

The dilemma of Chinese pharmaceutical market

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Abstract

Dramatic increases in health expenditures and pharmaceutical expenditures have led to a substantial number of regulatory interventions in the health and pharmaceutical markets over the last years. The aim of this article is to describe and discuss current policies for regulating pharmaceuticals in China. We begin with the brief introduction of the Chinese health care system and performance of current pharmaceutical market. Then, we explore the policies pursued by China and the countermeasures from other stakeholders, and explain the failure of the existing regulation pattern. Finally, we draw a number of policy implications to balance between improving access to pharmaceuticals and restricting market forces to contain costs and ensure affordability based on our analysis.

1. Introduction

The rapid increase of medical and pharmaceutical expenditure has become a critical barrier to health care for less advantaged people and its control is a key objective for health policy makers. [1] China is no exception. China's economy has been booming since 1980s. However, economic development does not necessarily lead to investments in health. After decades of efforts to reduce its involvement, the Chinese government is currently in the process of reforming the sector through increase in public expenditures and expansion of health insurance. Pharmaceutical sector plays an important role in the medical and health system. Pharmaceutical policy, an important component of health policy, ensuring access to safe and effective medicines, presents a unique set of choices for policy-makers. The pharmaceutical market is heavily regulated in many countries due to the unique nature of demand and supply for drugs that brought about the identity of market [2]. The development of the pharmaceutical industry has ensured that the vast majority of Chinese people can access medicines easily now. However the ample and convenient supply does not mean affordable medicines. The high price of drugs has long been blamed for making medicine services unaffordable for less advantaged people and has triggered mounting complaints from the public. The negative impact on people's health caused by problems in the pharmaceutical market cannot be underestimated.

This paper aims to analyze the history and current policies environment for the pharmaceutical market in China. More specifically, we begin with the brief introduction of the Chinese health care system and performance of current pharmaceutical market. Then, we explore the policies pursued by China and the countermeasures from other stakeholders, and explain the failure of the existing regulation pattern. We conclude with some reflections on the implications of currently implemented reform policies. The experience of pharmaceutical regulation implemented in China provides some lessons for transitional economies around the world.

2. Background of health care system

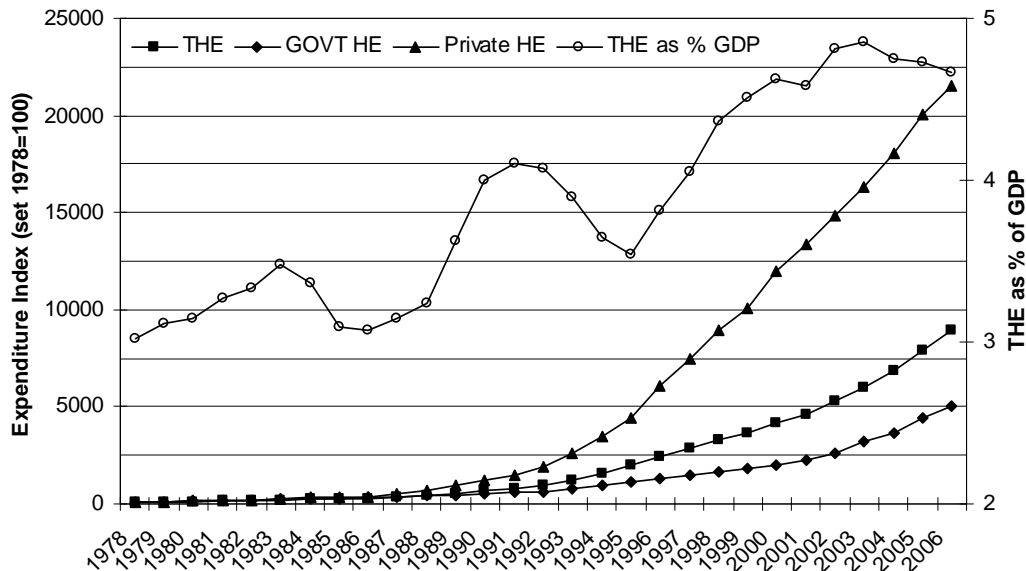
To provide health services to its 1.3 billion populations, China has 298,408 health establishments including 19,852 public hospitals. [3] The World Health Organization applied one set of metrics to a cross-section of countries in the World Health Report 2000. In a ranking for level of population health, China ranked 61 out of 191 countries. But in a ranking of health system performance, China ranked 144 out of 191 countries; it is one of the least equitable in the world.[4] China's system was deemed to be weak in the distribution of health and responsiveness, as well as particularly unfair in distributing financial burdens of health coverage and illness expense. Its economic miracle is not mirrored in its health care sector.

When China liberalized its economy in 1978, it transformed its centrally planned health care system to a market-driven system. Total Health Expenditure (THE) increased 17.3% annually between 1978 and 2006, which was notably faster than the general gross domestic product (GDP) levels. Health expenditure as a proportion of GDP ranged between 3% and 5% from 1978 to 2006.

Government health expenditure in China has increased during the last three decades. However, during the same period there was a 15.7% annually rise, which had been somewhat less spectacular than the rise in THE, and

considerably less spectacular than the dramatic rise in real personal health expenditure. Between 1978 and 2006, the latter increased at 21.2% annually, and increased as a share of total health spending from around 20% to nearly 50%.

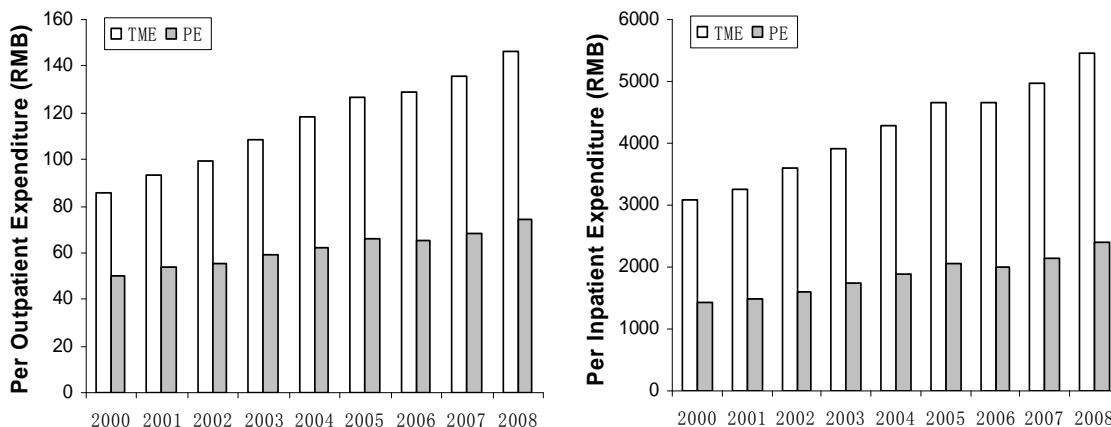
Over the past few years, there have been deep public concerns on fees that health service providers charged to patients (out-of-pocket payments). As a proportion of total health expenditure, out-of-pocket payments rose from 20% in 1978 to 60% in 2001, falling to 49% in 2006. Compared to many other countries with similar levels of THE, China's private share is considerably higher than the worldwide average level, which is 43% [5].



Source: China Health Statistics Year Book 2008, available at <http://www.moh.gov.cn/publicfiles/business/htmlfiles/zwgkzt/ptjnj/year2008/4.htm>, Table 4-1, accessed in January 2009.

Fig. 1. Trends of health expenditure index and THE as % GDP in China 1978-2006

During the 1990s, in rural health care facilities, about 70 percent of the outpatient care revenue and 55 percent of the inpatient care revenue were from drugs. In urban health care facilities, about 50 percent of the revenue was from drugs [6]. Fig. 2 shows that since 2000, pharmaceutical expenditure has increased per annum. Another trend can also be seen in Fig. 2: the percentage of per patient medical expenditure particularly for pharmaceuticals has always been maintained at a relatively high level. On average, 54 percent of outpatient expenditures and 44 percent of inpatient expenditures were spent on pharmaceuticals. Pharmaceuticals represent a significant cost driver in the health care systems and account for a large share of health expenditures in China.



Note: TME is total medical expenditure. PE is pharmaceutical expenditure. RMB is Chinese currency.

Source: China Health Statistics Year Book 2008, available at <http://www.moh.gov.cn/publicfiles/business/htmlfiles/zwgkzt/ptjnj/year2008/4.htm>, Table 4-13, accessed in January 2009.

Fig. 2. Per patient expenditure in China since 2000

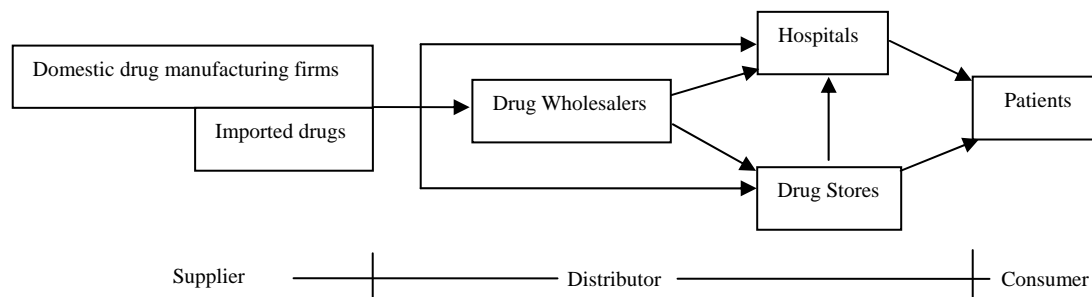
An emerging global concern for all patients and governments is the continuous rise in the cost of health care services around the world [7,8]. There are a number of potential explanations for this rise in health expenditure: general inflation, changing disease pattern, aging population, technological developments, increasing need for care, labour prices and so on [8,9]. The magnitude and share of these factors in health expenditures vary across countries [10]. For pharmaceutical expenditure in China, the evolution of the market structure has to be taken into account.

3. Performance of pharmaceutical market

A supply chain is the sequence of organizations—their facilities, functions, and activities—that are involved in producing and delivering a product or service. A typical pharmaceutical supply chain consists of the following members: primary manufacturing, secondary manufacturing, market warehouse/distribution centres, wholesalers, retails/hospitals and patients [11].

Previously, under a centrally planned economy, all the pharmaceutical products were distributed by a state-owned monopoly company (first-tier wholesaler) to several regional wholesalers (second-tier wholesalers) who would then distribute the products to local wholesalers (third-tier wholesalers) [12]. Hospitals at different levels usually purchased drugs only from different wholesalers. The advantages of the old supply chain included greater regulation on drug quality and price. However, such a regulated chain lacked competitive mechanisms, and can result in bureaucratic behaviours, inefficiencies and an imbalanced supply [13].

Due to the changing economic system, the Chinese government has reformed its pharmaceutical distribution network. It has been changed from a centrally controlled supply system to a market-oriented system. The competitive mechanism has been introduced into the pharmaceutical market, which improves the availability of pharmaceuticals. Fig. 3 shows the new pharmaceutical supply chain in China.



Source: Authors' analysis

Fig. 3. Pharmaceutical supply chain in China

Under this supply chain, domestic pharmaceutical production grew dramatically while numerous imported drugs began to enter in the Chinese market. This supply chain is different from the drug supply mechanism under central planned economy. Whereas earlier pharmaceutical manufacturing firms could only sell drugs to wholesalers, now they are able to sell their products not only to the drug wholesale stations and drug stores, but also directly to hospitals. Meanwhile, bigger distributors can sell drugs to smaller ones. The wholesale prices could be different because of the different purchasing volume. There is a considerable imbalance of retail market sales within the supply chain: the hospital pharmacies account for roughly four-fifths of all retail pharmaceutical sales [14]. The remainder of retail drugs are dispensed by drug stores, including retail enterprises and rural drug supply outlets. Patients can buy drugs from hospitals and drug stores. For the drugs, the choice of which one to prescribe to the patient is usually made by the delegated knowledgeable expert—the medical doctor.

The pharmaceutical industry expend rapidly in recent years. Here, follows a status quo of the main stakeholders of the supply chain.

3.1. Registration

A new drug must be registered for marketing in China. Applications for registration of new drugs are made to the pharmaceutical authority: the State Food and Drug Administration (SFDA), which bases its decision on pharmaceutical chemistry, toxicology, clinical pharmacology, clinical efficacy and safety.

In practice, SFDA had adopted a looser restriction for drug registration, which gave new drug licenses to minor reformulations or changing the dosage or the packaging of existing products. Before 2007, SFDA had approved 177,000 drug applications, even though Chinese manufacturers typically invested no more than one or two percent of their revenue in R&D, which was far lower than the 14-18 percent of leading global pharmaceutical companies. From 1986 to 2006, Chinese firms have independently developed only forty categories of chemical medicines [14]. In order to overhaul the administration of drugs, the SFDA tightened the drug registration review process by implementing an amended “Measures on the Administration of Drug Registration” in October 2007. This amendment promised to improve registration procedures by upgrading drug appraisal and approval standards to enhance the focus on drug safety while encouraging innovation [15].

3.2. Production

Drug manufacturing firms can make their own production plans and adjust them according to changes in the drug market. China currently has more than 5,000 drug manufacturing firms. Most of them are small-scale pharmaceutical industry, with a scattered geographical layout, duplicated production processes, and outdated manufacturing technology and management structure. Their productions are mainly generic drugs. These firms operate in an environment of lower market concentration and weak international trading competitiveness, coupled with a lack of patented pharmaceuticals developed domestically.

However, accompanied with the fast growing economy and the largest population, the pharmaceutical market has expanded tremendously in China, with an annual average growth of 16.1 percent in recent years [16]. China can produce 1,500 types of drug substances, many of which lead the world in terms of output, including penicillin and vitamin C. China's antibiotic, vitamin, hormone, antipyretic and analgesic, amino acid, and alkaloid products take up considerable shares of the international pharmaceutical market. The total output value rose from 137.1 billion RMB in 1998 to 667.9 billion RMB in 2007 [17]. The sales revenue of the top ten pharmaceutical enterprises in China account for only 10 percent of total pharmaceutical sales, compared to the top ten international pharmaceutical companies, which account for about 42 percent of global pharmaceutical sales revenue [14].

3.3. Distribution

Drug distributors create a link between the pharmaceutical factories and patients. In current distribution network wholesales, retailers, hospitals and even manufacturers take on a role as distributor. This makes drug distribution more complex and competitive.

In China, most patient visits take place in the hospital and patients typically fill prescriptions in the hospital's pharmacy. Patients prefer hospital pharmacies over retail drug stores for several reasons: convenience, physician recommendation, non-standardized prescription, and greater assurance of pharmaceutical quality. Pharmaceutical sales are a hospital's main revenue source, typically accounting for over one half of its total revenue. Hospitals account for roughly four-fifths of all retail pharmaceutical sales [14], even though retail pharmacies have been growing in recent years. By the end of 2007 China had 13,000 wholesale pharmaceutical enterprises, 341,000 retail pharmaceutical enterprises and chain store enterprises, and 554,000 rural drug supply outlets [17]. Most pharmaceutical manufacturers and large wholesalers have been actively promoting their products using a variety of strategies including hiring numerous salespersons, sending medical representatives to promote prescription in hospitals, advertising in public media for Over-The-Counter products, etc. These sales agents often contact hospitals and doctors directly to sell their products. They use sales commissions, kickbacks, or gifts to hospital managers and/or doctors who purchase or prescribe their products. The commercial promotion activities and profits for multiple layers of distribution is a substantial component of the total costs of pharmaceuticals.

3.4. Health insurance

The market for pharmaceuticals is substantially influenced by pharmaceutical demand and in particular, by the effects of health insurance. There are three main non-competing health insurance schemes in the market, each with its own administration bureaus, manage mechanisms, scheme design, targeting population, premium collection channel, and benefit packages. Urban and rural insurance are under the charge of the Ministry of Labour and Social Security (MOLSS) and the Ministry of Health (MOH) respectively.

According to current policy, every citizen of China is supposed to be insured. Urban employees are covered by the employment-based basic medical insurance scheme, which was established by the Chinese State Council in 1998. For the rest of the urban population, an urban-resident scheme was started in 2007, targeted for those not covered by other schemes, including children, students, unemployed and migrants. For the rural population, a

new rural cooperative medical system began in 2003, replacing older arrangements. Rapid expansion has resulted in coverage of 720 million agricultural households (85.9 percent of the total rural population) by the end of 2007 [18]. Commercial health insurance only accounted for 7.6% of the total market share, and it mainly served upper class individuals [19].

As part of the insurance schemes, the health insurance authorities have adopted drug formularies, which excluded some expensive and imported drugs that limited the scope of drugs that doctors can prescribe, to contain the escalation of drug expenditure and to improve the rational use of drugs through economically indirect restriction of prescription drugs. Because of the monopoly purchasing power of health insurance, listing on formulary provides a significant marketing boost. Manufactures are willing to offer their products to be listed on formulary.

4. Major problems of the current pharmaceutical market

We follow the supply chain division used above to frame a discussion of the major problems existing in the Chinese pharmaceutical sector. In the transition from a planned to a market economy, a pharmaceutical regulatory framework has taken shape. The incremental and piecemeal nature of reform has created a pharmaceutical market with a number of deficiencies.

4.1. Ineffective supervision

The SFDA, as the competent authority of drug regulation in mainland China, has many duties. The main mandate of this institution is to undertake executive and technical monitoring and supervision of the research, production, selling and usage of food, drugs, cosmetics and medicine related goods and equipment.

In pharmaceutical sector, the SFDA mainly focuses its work on overseeing units and individuals who deal with manufacturing, buying, selling and prescribing drugs. In other words, drug manufacturers, drug distributors and health facilities are all overseen by the SFDA. Manufacturers who want to register a new drug must first get the approval of the SFDA. Good Manufacturing Practice (GMP) certification is adopted to ensure the quality and safety of pharmaceutical products. Distributors such as wholesalers and retailers have to apply for Good Supply Practice (GSP) certification from SFDA.

In last three years, several high-profile incidents including the contamination of food, drug safety and also the execution of the former head of the SFDA for corruption, exposed serious questions about the SFDA's effectiveness as a regulatory body. SFDA did not serve well on the role of monitoring the efficacy and safety of pharmaceuticals. Including the new registration measures, a series of revised regulations were issued to introduce a higher level of transparency into approval process, limit the discretion of individual officials and raise the standards for the registration of pharmaceuticals.

4.2. Higher price equals greater profit

Between 1980 and 2000, the National Planning Commission (NPC) controlled the entire cascade of drug prices, from manufacturers' prices, to wholesale and retail prices. Manufacturers' prices were based on production cost plus a 5 percent mark-up, to which a 15 percent mark-up was added for the wholesale price, and an addition of further 15 percent mark-up constituted the retail price. However, faced with the rapid expansion of the pharmaceutical sector and asymmetry of access to cost information between price regulators and manufacturers, the government was unable to generate the necessary cost estimates for setting appropriate exit prices. Furthermore, since mark-ups for both wholesalers and retailers, including hospitals, were a fixed percentage, expensive drugs were preferred by both. In order to attract wholesalers and hospitals to their products, manufacturers requested higher prices. "New drug" registrations were pursued to obtain or extend eligibility for higher prices and greater revenue; this adds to the cost of medical treatment for consumers. Under this system, drug prices were thought to be unreasonably high [20].

In view of rapidly increasing pharmaceutical expenditure, NPC, the former body of National Development and Reform Commission (NDRC), especially set drug retail prices from 2000 [21]. NDRC has conducted several rounds of nationwide surveys evaluating drug prices in recent years. The pharmaceutical manufacturers are required to report their wholesale and retail drug prices and production costs to provincial-level drug regulators and price-setters. According the results of the survey, NDRC has cut the prices of the related drugs. However, the reliance on user charges for financing has driven the hospitals' focus on profit-seeking. Cost-effective generics have been substituted by expensive equivalents, though unnecessarily [22]. The inexpensive drugs apparently are no longer sufficiently profitable for manufactures to produce and other distributors to sell. Consumers could not benefit by these price reductions.

4.3. Distortion of the price schedule

China's hospital sector reforms have been characterized by the decentralization of administrative and managerial responsibilities, and an increasing emphasis on cost recovery through user fees. The government does not provide full fund to health facilities. Under the current rule, the government subsidized about 60 percent of their recurrent costs, calculated to pay for the salaries of health personnel. The remaining revenue came from fee-for-service activities under a government controlled price schedule, which set prices for basic health care below cost to keep health care affordable and prices for new and high-tech diagnostic services above cost and a 15 percent profit margin on drugs to make health facilities survive financially. This price-setting approach provides incentives for under-providing or over-providing certain services, depending on profitability. The system thus creates a leveraging effect whereby providers raced to introduce high-tech services and expensive drugs that give them higher profit margins. The profit earned from drug selling and excessive use of high-tech equipment functioned as a cross-subsidy to the under-priced services and enabled the hospitals to survive and thrive. In fact, the cross-subsidization shifts the cost from the government to the patients. According to a conservative estimate, 20–30% of China overall health care expenditure were spent on services and drugs that are unreasonable or unnecessary [23]. These distorted prices give perverse incentives, helping to drive cost escalation and compromise patient access to care.

In addition, many pharmaceutical companies send medical representatives to lobby doctors and drug purchasing managers to use their drugs, offering financial incentives. The return of the drug prescribers and managers are usually based on the quantities of the drug sold. This would stimulate hospital staff to use unnecessary and expensive drugs without strict regulations on drug prescriptions. The corruption in drug purchasing and prescribing within health facilities has contributed the rapid rise in pharmaceutical expenditure.

4.4. Lack of authoritative drug formulary

As mentioned above, the health insurance authorities have adopted drug formularies for different health insurance schemes. The main difference of the drug formularies is the reimbursement rate. MOLSS and MOH choose drugs to be listed. NDRC sets retail prices for drug listed. Unfortunately, those institutions do not monitor how drugs are prescribed and used at health facilities.

In practice, patients with insurance have more access to health care and a higher ability to pay for health care than uninsured people. They are partially insulated from the cost, despite co-payment being ubiquitously adopted to moderate the demand. Therefore they have a weakened incentive to trade-off the cost. According to patients' demands and also depending on whether they are insured, physicians prescribe and change prescriptions. A research investigation has found that insured patients have more expensive drugs, higher drug expenditure and medical expenditure per visit than uninsured patients [6]. Another comparison of village health stations with and without health insurance suggests a positive relationship between health insurance and opportunistic behaviour of health providers. The effect of the drug lists combined with coverage of health insurance was to exaggerate the problem of over-prescription, which results in the growth of pharmaceutical expenditure [24].

Generally, the decision to list an item on the formulary is not transparent nor does it consider the cost-effectiveness consideration. In addition, the pharmaceutical market is characterized by introduction of new products with an initial high price. Experience to date shows that the current health insurance system with drug formulary has not been an effective purchaser: it has not selectively contracted with providers on the basis of quality and performance, nor has it been able to contain providers' profit-seeking behaviour or keep cost inflation in check [25].

5. Discussion and conclusions

China is in the midst of health system reform. Regulation of the pharmaceutical sector needs to take into consideration both private and social objectives; public intervention in health care pursues multiple goals which relate to both health and industry policies. The Chinese government has recognized the problems that have been persistent in the process of health care reform and has begun to address the relevant reform issues more carefully. Almost daily announcements of new or revised regulations, policies and procedures aimed at all aspects of the current system. These vary from the practices of regulator to defects in registration procedures, illegal advertising, drug pricing, retail practices and punishments for defective products.

According to the latest issued health care reform plan, approved in January 2009, the government will spend 850 billion RMB (\$124.26 billion) in the next three years to provide accessible and affordable healthcare to the country's 1.3 billion people and set up a universal primary medical service. The plan has set up a goal of

building a "basic medicine system" combined with new drug pricing mechanisms to ease public complaints of rising drug costs. All drugs on the list will get a high reimbursement rate by the medical insurance systems [26]. The basic medicine system includes a catalogue of essential drugs that would be produced and distributed under government control and supervision. Apart from this, all medicine included would be deemed reimbursable by medical insurance, and a special administration for the system would be established. The goal is to ensure accessibility to a range of basic medicines and to prevent manufacturers and businesspeople from circumventing existing price controls. With the proposed reforms in this sector, the future structure of pharmaceutical sector is unclear [27].

While the details of the plan have not yet been completely announced, if the current problems discussed in this paper remain, the basic medicine system cannot be successfully established.

In the pharmaceutical section, demand and supply are less independent, with the doctor for example often assisting patients in determining their demand. When it comes to looking at how best to allocate resources in the pharmaceutical section, market prices often have a more limited role and some other mechanism is needed, such as government intervention. Although the Chinese government has adopted a series of price control regulation, effective market was not identified. Past failures offer insights into what does not work. Having taken into account all the factors discussed in this paper, higher-than-cost drugs preferred by all suppliers, including manufactures, wholesalers, hospital pharmacies and retailers can be diagnosed as the root cause of the market and government failures. Therefore, how to set up drug prices is fundamental and essential for building the new medicine system.

Pricing is a key component of resource allocation and purchasing in any sector of the economy and the pharmaceutical section is no exception. From the public view point, there are three essential objectives in pricing drugs: to ensure providers, including manufactures and distributors, are reimbursed fairly for their work; to guarantee that the prices accurately reflect the costs of correctly provided drugs and promote pharmaceutical industry sustainability, and to make sure that the pricing structure supports the practice of appropriate medicine that leads to good health outcomes.

Pharmacoeconomics focuses on the costs and benefits of drug therapy and pharmacoeconomic evaluations provide a basis for resource allocation and utilization. For reimbursable drugs, economic evaluation can minimize arbitrary decisions by the government about the listing for reimbursement of new and expensive drugs. The use of pharmacoeconomic tools has grown dramatically in the past decade as provision of health care throughout the industrialized world [28]. In many countries (Australia, Canada, New Zealand, etc.), pharmacoeconomic evaluations is a mandatory part of the dossier for new drug application and pricing, and also for the drug to be considered for reimbursement by health care or insurance companies [29].

While significant lessons can be drawn from overseas experience, reforms to the Chinese pharmaceutical section must reflect the historical, political and socioeconomic characteristics peculiar to China. Pharmaceutical policies must be closely integrated into wider health policies. New drug pricing mechanisms should be implemented in coordination with other health system reforms, such as expansion of health insurance coverage and governmental medical investments, if affordability and accessibility goals of pharmaceuticals are to be promoted in health system reform. Essential elements of well-intentioned policy should include the following strategies.

First, to bring healthcare costs under control, payment reform is needed, and payment models that do not encourage volume will be required. As long as fee-for-service payment is the dominant method, the incentive for increasing service volume, and thus revenue, will also be present. A variety of new payment structures are in discussion and testing. The most prevalent, although still unusual, is pay for performance, where physicians are paid bonuses for reaching quality targets. Other examples of payment reform include case rates, where physicians – and hospitals too, usually – are reimbursed a flat amount for care of patients with a given condition.

Second, public hospitals and other universal medical service providers should be provided full financing to remove the incentives to overprescribe drugs. If not, providers will charge fees that cover the gap between the costs and government subsidies. In addition, the price of medical professionals' labour, which has traditionally been under-valued, and the relatively high price of pharmaceutical should be adjusted. There is a growing awareness that few services had been evaluated on the basis of their costs and benefits. Economic evaluation is one of a number of tools that have been developed by various disciplines for the purpose of assessing the relative merits of health services.

Third, the government departments, such as MOH, SFDA, Ministry of Finance, MOLSS and NDRC should play an active role and work together to establish effective and adequate mechanisms or guidelines used for drug pricing, distribution, purchasing and utilization. The coordination among different ministries and agencies

should be strengthened. Independent agencies, which comprise representatives from different stakeholders such as manufacture, distributor, retailer, health facility, insurance and consumer, should be established to make prudent recommendation to related authorities about the registration, pricing and reimbursement. This strategy would not only relieve the regulatory burden for the government and reduce the direct governmental involvement in pharmaceutical market operation, but also make the government an effective policy maker and supervisor. All stakeholders should accept a shared responsibility for the maintenance and sustainability of the new medicine system.

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