit more people, no profit no people”, i.e. lack of benefit for regulators means no effort to regulate.

3.2. *The lack of a united “supreme regulatory” system*

As mentioned above, there is no supreme regulatory system in China, but only a vertical administrative system with several departments for different fields. The current problem is the disorder of the vertical coordinating system between the governmental agencies and regulatory fields. Duplicate regulations and regulatory conflicts are common. There is no separation between the functions of government and those of institutions, no separation between functions of administration and operation, and no effective coordination mechanism between relevant departments. Furthermore, there are many problems in the current regulatory system, such as incomplete regulations, unclear administrative procedures, arbitrary administrative interventions, no effective accountability system and unclear regulatory functions. These problems lead to the “blame game” in regulation, overlapping regulatory authorities, or regulatory empty spaces and holes. Sometimes the regulated are faced with contradictory regulatory policies on the same issue. This phenomena not only results in the waste of health resources, low effectiveness of regulation, high regulatory costs, little guarantee regulatory quality, congested and unreasonable health resource allocations, difficulties in effectively managing the warehousing and allocation of new instruments, and lack of balance between the strength and effectiveness of regulations, but leaving the regulated too exhausted to deal with differing inspection and evaluation requirements. The regulated are thus left with neither the time nor the energy to concentrate on providing medical and health services.

The complicated structures of China's regulatory system have caused not only duplicative regulation but also empty spaces within the regulatory framework. Meanwhile, some administrative departments are not authorized institutions, or lack necessary capacity in terms of technology or authority.

Box 4. There are "empty spaces" in the Ministry of Public Health's regulation of all medical institutions of each government department and industry

Firstly, the MoPH has limited knowledge and authority over all government departments and industries. The health institutions of each industry are authorized by their own authorities. The MoPH only have authority over health institutions within its own system, but no authority over those in other systems. For instance, there are a total of 48 colleges and universities at both the central and local levels. Based on a specific survey organized by the Provincial Education Committee, there are 29 colleges and universities that have established hospitals without authorization in WuHan. They represent a total of 673 hospital beds, 1103 health personnel, 1 329 260 outpatients and 13 150 hospital patients. But only one hospital was listed in the health statistics bulletin of HuBei province: the other 28 hospitals were not recorded. There are likely to be more unrecorded health institutions in industrial enterprises and scientific fields.

Secondly, the MoPH has limited power of control over medical institutions of all departments and industries. On the one hand, departments are under no obligation to request approval from health administrative departments before planning to establish their own medical institutions. On the other hand, MoPH does not have complete regulatory authority over personnel, finance or administrative management, which are under the supervision of relevant authorities.

The resulting deficiencies in the statistics for and management of medical institutions have not only challenged efforts to regulate the quality of health services, but also the redundant allocations of facilities. Such misallocations of resources have led to waste of healthcare resources and contributed to rising medical costs.

3.3. *Regulatory fields and overlapping functions in medical services*

States owned medical institutions are still the main provider of medical services in the health sector. The MoPH is an administrative department and a key supervisor. Overlapping regulatory functions create many regulatory problems consisting fall into two key categories: the first is combining the two functions of administrative manager and supervisor into one, and the second is combining the two the functions of "athlete" (operating hospital) and "referee" (hospital regulator) in one.

Under the planned economic system, China's health administration departments at different levels sponsored state-owned medical institutions. These health institutions by and large have remained to date. As a result, health departments at different levels have naturally became both administrative manager and supervisor, thus playing the roles of "athlete" and "referee" at the same time. As a supervisor, they treated the supervisee in different ways and with different measures due to their double roles. They carried out "internal regulation" and administrative disciplinary measures vis-à-vis their own medical institutions, but "external regulation" and disciplinary measures on others. This method was unfair and the "internal" regulatory measures were inadequate. Minister GaoQiang of the MoPH has indicated that the regulation of the health industry would continue to face systematic and mechanical obstacles at a deep level; especially if irregular and illegal practices by medical institutions are not be improved and strictly disciplined.

Health and quarantine stations were the basis of health regulation in China for a long period. But at that time, some health and quarantine stations were only responsible for "five fields" of health supervision, in which the regulation of medical institutions was not included. These "five fields" included heathcare, food, cosmetics, public health and school health. Along with the continuing development of health services and the changes in departmental functions, the public has recently focused increasing attention on the administration of medicine and law-enforcement, subjects on which they had no previous knowledge. Medical administration law-enforcement has had a brief period of enforcement in comparison with past

health law-enforcement activities such as those concerning food. Meanwhile, a spectrum of laws and regulations are involved. They included 15 laws or relevant regulations, such as the Law of Practicing Physicians, the Law of Infectious Diseases Prevention, the Law of Maternity and Child Healthcare, the Law of Blood Donation, the Law of Practicing Health, the Regulations on Medical Institutions, the Regulations on Nurses, and the Regulations on Medical Accidents. People called this internal law-enforcement “regulation between father and son”.

3.4. *A unified and authoritative regulation of public health has not been established*

Health administrative departments have established their internal health regulation institutions across the healthcare system since 2000. But no authoritative program for the establishment of a regulatory system for health has been implemented. Furthermore, some key issues such as the name of such an institution, its duties and its personnel administration have not been articulated. For instance, various health regulatory institutions have come into being including the “Health Regulation Bureau,” the “Health Supervision Office” and the “Health Regulation Law-enforcement Team”. Some are managed as technical personnel, while some as civil servants. Situations, such as crossed functions of government and institutions, unclear superior to subordinate relationships, separation of enforcement fields and enforcement executor, have not changed following attempts at systematic reform of health regulation. Moreover, the creation of another exam and certification institution (CDC) brought more difficulties and conflicts to the relationships between the three parties. In 2006, MoPH established the MoPH’s Law-enforcement Regulation Bureau on the basis of the former law-enforcement regulation department. This action improved the “government and institution in one” health law-enforcement system. MoPH also established a United Working Team on the basis of health administrative departments, which not only met the situation’s needs, but was also a logical choice of history.

3.5. *The related interests between the regulated and those of regulators for quality in fields such as medicine and food*

The relationship between the subjects of administrative regulation and those of regulators for quality and technology assessment and regulation in fields of medicine and food is often called a “father and son” relationship. Legal institutions supporting quality and technology assessment and regulation at different levels are always subordinate to health administration or regulation departments. They are independent technical services institutions or agencies. These kinds of relationships remained from the planned economic system, under which the interests of inspectors in technical dimension are related to inspected in administrative dimension. There were many continuing health problems due to this type of “father and son shop”. In reality, once the pharmaceutical or food manufactures caused heavy accidents, they were found to have completed the “five certifications” in accordance with the requirements of their producers and dealers. Normally investigations of type were obliged to dropped as part of an “information shielding” action.