

# A Generic Drug Policy as Cornerstone to Essential Medicines in China



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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 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 a rigorous process of 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](http://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](mailto: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 of International Affairs, or the Government of China.*



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# Acronyms, abbreviations, currency

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AAA	World Bank Analytic and Advisory Assistance
BD	Brand Drug
BMI	Basic Medical Insurance
CAA	Civil Affairs Administration (operates the Medical Assistance program)
CCCCP	Central Committee of the Communist Party of China
CHCs	Community Health Centers
CHEI	Center for Health Economics Institute
DDD	Defined Daily Doses
DfID	UK Department of International Development
DRC	State Council Development Research Center
DRGs	Diagnosis-Related Groups (medical insurance reimbursement system)
EDL	Essential Drug List
EM	Essential Medicines policy
FDA	United States (US) Food and Drug Administration
FFS	Fees for Services
GDP	Gross Domestic Product
GMP	International Standard of Good Manufacturing Practice
GWIS	Government Welfare Insurance System (medical insurance set up in 1992)
HAI	WHO Health Action Initiative, on essential medicines
HTA	Health Technology Assessment, UK
INN	International Non-proprietary Name
JV	Joint Venture
LHIS	Labor Health Insurance System
LMI	Labor Medical Insurance (state-and collectively, 1949–78)
LPGs	Lowest-Priced Generic Drug
MA	Medical Assistance (a social welfare program for poor families)
MAT	Moving Annual Time
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
MPR	Median Price Ratio
MRIs	Magnetic Resonance Imagery (a high-tech radiological imaging procedure)
MSAs	Medical Savings Accounts

NCMS	National Cooperative Medical System
NDP	National Drug Policy
NDRC	National Development Reform Commission
NEDL	National Essential Drug List (price caps on essential medicines, NDRC, 2009)
NEMS	National Essential Medicines System (established by MOH)
NHS	UK National Health Service
NICE	National Institute for Clinical Excellence, UK
NRCMI	New Rural Cooperative Medical Insurance
NRDC	National Reform and Development Commission
OECD	Organisation for Economic Cooperation and Development
PBMs	Pharmacy Benefits Management
PHI	Private Health Insurance
POU	Point of Use
PRC	People Republic of China, established in 1949
RCMS	Rural Cooperative Medical System
RHC	Rural Health Center
RUD	Rational Use of Drug
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
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

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**Exchange rate**  
6.82 RMB = 1 USD  
(May 1, 2010)

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# Executive Summary

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Pharmaceuticals account for approximately 40 percent of total health expenditure in China, a disproportionately high amount compared to most other countries. Pharmaceuticals are used—and overused—in ways that are neither financially nor medically efficient. With a rapidly aging population, they are likely to be a continuing driver of high costs. Thus, the Government of China has assigned high priority to pharmaceutical reform, including a forward-looking National Essential Medicines System (NEMS) announced as part of the major reform plan announced in 2009.

Essential medicines policies have been in place in China for nearly 20 years, yet their use has not gained much traction. Reinvigoration of the concept within the context of the national health reform plan represents a major step forward; however, structural impediments—which largely explain the lack of strong success in the past—remain in place and will need to be addressed for success in the future.

Section 2 of this paper discusses several structural impediments that will need to be overcome. Of these, the main problem is the provider payment system through which both institutions and individuals receive payments for health services and pharmaceuticals, including a supply chain in which distributors pay “bonuses” and “rebates” to prescribers who in effect serve as sales agents for manufacturers. Both health facilities and physician incomes have become reliant on the supplemental income that is received through this process. As a result, providers have a direct incentive to prescribe more expensive drugs and more drugs than are needed. These financial incentives exacerbate and are exacerbated by the widely held popular perception that essential medicines (which are almost entirely generic drugs) are not “as good as” brand drugs. The widespread perception of low quality is complicated by well-publicized failures in quality assurance, as well as the significant role played by pharmaceutical representatives at the service-delivery level in communicating the use and value of new drugs. These perceptions are further complicated by the lack of independent scientific assessment of drugs and medical technologies, and by inconsistencies and methodological difficulties in drug pricing.

Several factors are discussed for reforming this system based on lessons from recent reforms. These include the value of piloting itself, how essential medicines are selected, pooled (bulk) procurement, zero markup policy, and separation of prescription from dispensing of drugs. However, tools and insights from these experiences are unlikely to make a lasting difference unless deeper structural obstacles are addressed over the longer term course of reform.

Reforming the provider payment system—the most fundamental obstacle—will not be accomplished solely by prohibiting those who prescribe drugs from selling them directly or profiting from such sales indirectly. Changes are unlikely to be accepted unless revenue from drug sales is replaced by other sources of funding, such as direct subsidies, higher user fees, or higher insurance payments for medical services. Of these, the latter may be the preferable option as it does not increase the burden on patients and allows for inbuilt incentives to reward quality of care and efficient use of funds.

The government's current focus on an Essential Medicines Policy carries the risk of a protracted discussion on the definition of the term “essential” in the Chinese context, with significant differences in expectations between rural and urban populations. An elegant way to sidestep this discussion would be implementing a Generic Drug Policy—a necessary element of any Essential Medicines Policy—consisting of, first, changing the provider payment system to de-link income from drug sales; second, enforcing strict quality standards for generics; third, addressing perception issues among doctors and patients; and fourth, introducing incentives for prescribing and dispensing generics.

A generic drug policy along these lines would stimulate the market for high quality, low-cost generics and would increase the availability and affordability of drugs overall. The question “What is essential?” could be reframed as “Starting with providing basic services for the poor and taking into account a multilayered system, what is affordable and reasonable from the perspective of evidence-based medicine,?” This process would lead to a tiered reimbursement list, which over time and based on resource availability would generate a uniform list, further reducing the urban-rural divide in access to health care. The availability of reimbursement would also increase the supply of listed drugs without the need for further interventions. Stronger health insurance funds could use strategies adapted from other countries' experiences, using their bargaining power to obtain lower prices for generics and to limit the risk of cost increases from the introduction of innovative medicines. To ensure access to innovation without overburdening the system, an independent scientific review process for new therapies (Health Technology Assessment) could be considered, building upon experiences and lessons learned from other countries.

There is no country in the world that does not have problems managing its pharmaceutical sector. While certain conditions may be specific to China, other problems are familiar everywhere. The paper cites several examples of reform experiences from other countries that are potentially relevant to China. In particular, it looks at the effects of high levels of drug reimbursements (Romania) versus low levels (Bulgaria); conflicts of interest between the government wish to support the domestic drug industry and the need to achieve GMP standards (Iran); the use of market mechanisms to lower generic prices (Germany, and the United States); and the use of independent third-party scientific experts to provide guidance in assessing and adopting new essential drugs (United Kingdom).

The final section of this paper looks at the path forward—success factors for implementing an Essential Medicines program built on the cornerstone of low-cost generic drugs. The following key elements are discussed:

- A changed provider payment mechanism, including compensation for lost drug income
- Increased acceptance of generics among providers and patients—focusing first on ensured quality
- Flexibility to meet the demands of a multi-tiered drug market
- Pricing and reimbursement changes that allow market forces to play out
- Insurance funds as direct purchasers of health goods and services
- Promotion of generic drugs
- Independent scientific guidance on including new drugs into formularies
- Win-win negotiations with pharmaceutical multinationals
- Consolidation of the domestic pharmaceutical industry
- A long-term view on the need for broader systemic reforms

The World Bank strongly supports the direction of China's healthcare and pharmaceutical policy reform. It has been an active partner in the ongoing policy discussion for many years. Annex B of this paper list a number of concrete suggestions for continuing this partnership into the future.



# A Generic Drug Policy as Cornerstone to Essential Medicines in China<sup>1</sup>

## 1. The Challenge of Pharmaceuticals in the Context of Health Reform

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### Introduction

Compared with developed economies, health expenditure in China is not particularly high on a per capita basis or as a share of GDP. To the contrary, though rapidly growing, Chinese health expenditure is still relatively low. Similarly, pharmaceutical expenditure in comparative perspective is not particularly high on a per capita basis or as a percentage of GDP. Rather, the spending pattern that sets China apart from most comparators is disproportionately high pharmaceutical expenditure in relationship to total health expenditure. Pharmaceuticals account for nearly 40 percent of total health spending in China, compared with average rates of about 17 percent in most OECD countries.<sup>2</sup>

China's exceptionally high rate of pharmaceutical expenditure has important implications for the future of a health care system that not only serves a rapidly aging population, but

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<sup>1</sup> This policy note was prepared by the World Bank's China health team in Beijing and Washington led by Andreas Seiter, Huihui Wang, and Shuo Zhang in 2009 and early 2010. The paper draws upon and complements a more detailed paper prepared by Professor Shanlian Hu of Fudan University, "Financing, Pricing, and Utilization of Pharmaceuticals in China: The Road to Reform" (China Health Policy Note No. 1). The World Bank team wishes to thank Dr. Hu, several external reviewers, as well as comments on an earlier draft by Dr. Michael Borowitz of the OECD (Paris) and Dr. Shiyan Chao of the World Bank. Comments should be addressed to editor of the series, [jlangebrunner@worldbank.org](mailto:jlangebrunner@worldbank.org).

<sup>2</sup> Comparative statistical estimates on health and pharmaceutical expenditure (per capita, as a percentage of GDP, rates of growth, as a ratio to each other) vary considerably by source, methodology, and time period; so general patterns that are relatively consistent in the data, rather than precise numbers, are summarized in these opening sentences. For more detailed information and discussion of methodological issues in making such comparisons, see standard sources such as *World Development Indicators* (World Bank), *OECD Health Data: Statistics and Indicators* (OECD), the National Health Accounts website (WHO), as well as data for China published in *China Pharmaceutical Guide 2010* (Pharma China), various IMS health reports and forecasts (IMS), Government of China health statistics (Ministry of Health, various publications).

encourages overuse of drugs in ways that are both financially and medically inefficient.<sup>3</sup> Pharmaceutical reform is therefore a high priority for China's health policymakers. Along with the expansion of medical insurance coverage and the reform of public hospitals, the provision of "safe, effective, convenient, and affordable" pharmaceuticals is a central pillar in the ambitious national health-reform plan that the Government of China announced in April 2009.

The current healthcare and pharmaceutical reform builds upon strong political commitment, substantial financial commitment (850 billion yuan, equivalent to about US\$124 billion), and increasingly capable and accountable public-sector institutions. The reforms are strongly complemented by an increasingly strong private market for health services that is expected to increase the variety and competitiveness of overall offerings in coming years. The reforms incorporate significant learning from many pilot and demonstration efforts in recent years, as well as fruitful advisory partnerships with international partners such as the World Bank and the World Health Organization (WHO).

Health is a precious commodity, and health sector reform in any country is among the most difficult of political challenges. Few areas are quite so conducive to fear, misinformation, and political wrangling. The health sector comprises an enormous share of every economy, and it touches directly and often on the lives of every individual. Interest groups are articulate and powerful, and every major decision has sizeable financial implications. No area of policymaking faces a greater disconnect between industry goals for profit and government goals for broad, inexpensive, equitable access to costly goods and services—a disconnect that inevitably leads to distortions in the market and to particularly complex issues related to price controls.

The idea of essential medicines was championed by WHO starting in the late 1970s; and many countries, including China, translated it into policy by adopting Essential Drug Lists in the late 1980s and early 1990s. Despite nearly two decades of implementation, the notion of essential medicines has not had great practical impact on drug utilization and the pharmaceutical sector in China<sup>4</sup>—certainly not in delivering the original social vision for essential medicines: free (or nearly free), high-quality, easily accessible, basic drugs for the mostly treatable conditions that afflict large numbers of people, especially the poor.

By strengthening its approach to essential medicines and launching a new National System of Essential Medicines (NSEM) through the Ministry of Health, the government has taken an important step to control medical spending and improve efficiency in health care.

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<sup>3</sup> For more extensive discussion of utilization of drugs in China, including the question of "irrational" use of drugs, see "Financing, Pricing, and Utilization of Pharmaceuticals in China: The Road to Reform," China Health Policy Note No. 1 in the present series.

<sup>4</sup> World Bank, Health Policy Note No. 1. reviews history of Essential Medicine Policy in China, including rationale for reforms formally launched in April 2009, and phases in the development of China's Essential Drug List.

With this policy note, the World Bank’s health team is trying to stimulate the discussion and debate on how this can be done. In particular, it makes a pragmatic argument—that the government should implement a Generic Drug Policy, a cornerstone element of any Essential Medicines Policy. This would consist of changing the provider payment system to de-link health providers’ incomes from drug sales; enforcing strict quality standards for generics; addressing perceptions (and widespread misperceptions) about generics among doctors and patients; and introducing a set of incentives that would encourage broader prescription, dispensing, and utilization of low-cost generic drugs that comprise the core of the Essential Drug List.

The section following this introduction briefly reviews the expansion of basic medical insurance coverage in the 2000s and several structural features of the pharmaceutical sector in China. The related concepts of an essential medicines policy, an essential drug list, and a generic drug policy are briefly described. The second section of the paper looks at several hurdles that are built into the path of essential medicines reform. The most substantial of these is the present provider payment system and the nature of the pharmaceutical supply chain that channels Essential Drugs from manufacturers to health providers. Other structural impediments include the widespread perception among patients and physicians that essential medicines (almost entirely domestically manufactured, low-cost generic drugs) are primarily “poor people’s drugs” for those who cannot afford “better ones”; failures in quality assurance that unfortunately reinforce this perception; an unresolved role for traditional medicine; some complexities that have made drug pricing particularly difficult; and the rational (economic) basis for seemingly “irrational medicine.”

The third section considers some lessons for pharmaceutical reform based on China’s recent learning from regional experimentation and piloting initiatives. These include the value of piloting itself, how essential medicines are selected, pooled (bulk) procurement, zero markup policy, and de-linking health facilities’ budgets from their revenues from drug sales.

The fourth section considers several relevant lessons derived from reform experiences in other countries. In particular, it looks at the effects of high levels of drug reimbursements (Romania) versus low levels (Bulgaria); conflicts of interest between the government wish to support the domestic drug industry and the need to achieve GMP standards (Iran); the use of market mechanisms to lower generic prices (Germany and the United States); and the use of independent third-party scientific experts to provide guidance in assessing and adopting new essential drugs (United Kingdom).

The fifth section looks at the path forward—success factors for implementing an Essential Medicines program based on low-cost generic drugs. The key elements are:

- A changed provider payment mechanism, with compensation for lost drug income
- Increased acceptance of generics among providers and patients—focusing on quality
- Flexibility to meet the demands of a multi-tiered drug market
- Pricing and reimbursement changes that allow market forces to play out

- Insurance funds as direct purchasers of health goods and services
- Promotion of generic drugs
- Independent scientific guidance on including new drugs in formularies
- Win-win negotiations with pharmaceutical multinationals
- Consolidation of the domestic pharmaceutical industry
- A long-term view on the need for broader systemic reforms

The discussion draws upon several related concepts under the general rubric of essential medicines—essential drug lists, generic drugs, and essential medicine policies. These terms are widely used in the international health community, but also have China-specific meanings in this context. For clarity, several terms are briefly explained and differentiated in Box 1 (The Terminology of Essential Medicine Used in this Paper), on the facing page.

### **Health insurance and pharmaceutical coverage at the end of the 2000s**

By the end of the first decade of the 2000s, three parallel medical insurance systems will provide varying levels of coverage to most if not all urban residents, urban (migrant) workers, and rural residents of China. The two urban insurance systems are managed by the Ministry of Labor and Social Security (MOLSS) and the rural cooperative system is managed by the Ministry of Health (MOH). Official figures estimate more than 90percent coverage by the end of 2009.

All three medical insurance funds provide formularies to prescribers based on a single, centrally managed drug reimbursement list. Reimbursable drugs are grouped into Category A (fully reimbursable) and Category B (co-payment required). Local administrations have some latitude to determine the exact levels of reimbursements, which depend in part on their resource situation. This means that citizens living in poorer provinces are typically required to make higher out-of-pocket co-payments than citizens living in wealthier provinces.

Overall, more than half of all health expenditures (including both medical services and drug payments) are financed by patients' out-of-pocket expenditures. Experience from many countries confirms that a significant share of patients are less likely to follow through with medical advice and purchase drugs where co-payments are high, even though co-payments may not seem excessively high. This is especially true for illnesses that patients may perceive as minor—for example, asymptomatic hypertension. Poor patients are particularly tempted to ignore such conditions or pursue over-the-counter remedies rather than visit a health facility, spend time in the waiting room, and then pay for a visit as well as the drug co-payment. In such circumstances, the lack of fully affordable essential drugs effectively denies health care coverage, even though physical facilities and seemingly reasonable health insurance are available.

In implementing the April 2009 reform plan, the Chinese government is seeking to equalize public subsidies across insurance systems at the national level, with the objective of

**Box 1: The Terminology of Essential Medicine Used in this Paper**

As used throughout this paper, the term *essential medicine* broadly refers to the notion initially advanced by WHO and translated into policies by scores of countries, including the Government of China, since the 1980s. When capitalized in this paper, the term *Essential Medicines* (or *Essential Medicines Policy*) refers to particular policies. When capitalized, the term *Essential Drug List* refers to a list of specific medicines based on one of these policies during a particular historical period, versus the broader idea of such a list (uncapitalized). As of late 2000s, there were about 2,400 medicines on China's official Essential Drug List. However, with new thinking on essentials medicines that accompanied China's major health reforms of April 2009, this list was pared down.

The term National Essential Medicines (or Drug) System refers to a plan by the Ministry of Health to scale up an actual system to the national level over the coming decade. The system will be based on a particular Essential Drug List (EDL), which has been pared down from the previous undisciplined list. The notion of a minimal list of core drugs—selected on the basis of medical efficacy and low cost—is fundamental to the goal of universal health coverage, which relies on basic “packages” of core drugs and services that can be guaranteed to every citizen by continuous expansion and improvement of medical insurance coverage.

Virtually all medicines on the Essential Drug List in China are generic drugs. The term *generic* refers narrowly to any drug that is produced and distributed without patent protection. Drugs come off-patent after a legally defined period of time. A generic must contain the same active ingredient as the original patented formulation (referred to as the *originator drug*). The active ingredient is usually referred to as “the molecule” and the originator drug is referred to as “the innovative drug” in the Chinese context.

The relevance of generic drugs is that they are essentially identical to originator drugs from a clinical point of view. The term generic in no sense means counterfeit or illegal. Since the ingredients are essentially the same, differences in efficacy are either psychological or related to poor quality in manufacturing. (The generally accepted international GMP standard refers to Good Manufacturing Practices.) Other differences between generic and originator drugs primarily have to do with branding, packaging, effects of secondary ingredients (slow-releasing and so forth), and more importantly, who profits and how.

In addition to the legal and pharmacological meanings, the term generic has implications that are important in the context of the present discussion—economic implications (because they are off-patent, they are less expensive and therefore a better use of public funds); public health implications (they can be targeted at particular diseases with population-level health strategies); and political importance (their use tends to be strongly associated with wealth differences).

The term Generic Drug Policy that is used here does not refer to a particular generic drug policy. Rather, it refers to the process of narrowing a selection of drugs to a smaller specific list of essential medicines taking into account the broad range of legal, pharmacological, economic, public health, and political implications that are discussed above. This is a process that would go hand in hand with the evolution of a national Essential Medicines System to be implemented over the coming decade.

of the reducing discrepancies in benefit levels. One difficulty with standardizing pharmaceutical reimbursement rates is that provincial authorities are allowed to substitute up to 15 percent drugs on the central list reimbursement based on regional differences in health risks. While this flexibility is understandable and possibly necessary, it has also led to uncertainty and perceived ambiguity because the central list actually includes different drugs with different prices in each province.

In addition to the three health insurance funds, the Ministry of Civil Affairs operates the Medical Assistance (MA) program, which accounted for nearly 0.5 percent of China's total health expenditure in 2006. Medical assistance is a form of social welfare that is provided where medical costs are potentially unmanageable and threaten families with poverty. Applications are managed on a case-by-case basis. Allocations depend on income and whether a household meets certain social criteria. The program lacks specific rules for drug reimbursements.

### **Manufacturing, distribution, and where drugs are sold in China**

As of March 2009, 4,682 pharmaceutical manufacturers were licensed in China, including manufacturers of traditional Chinese drugs. Most are small companies that manufacture non-branded generics as well as traditional Chinese drugs. The largest group of producers is located in the southeastern region of the country, and the rest are relatively evenly dispersed. The sector is dominated by basic technology and simple production methods. Many of the larger producers are government-owned enterprises characterized by overproduction, outmoded methods, and constant operating losses. The very large number of government-owned producers raises the potentially thorny question of conflict of interest, as manufacturers and regulators report to the same government authorities. There is relatively little R&D and innovation, a weakness that the government is attempting to change, especially by encouraging joint ventures with multinational companies.

The thousands of domestic producers account for about 70 percent of the market (in terms of value). The 10 largest domestic companies account for only about 20 percent of the market (*Business China* 2009), in contrast to most OECD countries where the 10 largest companies typically dominate the market. Despite the relative backwardness of the industry, the balance of the domestic market and the size of the export market have steadily been shifting in favor of the domestic producers.

Multinational drug manufacturers view China as an opportune and important market—based on its sheer size (estimated to be the third largest prescription market in the world by 2011).<sup>5</sup> Faced with restrictive drug policies and sophisticated cost-containment strategies in their own markets, virtually every major international manufacturer has a presence in China,

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<sup>5</sup> Market data are from IMS Health, an international firm that specializes in sales data and consulting services to the pharmaceutical industry.

usually through joint ventures. These enterprises employ sophisticated teams of marketing professionals, sales representatives, and lobbyists. RDPAC, the association of research-based multinational manufacturers, reports that half of their members' revenues come from innovative drugs. The other half comes from the sale of well-known off-patent generic drugs, which have large followings among patients and health professionals.

With an estimated 110,000 wholesalers and distributors, pharmaceutical distribution is also highly fragmented and fiercely competitive on the ground. In general, pharmaceutical distribution is considered to be a business that demands economies of scale for efficiency and competitiveness. Massive consolidation has taken place in most OECD countries—for example, in Europe where only a small number of large, fully integrated, highly automated players remain. Based on the large number of wholesalers and distributors, it is probably safe to infer that China drug purchasers are paying considerably more for pharmaceuticals in both absolute and relative terms than their counterparts in other countries.

Unlike other countries, retail pharmacies in China play only a minor role in the pharmaceutical market. According to WHO, about 80 percent of all pharmaceuticals are sold through hospitals and health centers. These facilities typically generate significant operating losses as a result of underpriced medical services. They partially offset these losses through a net positive balance from selling the pharmaceuticals that they prescribe. Without this supplementary income, public hospitals and health centers would operate at a loss overall (see World Bank Health Policy Note No. 1, 2010).

In rural areas, there are few private retail pharmacies to fill the gap if hospitals and health centers were to stop dispensing medicines. Even in urban areas, few pharmacies operate modern online systems that would enable them to easily consolidate distribution systems and large databases (if such databases existed) containing the latest information on drugs, availability, and insurance reimbursements. While the blurring of roles between prescribers and sellers indisputably creates a conflict of interest, as a practical matter it is not easy to imagine a quick separation of roles along the lines of the “Western model.”

### **Essential Medicines, the Essential Drug List (EDL), and low-cost generic drugs**

Box 1, above, provides some definitions and distinctions in concepts relating to essential medicines, essential drug lists, and low-cost generic drugs. However, the simple principle underlying essential medicine policy is to provide least-cost/high-quality drug therapies for the most common and treatable health threats afflicting a population. Essential medicines are oriented toward large populations in developing countries, especially the poor. An essential drug list is the practical means for operationalizing essential medicines policies. A country's essential drug list needs to be tailored to primary causes of disease and mortality, as well as to the financial capacity of the health system to provide the broadest possible foundation of affordable, equitable care. Virtually all essential drug lists are based on the use of generic drugs, a challenge that often requires considerable negotiations with

manufacturers whose innovator drugs may not necessarily be off-patent (recently developed drugs to treat HIV/AIDS, for example).<sup>6</sup>

China has had a system of essential medicines in place since early 1993, and updates its Essential Drug List every two years. As of 2007, there were 2,400 essential drugs on the list. Yet despite a history of nearly 20 years in China, the use of essential drug lists has still failed to gain traction in hospitals and other treatment facilities. The reasons are discussed in this paper—misperceptions about “quality” among providers and patients; lack of enforceability of quality standards; and most importantly, financial incentives that reward prescribing drugs not on the list.<sup>7</sup>

A new system of essential medicines was included in the medical reform announced in April 2009. The State Food and Drug Administration (SFDA) was tasked with raising the production standards of all 307 national essential drugs, and the National Development and Reform Commission (NDRC) was made responsible for monitoring the supply and demand of essential drugs, and adjusting retail prices as necessary. Implementation of the system has been strongly endorsed and given added impetus through widely reported comments by President Hu Jintao in May 2010 following public uproar over reports of cancer drugs earning profits as high as 2,000 percent.<sup>8</sup>

In its first phase of implementation, the National Essential Medicines System (NEMS) was oriented toward the rural population. As of March 2010, the plan designates 1,020 counties (35.7 percent of the total in China) to be covered under the new system. This includes about 18,000 state-owned community health centers, about 38.7 percent of the country's total. The ministry aimed to promote and extend essential medicines to about 60 percent of the facilities in these counties by the end of 2010.

The essential drug list (EDL) included nearly 2,400 drugs as of 2007. In August 2009, the ministry issued a list of 307 essential drugs as part of its plan. The EDL is to be adjusted every three years.

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<sup>6</sup> A great deal of information is available on the history and guidelines for developing essential medicines policies—in particular, through the World Health Organization. The Medicines Transparency Alliance (MeTA) has generated considerable analytic work as well as practical tools in policy areas such as generics, transparency in procurement of essential drugs, monitoring pharmaceutical prices, and so forth. Such materials are readily available as part of the Advanced Technical Briefing course organized by the Medicines group in Geneva.

<sup>7</sup> These reasons are discussed in greater detail in World Bank 2010, *op cit*.

<sup>8</sup> Many examples of evident profiteering on brand drugs have been reported in the press—for example, Lusun pian, a medication to alleviate symptoms of cancer, sold for 213 yuan (US\$31) per box, a selling price nearly 14 times that of its production price of 15.5 yuan (see People's Daily Online, May 31, 2010). Similarly, state-run CCTV has reported an 8 milligram dose of the cancer treatment, Ondansetron hydrochloride, which costs less than 4 yuan to produce, being sold in Northwest China's Shaanxi province for 80 to 90 yuan—a markup of 20 times the production cost.

## 2. Structural Impediments to Essential Medicine Policy

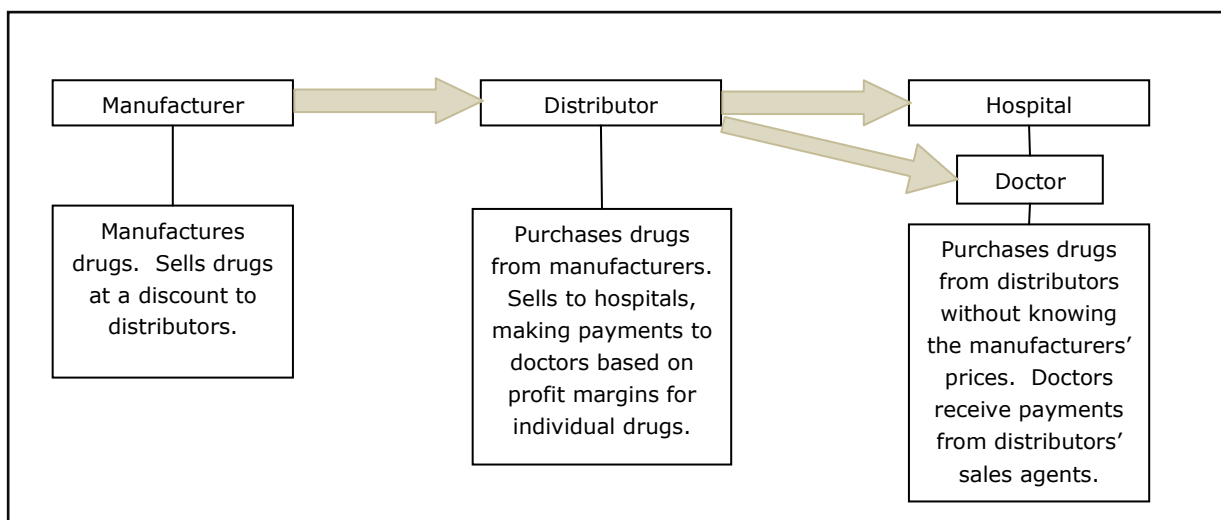
The National Essential Medicines System (NEMS) represents a significant advance, but implementation will encounter many structural hurdles on the road to reform.

### The distribution chain and the provider payment system

The pharmaceutical supply chain between drug manufacturers and patients, and the way that health providers receive payment for drugs, are major sources of overly high cost and medical inefficiency in the use of drugs in China.

Figure 1 illustrates the typical supply chain for drugs sold in public hospitals and community-level health facilities: many small manufacturers sell to distributors, and distributors sell to hospitals. Most of the 2,400 drugs on the essential drug list (as of 2008) are sold and distributed through this mechanism.

**Figure 1: Prevailing Pharmaceutical Chain for Public Hospitals and Health Providers**



(An alternative model to the one described above, “Figure 3: Reformed Supply Chain [Pooled Purchasing] for Generic Drugs”) is discussed below in Section 5 (See “Pricing and reimbursement changes that allow market forces to play out”).

The pharmaceutical market is fiercely competitive in China. Distributors occupy a critical niche as intermediaries between manufacturers and providers. Under this pharmaceutical business and distribution model, there is little incentive for manufacturers to increase their profitability by improving quality or lowering production costs. Rather,

manufacturers become more competitive by developing personal relationships with health providers through distributors, who act as their agents in paying “bonuses” or “rebates.” Distributors are selected for their personal connections to hospital pharmacies and doctors.

Cost-cutting initiatives, such as essential medicines, tend to fail in such environments, because the distribution system and provider-payment model itself create financial incentives for overprescription and expensive prescription.

### **Essential medicines (especially low-cost generics) are perceived as lower quality**

Medicine is a field where science maintains a sometimes uneasy coexistence with personal belief systems. Every doctor knows that interactions with patients are not simply about medical evidence, unambiguous diagnoses, and textbook prescription. The healing process is influenced by seemingly “irrational” factors, including mysteries such as the placebo effect. Indeed, patients seek healers who offer human insight and empathy as well as scientific knowledge.

In the psychological and perceptual realms, the choice of a drug to purchase (or prescribe) is influenced by factors that go beyond the efficacy and side effects that are established by clinical testing. Origin, name, packaging, shape, color, and cost can all affect how a patient responds to a particular drug. Manufacturers understand this, and make use of the full range of “attributes” in marketing their products. When thinking about their health, drug purchasers are quick to believe manufacturers who say that “you get what you pay for.” Thus, high cost can be reframed as a *positive* attribute, especially for wealthier or desperately ill patients. Patients take their cues from price. High cost is viewed as evidence of efficacy.

Perceptions of this sort pose a particular challenge for pharmaceutical policymaking, which is based on the opposite assumption—that all other things being equal, low price is better than high price. Governments are unwilling to spend limited public resources to purchase expensive brand-name drugs if generic versions manufactured to high standards produce approximately the same health outcomes, only at lower cost. Yet while this approach may be “rational” in terms of policy, policies that promote generics inevitably confront acceptance problems, especially when misinformation is strongly reinforced by marketing and financial incentives. The notion that generic are “poor people’s medicine” is strongly embedded everywhere, and a particular challenge for policymakers.

### **Failures in quality assurance**

The pharmaceutical industry in China is dominated by non-branded generic manufacturers who for the most part use basic technology and simple production methods. While generics in principle are medically equivalent to their brand counterparts, the perception of quality differences is not entirely a matter of misinformation. Until fairly recently, substandard production methods was taken for granted—in many cases, with dozens of fake and counterfeit varieties of well-known drugs.

The internationally recognized Good Manufacturing Practices (GMP) standard is a system to ensure that products are consistently produced and controlled according to quality standards. A directive issued by the Ministry of Health in July 1995 marked the official launch of GMP certification in China. Adherence to GMP standards is considered essential to both the health of the Chinese people and to success in the export market.

The Chinese Food and Drug Administration (SFDA) regulates the pharmaceutical sector. SFDA has established a code of GMP adherence that all manufacturers must meet to maintain their licenses. Enforcement efforts have resulted in several licenses being revoked in recent years. Central SFDA inspectors conduct surprise inspections to ensure that provincial inspectorates enforce standards consistently. The plan is to bring GMP requirements in line with international standards by 2011.

Addressing the quality-perception issue remains a fundamental barrier to implementation of any pharmaceutical reform based on increased acceptance of generic drugs. However, experiences from developed countries show that long-term efforts can gradually overcome these perceptions, assuming that the quality issue is addressed through relentless quality enforcement as well as physician and patient education on the value of generics.

### **An unresolved role for traditional medicines**

All countries have traditional medical systems based on their history and culture. The Chinese system of traditional medicine is well developed and widely practiced. Several universities conduct research in traditional medicine, and many “modern” treatments have their roots in traditional Chinese preparations.

Traditional medicine is inextricably linked to doctor-patient interaction, in contrast to western-style medicine where pharmaceuticals are typically viewed as separate inputs that work independently of drug prescribers. Traditional medicine, in contrast, provides personalized health care corresponding to Chinese patients’ expectations of being treated as individuals.

Traditional Chinese medicine cannot be discounted or banished to a gray area of “alternative” methodologies outside of the official provider system. Rather, it is complementary. On the other hand, giving traditional medicine a fair chance (if public funds are used) also means that it should be evaluated with objective criteria—for example, health outcomes, medical risks, and its cost–benefit ratio relative to modern healing methods.

### **The pricing of essential medicines**

The Ministry of Health has regulated the prices for virtually all Essential Drugs for many years. (For other drugs, price regulation is far more uneven.) The purpose of price regulation is to ensure affordability and availability of essential drugs, yet price regulation is a complex undertaking. Many efforts have backfired with results opposite from their intended effects—resulting in reduced usage, or even disappearance of regulated generics from the

market. Price ceilings, for example, are a common method for limiting what can be charged. In a given transaction, a buyer and seller can agree on a lower price (for example, if a large bulk purchase is involved), but not on a higher price. Another method of price regulation is to limit the profit margin that sellers can earn using a cost-plus formula based on the manufacturer's production price or the distributor's wholesale price. Yet in either case—where the selling price is capped, or the profit margin is limited—sellers can determine that financial returns are too low. They either withdraw their products from the market; or if this is explicitly prohibited, fail to market them aggressively. One way or another, patients are left with no access to lower-cost generics, so higher-price versions are restored and overall expenditure returns to “normal.”

Manufacturers frequently respond to price controls by marginally changing or rebranding established products whose active ingredients have not changed, because new drugs enjoy a higher degree of pricing freedom. Depending on the restrictions to be avoided, a “new drug” can be created through new dosage or quantity of active ingredient, additional ingredients (active or not) that change some aspect of the drug, or even packaging. The frequency of this practice is suggested by the fact that SFDA received 37,449 applications for drug registration in 2004, of which roughly half were approved.

Under these circumstances, it is not difficult for manufacturers or marketers of drugs, including generics, to stay ahead of price regulators by producing new “latest products.” Demand can be shifted to more-expensive products so long as different classes of drugs enjoy different degrees of pricing freedom. A good case in point is the use of modern cephalosporins instead of penicillin. So long as health facilities prescribe, dispense, and earn significant profits from selling essential medicines, regulation alone is unlikely to secure optimal prices for buyers.

Such practices have increasingly been discouraged or forbidden in recent years; however, in one form or another, the central features—displacement of demand in the direction of higher-priced items—continue. According to 2008 IMS and WHO, different brands of the same molecule can differ in price by many orders of magnitude. If the price of the best-selling molecule was 100, for example, researchers often found the originator brand selling between 200 and 250, and the cheapest generic was found selling between 30 and 50.<sup>9</sup>

Insurance reimbursement ceilings are often more appropriate as regulatory tools than direct price controls. Reimbursement ceilings can be particularly effective where insurance funds pay large shares of overall drug costs. Many countries have experimented with insurance reimbursement ceilings, which have been found to equalize prices, typically because competitors reduce their prices to or just below the ceiling (if patients perceive all drugs to be otherwise equal).

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<sup>9</sup> See WHO/HAI pricing survey, China, 2008; and MSH Drug Price Indicator Guide (Management Sciences for Health, [http://erc.msh.org/dmpguide/pdf/DrugPriceGuide\\_2008\\_en.pdf](http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2008_en.pdf)).

While reimbursement ceilings can drive prices to precisely that point, they have the disadvantage of not stimulating competition beyond that point and driving prices even lower. To keep this from happening, competing manufacturers adopt marketing strategies to incentivize the supply chain. They crowd out competitors with “bonus” offers (“Buy 100 packs and get 50 free!”). If this works, distributors increase their profits at the expense of payers and manufacturers.

Market forces generally prove to be the best method for finding the socially optimal point where consumers pay the lowest possible price at which producers are still able to make profits. However, this works only where buyers and sellers have equal access to information and neither is under undue pressure to buy or sell.

Effective procurement (discussed in Section 3) is a price control method that relies on market forces. Large institutional buyers gain advantage through pooled procurement. Groups of small buyers can obtain the same advantages by pooling purchases “virtually.” This can be done by setting up a framework contract to specify goods, prices, delivery, terms of payment, warranties, and complaint procedures. Individual facilities, such as community health centers, then order directly, paying suppliers according to the terms of the contract.

New life-saving drugs are constantly being developed, and they pose particular pricing challenges. Innovative drugs are invariably expensive, not only because alternatives are not available, but because manufacturers try to recoup their research and development (R&D) costs as quickly as possible. Manufacturers typically set global price bands, and they are seldom willing to make large concessions on published list prices. In part this is because many countries adopt external referencing methods to set prices that can be paid for these drugs; they obtain price information from several countries and set the price nationally based on the median or the lowest level observed. Large buyers such as governments and major insurance funds can sometimes address this concern by negotiating confidential agreements in which the “official price” is preserved but the buyer is granted substantial rebates.

Governments or insurance funds may limit the upside risk of total expenditure from a new drug by agreeing with the manufacturer on certain clauses about drug prices. In exchange for quicker cost recovery, a manufacturer can agree to reduce a drug price, or even provide it free, once a certain sales volume has been met. Similarly, some manufacturers will consider differential pricing—for example, the manufacturer sets its desired price for the wealthy segment of the market, but provides the drug at marginal cost or free to programs that target the poor. For China, such considerations could be relevant for medical conditions that affect both the wealthy and the poor, such as hepatitis B and C. While biological treatments have been developed, at current market prices they are unaffordable for poorer patients and their insurance funds.

### The rational (economic) basis for “irrational” medicine

“Irrational” medicine refers to overuse, medically inappropriate, or financially inefficient use of drugs. There are countless examples, ranging from innocuous folk remedies to highly sophisticated but unnecessary surgical procedures. Typical Chinese examples include drug delivery by intravenous injections; use of two or three drugs when one will do; overuse of antibiotics; a preference for advertised drugs, familiar brand names, and the belief that higher price means 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 general preference for and overconfidence in expensive drugs is only one example. Many patients have strong opinions related to *how* medicines are delivered. Injections are widely overused even where oral treatment has been shown to be effective. Similarly, parallel use of too many drugs—with no positive synergistic effects (referred to as polypharmacy)—is also extremely common.

At the same time, noncommunicable diseases—diabetes and hypertension, among others—are *undertreated* relative to accidents and more visible infectious diseases. Considerable evidence shows that patients suffering from chronic noncommunicable diseases receive hospital rather than appropriate secondary care on an outpatient basis.

Until recently, nongovernmental medical groups and Chinese health authorities did not treat irrational drug use as a reform priority, but this is changing. Irrational drug use is a problem not only with respect to medical safety and quality of care; it represents a waste of financial resources and a significant opportunity to contain individual and system-wide costs.

To a some extent, dealing with medically ineffective and overly expensive patterns of prescription starts with continuous medical education on the appropriate use of drugs, a function now largely relegated to drug company representatives. The MOH in 2009 developed a series of 150 clinical guidelines on the use of particular drugs and procedures. However, the misuse of resources is not simply a matter of medical education and dissemination of treatment guidelines.

On the other hand, irrational drug use is not entirely driven by medical naiveté among patients or lack of information among physicians. There is a “rational” basis in the narrow sense of financial self interest: physicians and health services overprescribe because they have economic incentives to do so—all the more because fees for medical services (a system based on similar incentives leading to high cost) are particularly underpriced relative to pharmaceuticals. Similarly, the bias toward more expensive hospital-based care, especially for chronic conditions, may be “irrational” in terms of overall health system efficiency, but not from the perspective of providers who lack financial incentives to manage chronic conditions on a continuous basis using low-cost generic drug therapies. In such cases, low medical knowledge among patients is a convenient justification, not an explanation.

## 3. Lessons from Piloting Pharmaceutical Reforms

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The government's 2009 reform effort is not the first effort at pharmaceutical reform in China. The government has worked on this challenge over many years in cooperation with academia and other stakeholders. The current plan represents a set of mature ideas and guidelines that have been informed and validated with pilot testing throughout the country. This section briefly summarizes some key aspects of learning from these experiences.

### The value of piloting

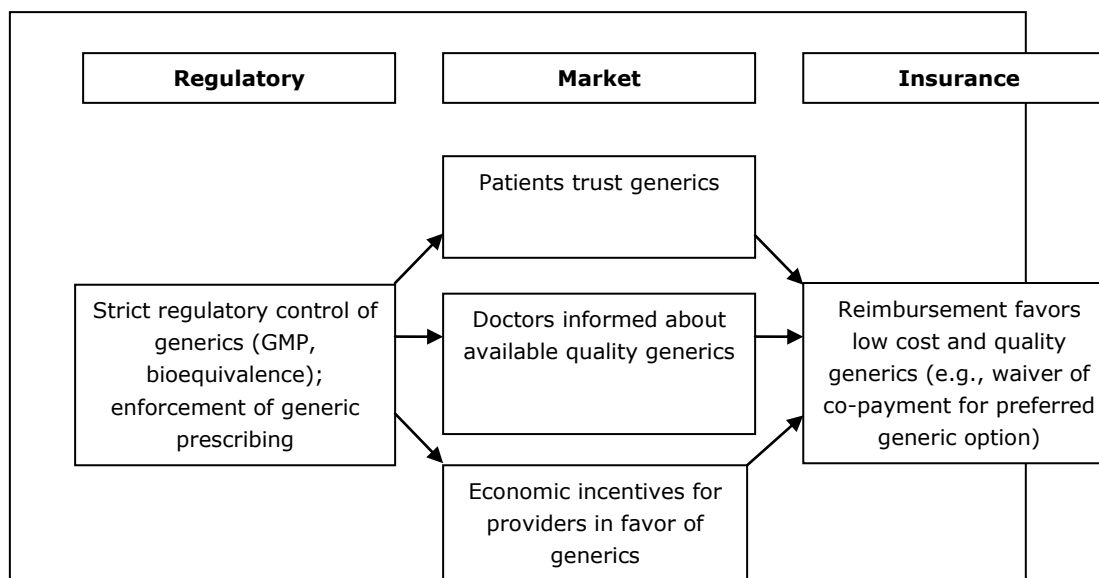
Something has been learned about learning itself. Testing an idea in a pilot setting has become standard practice in China, and has been criticized as a way of avoiding rather than implementing change. Yet in a large diverse country such as China—but in any setting defined by complex interactions among many interlinked parameters—pilot testing is a prudent course for moving forward. Complex realities cannot be modeled with precision in a lab. Early prototyping of new concepts is the best way to study their impact before taking the risk of full implementation. Adjustments can be based on real observations until the model has the desired effect.

### How essential medicines are selected

Essential medicines policies are all based on the use of essential drug lists, which serve as formularies specifying which generic medicines are to be recommended, supplied, or reimbursed in particular situations. A formulary lists only generic names, forms, and dosages of particular drugs.

Prior to establishing a formulary to be used as an essential drug list, there is a selection step specifying particular products and their set prices. This step of linking drugs to price is important for the cost-effectiveness of the essential medicines policy. This list is understood to represent judgments on price (“value for money”) as well as efficacy judgments. In effect, the list is an interpretation and concrete manifestation of a broad range of policy objectives.

Figure 2 shows the elements of a typical generic drug policy, as applied in countries that do not limit reimbursements only to Essential Medicines (e.g., Germany and the United States).

**Figure 2: Dimensions of Successful Generic Drug Policy**

How well does the model in Figure 2 apply to China? In general, it appears that most elements of a successful generic drug policy are still missing or incomplete:

- Enforcing regulatory standards has made good progress, but quality is still a concern. Neither doctors nor patients are convinced of the quality and efficacy of generics.
- Doctors continue to prescribe drugs by brand name, not generic name.
- Economic incentives work against low-cost drugs.
- Originator brands are heavily promoted despite the availability of lower-cost generic options. Pricing policy continues to favor originator drugs.
- Reimbursements and co-payments could be used to create stronger incentives for patients to choose generics over costlier alternatives.

There is a general assumption that essential medicines are cheap and available as generics. However, disease patterns can change, and new treatments are constantly being discovered. Thus, “essentiality” is a fluid concept demanding continuous reassessment in light of ongoing scientific and economic progress—just as diseases that can be inexpensively treated today were considered intractable a few years ago. This fluidity of concept is particularly relevant for China, where a growing middle class increasingly expects living standards similar to OECD levels.

Assuming that the Essential Medicines list serves as a model formulary for insurance reimbursement and facility procurement, a decision-making process is needed to assess the medical importance and cost-effectiveness of novel drugs. As of early 2010, medicines on the model reimbursement list are selected through a two-stage review process by expert panels randomly chosen from a pool of experts. Various academic disciplines contribute to the review. The process is repeated at the provincial level and sometimes at the facility level.

Pharmacy and Therapeutic Committees decide on actual reimbursement rates. Despite inconsistencies in the operating procedures for these committees, parallel anticorruption efforts have created a more restrictive environment in general. Manufacturers must pass many hurdles before they are granted market access.

The newer generation of drugs is not clearly linked to the Essential Medicines policy because they are broadly viewed as “beyond essential.” But are they? Other countries have adopted evidence-based approaches to address this question. High-level scientific bodies systematically assess new therapies and medical technologies using defined assessment methodologies, and based on subsequent findings, they issue guidelines on new product use. Guidelines of this sort are not necessarily binding on the specific formulary decision. Managers and decision making committees might lack the resources needed to include new products in their formularies, independent of whether they are useful and cost-effective. Similarly, decision makers may decide not to expend limited bargaining power that might be required to gain price concessions that would make use of these products feasible. Yet one way or another, there is at least a transparent process, and a defensible basis for decision. The overall process becomes more predictable, depoliticized, and less subject to accusation.

### **Pooled procurement**

The quality of public procurement is particularly important in China because such a large share of drug purchases are made or determined by publicly controlled health providers. Theoretically, pooled procurement and high-volume purchase of equally effective, lower-price generic drugs should produce better medical care at lower cost. In principle, benefits could be realized—at national, provincial, and even city levels—through clean, efficient, and open procurement. Pharmaceutical suppliers could be prequalified for competition based on their size and capacity, proven ability to deliver, financial strength, and assured compliance with GMP standards. The reality of public procurement is less straightforward. Contracts are often awarded for different reasons—such as kickbacks from bidders to influential officials, or rigging by suppliers who form cartels to divide up the market, deciding among themselves who will win particular competitions.

Pooled procurement has been introduced by regional entities (such as health bureaus and hospitals), particularly for drugs on the Essential Medicines list. As of late 2009, there was no central database for information on procurement prices and conditions. If pooled procurement is conducted properly, with close scrutiny to ensure fair and open competition, pooled procurement can reduce drug costs. Buyers and suppliers can collect sufficient information and establish necessary trust to reach optimal efficiency within a few procurement cycles. However, pooled procurement (whether through physical acquisition of goods or through framework contracts favoring certain preselected brands) also narrows brand diversity. Accompanying measures are needed to increase trust and acceptance of selected medicines among health providers and the patients who will use them. In an

environment where regulatory authorities are already suspect, a prequalification mechanism can help close confidence gaps in regulatory oversight. This also discourages prescribers from behavior that undermines the objectives of procurement and essential medicines policy—for example, by shifting demand toward more expensive drugs, or inducing patients to pay out-of-pocket for drugs that are not on the formulary.

### **Zero-markup policy**

In pilot initiatives to test the implementation of zero-markup policies, provincial or regional governments have provided financial subsidies to health facilities in exchange for eliminating mark-ups that they otherwise receive on basic drug sales. Not all basic drugs are covered; in fact most are not.<sup>10</sup> However, the zero-markup experiment is a partial success. A critical factor in this success was de-linking facility budgets and staff salaries from drug revenues and profits. Significant efforts were made to address perception barriers, to teach principles of rational use of medicines, and to promote the basic drug list wherever possible.

### **De-linking health facilities' budgets from their revenues from drug sales**

In 2005, the Ministry of Health piloted separation of primary providers' revenues from the fees that they generate. All revenues from user charges were turned over to the government, which in turn provided a fixed budget for volume-adjusted operating expenses. This was also piloted at the CHC level in Shanghai, Tianjin, Hangzhou, and Chengdu. Although this system may reduce the prescription of unnecessary drugs and tests, it remains to be seen whether new incentives will 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 along with an initiative to uncouple operating revenues to the health facilities from the volume of charges for services and drug sales to patients.

In the Nanjing pilot (Annex A), basic drugs were sold with zero price markup. Sales revenues were collected and aggregated at the district health bureau. The health centers then received budget allocations based on their requests and the availability of funds, but with no direct link to drug revenues generated by their pharmacies. Doctors and nurses received base salaries, topped up by government subsidies and bonuses based on medical services revenue. No drug representatives visited the health centers, and no bonus payments were made for prescribing drugs. Basic drugs were centrally procured by the municipality. All other drugs were procured under contract with a local distributor, which generated savings over the previous system of shopping from various suppliers. Medical staff received regular training on rational use of drugs. At the next stage of the pilot, the municipality will set up a pilot center in which the use of basic drugs will be increased stepwise to 90 percent.

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<sup>10</sup> In two facilities that were visited in Nanjing, for example, only 20 to 30 percent of basic drugs were found being sold at cost.

## 4. Reform Experiences from Other Countries

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There is no country in the world that does not have problems managing its pharmaceutical sector. While certain conditions may be specific to China, other problems are familiar everywhere. The World Bank has advised many countries in this area, and can draw on both positive and negative experiences from a broad range of countries.

### **Bulgaria and Romania: High versus low levels of drug reimbursements**

These two neighboring, economically comparable, new EU member states have adopted different approaches to reimbursement under their central public health insurance funds, which cover most of their citizens.

In Romania, an expert-driven mechanism was put in place, making it easy for companies to qualify for reimbursement for new, expensive drugs. Reimbursement rates are high; co-payments are low or not required, depending on a patient's health status and economic condition. Physicians gladly accept and prescribe new drugs. The top-20 drug list has several high-price drugs (such as PEG-interferon) at the top, although relatively few people need them. Some medically obsolete drugs are widely prescribed, absorbing a significant share of insurance funds. Due to a lack of controls, insurance fraud by private providers is common. For example, a physician prescribes four drugs for a patient, but the pharmacist finds an excuse to dispense only three—with the pharmacist collecting reimbursement for all four and sharing fraudulent profit with the physician. Not surprisingly, the cost of drug reimbursement has risen at more than twice the rate of GDP growth. At the end of the year, the insurance runs a deficit, which must be balanced by the ministry of finance.

In Bulgaria, health insurance is managed under a strict budget that limits the amount that can be spent on drug reimbursements. Per capita reimbursement expenditure is significantly lower than in Romania. To stay within budget, all drug reimbursement rates are limited to 50 or 25 percent (with the exception of a few, highly essential, life-saving drugs). Patients thus have high co-payments. As drug prices are relatively low compared to other European countries, many patients prefer to buy over-the-counter prescription drugs (illegal, but without sanctions), rather than spend time and money to see a doctor to obtain a reimbursable prescription. In general, health insurance is not perceived as a relevant social benefit. Indeed, there is political pressure from the neo-liberal political wing to replace social health insurance with a fully private system.

Both countries show that expectations concerning health insurance need to be carefully managed, and providers need oversight. While too much generosity can lead to financial problems, too much restriction on benefits can undermine public acceptance of the insurance model altogether.

### **Iran: Conflicts of goals between fostering domestic industry and GMP enforcement**

Iran has a domestically dominant, high-volume drug industry that is protected by high import tariffs. The industry manufactures generic drugs for domestic consumption. Prices are very low by international standards. Most drug companies are under a holding that is owned by the health insurance fund, which itself is controlled by the Ministry of Health (MOH). The minister of health appoints the chairman of the holding company. Prices for domestic drugs are set by the MOH, which is under political pressure to keep drug prices low. Because of low prices, companies lack the financial means to make upgrades necessary to achieve GMP standards. The MOH also regulates manufacturers; but knowing that many publicly owned companies would have problems meeting stricter standards, it hesitates to enforce GMP. Company management has been trained over many years to focus on the bureaucracy rather than increasing efficiencies or reducing production costs. The MOH has recognized the numerous conflicts of interest. It plans to expose manufacturers to market conditions gradually, by reducing import tariffs and by raising prices for GMP-adherent products. It is also considering modifying legislation that would facilitate mergers and foreign investment in the drug industry.

### **Germany and the United States: Market mechanisms for lower generic prices**

Germany has several social health insurance funds operating under one framework and offering comparable benefit packages. Drugs are reimbursed with a flat co-payment (prescription charge) of five euros. There has been a campaign to increase the use of generics, and compared to other EU countries, the percentage of generic prescription is high. Previously generics were reimbursed up to a ceiling, which was set by a formula based on market prices (manufacturers are free to set their prices). Once the reimbursement ceilings were defined, all manufacturers set prices at or slightly below the ceilings, thereby avoiding the need for additional co-payments that patients would have to pay on top of the flat fee. Most originator brands also lowered prices to the ceiling level. (Many German doctors and patients still prefer the original, but not enough to pay a premium.) The result was a market with static prices around the reimbursement level and manufacturers competing by offering incentives to distributors. As pharmacists have room for only one or two generics for each molecule, shelf space becomes valuable and defines market share. Incentives to distributors and pharmacists eroded manufacturers' profit margins, with no benefit for insurance funds or insured patients. Subsequently the rules changed. Today,

insurance funds can waive co-payments for generics priced 30 percent or more below the reimbursement ceiling. This creates an incentive for patients to ask for the cheapest generics. Many manufacturers have responded by lowering their prices under the new threshold. At the same time, all rebates, bonuses, and discounts to distributors have been prohibited. The new policy shows that discriminatory co-payments can create market pressure on generic drug markets—if (as in Germany) all drugs are perceived as the same, and if patients are sensitive to variations in co-payments.

In the United States, pharmacy benefit management companies (PBMs) use similar techniques. PBMs serve as intermediaries between insurers, suppliers, and patients. Unlike in Europe or China, drugs are dispensed in generic plastic bottles, with the pharmacy technician counting out pills from a bulk package. Patients wait to pick up their prescriptions, and do not become accustomed to particular packaging. Reducing the branding power of manufacturers increases acceptance of generics. Another factor is the high public visibility of the US Food and Drug Administration (USFDA), which inspires confidence that what is being sold in US pharmacies is safe and of good quality.

The PBMs contract with major suppliers; and if patients receive generic drugs, their average co-payments are around 10 percent lower than for branded drugs (lower by 20 percent or more, depending on the scheme). Generic drug prices are quite low in the United States, with several pharmacy chains now offering about 300 different generic drugs at the retail price of about US\$4 per month. Thus, the absolute difference in co-payment between a generic and a comparable brand drug can be quite significant.

### **United Kingdom: Independent Health Technology Assessment (HTA) and guidance to payers (NICE)**

The United Kingdom was among the first countries to systematically address the problem of including new drugs in its National Health System (NHS) benefits package. NHS does not decide alone in a situation of conflicting objectives—between, say, financial sustainability and optimal care. An independent body was set up, the National Institute for Clinical Excellence (NICE), to assess how new drug (as well as nondrug) technologies will be used, and to provide state-of-the-art guidelines on integrated treatment of diseases with high financial or public health impact.

The relatively small core staff draws on British academic experts and contracts out work to fulfill its mandate. Major efforts were made to institutionalize rigorous methodologies to gain the trust of professionals and the general public. NICE has survived considerable skepticism from industry, which tends to see cost-effectiveness and “need” as an added “fourth hurdle” to market access (the other three are quality, safety, and efficacy assurance).

NICE is a model for similar institutions in other countries. It is engaged in capacity building in developing countries interested in learning from its experiences. An important

factor in this context is that NICE does not make decisions on including drugs in formularies. Rather, it issues opinions supported by recommendations on the medical and economic value of new technologies and how they should be used. NHS then decides whether they will be included in the benefits package, and if so, with what restrictions. NICE opinions are frequently used to challenge industry pricing proposals.

## 5. Linking Essential Medicines to a Generic Drug Policy: Critical Factors for Success

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The desire to secure a basic benefits package for the rural poor has been the primary driver behind essential medicines for many years. However, given the differing expectations of China's rural and urban populations, the government's renewed emphasis on an Essential Medicines Policy risks a protracted discussion to define what is meant by "essential," and for whom. One way to sidestep a potentially digressive discussion would be to focus on a generic drug policy rather than an essential medicines policy. A thoughtful generic drug policy would be a foundation for any version of a reinvigorated Essential Medicines Policy.

Based on the foregoing discussion, a generic drug policy requires the following elements, which would greatly strengthen the implementation of Essential Medicines Policy: first, changing the provider payment system to de-link income from drug sales; second, enforcing strict quality standards for generics; third, addressing perception issues among doctors and patients; and fourth, introducing incentives for prescribing and dispensing generics.

A generic drug policy along these lines would stimulate the market for high-quality, low-cost generics and would increase the availability and affordability of drugs overall. The question "What is essential?" could be reframed as "Starting with providing basic services for the poor and taking into account a multilayered system, what is affordable and reasonable from the perspective of evidence-based medicine,?" This process would lead to a tiered reimbursement list, which over time and based on resource availability would generate a uniform list, further reducing the urban-rural divide in access to health care. The availability of reimbursement would also increase the supply of listed drugs and reduce the need for other intervention. Stronger health insurance funds could use strategies adapted from other countries' experiences (see some examples discussed in the previous section of this paper), using their bargaining power to obtain lower prices for generics and to limit the risk of cost increases from the introduction of innovative medicines. To ensure access to innovation without overburdening the system, an independent scientific review process for new therapies (Health Technology Assessment) could be considered, building upon experiences and lessons learned from other countries.

Making these changes would be a significant deviation from the status quo, and would require years to implement. At this point, it might make sense to consider a longer-range implementation plan with fixed benchmarks and a defined timeline. This would allow

various actors to acquire new skills and adjust “business models” that may be at odds with the direction of change.

The implementation plan for Essential Medicines issued by the Ministry of Health in August 2009 reinforced the key work areas for pharmaceutical reform and strengthened the process through concrete piloting initiatives. The following suggestions are consistent with those broader reforms as well as with the narrower proposal to develop a Generic Drug Policy. The suggestions below are listed in order of priority.

### **Changing the provider payment mechanism, including compensation for lost drug income**

So long as health facilities and doctors receive a significant share of their income from drug sales, compliance with proposed changes to pricing and reimbursement is likely to be low. Even if compliance *could* be successfully enforced, health facilities would still have to cut back on services if their income declines. Compensation to offset these losses is therefore necessary. There are three choices. First, fees for medical services could be increased, but this option is the least likely to be politically feasible. Second, health insurance schemes could increase their reimbursements for medical services. Payments based on diagnosis-related groupings (DRGs) could be introduced, or a capitation system that makes fix payments to providers at regular intervals. Third, direct government subsidies to facilities could be increased. This option could be implemented in a number of ways—for example, on a capitation basis, as top-ups to doctors’ salaries, as bonuses on medical service income (to individuals), or through other incentives that increase the volume or quality of services.

Pilot initiatives could help to determine the combination of methods that might work best. Over the long run, the insurance-based option could offer the best chance at creating a new incentive structure because insurance funds will have to set up systems for data collection and processing. Being able to define and monitor performance parameters would allow the insurance funds to adjust their payment systems as needed. (Some risks of the insurance-based model and strategies are discussed below; see “Insurance funds as direct purchasers of health goods and services.”) Government subsidies, the third compensation option, do not usually entail a built-in feedback loop, which is also a reason why they so easily lend themselves to distortions over time.

### **Increasing acceptance of generics among providers and patients—focusing first on assured quality**

Low-cost generics already constitute the largest category of drugs on the essential drug list. Lack of financial incentives is one reason why they are relatively less used, but widespread perception of lower quality is also a powerful explanatory factor. This was demonstrated in the Nanjing Zero Markup Pilot Program (see Annex A). While underlying financial incentives may be the key explanatory factor, other forces are also at work. The most important is the widespread perception, among health providers and consumers alike,

that generics cost less for a good reason—that they are worth less. This perception has a powerful influence on prescribing and purchasing decisions. Countering this notion will require a more profound understanding of how and why patients and physicians feel as they do, including systematic communication strategies aimed at consumer education and acceptance of generic drugs.

Many countries have proven that the perception challenge can be addressed. Improved awareness and confidence in generics have had major impacts on patterns of drug expenditure at national levels. Initial results from Nanjing’s zero-markup pilot project (see Annex A), as well as considerable experience from other countries, suggest that the perception of lower quality is a powerful influence on prescribing and purchasing decisions.

The first step to overcoming this obstacle is to make certain that there are *not* quality differences. This requires full enforcement of international GMP standards, which would also help consolidate a fragmented pharmaceutical sector with many marginal producers using out-of-date methods.

In addition, a better understanding is needed of physician as well as patient perceptions. Experimentation is needed with public education and communication strategies aimed at increased acceptance of generic drugs. Many countries have done this successfully. They have raised awareness and generated confidence in generics, which has had major impacts on drug expenditure in return.

### **Flexibility to meet the demands of a multi-tiered drug market**

Chinese officials acknowledge that it is futile to impose a “pure” Essential Medicines policy in urban environments, where people tend to be wealthier and are accustomed to a broader range of drug choices. For areas such as these, a realistic goal would be to expand the overall availability and use of essential medicines while not attempting to ban nonessential medicines.

One potential scenario could be a tiered system for urban areas. This might be layered according to various levels of insurance, starting with basic coverage and adding additional benefits through complementary public or private insurance. A system along these lines would require a well-thought-out legal and administrative framework. The effort that would be required is not currently viewed as a matter of high priority.

### **Pricing and reimbursement changes that allow market forces to play out**

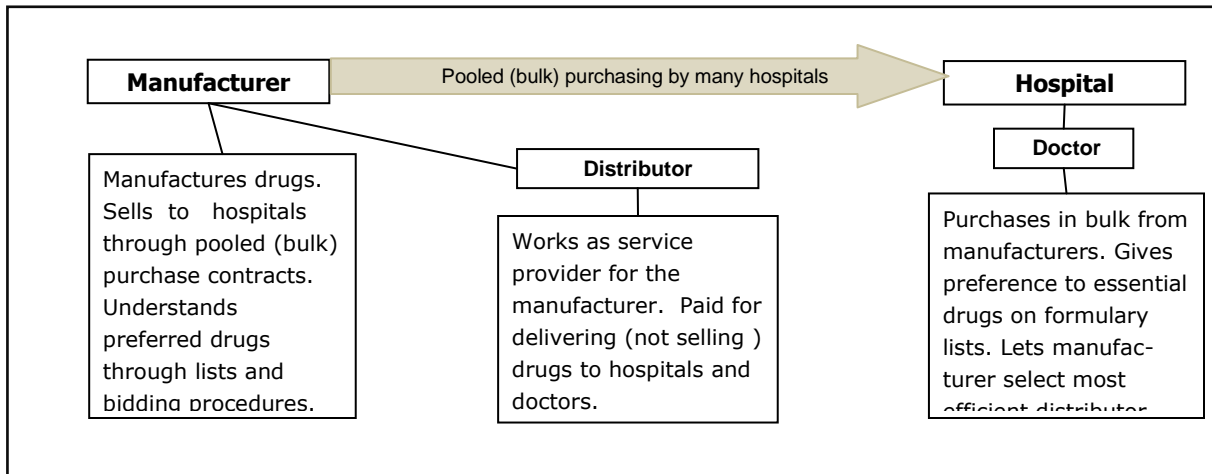
Pricing policies now in effect regulate only part of the overall pharmaceutical market—primarily reimbursable drugs and innovative patented drugs. This uneven coverage makes it easy for providers and suppliers to dodge price controls, and allows them to keep demand constantly shifting in the direction of more-profitable nonregulated alternatives. Similarly, providers are allowed to consider so-called “marketing costs” in the calculations that determine ceiling prices—in effect, legalized kickbacks are paid to doctors and are officially

factored into drug prices. Drug acquisition by hospitals and public providers should be conducted through competitive procurement, and the links should be broken where the same provider prescribes, dispenses, sells, and benefits from sales revenues. Prices paid by patients could be reduced without cutting into manufacturers' profit margins or encouraging distortions in the pharmaceutical market.

Pooled procurement based on transparency and open competition should be the standard method for acquiring essential medicines and would significantly help secure consistent low prices. Procurement specifications can be designed so that quality standards are vigorously reinforced, which is otherwise likely to be an ongoing impediment to public acceptance of generic drugs. Forming larger purchasing pools should be encouraged over time. One way to do this is for public institutions to share and disseminate price information at the national level. This would also help draw attention to those who unnecessarily overpay for drugs, generating public pressure for these "outliers" to join the larger purchasing pools. Insurers' reimbursement rates could also be directly linked to the more favorable pricing achieved by more efficient, higher-volume purchasing. (Adjustments could be made to reflect higher logistical costs in remote areas.) A national procurement strategy would emerge as the public-sector market gradually integrates, and this would create further pressure to consolidate the fragmented pharmaceutical industry.

An important question to be considered in the Chinese context is whether health institutions and insurance funds should contract with distributors, or directly with manufacturers. The large number of drug distributors can at least partly be explained by drug distributors' role as gatekeepers and as agents for paying "bonuses" and "rebates" to prescribing physicians who promote their brands. The cost of manufacturing, marketing, and distribution is higher than necessary. It is skewed toward the higher end because it must incorporate the high costs that are added by distributors. Pooled wholesale purchasing directly with manufacturers, enforcing use of the preferred brands, and allowing manufacturers to choose distributors based primarily on their ability to *distribute* (in a logistical sense) would realign incentives and optimize the profitability of efficient manufacturing and reduce costs to those who pay for drugs.

In Section 3 of this paper ("Structural Impediments on the Road to Pharmaceutical Reform"), Figure 1 ("The Prevailing Pharmaceutical Supply Chain for Public Hospitals and Health Providers") illustrates a typical supply chain transaction for generic drugs in a market with many small manufacturers. If the government reformed the provider payment system and replaced distributor-based sales with high-volume bulk (pooled) purchasing, significant cost reductions would accrue. If reformed along these lines, the modified supply chain would operate as shown in Figure 3 below.

**Figure 3. Reformed Supply Chain (Pooled Purchasing) for Generic Drugs**

### Insurance funds as direct purchasers of health goods and services

Currently, China's three main insurance funds (as well as the Medical Assistance program, which is not an insurance program strictly speaking) are all passive payers—they have no control over the cost and the quality of the goods and services that they pay for. Public health providers are responsible to government health administrators, while private health providers are controlled by owners who are not accountable for cost.

Thus, scaling up financing through health insurance may be problematic. Knowing that patient costs will only be partly reimbursed restrains doctors when writing prescriptions. (Doctors know that patients tend not fill prescriptions that are relatively more expensive, a phenomenon observed in many countries.) If financing is scaled up so that increasing cost does not constrain demand—particularly in the absence of adequate management systems (i.e., “pharmaceutical benefits management”)—the value and volume of unnecessary prescription is likely to increase as patient affordability becomes of less concern to doctors.

Experience from other countries shows that abusing reimbursement systems is common without effective control systems. Typical examples of insurance fraud are to bill insurance funds for drugs that are not dispensed, or to charge for expensive drugs and then dispense cheaper ones. In one Eastern European country, an electronic control fund reduced quarterly drug expenditures by over 20 percent, because doctors and pharmacists became aware that fraudulent claims could be identified and quickly traced to them.

The provider side of drug benefit management involves recording every aspect of prescription, including prescriber, dispensing unit, standard drug code, patient's name, date, quantity, and indications. State-of-the-art insurance systems use barcode readers to record data that is sent instantaneously to a central server. If the provider has an online connection,

red flags can be automatically raised and followed up on the spot.<sup>11</sup> Aggregating data allows for reporting and analysis of prescribing patterns, and monitoring adherence to guidelines on rational drug use. Data can also be used to monitor individual physician performance or to screen for potential fraud. A control system in Germany spotted a suspicious pattern in prescribing certain expensive drugs—with subsequent investigation revealing a physician–pharmacist team who were giving patients “free” cosmetic products and splitting insurance payments that were charged to their insurance cards but not dispensed. (Both physician and pharmacist went to jail.)

In developed countries with mature insurance systems, the lion’s share of health expenditure is generally channeled through insurance funds. These funds are regulated by frameworks specifying the kinds and levels of benefits offered, and how risk pooling and risk selection are handled. Government agencies supervise the insurance funds and act as clearing agents for complaints from patients and providers. A centralized bureaucracy or pooled purchasing agents (referred to as pharmacy benefit managers) act as demand aggregators for the funds. Working on behalf of their members, they contract with suppliers and service providers directly, using their combined purchasing power to ensure service, quality, and low prices. Rather than conduct procurement individually, service providers draw down on framework contracts that the insurers have set up at the national scale. By being able to enter into service contracts with both, the insurance funds are able to level the differences between public and private providers. To some extent, this creates oversight of private providers in a way governments are unable to do.

Insurance models of this sort could apply to China. One scenario might be a joint management system for pharmaceuticals in which the three public insurance funds combine utilization monitoring with demand pooling, framework contracting, and negotiations with suppliers. Uniform codes and consistent terminology, procedures, rules, and price all are important, because providers would be overwhelmed with paperwork if insurance funds use separate systems. Extremely high administrative costs in the US healthcare system provide an example of what happens when major payers fail to integrate their management systems.

### **Promotion of generic drugs**

Use of generic drugs can be promoted by appropriate management measures and by financial incentives. This has been demonstrated by health maintenance organizations in the United States—for example, through clinical practice guidelines (physicians are provided with detailed instructions on which drugs should be used and how); mandatory substitution with generics (asking pharmacists to provide equivalent generics even if brand-name drugs are prescribed), and step therapy (asking physicians to start with less-expensive generics and switch to more advanced drugs only when the first line of treatment has failed).

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<sup>11</sup> Automatic red flags can be generated for a variety of reasons—to find routine errors (“not enough time has passed for this prescription to be refilled;” for medical reasons (“use of this drug for this condition is contraindicated by ...”; or for prescriptions that make no sense (“this prostate patient appears to be a female”).

Would these measures work in China? The dominance of public providers in the market, the structure of the Chinese administrative system, and the government's strong leadership and commitment to health reform all work in favor of testing and implementing these approaches. Some piloting could be done on certain classes of drugs—for example, lipid-lowering drugs—to probe more deeply on the potential effectiveness of such measures.

### **Independent scientific guidance on new drugs in formularies**

Only a limited number of basic drugs are likely to be used in rural health facilities in the near future. However, debate is likely to be waged in thousands of urban hospitals on which new drugs should be added to formularies. The decentralized decision-making process for including new drugs is unsatisfactory for nearly all concerned. The number of review processes has multiplied; and without uniform methods and standards for assessment, inconsistencies have emerged in drug availability and treatment preferences, opening the door to influence peddling and bribery to gain approvals. At the same time, innovative companies complain that they must submit repeated applications and that decisions on accepting new drugs are slow and often delayed.

A central mechanism could be set up to evaluate new therapies (both drug and nondrug). These would be based on criteria such as clinical and cost effectiveness as well as safety. Assessment methodologies would be transparent and scientific—potentially, a major step forward in the advancement of evidence-based medicine in China.

Independent scientific guidance could be applied in several ways. Outputs from such a mechanism could include a model reimbursement list (emerging from the current list) structured in tiers, identifying which drugs should be used at which level (primary, secondary, tertiary) and providing specifications for use (first line, second line, only in specific disease combinations). The actual formulary and decisions on reimbursement would still lie with regional authorities and providers, but their decisions could be benchmarked against central recommendations based on scientific guidance. Once health insurance is the major payer on all levels, adherence to a standard formulary and treatment guidelines could be converted to contractual obligations and linked to provider and patient incentives.

### **Win-win negotiations with pharmaceutical multinationals**

Off-patent originator brands account for half of all sales of multinational pharmaceutical companies in China and a higher share of their bottom-line profits. The prospect of market-share reduction for the “cash cows” is a significant commercial threat. Thus, multinational pharmaceutical companies have been lobbying against a generic drug policy as a component of Essential Medicines. They use the “quality argument,” especially that Chinese-made generic drugs are lesser quality than their own. Doctors tend to be sympathetic to this argument given their responsibility for quality of patient care—all the more so because they are sales agents for drug companies when they receive direct compensation for drug sales.

On the other hand, the long-term business of multinational pharmaceutical companies is to make and sell innovative medicines. To overcome multinational companies' resistance to lower-cost generics and equal reimbursement ceilings for originator and generic versions of the same molecule, the government could make some concessions—for example, giving multinationals access to higher-income market segments with their innovative products.

Chinese hospital and urban insurance fund managers could adopt negotiation strategies used successfully elsewhere. In the United States and Europe, pharmacy benefits managers use various contracting models to ensure market access for innovative drug manufacturers. At the same time, they limit the cost impact by negotiating discounts or volume ceilings.

Manufacturers are sometimes willing to negotiate programs in which innovative, life-saving treatments are made cheaply or freely available to the poor. This is workable where a market can be segmented—where sales are not lost in market segments that can afford expensive new drugs. Negotiation strategies of this sort might work in China—for example, adding innovative drugs with “essential qualities” to the basic package for the poor.

### **Consolidation of the domestic pharmaceutical industry**

Chinese drug companies have significant potential to become major players in the global pharmaceutical market. To do so, they must overcome the added fragmentation to the home market that is “contributed” by the current provider payment model and inefficient procurement. In addition to using more efficient procurement strategies, industrial policymaking could help transform the underlying model—for example, encouraging industry consolidation by raising manufacturing standards, or by reducing restrictions on mergers and acquisitions. SFDA could raise manufacturing standards stepwise towards international GMP standards. This would also help build public confidence in generic drugs. Consolidation among fewer manufacturers would also facilitate quality-control assessment, thereby reducing the substantial burden that is now on SFDA. Rewards for provinces and municipalities whose policies support industry consolidation could also be considered.

### **A long-term view on the need for broad systemic reforms**

Pharmaceutical reform is a slow, complex undertaking involving interrelated elements of manufacturing, distribution, pricing, procurement, prescribing, and dispensing of drugs. While acknowledging the practical wisdom of a one-step-at-a-time approach, policymakers must recognize that broader system actions are needed for the long-term success of reform. Essential drug policy alone will not guarantee that essential drugs will be used appropriately and rationally. Pooled procurement will not make it impossible for manufacturers to profiteer on drugs—for example, by “updating” old products at higher prices. Different policies applied to different health providers (public vs. private) and to different types of drugs (essential vs. nonessential) may work against each other in the long run. For long-term success, these elements must work in harmony as part of broad systemic reform.

# **Annex A: Nanjing Pilot Project: Strengthening Primary Care through Community Health Centers and a “Zero-Markup-Policy” for Basic Drugs**

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The city of Nanjing has implemented a range of health policy reforms that could serve as a model for other regions. The Nanjing pilot project aims to move away from hospital-based care for most patients and to reform the financing system, which creates incentives to increase drug sales at facility-owned pharmacies. Nanjing has built or renovated several Community Health Centers (CHCs) to provide primary care services, including basic inpatient services and even routine surgery in some cases. Improving the quality and range of services is key to motivating patients to use these primary level facilities instead of going to the larger hospitals, which have higher costs per case. Overutilization of the hospitals leads to long waiting times and other barriers for patients waiting to be seen by doctors.

To reduce dependency on income from drug sales, the Community Health Centers have instituted a Zero-Markup Policy for basic drugs. The following case study data single pilot district provides some general parameters as an illustrative example:

Population:	63, 0000
Economic character:	Urban, upper middle class
Number of health centers:	9
Total staff:	800
Total annual revenue (RMB):	140 million
Revenues, drug sales (RMB):	100 million
Revenues, drug sales (% of total):	70 percent
Drug sales profit margin:	25 percent
Net income from drugs (RMB):	25 million
Prereform profit margin:	35-39 percent
Income, medical services (RMB):	40 million
Profit, medical services:	50 percent
Net income (RMB):	20 million
Net income per staff (RMB):	56,000

Government subsidy (RMB per staff):	10,000
Total income per staff (RMB):	66,000
Overhead costs (RMB):	26,000
Annual staff costs (RMB per person):	40,000

*Number of essential drugs.* About 360 drugs have been defined as “essential” or “basic.” There is 15 percent flexibility for the districts and their institutions to modify the basic drug list according to local needs and preferences.

*Procurement for basic drugs.* Centralized by the government. Prices are defined through a bidding process. Facilities order directly from (and pay to) suppliers under the terms of the centralized contract.

*Retail prices for basic drugs.* Equal to acquisition prices, i.e., zero mark-up.

*Publication of prices.* Prices are published inside the facility in various formats—for example, one facility uses an electronic display that flashes prices one after the other; another uses a board with all drugs and prices shown in overview.

*Formulary list.* The facility drug list (formulary) contains brand names and prices. In some cases, the list has different brands of the same generic, with nearly 100 percent price variation (international versus domestic manufacturer). Some patients prefer the more expensive international brand because they mistrust the quality of domestically produced generics.

Examples of price differences:

Amlodipine 5 mg from Pfizer: RMB 35 for 7 tablets.

Same generic drug from a domestic manufacturer: RMB 38 for 14 tablets.

Note: Both versions are procured in separate bids.

For comparison: Amlodipine 5 mg from IDA (a Dutch procurement agency that provides drugs to institutional buyers in developing countries): US\$2.75 for 100 tablets (Source: Drug Price Indicator Guide, Management Sciences for Health<sup>12</sup>)

Note: The Chinese generic procured by the municipality costs about 14 times as much as the IDA version.

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<sup>12</sup> MSH Drug Price Indicator Guide at [http://erc.msh.org/dmpguide/pdf/DrugPriceGuide\\_2008\\_en.pdf](http://erc.msh.org/dmpguide/pdf/DrugPriceGuide_2008_en.pdf)

*For non-basic drugs:* The district health bureau contracts with a distribution company for lower prices through pooling of demand. The average mark-up has been reduced from 30 to 20 percent. The reduced revenue is partially compensated by a government subsidy. In other districts, a differential mark-up is applied: from 30 percent for low price drugs to 15 percent for the highest price tier.

The total number of drugs sold in the health centers: 1,100 — meaning that the majority are outside the basic list.

*Revenues, nonbasic drugs.* Total value: 70-80 percent

*Volume:* 65 percent in urban, 43 percent in rural locations. (The difference between value and volume is accounted for by the higher average prices for nonbasic drugs.)

*Average drug expenditures:* Decreased from RMB 53 to 39 RMB over three years.

Terms of management and operations.

Offsetting incentives. The government provides a subsidy for lost income due to the change in drug policy.

Cash flow and budgeting. Revenues from operations (including drug sales) are collected at the health facility and passed on to the finance department of the District Health Bureau. The district bureau makes monthly payments to the facility based on a previously approved budget (there is no direct benefit from increasing drug revenue for the facility finances).

Staff salaries. A fixed component and a bonus based on the income from medical service fees (i.e., not including drug sales).

Pharmaceutical sales reps. Not welcome at the facilities. (Superficially at least, there is no indication that doctors are receiving any bonuses for prescribing specific drugs.)

Physicians. Instructed to follow rational treatment criteria and have to accrue CME credits on the subject. Health bureau monitors drug usage and puts pressure on facilities/doctors that deviate from the principles. A superficial check of prescriptions issued the day of our visit did not show any obvious signs of over-prescribing. Average number of items per prescription is given as 2-3; average cost per prescription in the center (urban environment) is 55 RMB.

Documentation. Prescription and purchase of drugs is documented with standard prescription forms. Printed receipts detail how the payment is allocated according to insurance, patient health savings account, and cash portion.

This example shows that despite the reforms implemented so far, the sale of drugs is still a major contributor to facility revenue and profit. However, the trend is clearly towards

lower drug costs and the de-linking of drug revenue and physician income seems to have curbed drug over-use. The adherence to the basic drug concept is not satisfactory. It appears that perception of drug quality and effectiveness are major factors influencing patient preferences and doctor's choices. An Essential Medicines policy based on generic drugs might be easier to implement in rural areas with lower purchasing power—patients in urban settings appear to be willing to pay more to obtain the drugs that are perceived as “better.” The inclusion of some originator brands in the “basic” list despite availability of much cheaper generics is a signal that preference can override rational choice—a phenomenon observed in other countries as well.

Overall, the model tested in Nanjing suggests that the incentives can be changed without physically separating prescribing and dispensing, by a range of administrative measures that de-couple facility revenue and profit from facility budget and staff salaries and reduce interaction between physicians and drug company representatives. However, in order to continue the chosen path and work towards further reduction of out-of-pocket payments, either the government must increase subsidies to the facilities or health insurance coverage needs to be increased and the basic benefits package expanded.

## **Annex B. New Collaborations between the World Bank and Government of China**

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### **An Agenda for Continued Collaboration between the World Bank and the Government of China**

Chinese officials are well aware of the obstacles to be overcome for their pharmaceutical policy and health-sector reform plans to succeed. In the short- and medium-term, objectives are clear: an essential medicines policy focusing on the rural poor; increased insurance and service coverage; economic separation between prescription and dispensing of drugs; and elimination of financial incentives that work against the rational use of drugs. Much is in their favor. Political commitment is high in China. Government officials as well as academics are well informed on experiences with reforms in other countries. Strong international partners, such as the World Health Organization in China, are supportive in providing know-how and technical assistance in formulating policies.

On the other hand, the critical part still lies ahead: implementing major changes in a multilayered system including groups of resistant stakeholders fearful of ending up worse off as a result of reform. The World Bank supports the ongoing reforms, which are essential to continued socioeconomic progress. The Bank commends these efforts and is committed to offering continued assistance that matches its capabilities with the government's needs. Bank expertise extends well beyond the content areas of health and pharmaceutical policy. It includes deep experience with the transformations that accompany policy change, including skill-building in the critical areas of good governance, communications, project management, and monitoring and evaluation. In addition, visible support from the World Bank enhances technical credibility of reform processes in the eyes of the international community, strengthening the hand of "reform champions" in the government.

There are many possibilities for ongoing and new collaboration between the Bank and the Government of China. Details can be worked out once the current reform plan has been published and moved to the next steps of implementation. In the meantime, here are some ideas—by no means a restrictive list—to illustrate the scope and richness for ongoing collaboration.

- *Workshops on pharmaceutical policy issues.* Organize a series of workshops—for example, reports on current piloting experiments to de-link doctors' incomes from drug sales; using insurance reimbursement policies to change incentive systems for providers; experiences with pooled procurement and contracting systems for basic drugs (for example, from Germany, USA, Chile, the Caribbean island states, and the countries of the Gulf Cooperation Council); and new thinking on criteria and processes for including new drugs in reimbursement schemes.

- *Frameworks for monitoring reform progress.* Develop a framework for monitoring of success parameters for reform implementation, in collaboration with a Chinese university. Research could test this framework at pilot sites for Essential Medicines policy.
- *Changing the “image” of generic drugs.* Assist SFDA with strategies to address perception issues around the quality of generic drugs. Help with reconciling quality objectives with regional industrial policies.
- *Strengthening capacity of health insurance schemes.* Organize capacity-building activities in areas such as analyzing insurance claims, monitoring and evaluating drug consumption, and designing performance measures.
- *Price monitoring for basic drugs.* Undertake a nationwide price-comparison study on basic drugs procured through public institutions. A mechanism to monitor prices could be developed.
- *Strategies to enhance China’s pharmaceutical competitiveness.* In partnership with IFC, conduct an assessment of the pharmaceutical industry’s global competitiveness. Develop new strategies to catch up with the world market.
- *Improving scientific assessment of new drugs.* Review the current mechanisms for assessing and deciding how drugs are included in reimbursement lists. Possible collaboration with a partner such as NICE (UK).

As a next step, a concrete proposal would have to be developed based on dialogue between the government and the Bank’s China Office.

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