CHINA HEALTH POLICY NOTES

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Financing, Pricing, and Utilization of Pharmaceuticals in China: The Road to Reform

THE WORLD BANK

Health, Population, and Nutrition

East Asia and Pacific Region

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China Health Policy Notes

China Health Policy Notes is a series of occasional papers on lessons and experiences from China's ongoing healthcare reform. The series is published by the World Bank in collaboration with the Government of China. The papers track and analyze the reform process, and evaluate early results. Each paper focuses on a key challenge that is central to success. The papers are written from a pragmatic perspective—namely, how the reforms can be refined and improved as the process unfolds over the coming 5 to 10 years. Experience is reported in the context of international best practice.

Research was carried out under the World Bank's Analytic and Advisory Assistance program, a particularly fruitful collaboration between the Bank and the Government that has been underway since 2003. Initial technical papers were prepared by teams of national and international experts. Preliminary versions were critically discussed with Chinese policymakers and technical counterparts, especially within the ministries that initially requested this assistance in mid-2008. All papers were then subject to rigorous peer review.

The purpose of *China Health Policy Notes* is to share these findings with a broader audience, especially to Chinese policymakers, health specialists, and scholars. Hardcopy versions of these papers can be obtained in English and Chinese by writing to the World Bank. They can be downloaded without charge at www.worldbank.org. The papers may be freely reproduced providing that source and copyright protection are clearly acknowledged. Comments and ideas are welcome. They should be addressed to the respective authors, or to the series editor (jlangenbrunner@worldbank.org).

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Opinions expressed in these papers are entirely those of the authors. They do not represent official views of the Executive Directors of the World Bank, the UK Department for International Affairs, or the Government of China.

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Acronyms, abbreviations, currency

AAA	World Bank Analytic and Advisory Services
BD	Brand drug
BMI	Basic Medical Insurance
CAA	Civil Affairs Administration (operates the Medical Assistance program)
CCCP	Central Committee of the Communist Party of China
CHCs	Community health centers
CHEI	China Health Economics Institute
DDD	Defined daily doses
DfID	Department for International Development
DRC	State Council Development Research Center
DRGs	Diagnosis-related groups (medical insurance reimbursement system)
EDL	Essential Drug (Medicine) List
EMP	Essential Medicines policy
FDA	United States (US) Food and Drug Administration
FFS	Fees for services
GMP	Internally accepted standards of good manufacturing practices
GWIS	Government Welfare Insurance System (medical insurance set up in 1992)
HAI	WHO Health Action Initiative, on essential medicines
HTA	Health Technology Assessment,
INN	International non-proprietary name
JV	Joint venture
LHIS	Labor Health Insurance System (Scheme) (workers and dependents in formal sector, merged with UBEMI in 1990s)
LMI	Labor Medical Insurance (state- and collective enterprises, 1950–98)
LPGs	Lowest-priced generic drug
MA	Medical Assistance (a social welfare program for poor families)
MAT	Moving Annual Time
MeTA	Medicines Transparency Alliance (MeTA)
MHIs	Mandatory health insurance systems
MNCs	Multinational Corporations
MOA	Ministry of Agriculture
MOF	Ministry of Finance
MOH	Ministry of Health
MOLSS	Ministry of Labor and Social Security
MOHRSS	Ministry of Human Resources and Social Security (previously MOLSS)

MPR	Median Price Ratio
MRIs	Magnetic resonance imagery (a high-tech radiological imaging procedure)
MSAs	Medical savings accounts
NCMS	New Cooperative Medical System
NDP	National Drug Policy
NDRC	National Development Reform Commission
NEDL	National essential drug list (price caps on essential medicines, NDRC, 2009)
NEDS	National Essential Drug System [established by MOH, 2009; sometimes written in English as National Essential Medicines System (NEMS), or National System of Essential Medicines (NSEM)]
NHS	National Health Service (United Kingdom)
NICE	National Institute for Clinical Excellence (United Kingdom)
NRCMI	New Rural Cooperative Medical Insurance
NRCMS	New Rural Cooperative Medical System
NRDC	National Reform and Development Commission
OECD	Organization for Economic Cooperation and Development
PBMs	Pharmacy benefits management companies
PHI	Private health insurance
POU	Point of use
NRCMS	Rural Cooperative Medical System
RHC	Rural health center
SDPC	State Development and Planning Commission
SDRC	State Development and Reform Commission
SETC	State Economic Trade Committee
SFDA	State Food and Drug Administration
SHI	Social health insurance
SPC	State Planning Commission (following reorganization of SDRC)
THE	Total health expenditure
TPE	Total pharmaceutical expenditure
UEBMI	Urban Employee Basic Medical Insurance
URBMI	Urban Resident Basic Medical Insurance
USFDA	Food and Drug Administration, US regulatory body
VAT	Value-added tax
WHO	World Health Organization

Exchange rate

6.82 RMB = 1 USD

(May 1, 2010)

Executive Summary

This paper examines the financing, pricing, and utilization of pharmaceuticals in China—the pharmaceutical system as it has evolved, and some changes that would improve it in the context of the national health reform process. The present paper builds upon earlier critical reviews and other papers published in the series *China Health Policy Notes*. The present version has been updated to reflect key steps, especially between 2005 and 2010, in the evolution of a formal Essential Medicines System as a product of the major national health reform formally launched in April 2009. A brief introduction is followed by substantive sections on the Chinese pharmaceutical market today, the national system of essential medicines, and the ongoing struggle to contain constantly rising pharmaceutical costs. Several ideas for strengthening the reform process are discussed in the final section.

The Chinese pharmaceutical market

Innovative drugs and Western medical technologies came into increasing demand in China from the mid-1980s onward. Hospitals began to use them—and then to overuse them—both to treat illness and to reduce operating deficits resulting from underpriced medical services and the loss of government subsidies in the 1980s. The higher prices and markups on imported and branded drugs helped hospitals to balance revenue shortfalls, a practice that persisted and eventually led to financial dependency. In 2007, hospitals showed a negative balance on medical services of RMB 108 billion and a positive balance from drug sales of RMB 17 billion. The surplus from drug sales is equivalent to 39 percent of their net subsidy from the government. Without pharmaceutical revenues, in other words, hospitals would operate at an overall loss.

China has emerged as an important player in the global pharmaceutical market. By 2004, China had become the ninth largest pharmaceutical market in world. Pharmaceutical sales grew at an annual rate of 28 percent during the mid-2000s, much faster than in the rest of the world (9 percent). The value of pharmaceutical imports was 350 times higher in 2007 than in 1978, and the value of exports was 86 times higher during the same period.

China's domestic pharmaceutical industry has grown substantially. In 2007, the gross value of China's pharmaceutical industry reached RMB 600 billion. The industry's share of GDP rose from 2.17 percent in 1978 to 2.71 percent in 2007. IMS reports (2006) indicate that domestic manufactures dominate the market, accounting for 70.3 percent in sales value.

China has become a major overseas market for many multinational pharmaceutical corporations. Sales growth in China of these companies was much higher than the global rate. For example, the growth rate of AstraZeneca was 25 percent for the China market and

7 percent for the global market. The IMS reports (2006) showed that 29.7 percent of the sale values in China were joint venture and import products. The share could be as high as 40-46 percent in large cities such as Beijing and Shanghai.

Pharmaceutical expenditures reached RMB 448.6 billion in 2006. It accounted for more than 40 percent of total health expenditure, which is about 10 percentage point lower than it was in the 1990s, but still substantially higher than many countries in the world. The high pharmaceutical expenditure is associated with both high retail prices of drugs and high utilization, some of which is irrational use of drugs. Furthermore, both price and utilization factors are deeply associated with policies including overall health sector regulation, health care financing policies, and pricing policies.

Essential medicines

The notion of essential medicine and an essential drug list was first advanced in the mid-1980s by the World Health Organization (WHO). The idea was to identify the highest-impact generic drugs and make them affordable and universally accessible on a global scale.

In 1992, China started to formulate an essential drug list combined with the launch of urban medical insurance reforms. The essential drug list served as the basis for the urban medical insurance drug reimbursement list. Although the list remained in place and has been revised every two years since 1996, essential medicines have had a limited impact in China for several reasons. First, prices imposed by government authorities were often based more on social ideals than on the economic realities of a competitive pharmaceutical market. As a result, unrealistically low prices left manufacturers with little incentive to produce essential medicines. Second, most essential medicines are generic medicines intended for use at the lowest possible cost; so even when local pharmaceutical manufacturers have produced them, hospital providers have not necessarily been eager to prescribe them, because they rely on drug sales (primarily brand drugs) to supplement their physicians' incomes. Third, until fairly recently clinical guidelines were not available on the utilization and medical management of essential drugs. Physicians are "educated" about new drugs primarily by manufacturers' representatives. The widespread perception that generic drugs are not safe, effective, or reliable compared to brand drugs has been reinforced by several extremely well-publicized failures in quality control.

Although there is only limited evidence available, the availability of drugs on the list appeared to be very low and the prices appeared to be high. One WHO/HAI evaluative survey in Shanghai (mid-2000s) found procurement prices of essential medicines to be 7.6 to 9.9 times higher than the international reference price for brand drugs, and about 1.4 times higher than the international reference price for the lowest-priced generics. The availability of essential medicines was estimated at between 13.3 percent and 33.3 percent in public hospitals and between 10 percent and 15 percent in pharmacies, with the generic drugs being more accessible than the innovator brand drug. Similar results for prices were found in

Shandong and availability was even lower. In addition, the Shanghai study indicated that the cost of some essential medicines may potentially pose financial burden for patients, especially those with chronic conditions.

The government has started another wave of reform to reinvigorate the National Essential Medicine System and this has high priority on the political agenda. The new wave of reform focuses on every aspect of the system, including production, pricing, distribution, procurement, payment, and use. There are still debates about the roles of government and market, whether it is appropriate to require exclusive use of essential medicines in primary facilities, and how to evaluate the use of essential medicines in other facilities.

Managing the costs of pharmaceuticals

In both absolute and relative terms, the cost of pharmaceuticals is extremely high in China, with pharmaceutical expenditure accounting for 41 percent of overall healthcare cost. For most of OECD countries, by contrast, this share is in the range of 15 to 25 percent.

Price controls

Price control strategies have evolved through several stages. During the planned economy prior to 1978, the government set all prices. In the early stages of China's economic transition in the early 1980s, drug prices were left largely to the market. However, when drug prices rose at nearly 10 percent a year, both the central government and local administrations stepped back in to control prices. A series of measures between 1996 and 2007 included a pharmaceutical law, a decree on administering drug pricing, and 23 separate price reductions. The number of items subject to control rose from about 1,500 to 2,400.

The effect of those past government-initiated price reductions appeared to be limited. Results were not satisfactory for a number of reasons. First, only a small percentage of drugs were actually affected (one survey in 2007 showed that 80 percent of drugs used in hospitals were *not* subject to price controls). Second, hospitals tended to limit the availability of priced-controlled drugs—for example, by not stocking or reordering them. Third, physicians were able to use the power of prescription to substitute drugs that were not price-controlled for drugs that were. Fourth, hospitals continued to rely on revenues from pharmaceutical sales to balance their perennial operating deficits. Their narrow financial self-interest was at odds with the broader goals of social policy, and they dragged their feet in implementing *any* price control measures that might place their financial viability in jeopardy.

New approaches to cost reduction, 2006-10

Comparing China with several other countries (using the cost-plus pricing methodology) suggests substantial "room" for significant additional pharmaceutical price reductions, particularly in the distribution segment of the pharmaceutical supply chain. For example, the cost-plus markup in China is in the 60 to 70 percent range (including VAT), compared with ranges of about 10 to 20 percent for the United States, and about 20 to 25 percent for Japan.

While pharmaceutical cost containment has mostly focused on government-directed price control, other approaches are increasingly being explored. Many new policy levers are being considered and tested—for example, reforming the payment system from fee-for-service to global budget control, implementing a capitation system in ambulatory services, and using disease-related groups (DRG) payment in inpatient departments.

In 2006, the State Development and Reform Commission (SDRC) announced measures to consolidate markets for pharmaceuticals and medical services. These included increasingly sophisticated (and transparent) price-setting methodologies. The practice of creating "new drugs" to avoid price regulation was banned, and specific incentives aimed to expand the production and use of lower-priced generic drugs. At the same time, more latitude was allowed for market-based competition to foster price reduction. Medical devices and high-tech services were subject to similar logic and more advanced pricing methodologies. Clinical guidelines were established to help physicians make better use of generics; and measures were taken to delink higher drug sales from higher income for physicians and hospitals.

Irrational drug use

The term *irrational drug use* refers to overuse, medically inappropriate use, or financially inefficient use of drugs. Studies reveal that irrational drug use is extremely high in China—for example, excessive demand for intravenous injections based on the belief that they "work better" to deliver drugs; prescription of two or three drugs when one or two will work as well; widespread overuse of antibiotics and steroids; preferences for heavily advertised drugs and familiar brand names; and the near-universal conviction that higher-price brand drugs cure more effectively than the same active ingredient sold under a generic name.

In 2009, the Ministry of Health developed a series of 112 "clinical pathways" (guidelines on appropriate use of particular drugs and procedures). These covered 112 diseases in 22 medical specialties. This effort was done in the context of continuing medical education, and begins to address serious deficiencies in up-to-date drug knowledge among practicing doctors. However, the misuse of resources is not simply a matter of medical education and dissemination of treatment guidelines. A key argument in this paper is that a pervasive pattern of irrational drug use is driven less by misinformation than by an underlying structure of financial incentives that reward physicians and hospitals for over-prescription.

Bulk (pooled) purchasing

Bulk drug purchasing refers to pooling of demand for better prices through shared wholesale procurement. Lower prices are achieved through increased leverage in price negotiation, competitive bidding, and reduction in intermediary distributor costs.

There is considerable controversy over the relative advantages and impact of bulk purchasing policies in regard to controlling pharmaceutical expenditure. As the role of hospitals shift from that of sellers to bulk purchasers, hospitals lose critical revenue that must be replaced by one means or another. In addition to direct revenue losses, bulk

purchasing requires alternative systems for procurement and logistics. These too can be costly—for example, the IT costs of decentralized web-based distribution can be substantial.

The government has reiterated its commitment to the notion of bulk purchasing on many occasions over the past decade. A policy notice on "Normalization of Drug Bulk Purchasing in Hospitals" was issued by the Ministry of Health (MOH) and the National Planning Council (NPC) in 2001, and "Some Regulations on Further Normalization of Drug Bulk Purchasing in Hospitals" was issued by Ministry of Health and the National Development Reform Commission (NDRC) in 2004. The Government subsequently announced that it will reform and expand the present system of bulk purchasing. The plan is to improve the existing system and to upgrade it from city level to provincial level, as well as pooling purchasing through designated websites. All drugs in the community health centers plan are to be purchased through web-based public bidding eventually, so the distributers' role will be reduced primarily to the physical distribution of drugs.

Zero markup

Zero-markup refers to a policy of *no* additional margin when a health institution sells drugs, that is, the retail price and the wholesale price are the same. In principle, the transaction costs are then to be subsidized by government. This policy was initially implemented at urban community health centers. Some centers (e.g., several centers in Shanghai and Nanjing) experienced success in reducing drug prices and average cost per visit after they implemented this policy. Zero-markup policy was piloted in urban hospitals as well, with results to be seen.

If zero-markup were scaled up to more CHCs, and to secondary and tertiary hospitals, overall pharmaceutical revenues would decline. One way or another, the subsequent losses would have to be compensated in reality as well as in principle—either by direct subsidy or by raising fees for labor-intensive medical services such as patient consultations, diagnostics, and surgery. The 2009 health reform plan specifies budgetary support for the notion of zero-markup. The working agenda describing five key areas of the medical and pharmaceutical reform includes the following statement: "Improve the compensation mechanism for urban and rural grassroots health institutions [facilitating] government financial subsidies in accordance with zero-markup policy." (The State Council, July 2009.)

The separation of drug prescribing from drug dispensing

Presently, most patients in China purchase their drugs directly from providers or hospitals. Direct provider benefit from drug sales represents a legally sanctioned conflict of interest that is at odds with the goals of financial efficiency and sound clinical practices. Several approaches have been proposed to delink prescription from dispensing. By whatever method, the underlying problem is complex and deeply engrained in China's healthcare system. A fundamental structural change cannot be expected to come about easily.

In 2005, the Ministry of Health began piloting a new way to separate primary providers' revenues from the fees that they generate for services and drugs. Under the pilot system, all revenues from user charges are to be turned over to the government; and the government in turn provides a fixed budget to the facility to cover volume-adjusted operating expenses. This has been piloted at the CHC level in many cities, including Shanghai, Tianjin, Hangzhou, and Chengdu. Although this system might reduce the prescription of unnecessary drugs and tests, it remains to be seen whether the new incentives will be sufficient to motivate a shift from curative to primary care, or to prevention and treatment of chronic diseases. In Shanghai, a global budget and pay-for-performance system was introduced in tandem along with an initiative to uncouple operating revenues to the health facilities from the volume of charges for services and drug sales to patients (see Hu et al., *The Lancet*, October 20, 2008 for further detail).

Refining the path to pharmaceutical reform

A significant series of healthcare and pharmaceutical reforms evolved during the decade of the 2000s, especially toward the end of the decade. Section 5 of this paper recommends a series of measures to deepen and strengthen the reforms in the following areas:

National System of Essential Medicines. Revise the essential drug list dynamically as needed; reduce the list based on medical and economic criteria; align the national Essential Medicine System with basic benefits packages for the health insurance systems; strive toward 100 percent affordability for the most basic of essential drugs; involve and coordinate with a broader range of stakeholders to create additional political and popular momentum; extend education on essential medicines within and beyond the medical community; extend the government's role in the logistics of distribution of essential medicines.

Generic drugs. Subsidize the manufacture of generic drugs; adopt the use of international non-proprietary (INN) drug nomenclature; designate a list of approved manufacturers to supply generics for bulk purchasing; take additional efforts to ensure strict adherence to GMP standards in manufacturing; and simplify drug packaging.

Improving drug pricing. Adopt pharmacoeconomic evaluation methods to set prices on innovative and new medicines; separate pricing according to categories of drugs; abandon one-off individual drug price-setting; reduce the scope of price-setting by the government.

Zero-markup policy. Support zero-markup with direct budgetary support from the government; separate drug revenues and expenditures accounts within health facilities; separate channels and accountability in the management of funds.

Pooled purchasing. Make the public procurement (bidding) system fairer, more equitable, and more transparent.

Learning from international experience. Test the applicability of a range of experiences and lessons from international experience—in particular, on designing a national essential

medicine policy, drug procurement and distribution, pricing of drugs, and reimbursement models within various insurance programs.

Deeper structural reforms. Recognize that pharmaceutical reform can only be effective in a broader context of successful health reform. Conceptualize pharmaceutical reform as a component of universal coverage of the basic medical security system and the development of the National System of Essential Medicine. Take a long view on the challenge of establishing a good drug provision and security system.

Financing, Pricing, and Utilization of Pharmaceuticals in China: The Road to Reform[1]

1. Introduction

The Government of China is committed to affordable high-quality health care for all citizens. It has worked toward that vision by building on four pillars of reform—to medical services, public health services, medical insurance, and pharmaceutical supply.

In November 2008, the State Council issued a draft document, "Guidelines for Deepening Health Care and Pharmaceutical System Reform,"[1] which articulated principles as well as a strategy for reform. For the pharmaceutical pillar, this included a national policy on essential medicines and a commitment to standardize the production and distribution of drugs. A month of hearing and public input followed, yielding more than 35,000 comments from the public, received by email, fax, and post. Of these, nearly a quarter addressed issues related to the high cost and difficult access to pharmaceuticals.

The present Health Policy Note, intended to contribute to the evolving discussion of pharmaceutical reform, examines the financing, pricing, and utilization of pharmaceuticals. It discusses how the present system evolved and key issues that should be addressed, and suggests areas where policy reform should be refined. Following this introduction, the paper is divided into four parts. The first section provides an overview of the Chinese pharmaceutical market: how the sector has grown; China's position in the global market; and size, composition, and trends in the domestic market. The second section examines the evolution and status of China's system of essential medicines, an area emphasized in the government's health reform plan announced in April 2009. It shows how the use of essential medicines has evolved over the two decades since the idea was formally adopted,

[1] This paper was prepared by Professor Shanlian Hu, MD, School of Public Health, Fudan University (Shanghai). He is grateful to the World Bank health advisory team, including Dr. John Langenbrunner (World Bank Beijing Office), Dr. Andreas Seiter (consultant), and Dr. Shuo Zhang (consultant); as well as to external reviewers Shiyan Chou (World Bank) and Michael Borowitz (Organization of Economic Cooperation and Development). Comments are welcome to hushanlian@hotmail.com.

and discusses why practice has fallen far short of the ideal. The third section looks at the issue that dominates today's debate: managing high pharmaceutical costs. It reviews the components of drug pricing, underscoring the argument that there is considerable scope for reducing prices. It looks at government attempts to control drug prices (23 separate price reductions!), and suggests why they did not succeed. It looks at an issue that has not been central to the discussion—China's irrational (in the medical and economic sense) use of drugs, as well as two strategies that have received much attention—bulk (pooled) purchasing and no-markup policies. Finally, the fourth section suggests measures to rechart the path to reform.

2. The Chinese Pharmaceutical Market Today

Background and overview

Today's pharmaceutical market was shaped by the founding of the People's Republic in 1949. From the earliest days, the health of Chinese citizens was viewed as a responsibility of the state. Preventive health care was fully funded, as were hospital and rural healthcare costs. Personnel costs were the exception. These were expected to be covered by fees for services, with rates jointly set by the Ministries of Finance, Health, and the Price Bureau of the State Planning Committee. The state provided subsidies so that fees paid by patients could be kept well below their actual costs. The system was expected to be financially sustainable based on a low-cost health model, patient fees, and government subsidies.

Price controls on drugs have been in effect since the early 1950s. The markup from wholesale to retail prices depended on the category of drug. The permissible markup was 15 percent for chemical (generally Western) medicines, and 20-25 percent for traditional Chinese medicines. The initial rationale for a markup was to compensate hospitals for losses such as spoilage and replacement costs. However, as the utilization, importation, and cost of drugs (and medical technologies) increased, the providers' markup became increasingly important in its own right. As pharmaceutical sales increased, they produced significant revenues that helped offset the growing operational deficits related to the general underpricing of fees for medical services.[2]

With collapse of the commune-era healthcare system that began in the early 1980s, the government tried to control escalating prices and suffering related to the loss of healthcare coverage. In the 1980s the government massively reduced prices three times. However, these reductions did not control increasingly unmanageable out-of-pocket household medical costs or their social consequences. The reductions also contributed to loss of revenues for hospital and healthcare centers, which faced soaring operating deficits as public subsidies were reduced. Faced with continuing revenue losses from both directions, medical providers responded in one of the few areas where they retained control—strategies to increase their pharmaceutical revenues.

Innovative drugs and Western medical technologies were gradually introduced and increasingly in demand from the mid-1980s onward. Hospitals began to use them—and then to overuse them—both to treat illness and to control their operating deficits. The higher

markup value on brand name drugs helped hospitals to balance revenue shortfalls, and this practice led to financial dependency. In 2008, hospitals showed an overall loss of RMB 60.7 billion yuan on medical services (Table 1). The positive balance from drug sales was RMB 17 billion, equivalent to 39 percent of the net subsidy from the government. Net revenue from the sale of drugs is greater than the overall net surplus of RMB 138 billion. Without pharmaceutical revenues, hospitals would operate at an overall loss.

Table 1. Hospital Revenues and Expenditures, 2008
(RMB 100 million and as a percentage)

	(A) Revenues	(B) Expenditures	(C) Net revenue (A – B)
Financial subsidy from government	776.8 (10.6%)	251.6 (3.6%)	525.2
Drug sales	3075.5 (42.0%)	2,848.7 (40.2%)	226.8
Other[/a]	152.2 (2.1%)	65.3 (0.92%)	86.9
Medical services	3,314.0 (45.3%)	3921.3 (55.3%)	–607.3
Total	7318.4 (100%)	7089.6 (100%)	231.6

Source: MOH 2008, final accounting of hospital revenue and expenditure data.

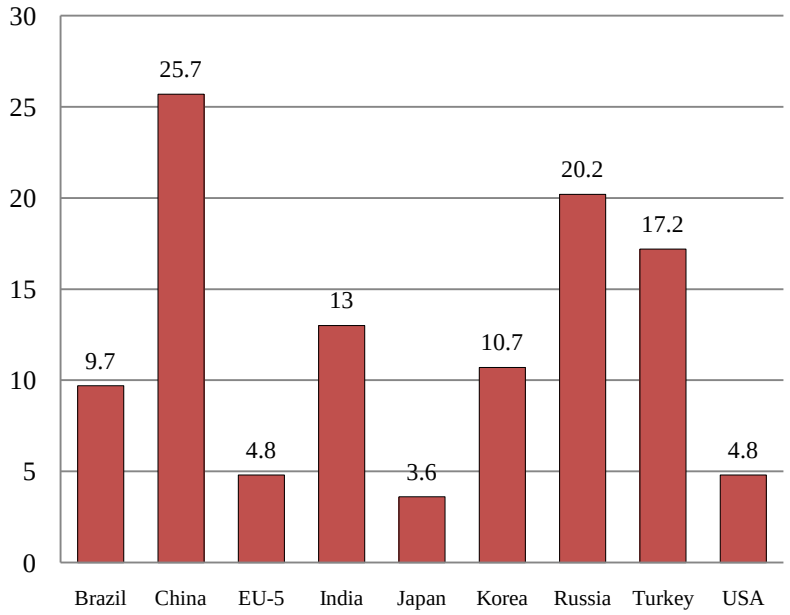
[/a] *Other revenue* refers to income from training services, ambulance fees, interest on deposits, donations, investment income, and sale of assets. *Other expenditure* refers to outlays such as malpractice penalties losses on assets or investments, and other expenditures not related to wholesale purchase of drugs or the costs directly related to the provision of medical services.

Size and composition of China's pharmaceutical sector

China's place in the global market

As the global pharmaceutical market has increased, China's share as an exporter, importer, and consumer has expanded. By 2004, pharmaceutical product sales reached US$9.5 billion, making China the ninth largest pharmaceutical market in the world. China's average annual growth rate was 28 percent in the mid-2000s, far exceeding the 9 percent average for the rest of the world.[5] For example, drug sales in China grew at 25.7 percent in 2007, compared to 4.8 percent in both the United States and the EU (see Figure 1).

Figure 1. Annual Growth Rate of Drug Sales (%)—China and Comparators, 2007



Source: Pharma China Report, 2007.

Driven by double-digit growth for the past two decades, the size of China's pharmaceutical market increased by a factor of 10.7 between 1990 and 2006. According to Pharma China Report, sales in China (including both Western and Chinese drugs) reached US$50 billion by the end of 2007, and the industry's share of total GDP rose from 2.17 percent in 1978 to 2.71 percent in 2007. The value of pharmaceutical imports rose from about US$40 million in 1978 to US$14 billion in 2007, while the value of exports rose from about US$290 million to US$25 billion. Overall, the value of the trade surplus reached approximately US$10 billion in 2007.

China is now a major overseas market for many multinational pharmaceutical corporations and for others it is likely to become *the* largest foreign market within a decade.[6] Pharmaceutical sales for many multinationals have grown at more than 20 percent annually. GlaxoSmithKline (China) has grown at 24 percent annually in China, compared with the company's global growth rate of 2 percent excluding China. Similarly, AstraZeneca grew at a 25 percent annual rate in China, compared with its 7 percent rate worldwide.[7] Novartis' 24.5 percent growth rate included six products whose sales each exceeded RMB 100 million. Sales of Lotensin (benazepril), a new Novartis product, reached RMB 400 million in 2007.

Altogether, the gross value of China's pharmaceutical industry reached about RMB 600 billion in 2007, 16 percent higher in value than the 2006 level. Sales growth amounted to RMB 270 billion. The over-the-counter market—important in out-of-pocket household expenditure—accounted for RMB100 billion, a quarter of the total pharmaceutical market.

Giant pharmaceutical distribution monopolies have been established through mergers — though there are still many small distributors, and a highly fragmented distribution market overall. The number of distributors dropped from about 13,000 in 2002 to about 7,000 in 2005. By 2007, the three largest distributors—Sinopharm Medicine Holding, Shanghai Pharmaceutical Co. Ltd., and Jointown Group—accounted for more than 20 percent of the market. The Sinopharm network sells drugs in about 7,800 hospitals and in 2,000 shops of its own, and its 3,000 distributors provide drugs to another 8,200 pharmacies. Sinopharm alone has sales of over RMB 50 billion.

Domestic market: Domestic manufacturers (traditional medicines), imports, and joint ventures

Hu (1996) studied pharmaceutical sales for domestic manufacturers, joint ventures, and importers in Shanghai. In 1992 drugs manufactured domestically (including those producing chemical generic drugs as well as traditional Chinese medicines) accounted for 46 percent of the market, followed by 36.4 percent for imports and 17.6 percent for joint venture products (Table 2). In 1993–94, the drug reimbursement list and a policy on hospital revenue-capping were introduced. As a result, by 1996 traditional Chinese medicines declined to 39 percent of the market, measured by the value of drugs sold; imports dropped to 28 percent and joint venture products rose to 32 percent. [8] The pharmaceutical value accounted for by Western chemical drugs rose from 54 percent of the market in 1992 to nearly 61 percent by 1996.

Table 2. Category of Pharmaceutical Products by value of Sale and by Year, Shanghai (in percent)

	1992	1993	1994	1995	1996
Domestic manufacture	46.0	41.7	39.9	39.2	39.4
Imports	36.4	36.5	31.6	30.8	28.4
Joint venture products	17.6	21.8	28.5	30.0	32.2
Total	100	100	100	100	100

Source: Author's calculations.

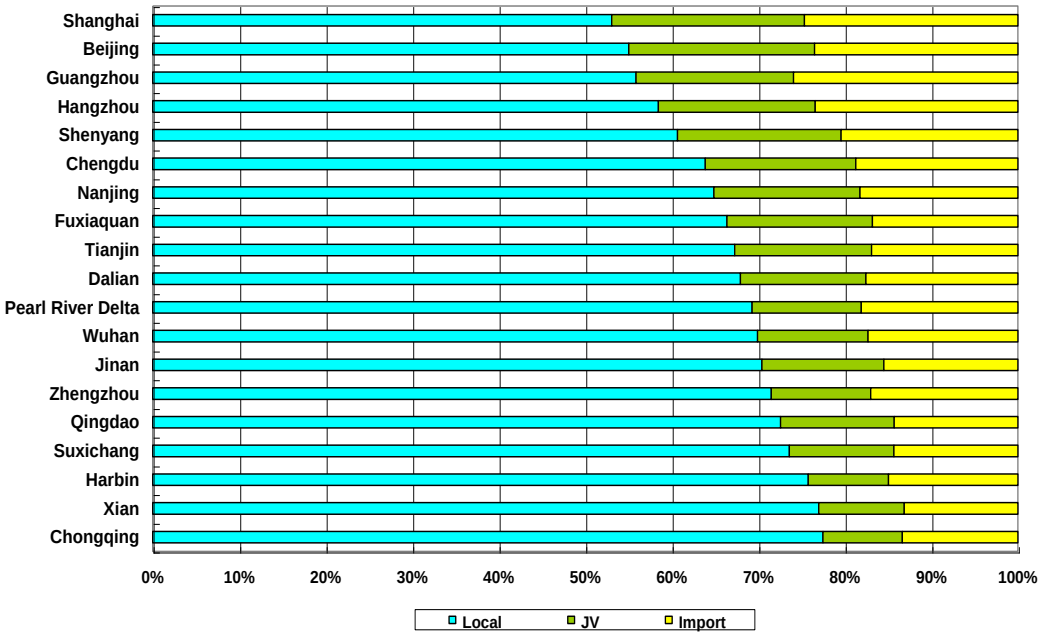
The IMS (2006) reports the value and volume of the Chinese pharmaceutical market by category of products. Traditional, domestically-manufactured products predominate, accounting for 70.3 percent of market share as measured by value of the products (Table 3). Domestic products are 84.7 percent of the market as measured by number of units sold.[9] Imported medicines account for only 5.5 percent of the market as measured in units, and 15.8 percent of the market as measured by value.

Table 3. Source of Pharmaceutical Products by Value (RMB) and by Units, 2006

	Market share and growth by value			Market share and growth by units sold		
	Value of sales (RMB millions)	Value growth rate (MAT %)	Value growth rate (QTR %)	No. of units sold (millions)	Unit growth rate (MAT %)	Unit growth rate (QTR %)
Domestic manufacture	84,735 (70.3%)	10.6	10.4	4,428 (84.7%)	15.6	14.9
Imports	19,062 (15.8%)	19.0	24.9	286 (5.5%)	14.2	21.8
Joint venture products	16,745 (13.9%)	13.9	12.2	515 (9.9%)	13.8	14.4
Total	120,531	12.3	12.8	5,228 (100%)	15.3	15.3

The value of joint venture and imported products varies significantly among municipalities and cities. In Figure 2, joint ventures and imported products together account for between 40 and 46 percent of the overall pharmaceutical market in the five cities at the top of the graph—Shanghai, Beijing, Guangdong, Hangzhou, and Shenyang. By contrast, joint venture and imported products account for only about 23 to 27 percent of the market in the cities such as Harbin, Xian, and Chongqing, shown at the bottom of the graph.

Figure 2. The Value of Sales Shared by Different Pharmaceutical Manufacturers in China's 19 Largest Cities



It is worth noting that there may be tradeoff to the nation in social benefits between fast growth of the pharmaceutical industry and rapid acceleration in domestic healthcare costs.

Domestic expenditures on drugs

The domestic pharmaceutical market in China is vast—approximately 620 billion yuan (RMB) for 2008 (approximately US$92.5 billion).[10] Between 2000 and 2008, health expenditure was equivalent to between 4.62 and 4.82 percent of GDP (Table 4, Column 4); and of that, pharmaceutical expenditure accounted for nearly half (Column 7).[10]

Table 4. Growth in Health Expenditure, Pharmaceutical Expenditure, and Relation to GDP, 1990–2008 (RMB 100 millions)

		Health expenditure (HE)		Pharmaceutical expenditure (PE)		
	GDP	HE	HE /GDP (%)	PE	PE / GDP(%)	PE /HE (%)
1990	18,667.8	747.4	4.00	418.3	2.2	56.0
1995	60,793.7	2,155.1	3.54	1,169.1	1.9	54.3
2000	99,214.6	4,586.6	4.62	2,211.2	2.2	48.2
2001	109,655.2	5,025.9	4.58	2,303.0	2.1	45.8
2002	120,332.7	5,790.0	4.81	2,676.7	2.2	46.2
2003	135,822.8	6,584.1	4.85	2,903.9	2.1	44.1
2004	159,878.3	7,590.3	4.75	3,621.3	2.3	47.7
2005	183,867.9	8,659.9	4.73	4,142.1	2.3	47.8
2006	211,923.5	9,843.3	4.64	4,486.1	2.1	45.6
2007	257,305.6	11,573.9	4.50	4,903.2	1.91	42.4
2008	300,670.0	14,535.4	4.83	6,202.4	2.06	42.7

Source: 2009 China National Health Accounts Report. China National Health Economics Institute.

As shown in Table 5, health expenditure per capita (HE in Column 2 and average rate of increase in Column 3) grew at about 17.9 percent annually between 1990 and 2008. Pharmaceutical expenditures per capita (PE) grew at an average of about 16.4 percent (Column 6 and Column 7). That is to say, overall health expenditure grew even *more* rapidly than fast-rising pharmaceutical expenditure. This is because of the disproportionately higher

costs of the newer medical technologies. PE as a share of HE went down from 56 percent in 1990 to 42.7 percent in 2008 (Column 3 compared to Column 6).

Table 5. Growth of Health and Pharmaceutical Expenditure Per Capita, 1990-2006 (RMB 100 million)

	Health expenditure (HE)			Pharmaceutical expenditure (PE)		
	HE	Avg. annual increase (%)	HE per capita	PE	Avg. annual increase (%)	PE per capita
1990	747.4	-	65.4	418.3	-	36.6
1995	2,155.1	23.6	177.9	1,169.1	.22.8	96.5
2000	4,586.6	16.3	361.9	2,211.2	.13.6	174.5
2001	5,025.9	9.6	393.8	2,303.0	4.2	180.4
2002	5,790.0	15.2	450.8	2,676.7	16.2	208.4
2003	6,584.1	13.7	509.5	2,903.9	8.5	224.7
2004	7,590.3	15.3	583.9	3,621.3	24.7	278.6
2005	8,659.9	14.1	662.3	4,142.1	14.4	316.8
2006	9,843.3	13.7	748.8	4,486.1	8.3	341.3
2007	11,574.0	17.6	876.0	4,903.2	9.3	371.1
2008	14,535.4	25.6	1094.5	6,202.4	26.5	467.0

Source: 2009 China National Health Accounts Report. China National Health Economics Institute

Total pharmaceutical expenditure increased more than 11-fold between 1990 and 2006, from RMB 418 hundred million to RMB 6,202 hundred million (Table 6). In relative terms, sales from hospital pharmacies went down—from nearly 95 percent of the total in 1990 to about 75 percent in 2008. On the flip side, the share of sales from community pharmacies went up—from about 5 percent of the total in 1990 to nearly 25 percent in 2008. There are several contributors to this trend, but the most important is that an increasing share of the population cannot afford hospital-based care and opts for self- medication and the seemingly more-affordable option of over-the-counter medications in community pharmacies.

Table 6. Where Pharmaceuticals are Purchased, 1990-2006

	PE (RMB 100 million)	Hospital PE		Community pharmacy PE (%)
		Outpatient (%)	Inpatient (%)	
1990	418.3	68.3	26.4	5.3
1995	1,169.1	60.0	30.8	9.3
2000	2,211.2	54.8	31.2	14.0
2001	2,303.0	54.1	30.8	15.1
2002	2,676.9	51.2	31.6	17.2
2003	2,903.9	49.9	33.0	17.1
2004	3,621.3	45.7	31.9	22.4
2005	4,142.1	46.1	32.5	21.4
2006	4,486.1	46.2	32.2	21.6
2007	4,903.2	43.2	34.1	22.7
2008	6,202.4	40.9	34.7	24.4

Source: 2009 China National Health Accounts Report. China National Health Economics Institute

The *kinds* of pharmaceuticals being purchased are also changing, another key driver behind the continuous rise in pharmaceutical expenditure. Sales of imports and joint venture products averaged remarkable growth of about 25 percent per year, far faster than traditional Chinese medicines. One recent analysis in sentinel hospitals found that imports and joint venture products increased from 31.7 percent of the market in 2002 to 40.2 percent in 2006.

Improved intellectual property protection and the streamlining of registration processes have speeded up the approval times for new drugs, and this has helped to increase their sales. In 2003, the average availability index for the 15 top-selling drugs in China (that is, the rate at which drugs are approved for import within two years of first-country approval) was only 27 percent that of the United States. [11]

It should be noted that some lag in approval is inevitable, because local clinical trials are required before China's State Food and Drug Administration (SFDA) will approve imported drugs. As part of its global strategy, the US Food and Drug Administration (USFDA) has opened satellite offices in Beijing, Guangzhou, and Shanghai to help speed up approvals. These new offices will work with manufacturers, SFDA, and the Chinese government so that approval times will be shortened without compromising standards for safety and quality.

3. Essential Medicines

The origins of today's policies

The World Health Organization (WHO) launched a forceful advocacy for the concept of essential medicines beginning in the mid-1970s. The WHO Action Committee for Essential Medicines, established in 1981, articulated a global strategy to provide low-cost drugs for the ubiquitous treatable diseases that affected vast numbers of people (primarily poor), mostly in developing countries. The starting point was formulation of national essential drug lists. Generic drugs with potentially the greatest impact were identified. Strategies were devised to make these affordable and universally accessible.[28, 29]

In the past three decades, over 70 countries have adopted national essential medicine policies. Today, there are many variants. At least 30 more countries are currently working to formulate such policies. Initiatives such as the DfID-sponsored Medicines Transparency Alliance (MeTA) have devised a wide range of tools to improve the supply of essential medicines, as well as to educate and improve general awareness. Recent work has emphasized transparency in procurement, improved tendering, pooling, and monitoring and publication of pharmaceutical prices. "Toolkits" are available at the national level as well as considerable international experience that is available to China.

Led by the Ministry of Health, the Chinese government published its first essential medicine list in 1982, including 278 essential medicines. The criteria for inclusion were subsequently refined, and these have remained largely unchanged. To be classified as an essential medicine, a drug must meet four basic requirements: first, that it is necessary for the treatment and control of a significant disease; second, that it has been proven safe and effective; third, that it is reasonably priced; and fourth, that it is convenient for general use. An additional criterion has been applied in China—that an even overall balance is sought between Western drugs and traditional Chinese medicines.

About 4,000 Western drugs and 5,100 traditional Chinese medicines were on the market when China's essential medicines policy was formulated in 1992. As shown in Table 7, there was a 50–50 ratio of western and traditional medicines when the essential drug list was first formulated in 1992. The list was subsequently revised every two years. In 1996 it was divided into 26 categories, including 699 Western and 1,812 traditional Chinese medicines. It was expanded to 27 categories in 1998, including 740 Western medicines.

Table 7. China's Essential Medicine List, 1992–2009

	1992	1996	1998	2000	2002	2004	2009
Traditional Chinese medicines							
Number	0	1,812	1,570	1,249	1,242	1,260	102
Percent of total	(0%)	(72%)	(68%)	(62%)	(62%)	(62%)	(33%)
Western medicines (chemical and biological products)							
Number	278	699	740	770	759	773	205
Percent of total	(100%)	(28%)	(32%)	(38%)	(38%)	(38%)	(67%)
All medicines							
Number	278	2,511	2,310	2,019	2,001	2,033	307
Percent of total	(100%)	(100%)	(100%)	(100%)	(100%)	(100%)	(100%)

Source: Author.

The names for most traditional Chinese medicines are commonly treated as "brand names." Thus, there are disproportionately more traditional drugs on the list than are actually used as essential drugs. The classification of essential drugs has gradually aligned with clinical use (that is, by hospitals, physicians, insurance packages, and pharmacies) over time. The table shows that the number of traditional Chinese medicines went down from 1,812 in 1996 to 102 in 2009, representing 33 percent versus 72 percent of the total. In 2006, the Ministry of Health further separated the lists for urban and rural health centers—398 essential items for urban centers (243 Western and 155 traditional medicines), and 215 items for rural centers (132 Western and 83 traditional medicines).

Weakening the role of essential medicines

The role of essential medicines was weakened with the application of the first drug reimbursement list under urban basic employees' medical insurance in 1994. Under China's medical insurance schemes, drugs are not categorized as essential and nonessential, but as Category A (reimbursable) and Category B (nonreimbursable). Thus, "reimbursability" came to overshadow "essentialness."

The reimbursement level for Category A drugs depends on the benefits package and the local scheme. Category B drugs require a co-payment of 10 to 15 percent.[3, 4] Among antibiotics, for example, essential medicines such as benzlpenicillin, amoxicillin, ampicillin, piperacillin, oxacillin, and cloxacillin belong to Category A. Piperacillin and sulbactam, amoxicillin and potassium clavulanate belong to Category B. The 2009 version of UBEMI

drug reimbursement list included 2,151 drugs as reimbursable. (Of these, about 54.1 percent are Western medicines; the rest are traditional Chinese medicines.) Category A has 349 items; Category B has 815 items. While all 307 essential medicines are included in Category A, a large number of (more profitable) nonessential medicines can also be reimbursed.

Although the list remained in place and was regularly revised from 1996 onward, essential medicines had a limited effect for several reasons. First, the prices imposed by government authorities were often based on social ideals (i.e., basic medicines should be available to everyone independent of their ability to pay) but were not equally grounded upon the on the economic realities of a fiercely competitive pharmaceutical market (i.e., profitability to those who produced and sold them). Thus, prices set for essential medicines tended to be socially just but economically unrealistic, leaving manufacturers with little incentive to produce essential medicines. The government did not address this problem by providing offsetting incentives to make essential medicines equally attractive in the marketplace. Second, essential medicines by definition are selected based on lowest-possible price. That is their purpose. However, this meant that even if domestic manufacturers were willing (or even subsidized) to produce them, hospital providers were not necessarily eager to prescribe them, because (as discussed above, see Table 1) hospitals rely on drug sales (primarily brand drugs) to counterbalance the deficits that they incur from underpricing of medical services. Third, until fairly recently, "education" on the use of new drugs was primarily provided by pharmaceutical distributors and manufacturers' representatives. Disinterested clinical guidelines were not available, especially on the utilization and medical management of essential drugs. Thus, it has been fairly easily to promote and reinforce the widespread perception that generic drugs are not as safe, effective, or reliable as brand drugs—and all the more so because of extremely well-publicized failures in quality control.

Availability and utilization of essential medicines

In light of these disincentives to use, it is not surprising that essential medicines have not necessarily been widely available or well utilized. In 2004, Shanghai municipality and Shandong province evaluated availability and pricing using the WHO/HAI (Health Action Initiative) method.[30, 31] Thirty hospitals and 20 pharmacies were surveyed in four districts of Shanghai,[30] as well as 20 hospitals in Jinan and in three counties of Shandong.[31] A total of 41 medicines were selected in Shanghai (19 from the core list, 22 from the supplementary list) and 39 in Shandong (24 from the core list, 15 from the supplementary list). Price data were collected for the "innovator"[2] brand drug and for the lowest-priced generic drug, and compared to an international benchmark, the median price ratio.

[2] Traditionally, when a drug enters the insurance reimbursement list, the National Development and Reform Commission (NDRC) selects one brand to receive an "innovator" price, while all others receive a "normal" price. The innovator price is generally awarded to the brand with the original drug patent (often from a multinational corporation), allowing the brand to be reimbursed at a premium over the normal price. This practice allows drugs to receive favorable reimbursement rates even after a company's patents expire.

The survey revealed high procurement prices and poor availability of essential drugs. In public hospitals in Shanghai, the average procurement price was 7.6 to 9.9 times higher than the international reference price for brand drugs, and 1.4 times higher than the international reference price for the lowest-priced generic. Retail prices were found to be lower in pharmacies than in public hospitals. (Most patients purchased their medicines in hospitals; only 20 percent of drug sales by value was from pharmacies.) The availability of essential medicines was estimated at between 13.3 percent and 33.3 percent in public hospitals and between 10 percent and 15 percent in pharmacies, with the generic drugs being more accessible than the innovator brand drug.

Even more significant: many essential medicines had reached prices beyond most peoples' threshold of affordability, undermining the fundamental goal of the policy. This was especially true among patients needing treatment for chronic conditions such as hypertension and diabetes mellitus. In Shanghai, for example, the cost of a one-month supply of meltformin (an antidiabetes drug) was equivalent to four days of salary at the minimum wage, and the costs of amlodipine (a hypertension drug) and fluoxetine (an antidepressant) were equal to six days of salary. In contrast, a one-month supply of the least-expensive generic was typically closer to one day of salary at the minimum wage. In addition, all 14 of the brand drugs and 25 of the lowest-priced generic drugs were being sold at more than four different prices.

The Shandong survey revealed poor availability of essential medicines and significant price discrepancies in both public and private health facilities. Fifty-four percent of the generic medicines on the essential drug list were found to be available overall, yet half of the hospitals had fewer than 5 percent of the drugs on the list. The median price ratio (MPR) of six innovator (brand) drugs was 4.1 times higher than the international norm (P_{25} to $P_{75,}$ 1.71—7.28), while the MPR of the ten lowest-price generics was 0.93 of the international norm (P_{25} to P_{75}, 0.69—2.88).

In March 2008, SFDA supported an evaluation focusing on the supply of essential medicines (previous studies typically focused on the demand side). The study examined the distribution system, supervision of drugs and medical devices, drug quality, adverse reaction, and possible restrictions on advertising drugs. Guidelines were proposed, followed by heated public hearings. Three key issues were argued back and forth. The first is that the government is already too involved in the production and provision of essential medicines, which leads to rent-seeking behavior and corruption. Second, all urban community health centers, township health centers, and village health posts should be required to use *only* essential medicines—in other words, patients requiring other medicines or those classified as nonessential would have to get them at higher-level hospitals. Third, essential medicines should be prioritized across a broader range of health-service institutions, including rigid requirements such as fixed percentages.

Essential medicines in the health reform process, 2008-2010

In March 2009, the Central Committee of Chinese Communist Party and the State Council published a basic policy directive to guide healthcare and pharmaceutical reforms. The fundamental goal was clearly enunciated—"universal, basic health service for all," meaning quality health care including effective and affordable drugs for 100 percent of Chinese citizens. The guidelines were accompanied by broad strategy based upon four "pillars" (component systems) of reform—the public health system, medical services, healthcare insurance coverage, and drug provision.

A National Essential Medicines System (NEMS) was mandated as the future centerpiece of drug provision, the fourth pillar of reform. (See the footnote below[3] for clarification of the often-confusing terminology as these programs, policies, and concepts variously translated from Chinese to English.) Fundamental features were laid out, including pooled (bulk) procurement; zero-markup, at least in government-run health institutions providing essential medicines; reimbursement policies of basic medical insurance Essential Medicines System. Complementary measures were also defined to improve quality and safety in the production of pharmaceuticals.

In November 2009, the Ministry of Human Resource and Social Security (MOHRSS, previously the Ministry of Labor and Social Security) revised the drug reimbursement list of Urban Employee Basic Medical Insurance (UEBMI). All essential medicines have been reclassified as Category A (fully reimbursable) drugs, with the reimbursement ratio significantly higher for essential versus nonessential drugs.

In 2009–10, a multisectoral process was used to formulate an overarching set of policy documents specifying the administration and implementation of the National Essential Medicine System and the National Essential Medicines List. Improvements were made to supervision of the system as well as enhanced quality control in production. New price caps were announced for retail prices. The revised list of 307 essential medicines was announced in 2009, following intense public debate over issues related to price caps and the transparency of procurement.

The government also announced a target of 30 percent of government-run community health centers and township health centers being required to implement NEMS by the end of 2009, with anticipated expansion to 60 percent by the end of 2010. At this writing (mid-

[3] The terminology of the present discussion is often confusing because the programmatic titles in Chinese are translated and converted to English acronyms in various ways—National Essential Medicines System (NEMS), National Essential Drug System (NEDS), National System of Essential Medicines (NSEM), and National System of Essential Drugs (NSED). Such terms are also easily confused with the institutional terminology that was used for predecessor programs or official policies during previous eras—for example, the system that evolved in the 1990s as described in this chapter above. In addition, these terms written with lowercase when referring to concept in a general sense but not necessarily to a particular program or formally named policies during a particular era. Similar principles of nomenclature hold when referring to the Essential Drug List, the Essential Medicines List, the essential drug list, and so forth. Some additional clarification is provided in "Box 1: The Terminology of Essential Medicines Used in this Paper," in "A Generic Drug Policy as Cornerstone to Essential Medicines in China" (*China Health Notes*, No. 4, June 2010).

2010) it is projected that the fundamental features of the system will be broadly in place and increasingly used by the end of 2011. In principle, a "mature" system of this sort would incorporate the following key elements:

(1) A refined National Essential Drug List (NEDL) managed by the central government.

(2) A rational, scientifically grounded system in place to specify why and how new essential items would be added to the list. This would strongly reflect the changing health characteristics and demographic structure of the Chinese population. It would incorporate state-of-the-art best-practice methodologies in complex areas such as prioritizing the importance in new treatments; setting standards for safety and efficacy; and methodologies for price-setting. A balance would again be sought between Western and traditional Chinese medicines.

(3) A system would be set up at the national level to select designated manufacturers of essential medicines. Pooled (bulk) purchasing would be widely used to reduce the role of intermediary distributors in the supply chain.

(4) Unified retail pricing would allow reasonable latitude for profitability among manufacturers and distributors.

(5) Clinical norms would be established based on scientific evidence, accompanied by well-disseminated guidelines on their application by health professionals.

(6) All essential medicines would be included in the insurance reimbursement list, and the reimbursement ratio would be higher for essential than for non-essential medicines.

In October 2009, the Ministry of Health established a Department of Drug Policy and Essential Medicines to translate these objectives into reality. The functions of the new department are to:

(1) Set up and implement the National Essential Medicine System.

(2) Formulate a drug code and the National Essential Drug List.

(3) Formulate national drug policy.

(4) Draw up policies for procurement, distribution, and utilization of essential medicines.

(5) Coordinate with other sectors to encourage and establish a subsidy policy for the production of essential medicines, as well as providing policy advising on pricing. (The Ministry of Health is also responsible for managing the State Food and Drug Administration.)

In 2010, the National Development and Reform Commission (NDRC) set caps (i.e., the maximum retail price that consumers can be charged) for all 296 drugs on the National Essential Drug List (NEDL). In addition, price markups by hospital markups were banned.

The caps did *not* affect prices for about half the essential drugs on the list; and the caps were raised for about 6 percent of drugs on the list. On average the price reductions averaged 12 percent. The price caps seek a delicate balance. Prices must be kept low enough to encourage use by patients without undue hardship, while high enough to incentivize drug companies and hospitals to maintain quality. The new price system is being rolled out gradually. For government-run hospitals, nationwide implementation is expected by 2011. [43]

Though hospitals price markups have been banned, many challenges stand in the way of full implementation (see the following chapter). Nevertheless, much has been learned from recent pilot experiences. The array of available models has widened. Jiangsu province, for example, implemented a pilot in which zero-markup was implemented in tandem with fixed salaries for village doctors subsidized by the government. Tianjin conducted a pilot in which hospitals were paid the equivalent of their previous markup (about 15 percent). In this case, 6 percent was provided by the local government, and 9 percent was provided by the medical insurance fund. The city of Qingdao subsidized zero-markup based on the idea of pay for performance. Community health centers receive a subsidy by means of a government–financed services contract. The amount of the subsidy varies depending upon the volume of clinical visits that are provided and the degree to which essential medicines are utilized.

4. Managing the Cost of Pharmaceuticals

Government price setting

Strategies to control pharmaceutical cost have evolved through several phases since the founding of the Peoples' Republic. During the era of the planned economy prior to 1978, all pharmaceutical prbbbices were set by the government. When the early stages of economic transition began in the 1980s, prices were left largely to the market. However, as prices started to rise at 10 percent or more a year, both local governments and the central government stepped in. In the mid-1990s, price controls were reintroduced. As shown in Table 8, a series of policy measures were enacted between 1996 and 2007, including a new pharmaceutical law, various decrees on how pricing would be adjusted, and several approaches to setting and adjusting prices.

Table 8. Policy Measures Related to Pharmaceutical Cost Containment, 1996–2007

	Document	Key measures
State Planning Commission (SPC), 1996	Temporary Measures of Drug Price Administration	• Strengthens drug price measures and consolidates how drug prices are to be set. • Controls prices of monopolized and essential medicines. • Preliminary adjustment on the differences between government-set and market prices.
SPC, 1998	Notice on Strengthening Drug Price Management	• Further consolidation of drug price reform. • Reduction of drug prices, especially for those with high commissions and rebates.
SPC, 2000	Guidelines on Reforming the Management of Drug Prices	• Establishes two methods for drug pricing: government pricing and market adjustments. • Drug prices controlled by the government to include all essential medicines, medical insurance drugs, mental health drugs, anesthesia drugs, vaccines, as well as drugs for family planning. • Authorities set the highest permissible retail price; hospitals and other retail enterprises (including hospitals) decide the retail (i.e., actual price at which drug is sold), which cannot exceed the government-set price.
SPC, 2000	Measures of Government Pricing	• Further reforms and refinements of national drug price administration policy. • Improved scientific management of drug prices.

SPC, 2005	A Notice of Drug Pricing List Set by SDFC	Elaboration of products covered by government pricing, including prescription drugs on the health insurance reimbursement list, Chinese traditional drugs, anesthesia drugs , mental health drugs, family planning drugs and devices, the vaccines used in the expanded program of immunization (EPI), and blood products
SPC, 2005	Notice of Pilot Study on Ex- Factory Pricing in Some Drugs	• Control drug price from ex-manufacturer by lowering the retail price and standardizing purchasing methods • Using highest ex-manufacturer price (versus the highest retail price).
Eight Ministries, including SPC & MOH, 2006	Further Consolidation of the Market Order for Pharmaceuticals and Medical Services	• Consolidation and review of all drugs prices; price adjustments for high- and low-cost essential drugs. • Prohibit price increases through changes in dosage or strength; permits a maximum markup of 15 percent for drugs sold retail in hospitals. • Limitations on markups related to distribution. • Strengthens the supervision of price adjustments through the market, as well as labeling of retail prices on packaging. • Gradually shifts market-based pricing to pricing based on the government's price list.
State Development and Reform Commission (SDRC), 2007	Working Guidelines for Pharmaceutical Pricing	• At least two pricing professionals will carry out studies on pharmaceutical manufacturing costs and will exchange views with the manufacturers. • Public hearings to be conducted by the Discipline and Supervision Authority. • Basic data on pricing and recommendations for adjustments to be presented in public hearings.
SDRC, 2007	Working Rules on Medical Services and Pharmaceutical Prices	• All prices set for medical services or pharmaceuticals should go through five steps: (1) cost investigation and audit; (2) market price investigation; (3) regional coordination; (4) expert review and confirmation; and (5) public hearing on issues of price.

The government intervened to directly set prices 23 times between 1997 and 2007 (Table 9). The number of drugs subject to price controls rose from about 1,500 to 2,400 during this decade (1,600 products regulated by the central government and 800 by local governments). By 2007, these drugs still represented only about 20 percent of all medicines; however, price-controlled drugs represented about 60 percent of the value of all drugs sold.

Table 9. Drug Price Reductions, 1997-2007

	Month / year	Products and items	No. of Drugs	Average reduction rate (%)	Estimated annual savings (RMB 100 mill.)
1	October 1997	Antibiotics (15) and biological products (32)	47	15	20.0
2	April 1998	Anti-fever and analgesics	38	10	15.0
3	April 1999	Cefradine and others	21	20	20.0
4	June 1999	Imported drugs	150	5	8.0
5	August 1999	Biochemical drugs	2	15	1.2
6	January 2000	Bioproducts	12	10	3.4
7	June 2000	Cefradine and others	9	15	12.0
8	October 2000	Ampicillin and others	21	20	18.0
9	April 2001	Anti-infection drugs on EDL	69	20	20.0
10	July 2001	Chinese traditional medicines on EDL	49	15	4.0
11	December 2001	Essential drugs	383	20	30.0
12	December 2002	Chemical drugs on essential drug list	199	15	20.0
13	March 2003	Chinese traditional medicine on EDL	267	14	15
14	May 2004	Fentanyl and others	3	n.a.	n.a.
15	June 2004	Antibiotics	24	30	35.0
16	July 2004	For drugs individually priced	18	n.a.	n.a.
17	October 2005	Antibiotics	22	40	40.0
18	June 2006	Anti-tumor drugs	104	23	23.0
19	August 2006	Anti- microbiologic drugs	99	30	43.0
20	October 2006	Chinese anti-tumor drugs	32	14.5	13.0
21	December 2006	Arginine and other items	354	20	70
22	March 2007	Chinese traditional medicines	278	n.a.	n.a.
23	April 2007	CTM drugs	188	16	16

Source: Hu, based on National Price Bureau data for these years.

Note: n.a. = data not available

Impact of government price setting, 1996-2007

The impact of these price reductions was not insignificant—an estimated savings of RMB 42.7 billion (excluding items for which data are not available). The average price reduction on these items was 18.4 percent. Yet while savings and price reductions at this level were meaningful, they were insufficient to offset the much faster increases in expenditure that were simultaneously taking place. The impact of a decade of price controls was generally disappointing. The larger lesson was that price is only one (but not necessarily the most important) element in cost containment.

Several evaluative studies have assessed the impact of price controls on expenditure and utilization of various categories of drugs. One before-and-after study of price reductions on antibiotics in 1999 assessed how price reductions affected expenditure and defined daily doses (DDDs). For the price-controlled antibiotics, expenditures were found to have gone down (yet by only 6–7 percent, rather than by 20 percent as had been expected); however, *overall* expenditures on antibiotics went up—by an average of 3 to 18 percent.

Why? The causal relationship cannot be inferred with certainty from these data. However, the most likely explanation is that expenditure did not go down because drug prescribers did not *let* them go down. Basically, they shifted demand in the direction of higher-priced alternatives. They were able to do this by substituting non-price-controlled for price-controlled drugs. The State Planning Commission responded by defining categories more inclusively, so that similar versions of the same product were all included in the same price-regulated category. This made it more difficult for manufacturers, pharmacies, or prescribers to circumvent the intent of price controls. What mattered, however, is that they had financial incentives to do so, so a cat-and-mouse game ensued. Different classes of antibiotics could be prescribed, for example; or non-regulated "new" drugs could be created by slightly changing the name, dosage, packaging, or nonactive ingredients of an otherwise regulated product.[12, 13]

Virtually every country has made efforts to control prices of at least essential medicines; and these efforts have been helped to make such medicines more accessible or more affordable, especially to the poor. However, sector-wide price control efforts have generally not worked. The experience of India is well described in M.B. Shah and A.S. Patel's study, *Price Controls in India: An Overview* (2003). As in China, the central government set all drug prices prior to 1979. In India, national-level price controls came to be associated with corruption and shortages rather than low prices. Significant conflict emerged among social groups and economic interests. The controls were almost universally viewed as a failure and were gradually abandoned starting with the implementation of the Drug Price Control Act in 1979. The number of price-controlled medicines went down from 349 drugs in 1979, to 74 by 1995, to just 28 drugs by 2002. By the middle of the 2000s, price-controlled drugs accounted for barely 19 percent share of the pharmaceutical market in India.

Room for price reductions

There are four basic components of drug pricing—the manufacture price, the ex-factory price (price for wholesale acquisition), the distribution and wholesale price, and the retail price (selling price to consumers). Cost-plus is a simple price-setting method based on calculation of the markups in the various steps that define the cost of production. Breakdown in this way provides a useful way to compare the added cost contributed by each step in the process. Suppose, for example, that the manufacture price for a product is RMB 100 yuan. The cost-plus price would be calculated by adding tariffs and taxes (such as import taxes and VAT—the range is between 17 and 24 percent); a distributor's margin (8 to 10 percent); and a hospital margin (20 to 25 percent). In this case, the cost-plus price would then come to about RMB 170 yuan.

Cost-plus rates for pharmaceuticals (as well as VAT rates) are considerably higher for China than those of other major drug-exporting countries. As shown in Table 10, the average cost-plus rates for drugs average between 60 and 70 percent for China. This compares with average cost-plus rates between 10 and 20 percent for the United States and 20 to 25 percent for Japan. In other words, despite more than a decade of government efforts to control prices—efforts that were generally far more aggressive and far-reaching in China—prices along the pharmaceutical supply chain generally remained considerably higher than those in comparator countries. (This does not necessarily pertain to the manufacture and export prices. These were kept razor-thin so that China was able to maintain its competitive position in the global export market.)

Table 10. Cost-Plus Prices and VAT Rates Differences—China and Comparators

	Cost-plus rates (% range)	Value-added tax (VAT) rates (%)
USA	10–20	0
Japan	20–25	5
France	30–40	2
Korea	20–30	10
Thailand	45–55	7
Brazil	55–65	18
China	**60–70**	**17**

The high internal margins on the components of ex-factory prices have an important implication for pharmaceutical cost management. This analysis suggests that there is scope for considerable reduction in the domestic prices, and it also points where to look.

Alternative approaches to cost reduction, 2006–10

With primary attention in the past focused on price setting, too little attention has been paid to other approaches to cost containment, as well as to broader socioeconomic shifts that have reshaped the nature of pharmaceutical expenditure —for example, the aging of the population, the tendency of a wealthier population to spend more on health and quality of life, and the transition from communicable to "lifestyle" diseases.

Much new thinking has occurred over the past decade, especially in the past few years. Several projects have tried alternative payment models, such as case-payment methods. A payment system can be changed from fee-for-service to global budget control. Capitation systems can be used for ambulatory visits, disease-related groups (DRG) payment for inpatients, and case-payment methods based on a single disease or surgical procedure.

Capping of hospital revenues is another approach. Experience in Shanghai hospitals in the 1990s confirmed the effectiveness of capping hospital revenues to control medical and pharmaceutical expenditure.[29]

DRG payment systems were studied in some pilot hospitals in the early 1990s and have become of increasing interest in recent years. In general, the necessary conditions for DRG are not yet broadly present in China—such as the use of disease ICD-10 classification, hospital information system, quality assurance systems, sufficient management autonomy, capacity building, and so forth. Looking toward the future, a Chinese DRG system could be devised combining elements of experience from the United States, Australia, and Germany.[4]

More-sophisticated methodologies for drug pricing

In 2006, the State Development and Reform Commission (SDRC) announced a series of measures to consolidate prices for pharmaceuticals as well as for medical services (Box 1).[36]

[4] International research along these lines was undertaken in 2008 by the Center for Health Economics Institute (CHEI) under a grant from Medtronic Corporation.

Box 1. Key Pharmaceutical and Medical Service Reforms, 2006

1. *Further reductions in drug prices.* All drug prices were adjusted in a comprehensive manner. Prices on some expensive items were reduced. Prices were raised for some inexpensive drugs with high clinical demand that manufacturers had not been willing to produce because of low profitability. Rules to regulate differential price setting were established to prohibit manufacturers from changing dosages, strengths, and packaging in order to avoid price controls. All hospitals above the county level required to limit their markup to no more than 15 percent (except Chinese medicines, which could be increased gradually up to 25 percent).

2. *Implementation of the ratified ex-manufacturer price*. To ensure the scientific characteristics of government pricing setting and to control excessive profits from drug distribution, certain drugs were selected with high distribution price differentials. Prices were reduced on these drugs in order to reduce retail prices.

3. *Drug priced adjusted by the market*. To improve transparency, the government suggested that manufacturers add retail price labels on drug packaging. These prices would reflect: (1) approved prices, including any increases; (2) the adjusted price of record; (3) limitations on price differential; (4) restrictions on excess profits. Any market-adjusted pricing for prescription drugs must be incorporated into the government pricing system.

4. *A supervision system for pricing of medical devices*. Domestic and international price information will be published regularly for medical devices. These benchmarks will serve to rationalize prices, as well as the allowable level of markup during the distribution process.

5. *Rational adjustments to prices for medical services*. Adjustments to raise the price of medical services to reflect the true value of the technical skill and labor that they require, while reducing the fee schedule for high-tech examination procedures.

6. *Standardization of the hospital norms for treatment and medication*. Revision and improvement of clinical guidelines. Physicians to write prescriptions using generic names (active ingredients by molecule name) and, gradually, generic drugs. De-link the relationship between hospitals revenue and personal income, and promote competition before medical services and pharmacy.

Source: Summarized from SDRC, Document No. 912, "Further Consolidation of the Market for Pharmaceuticals and Medical Services, State Development and Reform Commission") 2006.

The pharmaceutical reforms in 2006 included several new measures related to cost containment. The practice of creating "new drugs" to avoid price regulation was banned, and specific incentives were aimed at expanding the production and use of lower-priced generic drugs. At the same time, more latitude was allowed for market-based competition as a dynamic in price reduction. Medical devices and high-tech services were subject to similar logic and pricing methodologies. Clinical guidelines were established to help physicians understand and make better use of generics, thereby broadening their perception; and measures were taken to delink higher drug sales from higher income for physicians and hospitals. The pharmaceutical reform measures in 2006 included not only further price reductions; but increasingly sophisticated (and transparent) methodologies as well.

In April 2007, SDRC announced that pharmaceutical costs would be monitored more closely. Further improvements in pricing methods were announced, and the number of price-controlled drugs was expanded to include virtually all prescription drugs. These new guidelines were more responsive to manufacturers' arguments that drug pricing should reflect the costs of manufacturing inputs, distribution and marketing expenses, and reasonable profit margins. Manufacturers were permitted to set prices for new drugs (as well as for some existing drugs) based on their assessments of costs; however, once set, prices are closely monitored by the central government. Foreign pharmaceutical manufacturers were also allowed to set prices taking into account actual costs related to sales, rebates, commissions, and promotions.

SDRC has adopted a wider range of pricing methodologies, including:

- *Differential pricing.* A drug's differential price is based on the price ratio value on forms ($K = 1.9 \log_2 X$), strengths ($K = 1.7 \log_2 X$), and packages ($K = 1.95 \log_2 X$), where X= ratio (i.e., defined test drug strengths / the standard drug strengths). For the same medicine, this will be influenced by factors such as average production cost, production technique, the efficiency and effectiveness of clinical application, convenience, and treatment cost.

- *Combined pricing.* A combined pricing policy uses both the fixed-margin (15 percent) added-pricing method, and the fixed-value added-pricing method. Low-price drugs will use the 15 percent margin for added-pricing. When a drug price reaches a threshold, a high price drug will only have a fixed margin, usually less than a 15 percent markup; and in principle, this should work to hold the price down. To illustrate the application of combined pricing in setting differential prices in distribution process, suppose for example that the drug price is RMB 1,000 yuan and the markup rate is 15 percent (i.e., RMB 150) as set by the government. The final drug price would then be RMB 1,000 + RMB 150 = RMB 1,150. To limit the retail price (i.e., because the price of the drug is greater than RMB 1,000), the distribution markup would be restricted to the fixed margin of RMB 75. So in this case the final retail price would be reduced to RMB 1,075.

- *Reducing the profit margin on distribution.* An estimated 30 percent of drug costs are attributed to the manufacturing process (ex-factory price); 55 percent to the cost of commercial distribution (commissions and rebates); and 15 percent to retail markup at the point of sale (the hospital). In principle, if drugs were provided directly from the manufacturer to the hospital, the distributors' share could be reduced and significant savings could be passed on. (See discussion of cost-plus pricing, Table 9 above; and bulk (pooled) purchasing in the corresponding section below.)

Guangdong was one of the first provinces to pilot the newer approaches to pharmaceutical and medical cost containment. Previously, most retail prices in Guangdong were set by the market, and only about 20 percent of drug prices were controlled by the government. Under the demonstration project, the provincial government supervises the entire production and distribution process. As a first step, the regional price bureau published its plans. Prescription drugs for treating common diseases are almost entirely managed by the government. Price changes were phased in gradually to avoid speculative retail buying. Three price control measures were adopted: fixed ceilings on retail prices; transparency in reporting actual post-manufacture prices; and setting limits on allowable price differences arising from the distribution process. So far, these measures are estimated to have saved an estimated 5 billion (authors' calculations).

Bulk (pooled) drug purchasing

Bulk drug purchasing refers to pooling of demand for better prices through shared wholesale procurement. Lower prices are achieved through increased leverage in price negotiation, competitive bidding, and reduction in intermediary distributor costs. The savings, in principle, can then be passed on to drug purchasers and medical insurance payers.

The present system of bulk purchasing has been in use since the early 2000s. By 2007 prices for approximately 2,400 out of 7,000 drug items were managed by some form of bulk purchase. According to a report from the pharmaceutical industry, bulk purchasing methods reduced overall sales revenues by about RMB 100 billion between 2006 and 2007.

Unfortunately, many ways have been found to redirect the savings that should in principle be passed on. In 2007, SDRC conducted a nationwide survey of 114 hospitals in ten provinces.[14] After being bulk-purchased, 244 items were found to be "out of stock," meaning that they can be replaced with more expensive imported drugs, or so-called "new drugs" (i.e., strength or recommended dosage have been changed). Of the out-of-stock items, only 20 were found to be not actually produced or commercially available. Absence of the other items was explained by three factors that are not substantially changed by bulk purchasing—high production costs, unrealistically low controlled prices, and lack of compensation mechanism for hospitals.

The SDRC study pointed to a broader problem—the overall lack of profitability in the generic drug market, which altogether accounts for only about 20 percent hospitals' overall drug expenditure. The issue is not the merits of bulk purchasing, but rather, hospitals' continued dependence on the sale of more profitable drugs.

There is considerable controversy over the relative advantages and impact of bulk purchasing policies. As hospitals' role shifts from that of sellers to bulk purchasers, they lose critical revenue that needs to be replaced by one means or another. In addition to the financial disincentive to providers, alternative systems for procurement and logistics have requirements that can also be costly—for example, the IT costs of decentralized web-based

distribution. New bidding processes could drive up costs among manufacturers, with too much emphasis on competition at the expense of pharmaceutical quality. Potentially high profit rates through bulk purchasing could create a new set of possibilities for corruption and profiteering, including intermediary nongovernmental IT organizations.

Reform alternatives are being tested. In 2007, the Guangdong provincial government launched an innovative bulk-purchasing system in the context of the larger cost-management pilot program briefly described above. The acquisition all prescription drugs was taken over by the provincial government. Bulk purchasing is managed with a website using up-to-date information technology. All price information is published on the site and fully transparent. Hospitals compare prices and then select medicines make based on quality and volume of a pooled purchased.

In Ningxia Autonomous Region, an area that is different from most other parts of China, the provincial government has for some time monitored and controlled virtually every aspect of pharmaceutical supply, including bulk purchasing. The regional government is involved in virtually every aspect, including procurement, pricing, and distribution. This comprehensive approach is referred to as the "three unification" policy.[18] The role of pharmaceutical sales agents has been eliminated, and the commercial links between manufacturers and hospitals have been severed. It remains to be seen whether this approach will have unintentional negative consequences through the government's virtual takeover of distribution, or whether it will be able to successfully balance its multiple roles in the market.

The central Government has also announced its intention to reform and expand bulk purchasing. The objective is to delink hospital budgets from their dependence on direct incentives from manufacturers. The 2009 national reform plan specifies the improvement of bulk purchasing. The system is to be upgraded from city to provincial level, and pooled purchasing is to be managed more broadly through designated websites. Drugs used by community health centers plans are to be purchased through the web-based public bidding system, which is ultimately intended to limit the distributers' role primarily to the physical distribution of drugs.

No-markup drug sales

"Guidelines for Developing Community Health Service in Urban China" (State Council, 2006) stipulated that community health centers would institute zero-markup—in other words, sell medicines solely to recover their costs.[19] Profit from the customary markup was to be converted to lower prices for patients.[5] Initially, 29 community-level sites were selected for demonstration projects.

5 Other elements of 2006 community health service reform include: (1) A greater government role in strengthening community health care as a social benefit; (2) ensuring government's public spending; (3) integration of health resources; (4) reforming the mechanism for hiring and firing personnel; (5) implementing new incentive systems, such as pay-for-performance and consumer satisfaction; (6) separation of financial

Yinchuan , the capital city of Ningxia Autonomous Region, was among the first demonstration cities to conduct pilot studies on the new community healthcare policies(March 2006), followed in December 2006 by Sichuan, Zhejiang, Hubei, Shandong, Jiangsu, and Guangdong provinces. In December 2006, Beijing became the first municipality to implement "pooled procurement, direct distribution, and the zero-markup rate."

Since 2007, more than 2,600 community health centers have implemented zero-markup. Under the 2006 guidelines, 312 essential medicine items (923 strengths) were covered in urban community health centers. Early evaluative studies found that about a third (312 of 957 community health centers) between 2006 and 2008 were successful in submitting bids and distributing essential drugs using zero markup (that is, one drug item and one bidding tender). In this case, the cost of distribution (about 3 to 5 percent) is absorbed by the pharmaceutical companies.

Table 11 shows drugs as a share of inpatient and outpatient costs after three years of implementing the larger package of reforms (including zero-markup). The data are from community health centers (CHCs) in the pilot districts of Changning and Songjiang in Shanghai. The cost of both inpatient and outpatient visits went down slightly over the three-year study period under study. The share of costs accounted for by drug expenditure went up, basically because the cost of the nondrug portion went down relatively more due to the larger package of reforms. In addition, rates of clinical utilization went up. The percentage of persons receiving primary care from the CHCs rose from 45 to 63 percent.

Table 11. Drugs as a Share of Costs per CHC Visit at Two Demonstration Sites in Shanghai, 2004-2006

Costs of visit to health center	2004	2005	2006
Changning District (Shanghai)			
Outpatient costs			
Ambulatory visit (RMB)	131.6	131.9	115.0
Cost of drugs (RMB)	87.0	94.2	92.0
Drugs as a % of outpatient cost	66.1	71.4	79.9
Inpatient costs			
Cost per bed day (RMB)	124.7	121.2	105.8
Drugs as a % of the cost	36.6	35.9	41.5

revenue and expenditure accounting system; (7) making drug sale based on zero-markup rate with government subsidy; and (8) global budgeting for medical health insurance.

Songjiang District			
Outpatient costs			
Ambulatory visit (RMB)	102.1	106.0	98.4
Cost of drugs (RMB)	67.1	70.0	66.5
Drugs as a % of outpatient cost	65.7	66.1	67.6
Inpatient costs Cost per bed-day (RMB)	80.2	88.2	74.7
Cost of drugs per bed-day(RMB)	23.8	27.6	19.1
Drugs as a % of the cost	29. 7	31.3	25.6

Source: Hu 2008.

Nanjing is a pioneer city in implementing zero-markup. Four community health centers in Qinghuai District participated in a pilot study in April 2007. The centers established a budgetary management system in which the local government paid doctors' and nurses' salaries, thereby reducing the direct financial benefit from the sale of a large amount of highly marked-up drugs. A total of 350 essential medicines in urban areas and 180 in rural areas were subject to zero-markup, accounting for approximately 80 percent of all CHC pharmaceutical expenditure. As a result, retail drug prices went down by an average of 41.5 percent. The average cost per prescription declined by 14.6 percent, and the average cost of a clinical visit (which includes cost of prescriptions) went down by 15.4 percent. The total number of visits to CHCs increased by 28.2 percent. In 2008, the city government budgeted RMB 42.3 million to subsidize implementation. With a population of 7.5 million, this subsidy is about RMB 5.64 yuan per capita.

At the beginning of zero-markup implementation, only community health centers (CHCs) were affected. Evaluation at pilot sites confirmed that costs per visit and drug prices at the CHCs declined—28.0 percent for the cost of an ambulatory visit in Beijing CHCs and 18.8 percent in Shanghai CHCs. The cost of drug purchases went down by 32 percent at the Beijing sites and 40 percent in Nanjing. Zero-markup was next piloted in urban hospitals.

Prior to the national health reform in April 2009, Guangdong province announced that nine hospitals in Shenzhen, Shaoguan, and Zhanjiang would eliminate the 15 percent wholesale–retail price difference. Preliminary results have not yet been evaluated as of this writing in mid-2010. However, as secondary and tertiary hospitals implement the zero-markup rate policy, their pharmaceutical revenues are expected to decline, which will require compensation. This will have to be provided either by government financial subsidy or by adjusting the fees charged for labor-intensive services such as patient consultation, diagnostics, and surgery.

Recent experiences have underscored that price controls alone do not reach the root causes of high pharmaceutical expenditure. The deeper problem is insufficient budgetary support for public hospitals. As government subsidies cover only about 10 percent of hospitals' operating revenues, 90 percent must be generated through fees for medical services or pharmaceutical markups. Permissible fees for medical services have not been adjusted in many years and are considered relatively fixed, despite guidelines such as the pilot study on hospital reform (MOH 2009). Hospitals argue that they have little alternative other than to offset operational deficits through pharmaceutical sales. Without financial support from central and provincial governments, it is difficult to imagine successful implementation of zero-markup on a broad scale, especially in the midland and western China.

The separation of drug prescribing from drug dispensing

As argued here, health providers depending on profits from drug sales represent a legally sanctioned conflict of interest. It is a practice that is at odds with both financial efficiency and sound clinical practice. Several approaches have been proposed to delink prescription from dispensing. One method is to separate the physical source of drug supply so that hospital outpatient centers do not operate pharmacies. With this model, patients are required to obtain their medicines from community pharmacies. Another method is to separate the administration of dispensing—that is, the outpatient pharmacy remains in place, but operations are contracted out to a third-party dispenser of drugs such as a pharmaceutical distributor. A third method is to cut off the financial benefit from pharmaceutical sales, replacing it with measures such as bulk purchasing, and separating the revenue and expenditure accounts in the management of the hospital.

Each of these methods has several variants and positive–negative tradeoffs. For example, with the first method patients can be instructed to take their prescriptions to any pharmacy, with expectation that transparent pricing will encourage market competition and hence lower pricing. Alternatively, hospitals can offer pharmacy services for inpatients only. The doctor's role is restricted to diagnostic services, treatment, and prescription only. Another variant is to start the delinkage with community health centers rather than hospitals.

By whatever method, the underlying problem is complex, and the dependency is deeply engrained in China's healthcare system. A fundamental structural change cannot be expected to come about easily. The challenge was well illustrated by Korea's experience attempting to implement similar reforms in the early 2000s.[20] Similarly, reforms that change the players but do not change the underlying incentive structure—such as the trusteeship arrangement piloted in Nanjing, briefly described in Box 2—do not appear to reach deeply enough to alter the basic result.

Box 2: A New Policy on Trusteeship of Hospital Pharmacies?

In 2007, the city government of Nanjing instituted a new policy on trusteeship for pharmacies in all secondary and tertiary hospitals. The hospital maintained ownership of its pharmacy; however, daily operations were delegated to a corporate or trust enterprise, i.e., drug distributors. Profits from drug sales are shared by the hospital and the distributor. A team organized by Nanjing Pharmaceutical Ltd. designed a strategy with a sales network to cover all primary, secondary, and tertiary hospitals in urban as well as rural areas. Hospitals would no longer incur the cost of storing drugs. Waste was to be reduced through quicker turnover on drug sales. Salaries of hospital pharmacists and workers were to be paid by Nanjing Pharmaceutical Corporation Ltd.

Pharmacy trusteeship along these lines was primarily intended to counter direct bribery as well as to break monopolistic price-setting practices. It is not yet clear whether that happened. However, in regard to broader change, results to date do not appear to be encouraging. Under the new arrangement, the trustee company is typically required to return about 40 percent of its profit to the hospital; and for their part, hospitals as drug retailers remain dependent on income from their pharmaceutical sales, which are equivalent to between 25 percent and 50 percent of their total income from medical services. In some instances, distributors maintain privileged positions through the requirement of large cash payments upfront. Basically, the hospital is still in the position of buyer, prescriber, and seller of drugs. Though their commercial interest is less direct, doctors still play an important role in the selling of drugs; and through it may be more difficult, opportunity is still in place for collusion among doctors, distributors, and hospitals. In short, the trusteeship arrangement has not changed the role, relationship, or profitability of drug distribution.

Sources. See, for example, Chen Ying and Zhang Xin, *Modern News*, November 5, 2007; and *Nanjing Daily News*, April 24, 2008

In 2005, the Ministry of Health began piloting a new way to separate the revenues that primary providers generate from expenditures of the facilities at which they work, including income that they receive personally. Under the pilot system, all revenues from user charges are turned over to the government; and the government in turn provides a fixed budget to cover volume-adjusted operating expenses. This has been piloted at the CHC level in many cities, including Shanghai, Tianjin, Hangzhou, and Chengdu.

In Shanghai, a global budget and pay-for-performance system was introduced in tandem along with the initiative to separate revenues from charges. This may help reduce the prescription of unnecessary drugs and tests. It is not yet clear whether the new incentives will affect other goals, for example the shift from curative toward primary care, or from treatment to prevention of chronic diseases.

The related problem of irrational drug use

Irrational use of medicines refers to overuse, medically inappropriate use, or financially inefficient use of drugs. There are countless examples of irrational drug use in China, ranging from innocuous folk remedies to excessive faith in highly sophisticated but pointless surgical procedures. Typical Chinese examples include: overconfidence in drugs delivered through intravenous injections; use of two or three drugs when one will do; widespread overuse of antibiotics; a preference for advertised drugs, familiar brand names, and the belief that higher price equates with better curing.

Providers, like patients, also practice irrational drug use, though usually for different reasons—lack of information about actual efficacy, personal profit, habit, and to satisfy patient demand. Irrational drug use is especially common in rural areas, and overall it is an important contributor to excessive drug expenditure.

The MOH Department of Maternal and Child Health and Community Health conducted a baseline study (2008) on irrational drug use at community health services in 28 demonstration cities (2008).[47] Prescription patterns were analyzed in a random sample of prescriptions drawn from 1,917 community health centers and 5,321 health posts. The results suggested wide deviation from international norms (articulated by WHO and others) generally associated with sound practice. Irrational drug use was measured by five indicators (see Table 12). It was found that an average of 2.6 medicines are used per prescription; 35.4 percent of prescriptions included intravenous drips; 45.1 percent included antibiotics; 8.2 percent included steroids; and more than 13.5 percent of the prescriptions prescribed more than two antibiotics. No major differences were found between community health centers and community health posts (stations).[6]

[6] Individually, none of the five indicators shown in Table 11 is necessarily irrational. The problem is overuse and inappropriate use, which is suggested by the very high rates shown in the table. A large body of comparative data is available to suggest rates that might be considered "reasonable" or clinically justified under local conditions. (Also, it goes without saying that high rates such as those reported here are by no means unique to China.)

Table 12. Indicators of Irrational Use of Medicines, MOH baseline study, 2008

	No. of medicines per prescription	Having intravenous drip (%)	Having antibiotics (%)	Using steroids (%)	More than 2 antibiotics (%)
Average rates (1,917 CHCs and 5,321 CHPs)	2.6	35.4	45.1	8.2	13.5
Selected municipal rates					
Beijing*	2.3	11.0	25.0	2.7	2.6
Changning (Shanghai)*	2.5	9.67	19.7	1.5	2.3
Songjiang (Shanghai)*	2.6	15.5	23.5	1.5	2.5
Tianjin*	2.0	21.9	27.0	7.0	5.0
Chongqing (Yuzhong)**	2.5	27.5	54.5	2.5	18.0

Source: MOH 2008.

Notes: * indicates rates *below* the overall average.

** indicates rates *substantially above* the overall average.

Irrational drug use was found to be surprisingly high in many urban as well as rural community health centers. In Kunming (the capital of Yunnan), 92.9 percent of prescriptions included intravenous drips. In Yangquan (a district in Shanxi), 68.7 percent of prescriptions included antibiotics. In Yinchuan (Ningxia Autonomous Region), 37.5 percent of prescriptions used steroids. On the other hand, many urban areas have made considerable progress in reducing irrational use. Four municipalities—Beijing, Changing (Shanghai), Songjiang (Shanghai), and Tianjin—have rates below the overall average; while Chongqing (Yuzhong) has rates above the overall average.

Until recently, nongovernmental medical groups and Chinese health authorities did not treat irrational drug use as reform priority, but this is changing. Irrational drug use is a problem not only with respect to medical safety and quality of care; it is an unacceptable waste of financial resources and a significant opportunity for cost containment.

Dealing with medically ineffective and overly expensive patterns of prescription starts with continuous education on appropriate drug use. To a great extent, the "education" function has largely been relegated to drug company representatives. In 2009, the MOH developed a series of clinical pathways that provide a more neutral view on how to diagnose 112 common diseases and utilize the correct drugs for their treatment. Guidelines of this sort help to fill an important information gap.

On the other hand, the pervasive misuse of resources cannot be attributed merely to folk beliefs or insufficient training in effective treatment pathways. So-called "irrational drug use"

is driven by powerful financial incentives that are "rational" in the classic economic sense of narrow self interest. Physicians and hospital are generally trusted; their opinions are authoritative; and they exert vast direct and indirect influence over what patients believe, request, and obtain. To the extent that they are no longer neutral or financially disinterested, so-called irrational drug practices are likely to persist.

5. Refining the Path to Healthcare and Pharmaceutical Reform

Accomplishments during the 2000s

Healthcare and pharmaceutical reform has been an area of intense public concern over the past decade—especially since the World Health Report in 2000 that ranked China's system at 144th in performance and 188th in "fairness of financial contribution" out of 191 WHO members.[21] Great strides have been made since March 2005, when the Development Research Center (State Council) and the World Health Organization (Beijing Office) jointly released "Evaluation and Recommendation of China Health System Reform," which concluded that healthcare reforms of the previous two decades had largely failed.[22]

As a result of subsequent reforms, China by the end of the decade operates four main medical insurance schemes.

First, urban workers are covered by the employment-based Basic Medical Insurance (BMI) scheme, established by the State Council at the end of 1998. BMI consists of a pooled fund for inpatient care and individual medical savings accounts for outpatient care. It is financed by payroll taxes shared by employers (6 percent) and employees (2 percent). About 180 million people—30 percent of the urban population—were covered in 2007. [23]

Second, an Urban Resident scheme was started in 2007, primarily for children, students, elderly dependents, and migrants not otherwise covered. Some 79 pilot-study cities were launched initially. From 2009 through 2011, the effective coverage rate is expected to rise to about 90 percent (State Council 2009)[24] Approximately half the financing is provided by premiums and co-payments from participating urban residents, and the other half by local government authorities.

Third, a new Rural Cooperative Medical System (RCMS) was launched in 2003,[25, 26] with an estimated[7] 800 million people (94 percent of the total rural population) projected for coverage by the end of 2009. About 5 percent of inpatient beneficiaries account for 67 to 79 percent of risk pooling funds, a proportion that is not unusual by international standards (20

[7] Estimates such as 94 percent rural coverage (RCMS) by the end of 2009, as well as 100 percent BMI coverage by the end of 2010, have been the subject of considerable controversy—in part, over the meaning of terms such as "effectively covered." By any standard, however, there has been vast expansion of coverage over the past decade at an extremely rapid rate.

percent of beneficiaries consume about 80 percent of benefits in most countries).[8] Since household medical saving accounts have little risk-pooling effect, the scheme for ambulatory visits has gradually been converted to risk pooling. (According to MOH, about 41 percent of counties had transferred from household medical saving accounts to the ambulatory pooling fund by 2009.)

Finally, Medical Assistance (MA) is not literally a medical insurance program, but a social welfare program that offers financial assistance to households faced with unmanageable medical cost and the threat of poverty. The program is operated by the central and provincial governments in conjunction with the Civil Affairs Administration. [27] Pharmaceutical benefits are not standard or narrowly specified. The nature of the coverage depends on particular circumstances and varies widely across provinces and municipalities.

At the 141st Standing Committee Meeting (June 2006), the State Council named a 16-member intersectoral coordinating committee to rethink health reform. Led by the National Development and Reform Commission (NDRC) and the Ministry of Health (MOH), the committee prepared a series of recommendations that were submitted to the State Council. A draft document was subsequently released for public comment in October 2008, and the national health reform plan was officially released in April 2009.

The 2009 health and pharmaceutical reform plan, which is described and discussed throughout this paper, lays out an ambitious vision to achieve "safe, effective, convenient, and affordable" healthcare coverage for all urban and rural residents. Its specified that between 2009 and 2011, 30 percent of government-run urban community health centers and county health centers would procure and distribute essential medicines at the provincial level through a web-based bidding system with a zero-markup system for hospitals By 2011, the main elements of the National System of Essential Medicines (NSEM) would be substantially up and running. By 2011 there will be NSEM will provide complete essential medicines coverage to all Chinese citizens.

The 2009 health reform also sets out improved price-setting methods. The principle of retail pricing is for the government to set a maximum retail price, with some flexibility allowed at the provincial level. Retail pricing is to allow fair and realistic profit margins linked to actual production costs. A no mark-up policy will be in effect for hospital sales. A pilot study will be conducted on the use of pharmaceutical dispensing fees as means to compensate hospitals for the revenues that will be lost from drug sales.

[8] The reimbursement rate for in-patient care depends on the level of hospital and varies by region. According to the MOH Department of Rural Health (April 2010), the average reimbursement rate reached 55 percent per hospitalization (RMB 1,235.34 yuan) and the utilization of pooled fund reached 97 percent in 2009. The rate grew by 13.3 percent compared to 2008.

Looking ahead: Pharmaceutical reform in the coming decade

Strengthening the National System of Essential Medicines

A National System of Essential Medicines is now starting to be put in place and can serve as a cornerstone for pharmaceutical reform. As the system evolves from concept to reality, it needs to be monitored and strengthened in the following ways:

- *Revise the Essential Drug List according to medical needs.* A dynamic Essential Drug List is needed, reflecting the continuous advancements in pharmacology as well as changing health profile of the Chinese population (e.g., the large relative increase of noncommunicable diseases such as hypertension and diabetes.[34, 35]). The core list of essential drugs should be far fewer than the 2,400 that were listed until 2004. According to WHO, the list should be refined every 2-3 years. Experts generally concur that the "ideal" number for China is probably in the range of 400 to 800, including traditional Chinese medicines. As of 2010, the number for used in grassroots facilities was reduced to 307; however, this does not include a large additional number of essential medicine for use secondary and tertiary hospitals (to be announced by late 2010, after publication of this paper). Provinces should be allowed to add certain medicines taking into account their particular socioeconomic conditions and epidemiological characteristics.
- *Make the Essential Drug List economically as well as medically sound.* In addition to medical and epidemiological criteria, the Essential Drug List needs to be congruent with the economic realities of pharmaceutical manufacturing (e.g., reasonable and realistic profit margins), the changing methods or paying for and distributing drugs (i.e., bulk purchasing), legally mandated cost-containment approaches (e.g., zero-markup), and trends in the direction of more deeper structural reforms (e.g., changing the provider payment system.
- *Align the Essential Medicines System with the pharmaceutical requirements of basic health-insurance benefits packages.* Essential medicines are key to basic health-insurance benefits packages. They should be fully affordable under insurance reimbursements, and free of charge to those who are not insured or able to afford co-payments.[9]
- *Strive toward full 100 percent affordability.* Essential drugs on the core list should be fully covered by medical insurance reimbursements, and free of charge for those who cannot afford to pay for them. Medicines on the complementary list (i.e., non-core drugs that are medically necessary) can require patient co-pays, but still should be selected based in part on affordability.

[9] Ningxia province directly subsidizes the provision of essential medicines within insurance packages. Thirty items of basic health services and 78 essential medicines are provided free to beneficiaries covered by rural cooperative medical system. Patients pay only one yuan (RMB) prescription fees at clinical visits.

- *Extend coordination among a wider range of stakeholders.* The essential medicine system has many diverse stakeholders; and the ways that the system evolves will affect each group differently—government, enterprises, hospitals, and consumers. Coordination needs to be strengthened between the health sector, the pharmaceutical industry, and the insurance sector. Many contentious issues will need to be resolved—such as a hospital compensation mechanism, ensuring legal profits for pharmaceutical manufacturers, and balancing the pooled fund in medical insurance system.
- *Provide education on essential medicines—starting with doctors.* Through professional education, doctors should be encouraged to understand and promote the use of essential drugs. The Chinese Medical Association, Chinese Physicians Association, and the Ministry of Health should assume joint responsibility for improving clinical guidelines to support implementation of the Essential Medicines policy.
- *Carefully delimit the government's role in the logistics of drug distribution*. The distribution system of essential medicines could have both government exclusive selling rights and circulation through market. The distribution system of essential medicines should be gradually shifted to the direction of "government purchasing, unified distribution, and no markup when hospitals sell the essential medicines." All bidding and pooled purchasing fees should be borne by the government.

Expanding the scope for generic drugs more broadly

Generic drugs play a central role in Essential Medicines policy, but their utilization, availability, need to be improved, including both production and perception.

- *Subsidize production*. Several subsidized policies could be used to support the production of generic medicines, such as compensation to the pharmaceutical companies that manufacture essential medicines, low-interest loans to the manufacturers, support for R&D, and lower VAT or exemption of taxation.
- *International non-proprietary names (INN).* The use of international non-proprietary names should be expanded and pricing standardized for equivalent ingredients.
- *Select a designated list of approved generic manufacturers.* To ensure the quality of essential medicines, designated manufacturers should be carefully screened and selected at the provincial and municipal levels. Designated manufacturers would facilitate economies of scale in production, helping to further reduce production costs. The selection of designated manufacturers has been held up, largely through resistance from the pharmaceutical sector. However, necessary criteria have been agreed to as part of the selection process of manufacturers to participate in the newly mandated programs for bulk purchasing. This step needs to be followed through.
- *Ensure quality*. In every aspect of manufacturing and distribution, the principle must be enshrined: quality first, then price. There can no leeway in conformity with strict

GMP standards—a message that also has to widely disseminated among those who prescribe and use these medicines.

- *Simplify the package.* The Ministry of Health (MOH) and State Food and Drug Administration (SFDA) should encourage pharmaceutical manufacturers to simplify drug packaging

Improving methods for pricing drugs

In formulating the "Healthy China 2020" master plan (January 2008), the government substantially improved drug price management, making the pricing system more scientific, rational, and transparent. Efforts along these lines should be continued.

- The pharmacoeconomic valuation method should be used to select and price essential medicines. (The less-sophisticated selection/pricing method presently in use is based more narrowly on the traditional criteria of clinical necessity, safety and efficacy, price, and balance between Western and traditional Chinese drugs.)
- Drug price policies need to be specified by category of drugs—innovative drugs, breakthrough drugs, orphan drugs, low-price generic drugs, and so forth.
- Other objectives of price-setting policies should be strengthened—for example, the need to fully protect and encourage innovation; facilitating healthy market competition; and continuing support for traditional Chinese medicines.
- The so-called individual drug price-setting system should be abolished. The time lag between the pricing of originator drugs (i.e., those for which patents have expired[10]) and generic medicines should be shortened.
- Gradually reduce the scope of government price setting—from about 2,400 items (representing 20 percent market share and 60 to 70 percent of value) to all prescription drugs. It is not realistic to audit the production cost for every medicine, even using a standard panel drug as a benchmark.
- The drug reimbursement list can and should vary according to the basic insurance packages offered by existing insurance schemes (the urban employee's basic medical insurance, urban resident basic medical insurance and new-type rural cooperative medical system). Realistically, these will not be merged, nor their pricing fully standardized, within the near term.
- A general principle of pricing methods is that they should consistently work in the direction of closing the gap between branded and generic medicines.

Implementing zero-markup

[10] In China, the drugs can be classified into five groups, i.e. (1) patent drugs; (2) originator drugs; (3) individual drug required price setting; (4) traditional Chinese medicines with good quality and reasonable price; (5) GMP products.

The zero-markup rate policy for drugs is not isolated, and it should be combined with government budgetary management and separation of revenue and expenditure accounts. Another important issue is related to the incentive of professionals. Where the economic linkage between prescribing and health center revenue is blocked, performance evaluations of health workers can serve as important tools in establishing alternative compensation.

Zero markup policy is likely to save on medical insurance expenditures and can help to cut unnecessary utilization. However, a close eye needs to be kept on the sustainability of the zero-markup policy, primarily because a mechanism has not yet been worked out on how to compensate hospitals for their lost revenues.

The extent to which zero-markup succeeds realistically depends on offsetting subsidies. Government financial support is uncertain, and its allocation may be geographically uneven. The amount of subsidy that a hospital or CHC would receive would depend on the number and volume of zero-markup drugs described by each community health center.

The zero-markup policy faces considerable political challenges under health reform. Most CHCs oppose zero-markup because of fears that pharmaceutical revenues will be lost. Patients, too, often do not perceive substantial benefit. Zero-markup needs to be combined with government budgetary management and separation of the revenue and expenditure accounts. Unless separation of CHC revenue and expenditure accounts is implemented and local governments fully support implementation, zero-markup is not likely to be sustainable.

More effective use of bulk (pooled) purchasing

A relatively small number of top drugs account for a disproportionately large share of hospital pharmaceutical sales. If bulk purchasing systems were implemented effectively for these drugs, substantial savings would accrue.

- To establish the production and supply system of essential medicines, the government could conduct bulk purchasing using market competition. When organizing designated production, a supervision system will help to avoid market monopoly and government corruption.
- The distribution system of essential medicines could have both government exclusive selling rights and circulation through market. The distribution system of essential medicines should be gradually shifted toward "government purchasing, unified distribution and no markup when hospital sale the essential medicines". All bidding and pooled purchasing fees should be borne by the government.

Continued learning from international experience

There is much to be learned from international experience in area of cost containment. Virtually every government has employed direct or indirect interventions to control pharmaceutical prices. China can benefit from these experiences, especially in areas such as setting maximum prices, price negotiation, reference prices, profit controls, volume-based price policy and application of pharmacoeconomics evaluation.[38, 39, 40, 41] On issues relating to prices of imported drugs, China should select several Asian or OECD countries at a similar economic level and undertake rigorous comparative price analyses.

Taking the longer view on deeper structural reforms

The measures discussed here are primarily short and medium term. Longer-term measures must confront the structural characteristics of the system itself, a taller order on the reform agenda. The present system of provider payments is itself at the top of the list. This topic is discussed in more detail in China Health Policy Note number 5.

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