



## Regulatory reform in China's health sector

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### Introduction and executive summary

This study reviews three generations of China's health sector reforms in light of OECD experiences and best practices. The ultimate objective of this study is to provide recommendations for Chinese policymakers to consider as they continue the current generation of health sector reforms.

In the late 1980s, domestic policymakers implemented a first generation market-based health sector reforms designed similarly to those that had proven successful in other sectors of China's economy, but with different results. These reforms devolved the central government's administrative control and financial support over healthcare to provincial and local authorities.

From 1978 to 1999, the contribution of the central government to national healthcare spending dropped by over half from 32% to 15%<sup>1</sup>. This overall figure masks the tremendous inequalities these reforms created as cross-subsidies from more prosperous regions, provinces and urban centres to poorer areas were curtailed. In contrast to positive results that similar reform packages created in other sectors of the economy, the structure of incentives created by the health sector reforms that have been linked to: the loss of socialised healthcare coverage in rural areas; the exit of healthcare providers from the health sector; drastic increases in the price of healthcare; and deteriorations in the quality of healthcare provision.

Significantly, the overall health of the Chinese population continued to improve at least through 1995<sup>2</sup>. This was likely due to the continuing economic growth that improved living standards, reduced poverty and lifted nutritional standards, thus masking the deterioration of the health system. However, growing deficiencies in the public health infrastructure were brought to national and international attention most notably during the Severe Acute Respiratory Syndrome (SARS) epidemic of 2003.

The second generation of health sector reforms was marked by a return to gradual reforms characterised by geographically limited trials of differing reform packages, which were often designed by western academics specialised in public health. Policymakers in China have re-established universal healthcare as a final objective of the third (and current) generation of health sector reforms. Leveraging experiences from the second generation of limited reform trials, they are improving upon health challenges created during the first generation of reforms. Examples of OECD experience and best practices are presented throughout this study for policymakers to consider as they engage the current generation of health sector reforms. The recommendations are provided at the end of the study suggest approaches to reform informed by health sector reform experiences in the OECD area.

## **From Mao to market – shock therapy in China’s health sector**

The introduction of market forces within China’s health sector followed economic principles that had been successful in other sectors of domestic reform such as agriculture and light manufacturing. Dating back to the establishment of the People’s Republic of China in 1949, China’s pre-reform healthcare system – like other sectors of the economy – was characterised by a lack of market mechanisms (see Box 1). However, China’s health sector reforms in the 1980s differed from reforms in other sectors in that they unfolded with uncharacteristic speed, and left significant unintended consequences in their wake.

### **Box 1. The pre-reform era of socialised healthcare insurance**

The current situation of the Chinese healthcare infrastructure contrasts markedly with that prior to 1980s reforms. The pre-1980s health system recorded considerable achievements in comparison to the medical resources it governed. Beginning in 1949 and throughout the Mao period, the Ministry of Health (MOH) supervised a multilevel system of healthcare throughout China. This system guaranteed citizens access to healthcare coverage through place of employment. The legal right to work guaranteed to every citizen during the Mao era essentially meant that access to some form of healthcare coverage was universal prior to the reforms implemented in the early 1980s.

In the rural sector, the MOH erected a three-tiered administrative architecture to provide healthcare. The first two tiers relied on the Cooperative Medical System for financing while the third relied on the central government. The first tier consisted of the well-known “barefoot” doctors, which covered the rural population at an average rate of two per 1000 people. Paramedics in essence, barefoot doctors supplied preventative and primary care services from village medical centres. The second tier consisted of township healthcare centres staffed by assistant doctors. Although normally having 10 to 30 beds each, they functioned mainly as out-patient clinics and served populations ranging between 10 000 to 30 000 people. The third tier was composed of county hospitals staffed by doctors with five-year medical degrees. Access to county hospitals was limited to the seriously ill and each served populations ranging between 200 000 and 600 000 people<sup>3</sup>.

The urban health system similarly provided a three-tiered system of healthcare facilities. Paramedics supplied the first tier of primary healthcare normally working on-site at workplaces and in neighbourhood health stations. The next two tiers of healthcare facilities included district and municipal hospitals. Although access to these two tiers was formally limited based on severity of illness, some state owned enterprises (SOEs) and government agencies routinely bypassed the paramedic tier of the health system to secure better quality health services for their employees<sup>4</sup>.

Over the three years leading to the reforms implemented 1980s, significant achievements were recorded in the health of the Chinese population. Between 1952 and 1982, average life expectancy in China nearly doubled from 35 to 68 years, while infant mortality rates plummeted from 200 to 34 deaths per 1000 live births<sup>5</sup>. It should be noted, however, that a number of factors not entirely related to medical care access certainly contributed to these achievements. Among these were improving nutrition and a strong emphasis on preventative medicine – that included sweeping “patriotic health campaigns” which improved basic hygienic conditions and practices. It is also worth bearing in mind that although rates of healthcare coverage in rural areas were certainly much higher in the pre- than in the post-reform period, front-line healthcare personnel had very limited technical training.

### ***The strategy of the reforms and the policy flexibilities they provided***

The underlying strategy of health sector reform was to increase economic efficiency by devolving finance for healthcare from the central government to local health systems, and providing regulatory leeway for local managers to rationalise productive resources under market forces. To safeguard basic healthcare, price controls were placed on essential health services. Two main regulatory flexibilities were then introduced for local health systems to make up shortfalls in central government finance. The first was to allow local health systems to offset decreasing central government financing by increasing local taxation. The second was to allow local health institutions to generate additional revenue by pricing non-essential health services above cost recovery.

To protect access to basic healthcare, the government established the “State Scheme Drug List for Basic Medical Insurance” (Catalogue)<sup>6</sup>. The Catalogue implemented a system of price caps at or below cost recovery for basic health services including: routine visits, essential services including surgery, basic diagnostics and common pharmaceuticals. To keep pace with advances in healthcare technology, the National Development and Reform Commission (NDRC) updates the Catalogue on a periodic basis.

While greater local taxation could in theory have allowed local health systems to offset cuts in central government financing, evidence suggests that this first policy flexibility was not widely employed<sup>7</sup>. As a result, the second policy flexibility of allowing healthcare facilities to set pricing for non-essential healthcare above cost recovery often became the key source of new revenue. Premiums paid for “non-essential” health services thus often became the mainstay by which local healthcare providers made up for declines in central government financing.

### ***The impact of healthcare reform on the rural sector***

The impact of health sector reforms on the rural areas cannot be justly assessed without considering how agricultural reform impacted the health sector. Indeed, it could be argued that the severest negative impacts on healthcare in rural areas resulted less from healthcare than from agricultural reforms. The collective consequences of health and agricultural reforms established economic incentives that have been linked to: the loss of socialised healthcare coverage in rural areas; the exit of healthcare providers from the health sector; drastic increases in the price of healthcare; and deteriorations in the quality of healthcare provision<sup>8</sup>.

Gradual liberalisation in the agricultural sector was credited with impressive gains during the early period of economic reforms in China. In contrast, the manner in which the later stages of agricultural liberalisation were implemented had swift and detrimental effects on rural healthcare. Agricultural reforms began by incrementally reducing the control of rural collectives over crops that farmers grew and sold. Successive rounds of liberalisation, however, led to the dismantling of the rural collectives altogether. The purpose of the rural collectives under the pre-reform system – which was to decide what crops farmers would plant and sell to the state – became obsolete over time.

When the rural collectives were dismantled, the Cooperative Medical System that they had financed collapsed. This domino effect had two instant and far reaching implications. First, the reliance on of China’s health system on place of employment for providing healthcare coverage meant that socialised healthcare insurance virtually disappeared overnight in the rural areas. Second, the first two tiers of the rural health system (*i.e.* medical and township healthcare centres), which relied on the Cooperative Medical System for finance, were abruptly deprived of income<sup>9</sup>. Healthcare providers employed in the third tier of the rural health system (*i.e.* the county hospitals) retained central government financing, but nevertheless saw cuts in central government financing.

Over time, these reforms resulted in a paradoxical array of unintended effects. The rural population lost healthcare coverage while resources exited the rural health sector, and ballooning healthcare costs were often accompanied by declines in the quality of service. As healthcare providers originally employed in the first two tiers of the rural health sector lost job security and stable incomes, many left the profession entirely in order to take up more lucrative occupations such as farming<sup>10</sup>. By contributing to the systemic loss of healthcare practitioners, the reforms reduced healthcare resources throughout the rural areas.

The healthcare providers that chose to remain in the first two tiers of the rural healthcare system adapted to the environment of liberalised health services by selling prescription drugs

and non-essential health services. The fact that standard drugs and treatments had price caps set at or below cost recovery under the Catalogue, meant that strong incentives existed for healthcare providers to rely on new and high-tech treatments not listed under the Catalogue as their primary source of income – some of which they had inadequate training to perform<sup>11</sup>. Doctors working in third tier of the healthcare system faced similar financial pressures although not as severe. To address cuts in central government financing, county hospitals regularly tied doctor's bonuses to sales of more profitable medical treatments and drugs<sup>12</sup>.

The question of whether increasing the role of market-based incentives within the health sector tends – counterintuitively – to increase healthcare costs, is one that has been subject to substantial research in OECD countries. Definitive conclusions on this subject, however, remain elusive (see Box 2).

### **Box 2 OECD Experience: Does Hospital Competition Lead to a Medical Arms Race?**

Many policymakers have suggested that hospital competition is wasteful and that as a result introducing competition into the market for the provision of hospital services would raise health-care spending. There is mixed evidence on this question and much of the response depends on the characteristics of the health care system as a whole. There is, nonetheless, an increasing consensus that, while hospital competition may promote a medical arms race, this is likely to account for a very small percentage of costs, to the extent it occurs at all.

Robinson and Luft (1985) suggest that hospitals in more competitive markets will invest in duplicative services that are in excess of what would be demanded by the market. "While hospitals obtained some of their patients directly from emergency rooms and ambulatory care clinics, the majority are admitted by community-based physicians affiliated with the institution...the hospital is dependent on its affiliated physicians for clients; conversely, the physicians are dependent on the hospital for those types of services that physicians cannot profitably and conveniently provide in their own offices." (Robinson and Luft) The MAR hypothesis is based on the idea that, in the absence of price competition, hospitals will compete for physicians because the physicians determine admission patterns. One way to attract physicians is to offer high technology services. For example if a geographic area has sufficient population in demand to support the use of one MRI scanner, but has two hospitals, once one hospital obtains an MRI scanner, the other may also seek a scanner in order to be equally attractive to physicians. But the result can be that an area with an intrinsic need for one MRI scanner ends up with two partially utilized scanners. Another rationale for the MAR hypothesis is that hospitals will raise quality in order to attract patients who do not have to bear the full costs of that quality, owing to insurance.

Robinson and Luft examined U.S. hospitals in 1972, a period before significant price competition was present in U.S. hospital markets. They find that, in comparison to monopoly hospitals, the average cost per patient day was 5.6% higher for hospitals with one neighbour, 9.1% higher for hospitals with two to four neighbours, 16.3% higher for hospitals with five to 10 neighbours and 20.5% higher for hospitals with 11 or more neighbours. (p.347) (Note that these estimates do not actually directly test for technological intensity and could arise for reasons not related to the MAR hypothesis).

None of these studies provide a direct test of the presence of high technology over-investment that is consistent with the MAR hypothesis. Dranove, Shanley and Simon (1992) perform a careful analysis of 11 high-tech hospital service categories provided in 1983 at a time before aggressive price competition grew common between hospitals. The services they study are open-heart surgery, full body CT scans, radiation therapy, and radioisotope therapy and seven groupings of services along clinical or technological lines, focused on cardiology, deliveries, diagnostics, emergency, neonatology, paediatrics and teaching. They find that there is an identifiable MAR effect but that it is small in economic import. Most hospital mergers would not be predicted to reduce capital spending from the elimination of the MAR.

Dranove *et al.* conclude that the MAR is relatively unimportant by examining plots that show the number of service providers *per capita* against the number of hospitals. For cardiology the first specialized provider enters when the local population is roughly 62 000, the second provider enters at 277 000 in additional providers enter in population increments of 680 000 to 830 000. "If the MAR was the dominant determinant of specialized service supply, and we would expect to these plots to show a general upward trend – as more hospitals appeared in the market, competition would drive them to add services beyond the level demanded by the population. In fact, the plots show a downward trend. This suggests that as

markets grow and more hospitals enter, the dominant effects are probably scale and scope economies, with the MAR having its effect only on the margin." (p.257)

Source: OECD (2007a), p. 12.

### ***The impact of healthcare reform on the urban sector***

Unlike the rural population, a much larger proportion of the urban population retained healthcare coverage following the reforms of the 1980s. This was because urban residents were primarily employed in SOEs, which were not privatised nearly as comprehensively as were rural collectives. Healthcare providers in the urban sector nonetheless faced financial pressures with their severity linked to the relative prosperity of their geographic locations. Departing also from the rural experience, limited increases in local taxation served to reduce financial pressures in urban health systems, but pressure to increase revenue from profitable medical treatments and drugs not appearing in the Catalogue nevertheless remained. As in the case of county hospitals located in rural areas, the practice of linking doctor's bonuses to profitable treatments impacted quality of service<sup>13</sup>.

Although the rate of coverage among the urban population was 49% in 1993, such figures are deceptive due to the structure of healthcare coverage in urban areas<sup>14</sup>. This is because populations in urban areas with healthcare coverage were covered by one of two benefits schemes including the Government Insurance Scheme (GIS) covering 9% of the urban population and the Labour Insurance Scheme (LIS) covering 40% of the urban population. Whereas the GSI is financed *via* government budgets, the LIS is essentially an employee benefits scheme run by employers based on withholdings of 11-14% from monthly salaries. This difference meant that risk-pooling under the LIS scheme was limited to the number of employees at individual organisations. Thus, in periods when healthcare costs increased at a rate 9% higher than wages such as that between 1985 and 1990, shortfalls could either be financed by profits, or absorbed by employees<sup>15</sup>. Estimates that roughly one-third of SOEs were running deficits in 1995 suggest that the rate of *de facto* uninsured within urban populations is much greater than the formal healthcare coverage figures indicate. A survey conducted in 1992 and 1993 showed that one-third of state enterprise employees with healthcare coverage were not receiving insurance-paid care<sup>16</sup>.

### ***The four unintended consequences of the healthcare reforms***

The healthcare reforms implemented in the 1980s did not produce the expected results of lowering healthcare costs or improving service quality. And, due to the structure of the health sector, attempts to halt or roll back health sector reforms would have hindered reforms in all sectors of the economy under or slated for liberalisation. The reforms thus created a number of unintended effects including: (i) dramatic increases in the costs of health services; (ii) the removal of incentives for supplying preventative medicine; (iii) drastic reductions in the proportion of the population covered by socialised healthcare insurance; and (iv) the exacerbation of regional and urban/rural disparities in access to healthcare.

#### ***Dramatic increases in the costs of health services***

The underlying reform strategy was to introduce market forces into the health sector by shifting the basis for healthcare finance from central government to fee-for-service (FFS). Although this reform is a prerequisite for price signals to guide efficient allocations of resources – and had worked well in other sectors of the economy – the rapid declines in public finance for healthcare had the contrary effect of increasing healthcare costs overall. As healthcare facilities now faced commercial incentives *and* liabilities, those recording large declines in public finance faced extraordinary pressures to create new sources of revenue. The resulting emphasis placed on purchasing high-tech medical equipment and providing

advanced medical services led to sharply increasing healthcare costs, thus bypassing the regime of price controls for basic healthcare governed by the Catalogue. Indeed, from 1979 through 2002, out of pocket healthcare expenditures rose by a factor of nearly forty on a *per capita* basis<sup>17</sup>. High prices for healthcare are an important factor contributing to the current healthcare situation in China, under which illness is the primary cause of poverty in 15-22% of families in rural areas<sup>18</sup>.

#### *The removal of incentives for supplying preventative medicine*

A further general effect of the reforms was to reduce overall incentives for the medical system to provide preventative medicine, *e.g.* education for basic hygiene, pest control programmes and maintenance of healthcare infrastructure to deal with infectious diseases. Indeed, one of the first subsidies provided by the central government to be drastically scaled back was funding for preventative medicine. Local health systems rarely filled this gap as preventative medicine is not profitable and, as a result, important preventative medicine programmes such as vaccinations either disappeared or came to be provided on an FFS basis<sup>19</sup>. Reduced incentives for providing preventative medicine were thus creating long run costs unlikely to be offset by short term cost savings.

#### *Drastic reductions in the proportion of the population covered by socialised healthcare insurance*

The depth and breadth of the reforms applied by China in its health sector during the 1980s was probably the most pronounced in the sharp fall of the domestic population covered by healthcare insurance. Estimates indicate that the percentage of China's rural population covered by any form of healthcare coverage plunged from 92.6% in 1976 to 6.1% in 1990<sup>20</sup>. As late as 2005, only 29% of the Chinese population as a whole had healthcare insurance<sup>21</sup>. In 1999, only 49% of the national urban population had healthcare insurance in comparison to 7% for rural residents as a whole<sup>22</sup>. The corresponding figure for residents in the poorest western regions was 3%.

#### *The exacerbation of regional and urban/rural disparities in access to healthcare*

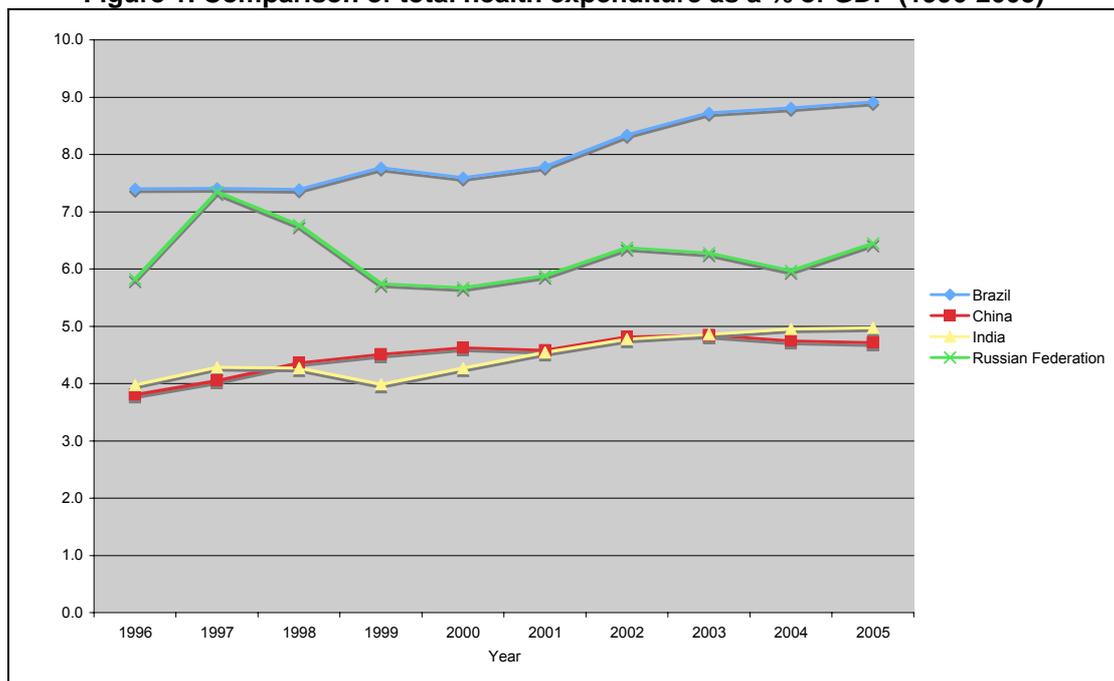
The three unintended consequences described above served to exacerbate income inequalities with those in healthcare as the poor are: less likely to have healthcare coverage; more likely to benefit from preventative medicine; and more likely to be negatively impacted by higher costs for healthcare. Indeed, the collapse of the Cooperative Medical System severely impacted the rural areas comprising 70% of China's population<sup>23</sup> and significantly increased the likelihood of poverty due to severe illness in rural areas, due to loss of socialised healthcare coverage. Urban areas were affected differently by health sector reform due to the fact that SOEs and government bodies and agencies were not privatised as rapidly or as completely as rural collectives in the agricultural sector. While healthcare coverage among the urban population was just below half in 1999, health sector reforms nevertheless had negative effects on healthcare provision in urban areas<sup>24</sup>. Curtailed provision of preventative medicine and higher prices exacerbated inequalities whether regional or rural/urban.

## Trends in China's health system

In arguing that the reforms implemented in the 1980s have negatively impacted the improvement of China's health status, this section reviews the efficiency of China's health system in relation to other large and populous countries. Although the sections above illustrate China's deteriorating healthcare infrastructure, it is important to recognise that health indicators have continued to improve, however incrementally, since the 1980s. This section will show that China currently boasts good overall health status in comparison to Brazil, India and the Russian Federation<sup>25</sup>. The analysis highlights that despite having relatively low levels of healthcare resources, China fares surprisingly well. In highlighting China's declining share of government expenditures for healthcare, this section will show that the gap was filled by private expenditures: or avoidance of health services altogether.

Despite its modest healthcare resources *per capita*, China records impressive results in its core healthcare indicators. While China is almost equal with Brazil in terms of doctors per 1000 population, Brazil has nearly four times as many nurses per 1000 population as China. China has nearly twice the number of doctors per 1000 population in comparison to India, but is roughly equal in terms of nurses. In comparison to the Russian Federation, China has just above a quarter the number of doctors per 1000 population and just over one-eighth as many nurses. In other categories such as dentists, pharmacists and "other health workers", China's resources vary widely in comparison to other countries under comparison (see "Comparison of health system indicators" in Annex I), but none of these variations detract from the fact that China's healthcare resources are modest except in comparison to India.

**Figure 1. Comparison of total health expenditure as a % of GDP (1996-2005)**



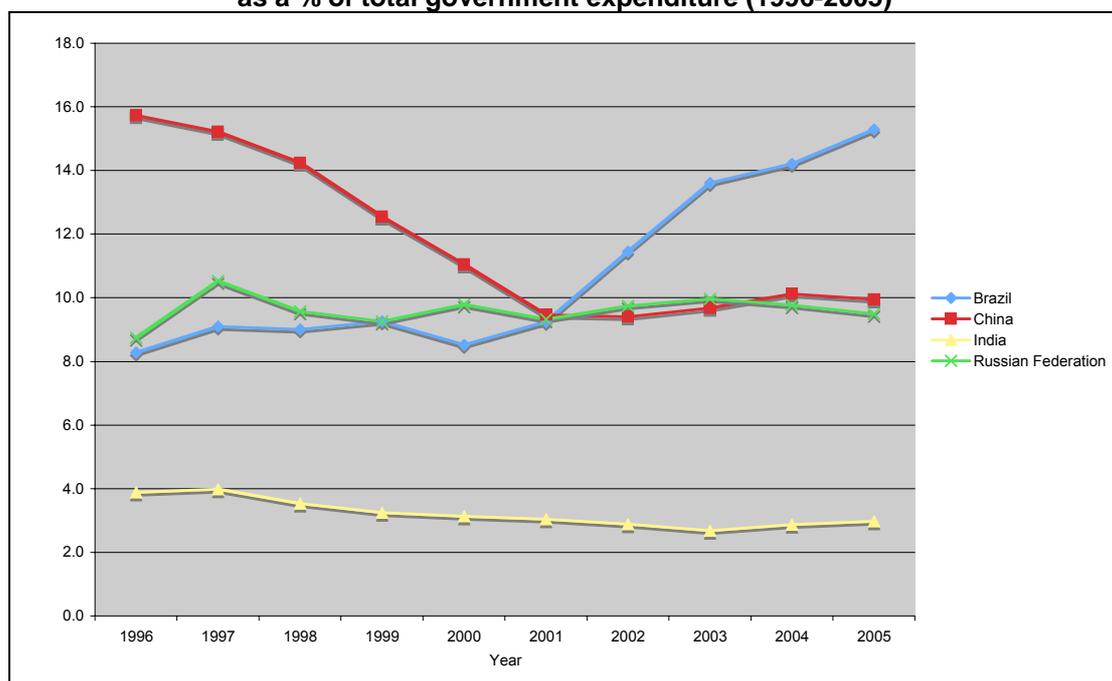
Source: WHO.

Despite having a relatively small stock of healthcare resources, China's core health statistics compare favourably with that of its counterparts. Either equalling or surpassing other countries in the areas of life expectancy and mortality rates for adults, China ranks behind Brazil and the Russian Federation only in terms of neonatal mortality rates, and behind only the Russian Federation in terms of infant mortality rates and child survival beyond age five (see "Comparison of core health indicators (2004)" in Annex I). With an average life expectancy of 70 years, men in China are likely to outlive their Brazilian, Indian and Russian Federation counterparts by three, nine and eleven years. The equivalent figure of 74 years for

Chinese women equals that for their Brazilian counterparts and is two and eleven years longer than that for women in the Russian Federation and India. Although twice as likely to die at birth that their Russian Federation counterparts, infants in China have a survival rate roughly 23% and 130% higher than their Brazilian and Indian counterparts. In terms of annual mortality rates for the adult population, men and women in China have better prospects than all other countries under comparison.

Despite favourable health indicators, China's total expenditures on healthcare as a percentage of gross domestic product (GDP) is similar to the low level recorded for India both in terms of magnitude and trajectory, but is far below that for Brazil and the Russian Federation (see Figure 1). Indeed, China's 4.7% figure for total health expenditures as a proportion of GDP in 2005, ranked it as the lowest among the countries under comparison for that year.

**Figure 2. Comparison of government expenditure on health as a % of total government expenditure (1996-2005)**



Source: WHO.

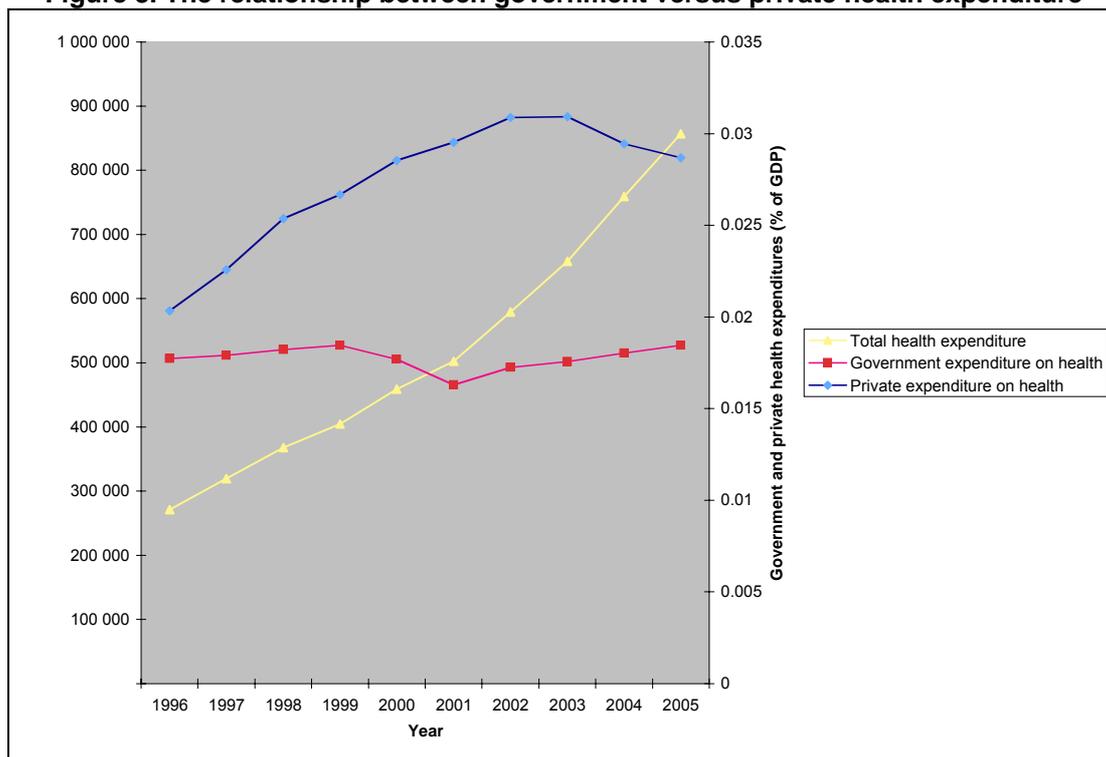
China's government spending healthcare as a proportion of total government expenditure declined sharply between 1996 and 2005 (see Figure 2). Its government spending on healthcare as a proportion of total government spending – which was the highest among the countries under comparison in 1996 – declined by more than a third between 1996 and 2001. China now places well below Brazil's levels by this measure. Representing 10% of total government expenditures through 2005, China's government expenditure on healthcare has stagnated since 2001. Comparable to that of Russian Federation, China still spends well over double the proportion of its government expenditures on healthcare in comparison to India. In short, while China's total health expenditure as a proportion of GDP is the lowest among the countries under comparison, the proportion of its total government spending on healthcare is higher only than that of India.

The macroeconomic data suggests not only that rapid nominal increases in healthcare costs have been paid for by out of private funding, but that declines in government funding for healthcare have exacerbated this trend. Throughout the period from 1995 to 2005, total and private expenditure on healthcare as a proportion of GDP has risen dramatically while government spending has remained relatively stagnant (Figure 3). The composition of total health expenditures during this period is suggestive of an inverse relationship between

government and private spending. Although both private and government expenditures on healthcare increased until 1999, a negative correlation becomes apparent after that year. Indeed, the recovery of government spending on healthcare relative to GDP beginning in 2001 is followed two years afterwards by a decline in private spending.

When the responsiveness of private financing when faced with declines in public financing of healthcare is considered against the fact that the majority of rural as well as urban residents actively avoided health services as of 2003 (Box 3), the implication is that reductions in public financing for health services have negatively impacted equity in the distribution of health services.

**Figure 3. The relationship between government versus private health expenditure**



Although the poor are avoiding health services, the proportion of the population able to afford them – or with no choice due to catastrophic illness – have more than made up for cutbacks. According to a report by the Chinese Academy of Social Sciences, two-thirds of government health expenditure goes to urban areas (representing only one-third of China’s population), and 80% of that amount is consumed by 8.5 million people, composed mainly of officials at various levels<sup>26</sup>. The decline in central government financing of healthcare has exacerbated this trend.

**Box 3. The impact of SARS:  
Exposing frailties in the Chinese health system**

The effects of rapidly increasing healthcare costs together with the low level of socialised healthcare instance coverage were highlighted during the SARS epidemic of 2003, when government officials were obliged to announce free treatment for SARS victims to prevent the affected from shunning hospital care due to high cost of treatment<sup>27</sup>. The effectiveness of this measure was limited, however, due to concerns by the ill that should SARS not be the cause of their symptoms, they would be unable to afford the high cost of treatment that they could otherwise have avoided. In that same year, a national health survey indicated that 73% of the rural, and 64% of the urban, residents who should have sought medical treatment, chose not to do so because of high costs<sup>28</sup>.

In response to the SARS epidemic of 2003, the central government had over the three years from 2003 through 2006 allocated RMB 10.5 billion (USD 1.31 billion) to establish a disease prevention and control system comprising facilities at the provincial, city and county levels.

To restore and enhance the healthcare infrastructure in the poorer regions, RMB 3 billion (USD 375 million) has been directed towards establishing healthcare clinics in towns and townships in the central and western regions. Such new financial outlays hold the potential for reducing the financial pressure on healthcare providers to rely on high cost (non-essential) treatments for revenue.

*Sources:* CHINA.ORG.CN (2006i) and Economist (2004).

The relatively high health status of the Chinese population was achieved in an era when public finance of healthcare was much higher than today. And, the data presented above suggests that health sector reforms implemented in the 1980s are an important explanation of the declining rate of improvement since. While average life expectancy doubled from 35 to 68 during the thirty years between 1952 and 1982, it increased by only 4 years over the following two decades. Infant mortality rates declined by 166 deaths per 1000 live births between 1952 and 1982, however, the two decades since have seen a further reduction<sup>29</sup> of only 8. Although a significant proportion of this slowdown results from the demographic transition from a young to an older population over the last half-century, deteriorations in the health system since the reforms in 1980s have also reduced that would otherwise have possible over the last two decades. China continues to reflect robust health status in comparison to other large and populous countries. The reforms implemented in the 1980s have not contributed to sustaining this enviable result.

## China's second-generation reforms...rehabilitating the doctrine of "gradualism"

The negative impacts of healthcare reform resulted from specific regulatory failures that are often characteristic of the health sector reform (see Box 4). They were further exacerbated by China's severe regional and urban/rural inequalities, which meant that no single approach could effectively address the diverse health conditions making up China's economic topography. The composition of market failures characteristic of the health sector that domestic regulatory institution failed to overcome (see Table 1), likely reflected considerable variation due to differing local circumstances.

### Box 4. Wither reform?

#### The challenges of reforming market imperfections in the health sector

Reform in the health services is difficult due to the numerous "abnormalities" distinguishing it from other forms of economic activities. Among these abnormalities (market failures) are those of asymmetric information, imperfect agency relationships and moral hazard<sup>30</sup>. Indeed, "diagnosis" of health problems is at once an essential healthcare service and also a situation where consumers explicitly seek to obtain medical services from various service providers under conditions of "perfect information" (*i.e.* consumers normally have no or little technical ability to assess the quality of healthcare providers or their services). Under circumstances such as China's where healthcare providers are driven by reductions in public funding alongside price caps for essential services, moral hazards are created which tend to reduce quality in healthcare service provision.

This reality is interwoven with various other potential sources of market failures characteristic of healthcare economics such as the tendency toward "adverse selection", under which unhealthy consumers have the strongest incentives to seek the most comprehensive healthcare coverage, and "risk selection", under which healthcare insurance companies have the strongest incentives to limit coverage to only "healthy" consumers. These complex and often diametrically opposed relationships existing between consumers, healthcare providers, and drug and medical instrument producers act in concert to make regulatory reform of the health sector for effectiveness *and* equity, a complex undertaking for policymakers charged with regulating a "public good".

To the extent that there are no health systems entirely free of individuals with treatable health problems left untreated, no perfect health system exists today. Indeed, Hsiao and Shaw (2007) argue that no single health system could be optimal for societies at all levels of economic development. The differing healthcare challenges prevalent in developing economies (*e.g.* pre-natal health, infectious diseases and poor sanitation) when compared to those of advanced economies (*e.g.* degenerative diseases, ageing societies and obesity), clearly illustrate how regulatory systems for health sectors optimised for one circumstance would be intuitively suboptimal for others. The question of which regulatory framework is best is as much a question of the context in which health system is situated, as it is of design.

In recent years, myriad activities have been initiated at the national and international level to seek out realistic "second generation" policy architectures for health system reform in China. These activities are being implemented in consonance with the gradualist and experimental manner that reforms in other sectors of China's have been carried out. This return to the gradualist approach is largely possible due to the fact that many non-health sector reform programmes that had negatively impacted the first generation of health sector reform, are now relatively mature. The Collective Medical System has already been disbanded for sometime and the privatisation of SOEs is well advanced.

**Table 1. OECD Experience: Examples of market failures in the health care market and possible regulatory responses**

Market failure	Providers	Regulatory response	Insurance	Regulatory response
Anti competitive practices	Price fixing by doctors	Prohibit publication of tariffs by professional associations	Mergers of insurance funds to create local monopolies or oligopoly	Monitor proposed mergers and refuse where concerns about market share
Lack of consumer information	No information on quality of services provided by hospitals	Minimum reporting requirements on set of healthcare quality indicators with public disclosure	Individually written policies with variations in price, benefits, exclusions and deductibles	Standardised health insurance plans with the same benefits/ levels of copayments/deductibles
Barriers to market entry	Entry restrictions to medical register for overseas qualified doctors	Agree mutual recognition of equivalent qualifications	Only enrolees of social insurance eligible for supplementary insurance	Allow individuals to purchase supplementary insurance from any insurance provider
Externalities	Undersupply of immunisations	Require all children entering public schools to be fully immunised	Low risk individuals choosing not to insure	Mandate health insurance

Source: OECD (2007b), p. 12.

### *The economic context and policy objectives of the current reforms*

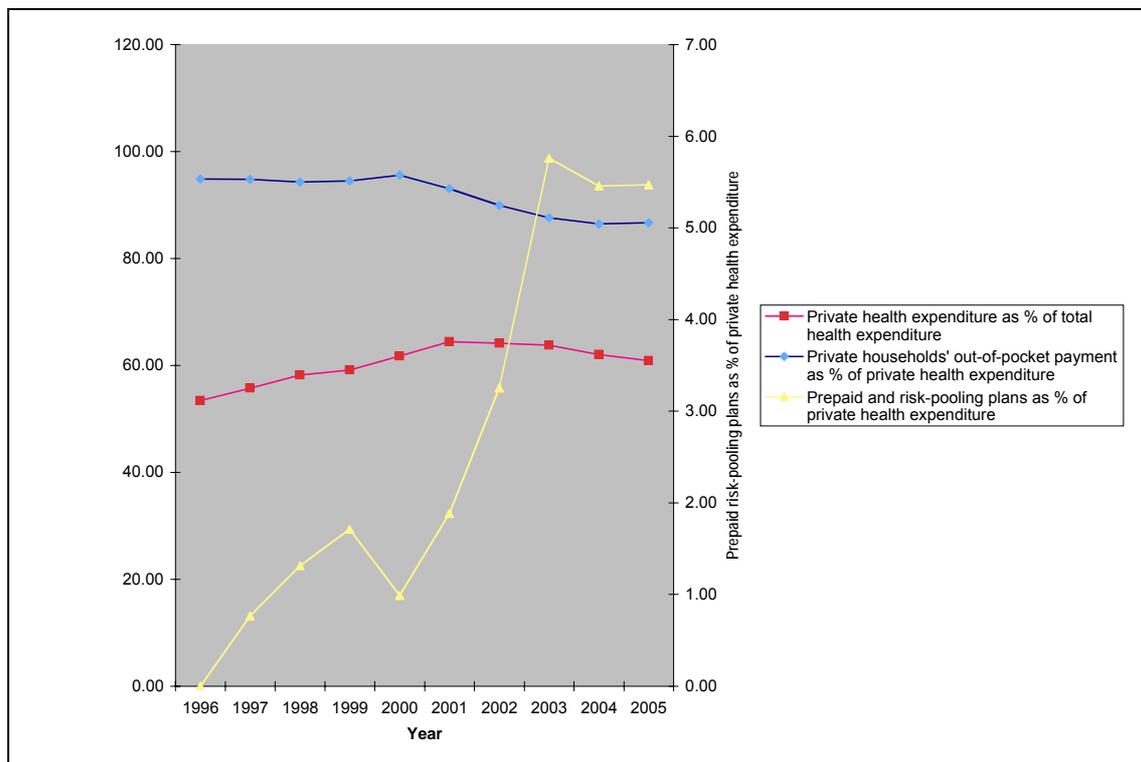
The single most pressing challenge facing the reform of China's health systems is the large proportion of the population without socialised healthcare coverage. China has embarked on the current post-1980s "second generation" reforms of the health sector from an enviable position. The government has accumulated significant financial reserves over the last three decades as reforms have overall sustained high levels of economic growth. Blumenthal and Hsiao (2005: 1169) observe that China's "national and local governments have sufficient tax revenues to make substantial health investments without reducing spending for competing social services". A variety of trial reforms have already been implemented within the rural and urban sectors, and their results are being studied as inputs for more comprehensive reforms.

Although domestic regulatory- and market-based processes are responding to concerns over the financial risks of catastrophic illness, both remain insufficient. The NDRC continues to pursue healthcare cost containment by expanding the list of price-caps governed under the Catalogue to new essential healthcare products. Similarly, the market has reacted by vastly expanding the provision of private healthcare insurance schemes. The following will review the shortcomings of these two developments and continue by assessing trials and reform efforts at both the rural and urban levels.

In recent years, the market has addressed the problem of declines in socialised healthcare insurance through private risk-pooling plans. This development may itself be a cause of further inequalities, but merits further research. Reductions in government spending on healthcare have had their most pronounced effect at the household level as private

households' out-of-pocket payments for healthcare now make up the overwhelming component of private healthcare spending. Notably, however, households' out-of-pocket payments as a percentage of total private health expenditures<sup>31</sup> declined from 95% to 87% between 1996 and 2005. A possible explanation for this gap between private households' out-of-pocket expenses relative to total private health expenditures can be found in Figure 4, which illustrates a rise in private risk-pooling plans as a proportion of total private health expenditures. As China's health insurance system continues to develop and mature, domestic regulators may consider experiences in the OECD area on increasing the efficiency of transactions between health insurance and healthcare providers (see Box 5). Developing regulatory strategies based on lessons from these experiences is likely to yield significant returns within the domestic health sector, as the proportion of the population enrolled in private healthcare insurance schemes increases in the coming years.

**Figure 4. The evolution of China's private spending on health**



Source: WHO.

Private spending on health risk-pooling plans has emerged to address the harsh financial implications that catastrophic illness can bring to private households. But, anecdotal evidence suggests that such private risk pooling activities are biased towards wealthier segments of society, which are better able to withstand the financial challenges of catastrophic illness<sup>32</sup>. The market's response to the problem of pooling health risks may contribute to further erosions of equity in China's health system. One way to reduce health insurance costs and thus increase the accessibility of health insurance, is to reduce possibilities for anticompetitive behaviour between health insurance and healthcare providers (see Box 6).

**Box 5. OECD Experience: Streamlining transactions between health insurance and providers in the United States<sup>1</sup>**

The Health Insurance Portability and Accountability Act (HIPAA)'s Administrative Simplification was introduced to reduce costs by standardizing electronic healthcare transactions. The huge number of customized electronic formats previously used presented a barrier to the use of electronic commerce in the healthcare industry. In the past, providers had to submit transactions in the specified format used by each health plan. Standardization of electronic transactions was meant to simplify the electronic data exchange between providers and health plans. It was hoped that this would both reduce the cost and encourage the use of electronic (rather than paper) exchange thereby reducing the significant administrative overhead and promoting the affordability of healthcare services and insurance coverage in the United States (ASPE, 2000).

Other industries have been able to adopt standards due to the presence of a small number of dominant companies. The highly competitive nature of the American healthcare system encouraged development of customized information exchange systems to limit provider choice. The Administrative Simplification provision directed the U.S. Department of Health and Human Services (HHS) to establish standards for healthcare data exchange. Private sector standard development organizations developed these standards (Lumpkin, 2000).

Standards apply whenever data is electronically transmitted between healthcare provider and healthcare plans as part of a standard transaction (such as a claim). HIPAA applies to private and public healthcare plans (including Medicare and Medicaid), health clearing houses, and healthcare providers that choose to carry out transactions electronically. An organization's internal information systems need not follow the standard, but organizations that choose to process standard claim, encounter, enrolment, eligibility, remittance advice and other transactions must adopt the standard (ASPE, 2000).

Transaction standards came into effect in October 16, 2003. HIPAA also included rigorous privacy standards that came into effect April 14, 2003, security standards effective 20 April 2005 and the National Provider Identifier (NPI), the standard for a unique health identifier for healthcare providers, effective 23 May 2007 (CMS, 2004). Progress towards full compliance is continuing despite missing some deadlines. The overall TCS compliance by January 2005 is estimated at 73% of providers and 70% of payers. Recent studies show that the transition has been difficult with many healthcare providers indicating that there has been insufficient guidance regarding interpretation and implementation of the regulations (HIMSS, 2005). The HHS estimated the total 10-year cost of adoption to be \$17.6 billion (Walden and Craig, 2003). However, the annual cost-savings achieved by administrative simplification has been projected in the billions (Fitzmaurice and Rose, 2000) (HIPAA Advisory, 2000).

Source: OECD (2007b), p. 36.

The longest standing approach to checking the cost of healthcare in China is the practice of bringing new drugs and medical treatments within the regime of price caps maintained by the NDRC under its Catalogue of essential drugs and medical treatments described above. The 19<sup>th</sup> medicine price cap implemented in August 2006 by the NDRC expanded the coverage of essential medicines to 99 new antimicrobial drugs<sup>33</sup>. This measure is expected to save patients roughly RMB 4.3 billion (USD 538 million) in healthcare costs *per annum*.

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<sup>1</sup> This illustration concerns the streamlining of transactions between health insurance companies and providers and thus strays slightly onto the financing side, in general not the focus of this report.

#### **Box 6. OECD Experience: Physician Hospital Organization Case: Piedmont Health Alliance**

In December 2003, the U.S. FTC "issued an administrative complaint against Piedmont Health Alliance, Inc. (PHA), a physician-hospital organization in North Carolina, and ten individual physicians, alleging that they engaged in a price fixing arrangement involving physician services. In a related action, Frye Regional Medical Center, an acute care hospital in Hickory, North Carolina, and its parent company Tenet Healthcare Corporation, settled FTC charges concerning their role in PHA's allegedly unlawful activities. The settlement with Frye and Tenet represents the first case in which the FTC has named a hospital as a participant in an alleged physician price-fixing conspiracy.

"The price-fixing charge is based on an alleged arrangement whereby PHA's physician members agreed to use PHA as their bargaining agent, agreed to participate in all contracts PHA entered, and agreed to accept PHA-negotiated prices. The complaints also state that, starting in 2001, PHA began using what PHA calls a "modified messenger model" to enter into contracts with some payers. Legitimate messenger arrangements can reduce contracting costs between payers and physicians, but without involving or facilitating coordinated responses by the physicians. In this case, however, the FTC alleges that the approach employed by PHA was a price-fixing mechanism. Although PHA did ask each member physician individually what minimum price he or she would accept under payor contracts, according to the complaint the contract price was not individually negotiated. PHA allegedly helped its physicians set a minimum price by sending pre-existing, PHA-negotiated contract prices to its physician members, which many used to develop their individual prices. PHA then allegedly negotiated with payers on the overall average price levels to be paid to its physician members, and then set individual fee schedules based on those price levels. According to the complaint, the essence of this pricing conduct is that the physicians, through PHA, collectively determined the size of the overall pie, and the fee schedules were a means of dividing up the pie. The complaint alleges that PHA's collective negotiation on behalf of its physician members was not reasonably necessary to achieving any efficiency-enhancing integration.

"Frye and its parent company, Tenet Healthcare, were charged for their alleged role in facilitating and participating in the physician price fixing. The complaints allege that Frye was instrumental in PHA's formation, expansion, and operation. Frye's Board of Directors allegedly authorized Frye's CEO to use Frye funds to develop a PHO that would include Frye and physicians who practiced at Frye, and Frye's Chief Operating Officer (COO) initially directed PHA's operations. The complaints state that Frye subsequently coordinated the inclusion of two other hospitals - Caldwell Memorial Hospital and Grace Hospital - and their respective medical staffs in the PHO, and has invested substantial funds in the project. Frye's Chief Financial Officer and COO served as PHA's principal contract negotiators from 1994 to 1996. Frye's representative on the PHA Board also participated in the Board's actions regarding payor contracts and physician fees.

"This case shows that hospitals face significant antitrust risks if they facilitate or participate in price fixing by physicians, absent a legitimate efficiency justification." (Creighton, 2004)

*Source:* OECD (2007a), p. 39.

Experts indicate however that expansions in the list of essential medicines covered under the Catalogue are often circumvented by: over prescribing medicines; alteration of drug names by drug manufacturers; simply ignoring the price caps; and sometimes turning down low cost medicines altogether<sup>34</sup>. A report by the World Health Organization (WHO) indicated that in rural areas, mark-ups for drugs could be as high as 40% to 80%. Similarly, an academic study published in 2000 found that 61% of drugs prescribed by doctors in rural areas for influenza were unnecessary<sup>35</sup>. Although traditions exist in many countries that providers of health services also dispense the pharmaceutical products they prescribe; such systems create incentives to prescribe more expensive or to over prescribe pharmaceuticals where more economic alternatives exist. A common regulatory approach to addressing such a situation in OECD economies is to separate the economic activities of health service provision and sale of pharmaceutical products (see Box 7).

### **Box 7. OECD Experience: Changing professional boundaries between pharmacists and doctors in Korea**

The Republic of Korea experienced dramatic healthcare reform in July 2000 when the 350 health insurance societies were merged into a single national health insurer (Kwon, 2003) and the complete separation of drug prescribing and dispensing was mandated by the new pharmaceutical reform. Up to this point, drug prescribing and dispensing had not been differentiated roles among physicians and pharmacists. In Korea, the role of pharmacists has long been significant; indeed pharmacists often play the role of primary care providers when the supply of physicians is scarce in communities.

Koreans consumed more drugs than people in other developed countries (Kwon, 2003) with pharmaceutical spending accounting for 31% of healthcare expenditure in Korea compared to below 20% on average in other OECD countries (OECD, 1996; National Health Insurance Corporation, 1997). The pharmaceutical reform aimed to reduce the overuse of drugs, improve the efficiency of the drug industry and drug distribution, and enhance patients' right to know about their medication (OECD, 2003).

The reform was implemented nationwide covering all healthcare institutions, all prescription drugs, and all patients. However, physicians resisted having their dispensing rights removed because it threatened to reduce their income (on average 47% of an internal medicine clinic's gross income was derived from the sale of pharmaceuticals)<sup>2</sup>. Consequently implementation was difficult and sparked protests and strikes (Kim, Chung *et al*, 2004). Medical and pharmaceutical associations appealed to the public by emphasizing that the new system would reduce consumer access to drugs and by deliberately devaluing its effects on potential cost savings and better health. Physicians led several nation-wide strikes, paralyzing the entire healthcare system. In February 2000, about 40,000 physicians participated in a demonstration and further strikes were held during April 4-5, June 20-26 and August 11-17 (Kwon, 2005). These physician strikes forced the government to raise medical fees substantially to compensate for the income loss of physicians and to modify some elements of the reform package (including returning injecting rights to doctors) but they failed to entirely block implementation (Kwon, 2003).

Evaluation studies considering the effects of the reform have found that there is less over-prescribing but there is an overall increase in drug spending since doctors have no incentive to prescribe cheaper generic drugs. Patients face greater inconvenience but benefit from higher quality and more appropriate prescribing with the possibility of the pharmacist checking the prescription. The position of domestic pharmaceutical companies has weakened as they have struggled to reorganise and compete with multinational drug producers. Finally total expenditure increased due to the increase in medical fees, greater use of branded products and the shift from pharmacy drug prescribing (paid out of pocket) to doctor's prescriptions which are reimbursed by the national health insurance. These trends have resulted in a greater deficit in the budget of Korea's national health insurance system (OECD, 2003; Kim, Chung *et al*, 2004:271-3).

Source: OECD (2007b), p. 44.

Without addressing the underlying incentive structure, which financially rewards healthcare providers for prescribing drugs and medical treatments not subject to price caps, the Catalogue cannot itself provide an effective solution to rising healthcare costs. It is against this backdrop that a number of gradual reform experiments have been implemented. Experiments in the rural sector focus on increasing socialised healthcare insurance whereas those in the urban sector address the rising cost of health services by restructuring the incentives facing healthcare delivery.

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<sup>2</sup> Providers are reimbursed on a fee-for-service basis. In return for strict regulation of fees for physician services, the government has allowed medical providers to profit up to a maximum allowable margin of 24% from drugs, though the government never actively enforced this limit and physicians commonly abused this opportunity.

## Health sector reform at the national level: the current state of play

In 2006, the key economic planning body in China, the NDRC singled out reform of the health system as a crucial component of its current 11<sup>th</sup> Five Year Plan<sup>36</sup>. Thus, under the overarching national policy objective of constructing a “Harmonious Society” from 2006 through 2010, health sector reform is now guaranteed attention, effort and resources. The NDRC similarly identified health as a pivotal sector for reform in its 2007 policy document *Programme of Action for Sustainable Development in China in the Early 21<sup>st</sup> Century*<sup>37</sup>. Promoting “quality” as opposed to “rapid” economic growth has become a hallmark of China’s efforts to build a Harmonious Society. Largely synonymous with the policy objective of ameliorating regional and urban/rural economic inequalities, seen as the root cause of social and political instability, the policy of Harmonious Society is unlikely to be achieved without significant reforms to enhance the equity and effectiveness of the health system.

The seriousness of the Chinese government in approaching new health sector reforms can be found in rare official admissions that the reforms undertaken in the 1980s had failed. China has openly sought international expertise to assist in developing effective reforms. In 2005, a report prepared by the Development Research Center (DRC – the State Council’s top research institution) in collaboration with the World Health Organisation, concluded that the health sector reforms had been “basically, unsuccessful”<sup>38</sup>. In 2006, Minister of Health Gao Qiang made a rare public apology acknowledging the failure of health sector reforms<sup>39</sup>. In 2007, another report on health sector reform in China<sup>40</sup> was prepared under a collaborative effort between the DRC and the Milbank Memorial Fund. It too contained thinly veiled criticism of the first generation reforms:

health sector reforms in the 1980s had assisted domestic healthcare facilities to become “more innovative” and had “encouraged investment in the medical delivery system, thereby increasing both capacity and consumer choice. But these market-based incentives have also had negative effects as well, *causing both social and political problems* in China. *The cost of services has risen, the utilization of appropriate services has declined, access to services has become more uneven, and the overutilization of inappropriate services has lowered their quality.*” (Emphasis added)

The report identified the regulatory objectives of healthcare regulation as:

- (i) ensuring the fairness of market exchange in the delivery system;
- (ii) correcting market failures in the delivery system; and
- (iii) ensuring equity in the delivery of medical services.

These three regulatory objectives essentially address the issues of spiralling healthcare costs, declining quality of healthcare provision and the drop in the proportion of the population covered by socialised healthcare insurance. Each of these subjects has been addressed in the gradualist and experimental trial reforms to be reviewed in the following sections. These trials highlight that reforms in the rural sector have focused on re-enrolling rural residents within some form of socialised healthcare insurance, whereas reforms in the urban sector have centred on containing increasing healthcare costs *via* hospital finance reform.

Over the long term, as the domestic health sector develops and the regulatory challenges it faces become more complex, health sector regulators in China may consider structuring reform packages based on a more comprehensive framework of regulatory objectives that have been developed based on a synthesis of OECD wide experience in health sector reform (see Table 2). Applying a consistent framework of objectives when assessing and

implementing regulatory reform at the sectoral level reduces the likelihood of reforms shaped by uneven reactions to idiosyncratic local conditions and health events, and reinforces capacity to achieve intended results in a comprehensive, balanced and calibrated manner.

**Table 2. OECD Experience: Objectives for healthcare regulation and examples**

<b>Quality</b>	accreditation of providers, training and licensing of health professionals, staff norms, protocols and guidelines, risk management and infection control requirements, technology appraisal
<b>Equity of financing and access</b>	open enrolment of insurance funds, risk adjustment of insurance capitation, income related contributions (mandatory), limits on user charges, duty to treat on hospitals, professionals codes of practice, planning regulations of the location of clinics/ hospitals
<b>Access and choice</b>	all willing provider contracts, service hours, waiting time guarantee, compulsory GP registration, entitlement rules, numerus clausus, planning number of beds, free choice of insurer/ provider
<b>Efficiency/effectiveness</b>	Gatekeeping ( <i>i.e.</i> no direct access to specialist care), generic substitution, contracting rules, cost effectiveness criteria for reimbursement of services (list of benefits, positive and negative lists),
<b>Cost containment</b>	fix reference prices <i>e.g.</i> for pharmaceuticals, set budgets for purchasers or providers, profit controls or limits on allowable deficits, fixed wages (national pay bargaining), borrowing restrictions

Source: OECD (2007b) p. 12.

The following two sections will provide an overview of OECD experiences and best practice on regulatory reform in the health sector. They will also recount experiences and progress in the China's efforts to reform the health sector since the first generation of reforms. The first section will present an overview the OECD regulatory perspective on healthcare delivery, and continue by reviewing second-generation reform trials. It will in turn be followed by a description of the current state of play in the rural health sector. The second section will distil OECD experience on reforms to strengthen efficiency in the provision of hospital services and, similarly, follow with a review of second-generation reform trials in China's urban health sector. That section will also conclude with a description of the current state of play in regulatory reform within the urban health sector.

## OECD experience: A regulatory perspective on healthcare delivery

High quality regulation involves a comprehensive cross-government approach spanning a wide range of economic sectors. This report considers the relevance of a high quality regulation approach for the health sector.

Health care regulation has a long and varied history. Recent reforms to healthcare systems and other changes in the social and political environment mean that regulation is of increasing importance to the successful functioning of healthcare systems and the delivery of health system objectives, as determined in each country. The apparent diversities in the underlying principles applied by regulators within the OECD area should not obscure the strong commonalities that underlie them (see Table 3).

**Table 3. OECD Experience: Principles of high quality regulation in selection of OECD countries**

UK	Canada	Australia
Proportionality	respects legal and constitutional requirements;	the minimum necessary to achieve objectives, with minimum compliance burden;
Accountability	gives the most regulatory protection at the least cost to both the private sector and the government;	not unduly prescriptive;
Consistency		integrated and consistent with other regulations;
Transparency	promotes a culture of openness and accountability;	accessible;
Targeting	enacts regulations based on input from stakeholders;	transparent;
	is user friendly, accessible and understandable; and	accountable;
	is continuously updated and improved	enforceable; and
		communicated effectively

Source: OECD (2007b), p. 14.

Regulation may take a number of forms – from traditional command and control regulation, in the form of legislation and administrative rules, to incentive-based regulations. When devising new healthcare regulations, it is important to consider the range of regulatory tools available and to analyse *ex ante* the implications of adopting different types of regulation. Regulatory impact analysis has some value in assessing healthcare regulations though there are limitations and refinements may be needed. Health impact assessment offers a tool for analysing the health impacts of a range of regulatory policies.

The type of regulation adopted may also depend on the institutional setting and the assumptions about the motivations and behaviour of those to be regulated. Flexible and responsive regulation, that is able to combine facilitative modes and punitive modes depending on the extent of deviation from the standards, is increasingly advocated.

States may decide not to regulate parts of the healthcare system but leave the setting of standards, monitoring and enforcement to the professionals or providers themselves. Self-regulation has advantages and disadvantages. There are a range of other institutional

arrangements between ministerial control and self-regulation where the responsibilities for some or all of the key regulatory functions are decentralised to independent public bodies (delegation) or to an independent external organisation (co-regulation). Another possibility is to decentralise the functions from the centre to local level: *i.e.* to a lower tier of government (devolution) or to a lower administrative tier (deconcentration).

A system with multiple regulatory agencies poses challenges of coordination, accountability and governance. Achieving high quality regulation in healthcare involves providing a clear framework for accountability and governance. Independent bodies need to be set clear goals, with corresponding powers and resources to achieve them. The institutional design needs to take into account the risk of capture. To ensure that self-regulating bodies should be constituted to act in the public interest. The regulatory framework needs to be consistent across levels of government, with provisions for high quality regulation at the local level. It also needs to ensure that the implementation of supranational regulations is proportionate.

Within any healthcare system, there are a complex array of regulatory tools and institutions operating. A clear map of who and what is being regulated can facilitate the identification of gaps in the regulatory framework or avoid duplication and conflicting regulations for individual entities and providers. This section advocates high quality regulation principles to examples of regulation in healthcare systems in the case of providers, professionals, goods and services and patients. This approach applied at a country level could usefully highlight areas for improvement from a regulatory and governance perspective.

In preparing new regulation for the health sector, policy-makers can benefit from applying the tools for high quality regulation such as regulatory impact analysis and consultation. Further development is needed to ensure that the results of such analysis and processes are able to influence regulatory decisions in a timely fashion, do not overburden stakeholders in lengthy consultations and accurately estimate compliance costs for all affected interests

High quality regulation may also involve reviewing the existing stock of regulations, as there might be scope for simplification in order to reduce administrative burdens. Transactions within the healthcare system can be made more efficient, information requests can be coordinated, for example through one-stop shops, and wherever possible rely on routine data, inspection and monitoring processes streamlined.

A high quality regulation perspective can offer useful insights for the health sector. Alternative regulatory policies can be assessed, appropriate regulatory institutions designed and existing regulatory tools developed and adapted to inform the development of future regulations within the healthcare system as well as improving the existing stock of regulations.

### **China's experience: Gradual reform trials in the rural health sector**

In the rural health sector, a number of trials have been implemented, documented and analysed by health policy departments at western universities. Two studies reviewed below include one assessing the results of an early scheme designed mainly to increase enrolment in socialised healthcare insurance scheme. The second established a more comprehensive programme that restructured the system healthcare finance in the city of Xinlian.

According to Wang *et al.* (2005), early trials of socialised healthcare insurance schemes in China reflected coverage plans that created regressive redistributive effects. The first study covering six villages in the Fengshan Township of Guizhou province supported this perspective. With low annual premiums (RMB 10 or USD 1.25) and high patient co-payment rates for treatment (80%), the study yielded three key findings. First, farmers with higher incomes were more likely to enrol than poorer farmers. Second, richer/sicker farmers

obtained greater net benefits from the socialised healthcare insurance whereas poorer/healthier farmers tended to subsidise benefits for the richer/sicker farmers. Third, rich farmers at all levels of health status tended to benefit more from the scheme. These effects were driven by high co-payment rates that deterred enrolment by poor farmers, despite low enrolment fees. The study found that even when sickness occurred, poor farmers – including those with insurance – underutilised health services.

The recommendations from this study focused on increasing equity in the distribution of benefits from socialised healthcare insurance schemes, and structuring reimbursement to better enable the poor to benefit. The recommendations by the researchers included: better targeting of the government premium subsidy to the poor; reducing co-payments by the poor; and decreasing the co-payment rate for outpatient care. An important regulatory tool applied regulatory institutions within the OECD area generally, and within the health sector particularly, is the use of public consultations. Public consultations not only allow for the diagnosis of the shortcomings in regulatory systems, and may themselves event become mechanisms for overcoming them (see Box 8).

**Box 8. OECD Experience: The role of Health Boards in Scandinavia**

In Scandinavia the financing and provision of healthcare is largely a devolved activity. In order to ensure national standards of care the National Boards of Health have traditionally played a significant role in regulation. All of the Scandinavian Health Boards have a supervisory function over the local/regional councils acting as the government's central advisor and supervisor for health services. In Sweden, the National Board of Health and Welfare supervises and evaluates implementation of policy and legislation in healthcare and social welfare services to ensure that it meets the intended goals. It also acts as the licensing authority for health professionals and requires that staff participate in quality assurance programmes. In 1994, the Board introduced a new regulation requiring all healthcare providers to produce regular, systematic and documented reports of quality (Hjortsberg and Ghatnekar, 2001).

In Denmark the National Board of Health was established in 1932 and is responsible for supervising health personnel and institutions and for advising different ministries, counties and municipalities on health issues (Vallgarda, Krasnik *et al.*, 2001). The counties are not obliged to follow their advice. It has powers to decide on the distribution of specialists and temporary training posts, reimbursement of professions and authorization of general practices in order to ensure geographical equity and match supply to need.

Source: OECD (2007b), p. 28.

In 2003, a more ambitious trial carried in Xinlian, a city of 60 000 residents, was carried out based on a healthcare insurance programme designed by academics<sup>41</sup>. With an annual subsidy per resident of USD 4.50 provided by foreign sponsors, and co-payment by farmers amounting to less than half that, this programme sought to address the issues of expanding coverage, mal-incentives facing physicians as well as corruption by public officials. Noting that a crucial regulatory challenge lay in convincing farmers to make payments into the programme due to concerns about misappropriation, a key component of this programme was the public election of a local resident to administer the programme. The trust of local residents in this elected administrator enabled the programme to manage a fund based on farmer's contributions and private sponsorship. The fund not only provided benefits in the event of illness, but also paid doctors a fixed monthly salary of USD 30 as a means to reduce their financial dependence on drug sales. Although detailed results of this experiment were not available at the time this paper is being prepared, the city of Guizhou with a population of over 1.7 million residents chose to adopt a similar programme in 2006.

### ***Nationwide reforms of the rural health sector***

Efforts to re-launch a system of socialised healthcare in the rural sector have reflected the orthodox Chinese approach to gradualist economic reform. Initiated in 2003, progress on healthcare reform has reached a stage where the government has publicly announced its intention to eventually make socialised healthcare insurance available to the entire rural population. Toward the end of 2006, the government announced that the basic infrastructure of a new Rural Health Care Service System (RHCSS)<sup>42</sup> should be in place to cover all rural areas by 2008. Although details relating to its implementation remain incomplete, news reports indicate that it will build upon an existing previous MSA system by doubling the government co-payment to RMB 40 (USD 5). Under this plan, the government would pay a maximum of 65% of medical charges for farmers per year<sup>43</sup>. This increase in the government co-payment level suggests that studies based on gradualist trials such as that described in Wang *et al* (which recommend better targeting of benefits to the poor), have influenced the design of health sector reform at the national level.

The current plan built on the new rural cooperative medical care system<sup>44</sup> established only three years earlier in 2003. Under that initiative, the government had established a new rural cooperative medical care system initially covering 671 counties or roughly 177 million of China's 900 million rural residents. It was based on a form of MSAs under which rural residents provided an annual co-payment of RMB 10 (USD 1.25) that the government matched at a rate of RMB 20 (USD 2.5). The Ministry of Finance announced in 2006 that it would provide additional financing of RMB 4.73 billion (USD 500 million) to expand trials to 1145 or 40% of all counties in China by the end of 2006.

### **OECD experience: Enhancing efficiency in the provision of hospital services**

#### ***Role of Rivalry for Provision of Hospital Services***

- 1. Market-oriented mechanisms can help to reduce costs of provision of hospital services, thus making limited healthcare funds have more impact, even systems with hospitals that are primarily government-operated.*

Increasingly, OECD members are seeking to increase the output from the limited financial resources that the state or private sector contributes to health care. Given that hospitals constitute 41% of Member country healthcare spending, increasing productivity and reducing unnecessary care is of great importance. Studies suggest that significant room exists to improve efficiency in the delivery of health services. While the health sector is one that involves many public-spirited motives, financial incentives do nonetheless have a significant influence on outcomes; appropriate incentives can increase outputs from a given level of spending, thus ensuring that public and private funds are used effectively. A number of countries that previously have not had significant market-based mechanisms for hospital services have taken steps to introduce stronger market mechanisms, including France, Germany, the Netherlands, Sweden and the United Kingdom. The introduction of market mechanisms is fully consistent with broad and equitable access to health care; it does not necessarily imply privatization or non-governmental control of facilities, but can take a variety of forms, including increased rivalry between government-operated suppliers of hospital services.

## ***Pre-Conditions for Market Mechanisms***

2. *A number of conditions must be met in order for market forces to have an effect in the health sector.*

Some of the most important pre-conditions for market mechanisms to work are that (1) financial support for a hospital is related to the number of patients treated and their treatments, so that hospitals have an incentive to seek to treat more patients; (2) selective contracting is permitted, so that hospital service purchasers do not have to purchase from all hospitals or that hospitals offering higher levels of services for a given level of funding can receive greater numbers of patients; (3) feasible alternative suppliers must be present and they must have the capacity to take increasing volumes of patients, otherwise providers will have monopoly power and rivalry will have little impact; and (4) sufficient information is collected to judge exactly what services are provided by hospitals, ideally, including indicators of quality of care.

Ensuring that hospitals that perform well are rewarded for good performance is critical to providing incentives for efficient use of funds. In some systems where hospitals have received global budgets, introducing payments for outputs has led initially to greater funding for the more successful hospitals, but then been followed by a reduction in “base” hospital funding in order to help other hospitals that face financial difficulties as a result of being less successful. Incentives like this will not work because management will not perceive long-term advantages from good performance or detriment from bad performance. Consideration should be given to closing or changing management for hospitals that continually fail (compared to their peers) to provide a good set of outcomes in relation to resources used.

One common form of payment is based on prospective payment, where payments are based on costs in an “average” or an “exceptional” hospital. This form of payment is based on benchmark competition; the benchmark changes over time as hospitals increase their productivity.

If all capacity is fully used and no new capacity is built, direct rivalry could have much reduced impact because providers will know that, even if they do not improve services, they will not lose significant business. This does not necessarily mean that new hospitals must be built. One of the impacts of rivalry and benchmarking can be that hospitals reduce often-excessive lengths of stay, hence freeing capacity, as was the case with the introduction of prospective payment in the United States in 1982, which resulted in reduced patient lengths-of-stay and shifting surgeries to outpatient settings so that hospital occupancy rates fell from 74.6% in 1982 to 63.6% in 1986. Improved surgical technology (with shorter recovery times) has led to a reduction in lengths of stay as well, freeing capacity. Even hospitals that are apparently full may have the ability to increase capacity. For example, in France, some hospitals provide the option of private rooms (with patients paying a premium for private rooms) but eliminate this option when patient numbers are high.

One of the most basic ways to reward efficient providers is by giving them more patients, which typically implies giving less efficient providers fewer patients. Selective contracting is one way to ensure these rewards, meaning that, in systems with multiple purchasers of services (such as insurance companies or physicians) the purchasers are not obliged to contract with all potential providers of a service, but can selectively contract with a limited number of providers. In systems with only one purchaser of services (such as the state), absolute selective contracting may be more difficult, because it could imply that a hospital without a contract would go out of business, but partial

selective contracting, in which “preferred” hospitals receive a higher percentage of patients for certain types of care, may be feasible.

In some healthcare systems, hospitals have not kept records of treatment in a consistent manner that is comparable across hospitals. In absence of such information, benchmarking and effective use of resources is difficult to ensure and manage, whether for government or private payers. Collecting detailed comparable information on treatments may help to promote rivalry and identification of best practices.

### ***Heterogeneity of Hospital Services***

3. *Some hospitals services benefit more from competition than others and this competition need not always come from hospitals themselves.*

Hospital services are a complex set of products and services that encompass many different types of patient-oriented activities. In addition to surgical, maternity and inpatient care, hospitals typically offer emergency care, a variety of diagnostic services and pharmacies. For some services, such as emergency services, a hospital may have few, if any, competitors because ambulances with patients needing critical care must go to the nearest hospital to ensure fast treatment. For other services, such as surgeries, hospitals may compete with other hospitals and ambulatory surgery centres and, for diagnostic and pharmacy services, hospitals may compete with a variety of non-hospital providers. Typically, more advanced surgical services will be provided by fewer hospitals and may be less competitive.

Healthcare services, including hospital services, combine unusual features that could result in excessive spending from the adoption of a pure free-market approach. In particular, health insurance implies that consumers pay a much lower cost than the marginal cost of services they receive, so they will demand services even when the cost of the service is higher than the patient’s expected gain. An information problem also exists, because consumers have difficulty assessing the quality of care both before and after the delivery of services, which could permit revenue maximizing healthcare providers to provide excess and low-quality services. As a result, most countries reasonably place constraints on the extent to which a complete free-market operates.

### ***Different Effect of Competition for Rural Hospitals and Highly Sophisticated Services***

4. *When hospitals are located in rural areas or services in question are highly sophisticated and provided by few hospitals, competition with other hospitals is likely less effective for encouraging better use of resources; when hospitals are located in areas with multiple competing service providers, competition will reward those who use resources better.*

Not all hospitals are equally susceptible to benefits of market forces. Canada stated that “Careful consideration is required of the feasibility of competition with respect to different hospital services and for different regions of the country. While it may be feasible in relation to relatively standardized services in densely populated areas, for other more complicated or rare services, teaching hospitals and less densely populated areas, the potential for competition may be limited.” For rural hospitals, for example, direct competition cannot be expected to provide a strong incentive for improvement in the provision of services. However, even for such rural hospitals, benchmark competition (based on prospective payment) can provide significant incentives for improvement. Benchmark competition may be difficult to implement, however, outside of a state-operated payment system. When a state-operated payment system co-exists with a non-state system, hospitals with market power because of limited direct

competition may seek to set higher prices to non-state payers in order to make up for shortages from state reimbursement. Often, in a mixed payer system, market mechanisms cannot be fully relied upon to provide a strong incentive for rural hospitals to improve service.

#### ***Anti-Competitive Restrictions on Labour Use***

5. *Anti-competitive restrictions by professionals and other staff can be reduced to permit more flexible uses of resources, according to patient needs and hospital resources.*

Professional and staff restrictions can result in significantly lowered hospital productivity, as when nurses are not permitted to perform certain tasks for which they are or could be easily trained, or when strict rules determine whether a person working in one area of the hospital can, in case of need, perform work in another part of the hospital. Such restrictions are sometimes put in place by professional rules that have the effect of limiting the ability of otherwise qualified personnel to perform tasks. Greater flexibility over tasks can greatly enhance productivity of personnel. Restrictive rules, particularly those developed by self-regulating professions, should be carefully examined to see whether their impact is beneficial to the healthcare system as a whole.

#### ***Non-governmental Provision of Hospital Services***

6. *Non-governmental operation of hospitals or non-hospital service providers will often result in better outcomes and, consequently, it is valuable to have such options present.*

Many countries have non-governmental hospitals, including Australia, Canada, Denmark, France, Germany, the Netherlands, Switzerland, the United Kingdom and the U.S. Many owners are non-profit organizations, while others, in some cases, are for-profits. For-profit hospitals often can serve both private and, increasingly, public patients. In the United Kingdom, a number of new hospitals are being constructed under private contracts in part because private hospital operators are able to construct new facilities more quickly than under government operation. In Denmark, as of 2002, a system was implemented that gave patients the option to receive funded care from private hospitals in Denmark or other countries if their home county hospital was not able to guarantee treatment within two months, provided that a contract exists between the society of Danish counties and the private service provider. Of the 160 private care providers with whom agreements have been struck, 20 are located in Germany and Sweden.

Better outcomes from non-government control are much less likely to occur when physicians are major financial beneficiaries of hospital profits, whether through direct ownership or other means. As in Sweden, hospital facilities themselves can continue to be run by the state even after some hospital operations are run by private operators. Some countries, such as France and the U.S, have introduced rules that restrict the ability of physician-owned facilities to serve patients who are paid by government funds. There is evidence that such hospitals will seek to siphon the less complicated cases for themselves while leaving more complicated cases for the public hospital system, raising the average cost for treating a condition in public hospitals.

### ***Benchmark Competition***

7. *Benchmark competition can be particularly effective for providing incentives for hospitals to achieve better performance.*

Prospective payment is often adjusted based on performance of median or best practice hospitals. Many countries are introducing prospective payment systems in order to encourage hospitals to improve their outputs for the funds they receive. When hospitals are paid based on the number of days of care they provide, they can have an incentive to increase lengths of stay unnecessarily. For example, a number of jurisdictions have recently introduced prospective payment systems including Denmark, Germany, France, Japan, Norway and parts of Sweden and Switzerland.

Benchmarking can also be used to provide incentives for hospitals to deliver higher quality care. In the United States, hospitals are given financial incentives to report data that provides indicators of quality of care. Those hospitals that are deemed to provide among the highest quality of care (compared to others) then receive extra payments from many government-reimbursed patients.

### ***Purchasing with Budgets***

8. *Physician-led or insurer-led purchasing can yield significant improvements in total hospital services received from given resources.*

Physician led purchasing by primary care physicians has been introduced in the UK. Physicians or physician groups are given a budget for their patients, based on expected costs of their register of patients. If there are catastrophic cases, these can be excluded from the overall budget, to provide better incentives for physicians to carefully select both which patients receive care and where they go for their care. Studies suggest that such approaches lead to better use of resources even when the physicians do not receive direct payments.

### ***Consumer Mobility and Choice***

9. *When waiting lists are long, permitting funds to follow patients will help to reduce length of waiting lists and increase output.*

Many countries have suffered from long waiting times for scheduled surgeries. One approach that can be adopted in such situations is to give physicians or patients the right to choose where they will receive care. In Sweden, where counties are responsible for providing care, if patients waited more than a certain amount of time, they were permitted to go outside of their county to receive care, and the counties would then have to pay hospitals outside of the county for the care that was provided. For cataract procedures, for example, the introduction of this law was related to a significant increase in the total number of procedures performed and a reduction in average waiting time. Long waiting times may have been discouraging physicians from proposing surgeries that they felt would be valuable for patients. However, relatively little switching occurred, in part because of poor information available to consumers and physicians about wait times in different hospitals. This lack of widely accessible information has led the Swedish Federation of County Councils to begin a project to collect and distribute information about wait times over the Internet.

### ***Centres of Excellence***

10. *While in general, limiting the number of hospitals that can perform a service will not promote best use of resources, for certain intensive, high-end services with large economies of scale, focusing on the creation of centres of excellence can help to increase both the quantity and quality of services.*

Open-heart surgeries and organ transplants have been shown to benefit from significant economies of scale in operation. This means that focusing patient care in a limited number of facilities can actually have significant benefits for reducing costs. Moreover, it has been shown that centres of excellence can increase quality of care, because the personnel have more regular practice in dealing with a given condition and its complications. An open-heart surgery unit that deals with more than 5 cases per week will often have much better results, per patient, than a unit that deals with just one case per week. Competition for open-heart surgery can result in more hospitals having lower numbers of patients, largely because hospitals perceive it is prestigious to have an open-heart surgery centre, even when few procedures are performed. This illustrates how competition with no entry constraints for certain very expensive and high-end services may actually increase system costs, and in these limited instances, restrictive entry may yield better outcomes.

### ***Competition Policy Applied to Hospitals***

11. *Introduction of market mechanisms requires that governments pay attention to structural conditions in the market (through merger control) and co-ordination among suppliers (through anti-cartel programs.)*

Many countries now have experience with competition law investigations or enforcement in the health sector, including Argentina, Australia, Brazil, Chinese Taipei, Germany, Italy, Korea, Mexico, the Netherlands, New Zealand, South Africa, Switzerland and the U.S. At least four of these countries had hospital merger cases in 2005. Largely because of longstanding existence of private markets in health care, the U.S. has had the longest experience of competition cases in this area and has actually had groups of attorneys dedicated to healthcare issues for decades. Cases related to hospitals can involve hospital mergers, planning licenses, system-wide negotiation, joint hospital and physician negotiations, hospital exclusivity and most-favoured supplier contracts. Hospital merger enforcement by competition authorities is complex, largely because of the necessarily predictive nature of merger enforcement, the public service nature of hospitals, the complications of defining geographic market appropriately and the complicated nature of hospital services. After a number of lost merger challenges by U.S. agencies, in a recent case, the U.S. Federal Trade Commission (FTC) challenged a previously consummated merger with the allegation that prices had increased substantially after the merger. The judge's decision found for the U.S. FTC, finding that prices had risen significantly as a result of hospital merger in a major metropolitan area with a number of non-merging hospitals nearby. Other countries have recently successfully challenged mergers or reached divestiture agreements in system mergers.

### **China's experience: Gradual reform trials in the urban health sector**

A number of policy experiments have been carried out in urban areas seeking to test approaches to check rapidly increasing healthcare costs. Two trials designed to contain healthcare costs by restructuring the economic incentives facing hospitals are reviewed below. The first shifted the central government's hospital reimbursements from a fee for service (FFS) basis to a prepayment plan whereas the second reconfigured patient medical savings accounts (MSAs).

Implemented in 1997, the first trial included six hospitals in Hainan province and comprised both a “control group” of three hospitals, for which no reforms were implemented, and a “trial group” of three hospitals with sizes and structures similar to that of the control group. The first study by Yip and Eggleston (2004) found that restructuring economic incentives facing hospitals under a prepayment plan could reduce the rate of increase in spending on expensive drugs and high technology services.

The trial hospitals had their central government reimbursements restructured from FFS to a monthly prepayment amount calibrated to 90% of that hospital’s FFS reimbursement for the same month in the previous year. The remaining 10% could be reimbursed provided that the hospital demonstrated an acceptable level of quality in its provision of health services at an end-of-year review. Additional quality safeguard measures were put into place including requirements that the number of patients treated must total at least 90% compared to the previous year, and that total spending was at least 90% of the budgeted amount. Under this scheme, hospitals have an incentive to reduce costs due to the fact that where they are able to bring their actual monthly costs below their prepayment allotment. This is because they are able to retain the difference as profit.

The system of incentives to contain costs was paired with a schedule of disincentives for cost overruns, which would have uncertain implications for the scheme’s efficacy over consecutive years. The schedule of disincentives for cost overruns made hospitals responsible for financial penalties amounting to: 30% of the cost overruns up to 10%; 50% of the cost overruns up to 20%; and 100% of the cost overruns beyond 20%. Under these conditions, aggressive cost cutting in one year meant that the prepayment level would be reduced in the next. Thus, disincentives were created for overzealous cost cutting in any particular year because subsequent cost rises above a previous year’s pre-pay level would activate the schedule of disincentives.

The findings of this study were consistent with similar trials in advanced economies. Removing incentives for the overuse of profitable health services under a FFS structure normally reduced their use in trial hospitals. During the observation period, rates of increase in the fees charged for high tech diagnostics in trial hospitals declined significantly relative to control hospitals, and at least in one instance even in absolute terms<sup>45</sup>. More importantly, while use of expensive drugs and high tech diagnostics and treatments declined significantly in comparison to the control group, the utilisation of essential health services that were relatively unprofitable under the FFS structure remained largely unaffected by the reforms<sup>46</sup>. These two results viewed together suggest not only that overt declines in quality of service did not occur, but that cost savings resulted largely from reductions in unnecessary treatments – which were previously profitable under the FFS environment.

Caveats to this study included the short six-month examination period, and the lack of a quality assessment component. In addition, data for this study came only from insured patients, and thus did not allow for an assessment of whether trial hospitals may have shifted costs from insured to uninsured patients. The study also identified the possibility that trial hospitals assigned expensive patients to other hospitals as an issue worthy of further research. Such uncertainties are of universal importance in that they connect the distributional qualities of health systems with the overall quality of the services they provide. In this light, a systematic approach to assessing the overall quality of health systems can be implemented by relying on a consistent framework of analysis as outlined in Table 4. Globally applied, such exercises may prove invaluable for designing balanced and yet well-targeted reforms with limited resources.

**Table 4. OECD experience: Examples of quality standards for institutional providers of health services**

Inputs	Staffing levels, bed numbers, facilities, items of equipment, scope of services
Processes	Waiting times, cancellation rates, readmission rates, length of stay, risk selection, type of care, clinical governance systems
Outcomes	Health outcomes, patient satisfaction/ complaints, medical errors, infection rates

Source: OECD (2007b), p. 40.

The second study by Yip and Hsiao (1997) reviewing a trial involving MSAs in Zhenjiang and Jiujiang (together comprising a population of 5 million people) similarly finds that MSAs contained healthcare costs, but points to anecdotal evidence that hospitals may have shifted costs to uninsured patients. Implemented in 1994 under a State Council mandate, an important first step of this programme was the generally successful attempt to require all government and private enterprises under the GIS and LIS to enrol in the programme. This measure established a much broader basis for risk-pooling in comparison to the standard company based schemes under the LIS, and addressed instances where unprofitable companies simply failed to provide healthcare benefits to employees that were, on paper, insured.

The programme itself consisted of an integrated regime of measures addressing both the demand as well as the supply side of the health sector. On the demand side, employers and employees contributed 1% and 10% of their total wage bill into two separate accounts including 6% into an individual account and 5% into a social risk-pool fund. Individuals would rely on the 6% contained in the individual account to finance routine medical expenses. In the event of catastrophic illness, insured individuals would have access to the social risk-pool fund after exhausting their individual savings accounts and paying an additional 5% of their total annual income out of pocket. To maintain incentives for cost reduction even after social risk-pool funds were being employed, a high 20% co-payment rate for diagnostic services exceeding RMB 200 (USD 16) applied regardless of total expenses accrued.

On the supply side, Zhenjiang established a schedule of fixed rates for the payment of inpatient and outpatient health services measures designed to safeguard quality of service. The schedule of fixed rates provided incentives for hospitals to cut costs by requiring hospitals to pay for excess costs of treatments above the fixed rates, and conversely allowed them to retain as profit the difference when treatment costs were brought below fixed rates. This trial also included a quality safeguard similar to the prepayment trial described above. Hospitals were initially compensated at only 95% of their fixed payments levels, and disbursements of the remaining 5% were conditioned on an audit of how hospitals performed with respect to a number of pre-designated criteria including: accuracy in diagnosis, appropriate outpatient prescriptions, length-of-stay for inpatient care and others.

Also, as in the case of the prepayment trial, cost savings were realised primarily *via* reductions in the use of expensive diagnosis and drugs while utilisation rates for less profitable health services such as hospital stays remained relatively constant. Hospitals reacted to the new framework of economic incentives through internal reforms. Among those recorded in the study was the de-linking doctors' bonuses from use of expensive health services, and re-linking them to keeping treatment costs at or below the fixed rates at which hospitals were reimbursed for health services. Notably, the use of co-payments had only a slight effect in reducing demand for visits. In Zhenjian, cost savings of 27% were recorded

for the average insured individual between 1994 and 1995, and total healthcare spending declined by 24.6% during the same period. Contrasting sharply with the results in Zhenjian, two neighbouring control cities recorded growth rates in total healthcare spending of between 35% and 40% during the same period.

The researchers highlighted an important shortcoming of the study. It was unable to systematically evaluate whether hospitals engaged strategies of cost shifting from the insured to the uninsured population to make up for declining revenue from the insured population. Analysis of cost shifting is important given that more than half of urban residents nationwide are uninsured. Anecdotal evidence of cost shifting was found in the experience of an enterprise interviewed as part of the study. The enterprise had initially decided not to enrol in the programme, but chose to do so after discovering that its employees faced an unprecedented 50% fee hike for hospital admission shortly after the trial began.

One approach to implementing regulatory mechanisms of oversight, to reduce the likelihood of practices such as cost shifting is *via* self-regulation by the providers of healthcare services, which have the specialised knowledge (both technical and of local circumstances) regarding practices that are to be prevented. Although such an approach is no panacea (see Box 9), it may nonetheless provide a useful component of governance within a broader regulatory framework.

#### **Box 9. OECD experience: Self-regulation and provider accreditation in the United States**

Safety and quality assurance in U.S. healthcare facilities have a long history of self-regulation by the medical profession. The first hospital inspections were performed in 1918 by the American College of Surgeons (ACS) based on their *Minimum Standard for Hospitals* report. By 1951, they were joined by the American College of Physicians, the American Hospital Association, the American Medical Association, and the Canadian Medical Association to form the Joint Commission on Accreditation of Hospitals (JCAH) to provide voluntary accreditation. Over time JCAH became more closely tied with the government, broadened its scope to accredit ambulatory healthcare facilities and established professional and technical advisory committees for each accreditation program. It was chosen in 1965 as the official organisation for accrediting facilities which would qualify for reimbursement by Medicare. In 1987 it changed its name to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) to reflect its expanded scope of activities (Franko, 2002).

The Joint Commission is the largest not-for-profit healthcare accrediting body in the United States and is governed by a 29-member Board of Commissioners (made up of nurses, physicians, consumers, medical directors, administrators, providers, employers, a labour representative, health plan leaders, quality experts, ethicists, a health insurance administrator and educators). The Joint Commission provides healthcare accreditation for more than 15,000 healthcare organizations in the United States (JCAHO, 2005). It is not a government regulatory agency and thus has no authority to cite or fine healthcare organizations for not meeting standards, but their standards carry considerable weight among both private and public payers of healthcare (Franko, 2002).

The significance of private third-party payers in the United States makes a reliable private accreditation system essential. JCAHO accreditation alleviates the need every third-party payer to independently assess the quality of their choice of providers (Kinney, 1994). Although the federal Centers for Medicare and Medicaid Services (CMS) has official regulatory authority over accrediting hospitals participating in Medicare and Medicaid, similar to private third-party payers, HCFA defers these activities to the Joint Commission (Shapiro, 2003). In fact, with JCAHO accreditation alone, a healthcare institution is deemed to meet the conditions for Medicare participation (Jost, 1994). Failing to meet the standards as evaluated by the JCAHO survey process can result in the loss of million of dollars from private third-party payers and Medicare and Medicaid programs thus participation is high (Franko, 2002). As a self-regulating body, the Joint Commission is accountable to a range of interests not only to the hospitals it accredits. It responds to the physicians who created it and still govern it, and to the federal and state governments and other purchasers of healthcare whose recognition effectively gives it monopoly power in the hospital accreditation business (Jost, 1994).

Critics of self-regulation believe that it is a poor means for protecting patients and ensuring quality. Indeed Medicare has come under fire in its 40<sup>th</sup> anniversary year for failing to assure quality of care and

its reliance on JCAHO brought under question<sup>3</sup>. The issues of conflicts of interest, as well as the possibility for JCAHO to conduct commercial activity have been highlighted as potential areas of concern. In theory, Medicare should check the Joint Commission's work to make sure that accredited hospitals meet federal standards, but the resources available for those checks have been limited in recent years. State regulators also play a role in the oversight of quality. In recent years, private outside contractors, named Quality Improvement Organisations, have also been used to assess the quality of health care.

Source: OECD (2007b), p. 21.

Despite reservations that patient's access to catastrophic illness benefits under this programme was overly stringent, the researchers considered the reductions in healthcare costs enabled by the programme a useful reference for Chinese policymakers to consider when engaging future reforms.

### *Nationwide reforms of the urban health sector*

The previous section suggests that a number of trials have focused on approaches to containing healthcare cost increases in the urban sector, but no official announcements of intentions to generalise any particular variation of such reforms across the nation. The State Department had however announced a pilot scheme on 10 July 2007 designed to establish a non-compulsory healthcare insurance programme for the uninsured living in urban areas<sup>47</sup>. The stated objective of the scheme is to address the impact that catastrophic illness has on creating poverty. The announcement also established a goal of making socialised healthcare coverage available to all residents in urban areas, which would address the potential for cost shifting from insured to uninsured patients highlighted in the urban trials. Notably, the government is officially and openly requesting public input on the programme<sup>48</sup>.

The effectiveness of public consultations is directly related to the quality with which they are applied. As with other regulatory instruments from which policymakers may employ, consistency in application and construction are pivotal. Over the longer term, domestic officials may consider developing capacity to conduct Regulatory Impact Assessments (RIAs). Key elements and considerations for implementing effective public consultations as part of RIAs can be found in Box 10; and an example of how one OECD member has applied public consultations can be found in Box 11.

#### **Box 10. OECD Experience: Consultation: identifying and involving stakeholders**

Consultation is another important regulatory tool for better regulation which promotes transparency and ultimately enhances accountability (OECD, 2002). Involvement of stakeholders can help to identify unintended effects and practical problems especially with implementation, act as a form of quality assurance for Regulatory Impact Assessments (RIAs) and their data, identify interactions between regulations as well as cumulative effects. It is important to involve all affected interests at every stage in:

1. the identification and understanding of the problem to be addressed,
2. agreement on objectives,
3. discussion and evaluation of alternative regulatory solutions
4. identification and quantification of impacts (cost and benefits).

It may also increase consensus and the ability to understand reform, the level of compliance and may contribute to a smoother reform process.

On the other hand, there are problems associated with opening up the process of regulatory policy development, particularly in health care. It has the potential to allow more powerful interest groups to unduly influence regulatory policy and expanded opportunities for specific provider perspectives, such as medical or nursing professions, various providers of medical and pharmaceutical goods, to have a stronger voice in the policy making process (Noll, 1989). There are clearly costs and time delays

<sup>3</sup> See Series of articles in the Washington Post, 24, 25, 26 July 2005.

involved in a lengthy consultation process. Finally, in some countries, it may challenge the authority of institutional interests such as the civil service who have traditionally had a privileged position in drawing up regulations.

In order to overcome these problems, consultation must be conducted in a timely and accessible manner to allow all interested parties to have a fair chance of making a contribution. Otherwise some interests may be more adept at getting their voice heard. Consultation can act as a counter balance to the dangers of regulatory capture, but if not sufficiently accessible can actually contribute to regulatory capture, with unrepresentative views dominating the consultation responses. Depending on the nature of the consultation process, the policymakers may only inform those they identify as having a relevant interest. They may intentionally or unintentionally fail to identify all interested parties thus biasing the outcome of the consultation. The use of the internet for consultation enables greater accessibility today than in the past.

Source: OECD (2007b), p. 33.

Although details provided in the announcement are limited (and somewhat ambiguously worded), the document indicates that designated provinces will be able to select 2-3 pilot cities to apply variations of the programme in 2008. An ambitious schedule of expansion foresees that 80% of cities in the designated provinces should be covered under the programme by 2009, and that the programme will be expanded nationwide by 2010. At present, only the uninsured are able to enrol in the programme, *i.e.* those already covered under the GIS and LIS are unable to enrol.

#### **Box 11. OECD experience: Involving stakeholders in healthcare reform in Canada**

Canada has an extensive tradition for using consultation when developing new regulations. This also applies to the health sector, and is illustrated through the following example. In April 2001 the Canadian Prime Minister established the Commission on the Future of Healthcare in Canada with Roy Romanow serving as its sole Commissioner. He was asked to inquire into and undertake dialogue with Canadians and to recommend policies to improve the Canadian health system. The Commission's Mandate specifically requests the recommendation of policies and measures to "ensure the long term sustainability of a universally accessible, publicly-funded health system that offers quality services to Canadians and strikes an appropriate balance between investments in prevention and health maintenance and those directed to care and treatment". The Romanow Commission analyzed existing reports on medicare, organized expert roundtable sessions, conducted site visits both in Canada and abroad, and held a comprehensive public consultative exercise with participation in the tens of thousands of Canadian citizens. The final draft of this report was published in November 2002 outlining a broad set of policies to improve the current health system.

Romanow led one of Canada's most comprehensive, inclusive and successful consultative exercises (Romanow, 2002:xv) consisting of 9 activities. A 6-part CPAC Televised Forum and a 12-part televised on-campus university-partnered Dialogue Sessions both featured health care experts discussing key health care issues to encourage informed discussion during the public consultations. Twelve regional one-day Citizens' Dialogue Sessions brought together 40 randomly selected Canadians to participate in organized discussion on revitalizing the health care system. Twenty-one days of Open Public Hearings were held to gain input from individual Canadians and healthcare stakeholders and advocacy groups. It was advertised in newspapers for the general public and, to facilitate access for those in remote areas, participants also had the option of presenting by telephone. Nine Expert Workshops and three Regional Forums consisting of members from the expert community were used to synthesize the results from all the Citizen's Dialogues Sessions and Open Public Hearings. Nine survey papers with questions for interested individuals to express their views and preferences were available to the general public *via* the toll-free information line or the website where the survey could be completed online. Other important means of gaining information included the Consultation Workbook, Site Visits and Meetings with National Organizations and National Caucuses.

Following Romanow's very public itinerary across Canada, the recommendations were made based on the conglomeration of the sources used above. In total, 47 recommendations were outlined which fell in 10 areas: governance, information and research, healthcare providers, primary health care, access and quality, rural and remote regions, home care, prescription drugs, health of Aboriginals and globalization. The recommendations included an improved funding arrangement to provide greater stability and predictability, improved transparency and electronic health records, a greater emphasis of prevention and wellness, methods for decreasing waiting times, creation of a national drug strategy, improve access and quality of healthcare services to Aboriginals and others in small rural communities, and

explicit inclusion of diagnostic services under a new Canada Health Act. A timeline was also proposed for implementation of the Commission's 47 recommendations over a long period from 2003 to 2020.

Despite this extensive consultation exercise to inform new legislation and reformed governance of the Canadian health system the implementation of the recommendations is not an easy task and may face unexpected hurdles. Indeed a ruling on June 9<sup>th</sup> 2005 in *Chaoulli v. Quebec (Attorney General)* guarantees a right to private insurance where the public system is inadequate. The Court's decision was based on factual findings from the evidence put before it. Thus despite the Romanow Commission's comprehensive study reaffirming Canada's publicly administered healthcare system as a defining national value, a panel of six judges on the Supreme Court have fundamentally 'overruled' this by deeming the publicly insured healthcare services as inadequate in providing reasonably timely access to care (Editorial, 2005).

Source: OECD (2007b), p. 34.

Apparently addressing recommendations from trials reforms relating to better targeting of healthcare subsidies, the programme provides special central government subsidies targeting individual and regional economic inequalities. Many aspects of the financial arrangement remain unclear including the levels at which individual co-payments are to be set<sup>49</sup>. Local governments thus have leeway under the programme to develop variations based on local conditions. Details that are available indicate that all pilot cities are required to provide a baseline minimum annual subsidy of RMB 40 (USD 5) *per capita*. In addition, families with severely disabled children in pilot cities will receive an extra minimum subsidy of RMB 10 (USD 1.25), and poor families with members over 60 or which are severely disabled will receive a supplementary minimum annual subsidy of RMB 60 (USD 8).

To address regional inequalities, pilot cities in poorer central and western regions will receive further central government transfers of RMB 20 (USD 2.5) *per capita* towards the minimum RMB 40 *per capita* subsidy<sup>50</sup>. Moreover, pilot cities in the poorer central and western regions will receive additional central government transfers of RMB 5 (USD 0.75) and RMB 30 (USD 3.75) per family towards subsidies related to the severely disabled, and poor families with severely disabled members or those over 60. The government has yet to release further details related to this healthcare insurance scheme.

## ***Conclusions and Recommendations***

### *Conclusion*

In describing the evolution of economic reforms in China's health sector and sharing OECD experience in areas where regulatory challenges have been underlined, this paper forwards a number of ideas for China's regulators to consider as they engage the current third generation of comprehensive reforms in the domestic health sector.

China's robust health conditions prior to the first generation reforms and the continuing improvements following them should not obscure the deficiencies they have created, particularly in the healthcare infrastructure of rural areas. China's population continues to have the highest level of health by a vast majority of measures, despite having modest healthcare resources, when compared to other large and populous countries.

Second-generation reform trials are currently being implemented throughout China with a focus not on economic liberalisation *per se*, but on establishing policy regimes to address regulatory failure, to increase access to healthcare and to engender equity *as well as* efficiency in the use of limited healthcare resources.

China is entering a third generation of health sector reforms to address regulatory failures linked to the first generation of reforms. Still in their infancy, the third generation of health sector reforms have explicitly established universal healthcare as a final objective. As a vast country reflecting diversity in healthcare infrastructure and circumstances, no single approach to reform is likely to be the most efficient or effective in all geographic locations.

### *Recommendations*

China's authorities have taken the most important step in identifying **the need for continued reform**. The consolidation of **political will** behind the reform process and the lessons accrued in the first- and second-generation reforms is clear augury of progress.

Progress in building institutional capacity for **regulatory governance** in the health sector will be crucial. Little is known about reforms being contemplated for regulatory institutions in the health sector in light of the objectives identified for health sector reforms. Such reforms must address issues including clarifying lines of accountability (among regulatory bodies and regulatory subjects), and increasing coherence among the overlapping regulatory institutions. Consideration should be given to establishing a temporary central oversight body, or empowering an existing government body such as the MPoH, with sufficient resources and regulatory powers to coherently restructure health related institutions, their authorities and the fields of health regulation they administrate (see further discussion in Annex II).

Advances in **regulatory transparency** are apparent in the solicitation of public comments as part of the healthcare reform process, and the public identification of three reform objectives:

- Ensuring the fairness of market exchange in the delivery system;
- Correcting market failures in the delivery system; and
- Ensuring equity in the delivery of medical services.

Experience in the OECD area and in this study shows that developing broad based and systematic **mechanisms for public consultations** is a useful instrument for determining the objectives of reform, designing reforms, as well as implementing them. This is particularly the case where healthcare circumstances, and hence reform needs, vary considerably across China. Undertaking an initial exercise in line with the Canadian example in Box 11 involving

systematic public consultations to map the particular healthcare circumstances in the various geographic locations of China, could be a powerful instrument for:

- Developing a nuanced map of the healthcare contexts spanning China in light of the three established objectives of reform;
- Underpinning better targeted, calibrated and designed reforms; and
- Elevating public credibility, trust and support for the reforms.

**Enhancing quality** in the provision of health services requires the development of a consistent framework of regulatory objectives, systematic collection of comparable data and active monitoring. Developing a systematic and comprehensive architecture of objectives to be pursued consistently across the breadth of China's health sector will be crucial. OECD experience suggests that bringing all healthcare institutions up to the same standard is difficult in practice due to variations in healthcare institutions and client base. However, developing and maintaining a systemic and ongoing process of data collection and analysis is nonetheless an invaluable regulatory mechanism enabling the dynamic identification *and* prioritisation of areas for reform. The implementation of consistent data collection and analysis process would provide not only a cornerstone for developing a coherent system of healthcare reform objectives to be pursued across the expanse of China's health sector, but would guide the allocation of limited domestic healthcare resources to most effectively meet the extensive healthcare needs of the nation over time.

If such a data system is even partially implemented, it could be useful to collect systematically data on wait times for various types of medical procedures across the country. Such a facility would, under ideal circumstances, publish real time data on a public Internet site. Maintaining such a system, not only enables monitoring of health service quality under this heading, but could itself contribute to improvements under a system where healthcare insurance reimburses treatments at multiple facilities.

**Regulatory governance is dependent on combining analytical systems for monitoring quality in health services *and* implementing systematic public consultation mechanisms.**

Experience in the first, and trials conducted in the second, generation of healthcare reforms both underline how the **structure of incentives** facing healthcare providers can either support *or* undermine traditional command and control types of regulations such as the Catalogue. Health sector reforms in the OECD area are increasingly deemphasising command and control based regulations in favour of regulatory strategies that structure incentives to support desired regulatory outcomes. Careful attention should be paid to how the structure of economic incentives created by future reforms impact the regulatory objectives of individual reforms *and* of the health system as a whole.

In this light, special consideration should be directed towards regulatory reforms allowing for the **separation of professional boundaries between drug prescription and dispensing** (an example from Korea can be found in Box 7). Flanked by concomitant policies (*e.g.* increasing physician base salaries), and refined based on experience from limited trials, such a reform could significantly reduce mal-incentives facing healthcare providers and thus improve the quality of healthcare provision on a systematic level.

Reforms to **enhance efficiency** in the health system is complicated due potential market failures arising from the significant information asymmetries existing between consumers and providers of health services. Developing a regulatory infrastructure for monitoring quality in the provision of health service is prerequisite to preventing unintended consequences that often result from reforms to enhance efficiency. Box 12 provides a framework for considering reforms to enhance efficiency in the health sector.

**Box 12. OECD Experience: What is the best mix of market and non-market tools to enhance health system performance**

All OECD healthcare systems involve both market and non-market tools. However the degree to which market tools are used varies substantially. This paper has explored a number of different mechanisms for introducing competition into the provision of hospital services and has found evidence to suggest that many of these mechanisms have at times either helped to reduce costs or increased quality of service provision. Underlying many transitions towards competitive mechanisms is better quality data about exactly what care patients receive and how long they must wait to receive those treatments. It is increasingly possible for researchers and government to determine the likely impacts of different competitive mechanisms.

*Technical efficiency benefits appear particularly significant for:*

- Private operation
- Contract payment methods, including:
  - Separation of purchasing and provision
  - Prospective payment
  - Payment for results
  - Physician purchasing
- Greater consumer choice
- Reduced control over allocation of tasks to professions
- Regional centres for complex care

Regulatory restrictions can place particular limits on the ability of market-oriented solutions to operate. Licensing controls, contracting limits and professional licensure rolls have all served as methods for limiting effective competition. Rules in these areas are not innocuous. Policy makers focused on introducing competition need to consider both the mechanisms that they desire and the regulations (whether government or non-government) that already exist.

As competitive forces become more significant, a natural reaction of service providers, including hospitals, is to form negotiating alliances that are thinly disguised cartels. While competition law may not be desirable in all areas of healthcare provision, especially when governments are highly involved in directing that provision, it may be essential in order to ensure that market-based solutions can have a chance to work. When hospitals merge while the introduction of a competitive system is in course but not yet finally decided, actors in the competition law arena should carefully consider the possibility of taking action if it appears likely that such a merger would diminish effective competition once a new regime is in place. Once market-based systems are formally introduced, the role of competition enforcement can become particularly important and the precedents that are set by merger challenges can have a broad impact on the effectiveness of market-based mechanisms. In such situations, competition authorities in health ministries are likely to find that they have many interests in common.

*Source:* OECD (2007a), p. 41.

## ANNEX I

### Comparative indicators on health systems, health of population and financing

Comparison of health system indicators*				
Indicator	Brazil	China	India	Russian Federation
<i>Physicians</i>	1.15	1.06	0.6	4.25
<i>Nurses</i>	3.84	1.05	0.8	8.05
<i>Midwives</i>	0	0.03	0.47	0.47
<i>Dentists</i>	1.11	0.11	0.06	0.32
<i>Pharmacists</i>	0.3	0.28	0.56	0.08
<i>Public and environmental health workers</i>	0.97	0	0	0.5
<i>Community health workers</i>	0	0.08	0.05	2.99
<i>Other health workers</i>	1.11	0.82	1.03	4.61
<i>Health management and support workers</i>	4.89	0.83	0	0
Comparison of core health indicators (2004)				
Indicator	Brazil	China	India	Russian Federation
<i>Life expectancy at birth (years) males</i>	67	70	61	59
<i>Life expectancy at birth (years) females</i>	74	74	63	72
<i>Probability of dying (per 1000 population) between 15 and 60 years (adult mortality rate) males</i>	237	158	275	485
<i>Probability of dying (per 1000 population) between 15 and 60 years (adult mortality rate) females</i>	127	99	202	180
<i>Probability of dying (per 1000 live births) under five years of age (under-5 mortality rate)</i>	34	31	85	16
<i>Infant mortality rate (per 1000 live births)</i>	32	26	62	13
<i>Life expectancy at birth (years) males</i>	13	18	39	7
Healthcare financing agents as a percentage of total health expenditures (2005)				
Indicator	Brazil	China	India	Russian Federation
<i>Government expenditure on health as % of total health expenditure</i>	53.7	39.1	17.6	64.3
<i>Private health expenditure as % of total health expenditure</i>	46.3	60.9	82.4	35.7
<i>Government expenditure on health as % of total government expenditure</i>	15.3	10.0	3.0	9.5
<i>Social security funds as % of government expenditure on health</i>	0.0	55.3	5.3	36.1
<i>Private households' out-of-pocket payment as % of private health expenditure</i>	64.4	86.7	93.8	77.3

\*The year of the data varies from 2000 to 2003 by country as well as indicator. Details can be found in Annex I.

Source: WHO.

## ANNEX II

### **OECD Experience: The challenges of governance with multiple regulatory institutions**

#### *Coordination between levels of government*

Many challenges to reforms in the health sector apply to the relationship between national governments and regional or local public bodies with responsibility for regulation. There are, however, a number of particular issues that are worth mentioning in relation to devolution and deconcentration.

Firstly, lines of accountability. Where regulatory functions are fully devolved, the responsibility lies with lower tiers of elected government. They have an electorate and are therefore accountable downwards to the local population through representative structures. This means there may be conflict between the regulatory priorities and principles of regional and local government and those of national governments. Depending on the structures and organisation of political devolution, reserve powers may or may not be held by the federal state which allow them to veto regional and local decisions. Where these do not exist the national government can only achieve regulatory coherence through cooperation and coordination between regional and local governments. Where regulatory functions are passed to lower tiers of state administration (deconcentration) the lines of accountability will flow upwards to higher levels of the executive branch of government, *e.g.* the Ministry of Health. In this case the national authority will usually have greater powers to direct local and regional bodies in the development of regulation in order to ensure it meets national objectives and principles for high quality regulation.

Secondly, duplication. Where there are multiple levels of regulatory authority there needs to be clarity about the responsibilities and scope of regulatory functions that have been devolved. Unless there is a clear separation of regulatory responsibilities between national and regional and local bodies there is likely to be duplication of function. This is not only inefficient but also results in an increased administrative burden on those who are being regulated. Furthermore, if there are discrepancies or differences in these overlapping regulations it may give rise to regulatory non-compliance as the rules governing behaviour are contradictory.

Thirdly, effectiveness and efficiency. Issues of economies of scale and scope may arise in systems of devolved regulation. There will be some areas of regulation that are more effectively and appropriately carried out at a national level. One area of health regulation that has traditionally been carried out nationally even in decentralised systems of healthcare provision are public health measures. The Nordic countries have retained national control of standards governing public health and quality which are overseen by the national boards of health. National regulations in the UK to prevent the spread of BSE through infected cattle were necessary in order that control was effective. The slaughter and sale of infected meat for human consumption is a national industry with significant movement across the country (controls on the export and import of meat were also needed due to global trade). On the other hand because the responsibility for education services is local, regulations to improve the nutritional value of meals and increase the level of exercise (in order to reduce childhood obesity) might appropriately be developed at a local level through consultation with parents, school governors, teachers, children and local government officials.

Determining which areas of health regulation can be more effectively developed, monitored and enforced at regional and local levels is important in defining the scope of regulatory functions for regional and local bodies. In countries where geographical equity is an important objective in health care, standard setting often remains the responsibility of national bodies. Whereas the monitoring and enforcement of standards may be more effectively implemented by local bodies who are closer to the organisations and individuals being regulated. The costs of having multiple local regulatory bodies should be calculated and economies of scale achieved where possible in order to ensure regulatory functions are carried out most efficiently.

The benefits associated with decentralised regulatory decision-making are (i) regulations are more responsive to local circumstances; (ii) regional and local bodies may find it easier to involve stakeholders and the public in the development of regulations; and (iii) monitoring of organisational and individual behaviour and compliance with regulations may be easier.

Devolution can also result in inconsistency. For example different regulations applying in different areas of the country with problems of complexity for the organisations or individuals who have to comply with regulations. For example, having regional physicians associations applying different requirements for licensing and registration would restrict the movement of healthcare professionals, complicate the system of qualifications for medical schools and trainees and cause problems for anyone wishing to work in another part of the country.

The Norwegian Board of Health is actually an autonomous agency and therefore is not hierarchically subordinated to the Ministry of Health. In collaboration with nineteen county medical officers, it is responsible for promoting quality and legal safeguards within the Norwegian health sector. It deals with user and patient complaints, upholding their rights, as well as responding to deficiencies identified in both institutional and individual providers. It monitors both population needs and services delivery at local level, supervises organizational audits and surveys and disseminates information about service quality and performance (Helsetilsynet, 2005). In addition the Board licences the production, trade and sale of drugs/pharmaceuticals (Furuholmen and Magnussen, 2000).

### ***Relationship between government and self-regulating bodies***

In a number of countries, particularly those with historical traditions of social health insurance, important regulatory functions have been handed over to private bodies. This is often termed self-administration (in German *Selbstverwaltung*). In the wider regulatory literature this type of regulation is more usually referred to as self-regulation or co-regulation (where the state continues to play some part). This section addresses the particular challenges presented by self-regulation, governance and accountability.

A number of countries have an historical model of policy making that can be characterised as corporatist, that is involving social partners not as organisations to consult but rather as equal partners in decision-making. In some cases the state hands over full responsibility for negotiating and agreeing regulations to the social partners and only retains the right to intervene if no agreement can be reached (Bartle, Müller *et al.*). In Germany, the sorts of decisions made through self-administration include additions to the benefits package, setting fee schedules and contribution rates (see Box **Erreur ! Source du renvoi introuvable.**14).

#### **Box 14. OECD Experience: Corporatist decision-making and social health insurance in Germany**

In Germany unelected bodies play a critical role in decision making with legislative power given to groups that represent economic, industrial and professional interests – so-called corporatism. In Germany, non-governmental corporatist bodies are delegated substantial powers in governing the Social Health Insurance (SHI) system. Yet, the state retains the position of coordinator, making sure that the various groups behave appropriately and that their behaviour is consistent with national interests (Stone, 1980:162). There is a strong legal separation of the state from self-regulating societal groups as well as a strong negotiation-based interdependency between them.

In particular, the associations of sickness funds and associations of providers play a major role in the newly organized Federal Joint Committee, which self-administers the SHI. The Federal Joint Committee was created during the 2004 Statutory Health Insurance Modernization Act which unified the various joint committees for the ambulatory sector, the hospital sector and the coordination committee (Busse and Riesberg, 2004:45-9). The Federal Joint Committee serves to represent the interests of all the major players and consensus must be met in order for legislation to be passed. In the case of disparity in their views, the State still has the power to step in and force change. Corporatist self-governance in health care, while maintaining a large degree of power over legislative decision-making, entails substantial state regulation and even emergency decree of power by the state. For example, problems occurred as early as 2002 with the implementation of DRGs. Sickness funds and hospitals with particular profiles of patient populations could not reach agreements and therefore no consensus was reached at the level of self-governance. Therefore, the Ministry of Health issued a federal ordinance. Thus the state has acted as regulator, facilitator and enabler to the parties in corporatist self-governance in Germany (Altenstetter and Busse, 2005).

Source: OECD (2007b), p. 27.

One problem that may arise is that the objectives of the government may not be reflected in the decisions taken by the independent bodies. This may precipitate the need for legislative intervention and reduce the autonomy of self-administrating bodies. For example the sickness funds in Germany were traditionally free to set their own contribution rates. This ran counter to the government's desire to contain health expenditure growth and ensure international competitiveness of the German economy. The Health Insurance Cost-Containment Act 1977 required growth in contribution levels to match the rate of increases in contributory income. Responsibility for ensuring

compliance lay with the Concerted Action in Health Care, (established in 1980). Due to continued conflicts between members it did not fulfil political expectations and ceased to function in 1997 and was abolished in 2003.

Self-administration arrangements need to have clearly established frameworks and rules of engagement in order to ensure as far as possible that there is a balance of interests in the decision making bodies. Because these bodies are often made up of representatives of particular sections of the healthcare system (*e.g.* physicians associations, employers, trade unions, sickness funds) they are primarily accountable to their members. Although these groups should in theory act impartially when reaching decisions and their self-interests should be mediated through the process of negotiation, it is not clear in practice that these bodies are at all accountable to the wider public interest. One answer may be to include lay membership on such regulatory bodies in order to balance the sectoral interests with a wider public interest. Unless these lay members are democratically elected officials, however, it is not clear who their constituency is and whether they are truly public representatives. Furthermore, many of the groups with seats on these bodies have opposing interests and this can lead to conflict and sometimes an impasse requiring state intervention.

Requiring that the deliberations and decisions of these bodies are transparent, either taking place in public or at least the minutes being made publicly available, is another way to ensure that the regulatory process is open to public scrutiny. Finally, there may be a right of appeal through the judicial process if the decision taken by the body is believed to contravene an individual's rights (for example by denying access to a particular drug).

The relationship of the state to these independent bodies may be one of oversight, ensuring that decisions are accountable to the wider population; of rule making, setting out the constitution of these bodies and how they should operate; of veto, making a decision when an impasse is reached; partnership, state officials taking equal status around the table in reaching decisions; or customer, using the accreditation, standards or certification for public employment, purchasing or procurement.

### **China's current circumstances: The need for a centralised body with coherent lines of accountability in the health sector**

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

### ***The absence of a united "supreme regulatory" system for healthcare in China***

China's regulatory system for health lacks a supreme oversight body. The current regulatory system for health is based on an administrative framework relying on vertically integrated departments and agencies implementing differing fields of health regulation. A lack of coherence exists among the various vertically coordinated agencies and the differing fields of health regulation. Duplicative regulations and regulatory conflicts are common. No clear separation exists between the functions of administration and provision. Deficiencies in the current regulatory system are reflected in incomplete regulations, unclear administrative procedures, arbitrary administrative interventions, unclear regulatory functions and the absence of a system of accountability. These problems have led to overlapping regulatory authorities as well as areas of regulatory vacuum. Sometimes the regulated are faced with contradictory regulatory policies. This phenomena results in inefficient use of health

resources, low effectiveness of regulation, high regulatory costs, inconsistent regulatory quality, inefficient health resource allocations, suboptimal management of physical healthcare resources and lack of balance between the rigour and effectiveness of regulations. The regulated are burdened by the array of inspection and evaluation requirements which further tax healthcare resources generally considered inadequate for the effective provision of medical and health services.

The complicated design of China's regulatory system has caused not only duplicative regulation but also "blind spots" within the regulatory framework (see Box 15). Meanwhile, some administrative departments remain uncertified, or lack necessary capacity in terms of technical resources or authority.

**Box 15. "Blind spots" in the Ministry of Public Health's regulation of all medical institutions in each government department and industry**

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

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

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

Source: Li *et al.* (2007), p. 22.

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

State owned medical institutions remain the main provider of medical services in the health sector. The MoPH is the key administrative department. Overlapping regulatory functions result in institutional conflicts of interest falling into two key categories: the first is combining the two functions of administrative manager and supervisor into one, and the second is combining the two the functions of "athlete" (operating hospital) and "referee" (hospital regulator) in one.

Under the planned economic system, China's health administration departments at different levels sponsored state-owned medical institutions. These health institutions by and large have remained to date. As a result, health departments at different levels have naturally become both administrative manager and supervisor, thus playing simultaneously the roles of "athlete" and "referee". As supervisor, they treated supervisees differently due to their dual roles. They carried out "internal regulation" and administrative disciplinary measures *vis-à-vis* their own medical institutions, but differing "external regulation" and disciplinary measures with respect to others. This led to inconsistent regulatory approaches and resulted in inadequate "internal" regulatory measures. Minister GaoQiang of the MoPH has indicated that the regulation of the health industry would continue to face systematic and idiosyncratic at a deep level; especially if irregular and illegal practices by medical institutions are not improved and remain inadequately addressed. Efforts to clarify lines of accountability and implement coherence among regulatory institutions and subjects of regulation can be facilitated if stakeholders are first able to agree upon a common template as a basis for reform. One such template appears in Table 5.

**Table 5. OECD Experience: Mapping healthcare organisations subject to regulation**

Delivery side	Financing side
Individual healthcare providers ( <i>e.g.</i> professionals)	Revenue collection agents ( <i>e.g.</i> association of sickness funds, local authorities, sickness funds)
Producers of healthcare goods ( <i>e.g.</i> pharmaceutical companies, medical aids and devices, diagnostic testing equipment, <i>etc.</i> )	Pooling organisations ( <i>e.g.</i> risk equalisation schemes)
Institutional healthcare providers ( <i>e.g.</i> hospitals, clinics, laboratory services)	Purchasers of healthcare ( <i>e.g.</i> sickness funds, primary care trusts, private insurance companies)
Institutional providers of non-clinical services ( <i>e.g.</i> catering, cleaning, <i>etc.</i> )	

Source: OECD (2007b), p. 38.

Health and quarantine stations have been the historical basis for health regulation in China. But at that time, some health and quarantine stations were only responsible for “five fields” of health supervision, in which the regulation of medical institutions was not included. These “five fields” included healthcare, food, cosmetics, public health and school health. Along with the continuing development of health services and the changes in departmental functions, the public has recently focused increasing attention on the administration of medicine and enforcement of regulation, subjects on which they had no previous substantive capacity. The enforcement of regulations concerning medical administration has only a brief history of existence in comparison with traditional regulatory activities such as those concerning food. A spectrum of new laws and regulations are involved. Included are 15 laws or relevant regulations, such as the Law of Practicing Physicians, the Law of Infectious Diseases Prevention, the Law of Maternity and Child Healthcare, the Law of Blood Donation, the Law of Practicing Health, the Regulations on Medical Institutions, the Regulations on Nurses and the Regulations on Medical Accidents. This system of internal law-enforcement has been characterised as “regulation between father and son”. Like the societies they govern, regulatory institutions must evolve to meet changing social, technological and economic environments (see Box 16). The challenge lies in maintaining consistent processes of diagnosis, assessment, planning and implementation as opposed to reforming only in reaction to crisis.

**Box 16. OECD Experience: Ensuring independence in the regulation of pharmaceutical products in the USA**

The US Food and Drug Administration (FDA) is a consumer protection agency, which enforces a variety of federal laws concerning human and veterinary pharmaceuticals, medical devices, food products, cosmetics, and products that emit radiation. Regulatory methods vary according to the type of product; medical devices and pharmaceuticals must prove safe and efficacious before the FDA allows sales. The FDA approves new drugs, regulates over-the-counter and prescription drug labelling, and enforces drug manufacturing standards. It also approves new medical devices, enforces adherence to manufacturing and performance standards, and tracks device malfunctions and adverse reactions after launch ([www.fda.org](http://www.fda.org)).

The FDA’s regulatory functions were established by the Federal Food and Drugs Act of 1906 which granted the then Bureau of Chemistry responsibility for ensuring the accurate labelling of food and drugs. There were repeated calls for and attempts to regulate food and drugs (from 1879 there were nearly 100 bills introduced in Congress) before finally on 30 June 1906 President Roosevelt signed the Food and Drugs Act. It was commonly known as the Wiley Act after the chief chemist at the Bureau whose research had established convincing evidence of the problem and who politically had won support for a federal act. The Act regulated the labelling of products rather than pre-market approval. Standards of strength, quality, and purity of drugs were defined in the *United States Pharmacopoeia* and the *National Formulary*. Any variations from these standards had to be clearly stated on the label (Swann, 2005).

The FDA’s powers were strengthened in 1962, by the Kefauver Harris Act, which required that new drugs were not only safe but efficacious (Jacobzone, 2000). Regulations have progressively been strengthened in order to prevent potential adverse effects with pre-trial animal testing and up to four human trial phases (including blind trials and long term toxicity tests). By the mid 1990s it was taking on average 9.1 years for a successful drug to reach the market (up from 6.7 years in 1970) (Jacobzone, 2000).

In 1992, Congress passed the Prescription Drug User Fee Act (PDUFA), which was reauthorized in 1997 with the Food and Drug Modernization Act and again in 2002 by the Public Health Security and Bioterrorism Preparedness and Response Act.

Companies seeking FDA approval for a drug must submit an application and a fee to support the review process. Companies also pay annual fees for each prescription drug marketed. Before PDUFA, drug reviews were paid for exclusively by taxes. The PDUFA was intended to speed the drug-review process through additional funding. It seems to have been successful in this regard: in 1996 the agency approved twice as many drugs in half the time as it did before the PDUFA (US House of Representatives, 1997). Median approval time for new drugs in the late 1980s was nearly 30 months with a yearly average of only 25.6 New Molecular Entities (NMEs) approved; in 1996 the FDA approved 53 NMEs with a median approval time of 14.6 months.

According to the FDA, "The industry provides the funding in exchange for FDA agreement to meet drug-review performance goals, which emphasize timeliness." In effect, the FDA is partially accountable to the companies it regulates. The FDA expects to collect \$305 million in user fees in 2005, which constitutes over half of its \$493 million drug evaluation budget (Food and Drug Administration, 2005). The PDUFA seems to have reduced average review times. However, a concern exists about the relative speed of approval for brand name drugs with attached user-fees compared to generic drugs. (United States House of Representatives, 2002).

The Food and Drug Administration Improvement Act 2005 was recently introduced to the United States' House of Representatives. The bill would overturn the PDUFA to end financial conflicts of interests between the FDA and the pharmaceutical industry (Lenzer, 2005). The FDA would be prohibited from negotiating agreements concerning the use of fees (especially pertaining to review times) and all current agreements would be terminated. Post-market safety and effectiveness would be addressed by establishing a separate centre charged with preventing the same individuals from both approving the drug and monitoring it after it enters the market. Scientists with financial stakes in pharmaceutical companies would also be prohibited from sitting on FDA advisory panels (United States House of Representatives, 2005).

*Source:* OECD (2007b), p. 51.

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## ENDNOTES

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- <sup>1</sup> Blumenthal and Hsiao (2005), p 1166.
- <sup>2</sup> Hsiao (1995), p 1054.
- <sup>3</sup> United States Library of Congress (1987).
- <sup>4</sup> *Ibid.*
- <sup>5</sup> Hsiao (1995), p 1047.
- <sup>6</sup> Li Zhen *et al.* (????).
- <sup>7</sup> Blumenthal and Hsiao (2005), p 1166.
- <sup>8</sup> *Ibid.*, p 1167 and Zaminska (2007).
- <sup>9</sup> *Ibid.*, p 1167.
- <sup>10</sup> United States Library of Congress (1987).
- <sup>11</sup> Blumenthal and Hsiao (2005), p 1167.
- <sup>12</sup> *Ibid.*, p 1167.
- <sup>13</sup> An econometric modelling exercise regarding the impact of these reforms on the incentives facing medical practitioners can be found in: Eggleston and Yip (2004).
- <sup>14</sup> Yip and Hsiao (1997), p 244.
- <sup>15</sup> Hsiao (1995), p 1050.
- <sup>16</sup> Yip and Hsiao (1997), p 245.
- <sup>17</sup> Blumenthal and Hsiao (2005), p 1167.
- <sup>18</sup> Wang (2005), p 366.
- <sup>19</sup> Economist (2004), p 4.
- <sup>20</sup> See Wang (2005), p 366.
- <sup>21</sup> Blumenthal and Hsiao (2005), p 1167.
- <sup>22</sup> *Ibid.*, p 1168.
- <sup>23</sup> *Ibid.*, p 1165.
- <sup>24</sup> *Ibid.*, p 1168.
- <sup>25</sup> Brazil is included as its per capita income is similar to that of China<sup>25</sup>, while Russia is selected as another large country with a socialist institutional legacy. India is chosen for its large population, which is expected surpass China in the coming decades.
- <sup>26</sup> *Ibid.*
- <sup>27</sup> *Ibid.*, p 3.
- <sup>28</sup> CHINA.ORG.CN (2006i).
- <sup>29</sup> Hsiao (1995), p 1047.
- <sup>30</sup> See Hsiao and Heller (2007), p 22.
- <sup>31</sup> See Chart 1.
- <sup>32</sup> Blumenthal and Hsiao (2005), p 1169.
- <sup>33</sup> CHINA.ORG.CN (2006i).
- <sup>34</sup> CHINA.ORG.CN (2006i).
- <sup>35</sup> Zaminska (2007).
- <sup>36</sup> Ma Kai (2006).
- <sup>37</sup> NDRC News (2007).
- <sup>38</sup> *Ibid.*
- <sup>39</sup> Thompson (2007), p 1.
- <sup>40</sup> Wang *et al.* (2007), p 2.
- <sup>41</sup> Zaminska (2007).
- <sup>42</sup> *Ibid.*
- <sup>43</sup> *Ibid.*
- <sup>44</sup> CHINA.ORG.CN (2006d).
- <sup>45</sup> Yip and Eggleston (2004), p 275.
- <sup>46</sup> *Ibid.* p 275.
- <sup>47</sup> Tom.com (2007).
- <sup>48</sup> *Ibid.*
- <sup>49</sup> Please note that the wording in the original text is ambiguous in areas. The original Chinese language text can be found at the hyperlink under the reference for Tom.com (2007).
- <sup>50</sup> This study found no details on the proportion of central and local funding for the RHCSS.