China’s Healthcare Reform

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Rising costs trigger reforms

**FIGURE 1.9** Composition of Health Spending in China, 1997–2013

Background of anti-corruption, safety concerns

- MNC pharmaceutical companies remain under pressure to review sales tactics following investigations that have seen several fined for corruption or anti-competitive practices.

- Fake vaccines, and sales of outdated drugs (in 2016 approximately 2 million improperly stored vaccines were sold from a Shandong-based supplier)

- Contaminated blood scandal in Henan
Insurance coverage

About 95% of the Chinese population has basic health insurance (up from less than 50% in 2005).

However, insurance coverage is shallow.

Three public insurance schemes provide health cover. **Urban Employee Basic Medical Insurance**, an employment-based insurance plan, was launched in 1998.

It was followed by the **New Rural Co-operative Medical Scheme** (NRCMS) in 2003 and **Urban Resident Basic Medical Insurance** (URBMI) in 2007.
Healthy China 2030

- In late 2016 the National Health and Family Planning Commission (NHFPC) announced "Healthy China 2030", the country’s first long-term strategic health plan. The plan, which builds on the five-year plans, aims to increase average life expectancy to 79 years by 2030. Life expectancy had been 35 years in 1949.

- Among several targets highlighted it aims to promote private health insurance, extend basic public health cover to the entire population and deepen institutional healthcare reform.
The policy response to rising healthcare costs

- **Reform agenda**: In December 2016 the State Council approved two blueprints on medical services and reform, in line with the 13th Five Year Plan for 2016-20. The aim is to improve primary care, reduce congestion at public hospitals, boost oversight and safety standards and encourage private-sector investment in services and insurance.

- China aims to provide "safe, effective, convenient and affordable" healthcare to all residents by 2020. This has become an important component of the “China dream” (no longer the “sick man of East Asia”)

- Total healthcare expenditure will remain low compared with OECD countries over the five-year forecast period, reaching the equivalent of 6% of GDP by 2021, up from an estimated 5.7% in 2016.

- Without reform, and with growing expenditures due to ageing, costs are expected to rise significantly
Projected spending on healthcare in China
## Healthcare: key indicators

<table>
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<tr>
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<th>2012&lt;sup&gt;a&lt;/sup&gt;</th>
<th>2013&lt;sup&gt;a&lt;/sup&gt;</th>
<th>2014&lt;sup&gt;a&lt;/sup&gt;</th>
<th>2015&lt;sup&gt;a&lt;/sup&gt;</th>
<th>2016&lt;sup&gt;b&lt;/sup&gt;</th>
<th>2017&lt;sup&gt;c&lt;/sup&gt;</th>
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<th>2019&lt;sup&gt;c&lt;/sup&gt;</th>
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<th>2021&lt;sup&gt;c&lt;/sup&gt;</th>
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<tbody>
<tr>
<td>Life expectancy, average (years)</td>
<td>74.8</td>
<td>75.0</td>
<td>75.2</td>
<td>75.4</td>
<td>75.8&lt;sup&gt;a&lt;/sup&gt;</td>
<td>75.9</td>
<td>76.1</td>
<td>76.3</td>
<td>76.5</td>
<td>76.7</td>
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<tr>
<td>Life expectancy, male (years)</td>
<td>73.3</td>
<td>73.5</td>
<td>73.8</td>
<td>74.0</td>
<td>74.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>74.4</td>
<td>74.6</td>
<td>74.8</td>
<td>75.0</td>
<td>75.2</td>
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<td>Life expectancy, female (years)</td>
<td>76.5</td>
<td>76.7</td>
<td>76.8</td>
<td>77.0</td>
<td>77.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>77.4</td>
<td>77.7</td>
<td>77.9</td>
<td>78.1</td>
<td>78.3</td>
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<tr>
<td>Infant mortality rate (per 1,000 live births)</td>
<td>13.1</td>
<td>12.9</td>
<td>12.7</td>
<td>12.4</td>
<td>12.2</td>
<td>12.0</td>
<td>11.8</td>
<td>11.6</td>
<td>11.4</td>
<td>11.1</td>
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<tr>
<td>Healthcare spending (Rmb bn)</td>
<td>2,867.2</td>
<td>3,223.6</td>
<td>3,559.5</td>
<td>3,984.9&lt;sup&gt;b&lt;/sup&gt;</td>
<td>4,254.0</td>
<td>4,631.8</td>
<td>5,043.1</td>
<td>5,446.5</td>
<td>5,902.7</td>
<td>6,386.6</td>
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<tr>
<td>Healthcare spending (% of GDP)</td>
<td>5.3</td>
<td>5.4</td>
<td>5.5</td>
<td>5.7&lt;sup&gt;b&lt;/sup&gt;</td>
<td>5.7</td>
<td>5.7</td>
<td>5.8</td>
<td>5.9</td>
<td>5.9</td>
<td>6.0</td>
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<tr>
<td>Healthcare spending (US$ bn)</td>
<td>454.2</td>
<td>520.3</td>
<td>579.4</td>
<td>639.9&lt;sup&gt;b&lt;/sup&gt;</td>
<td>640.2</td>
<td>679.1</td>
<td>713.1</td>
<td>751.8</td>
<td>811.9</td>
<td>888.2</td>
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<tr>
<td>Healthcare spending (US$ per head)</td>
<td>338</td>
<td>385</td>
<td>428</td>
<td>470&lt;sup&gt;b&lt;/sup&gt;</td>
<td>469</td>
<td>495</td>
<td>517</td>
<td>543</td>
<td>584</td>
<td>636</td>
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<tr>
<td>Healthcare (consumer expenditure; US$ bn)</td>
<td>328.0</td>
<td>244.7</td>
<td>284.7</td>
<td>316.6</td>
<td>326.8</td>
<td>345.0</td>
<td>362.5</td>
<td>384.5</td>
<td>417.1</td>
<td>461.1</td>
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<tr>
<td>Doctors (per 1,000 people)</td>
<td>1.9</td>
<td>2.0</td>
<td>2.1</td>
<td>2.2&lt;sup&gt;a&lt;/sup&gt;</td>
<td>2.3</td>
<td>2.3</td>
<td>2.4</td>
<td>2.4</td>
<td>2.4</td>
<td>2.5</td>
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<tr>
<td>Hospital beds (per 1,000 people)</td>
<td>3.1</td>
<td>3.4</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.7</td>
<td>3.7</td>
<td>3.7</td>
<td>3.8</td>
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<sup>a</sup> Actual.  <sup>b</sup> Economist Intelligence Unit estimates.  <sup>c</sup> Economist Intelligence Unit forecasts.

Dramatic increases in life expectancy
But, China is an ageing society, and healthcare costs will rise.

The burden of ageing
China’s population by age group, m

Source: The Brookings Institution
Baby bust
China, fertility rate and population
By province

Provinces with a decrease in population 2010-15

Fertility rate, %
2010
- Lower than 1
- 1.00-1.29
- 1.30-1.49
- 1.50 and above

Population
m, 2015

Source: National statistics
Economist.com
Too little, too late for the two-child policy

Government goals: A two-child policy will add 30 million to the workforce by 2050.

The authorities have also set a goal of raising the fertility rate to 1.8 births per woman.

China's fertility rate was 1.67 in 2014.

EIU Forecast: China’s fertility rate in urban areas to reach 1.34 by 2050.
**FIGURE 1.5** Hospital beds in China compared to OECD, 2000–2013

China is the world’s second-largest pharmaceutical market, with sales estimated at US$95bn in 2016, compared with about US$401bn in the US.

Pharmaceutical sales per head, at an estimated US$70 in 2016, were less than 6% of US levels.

**National Reimbursement Drug List (NRDL) and Essential Drugs List (EDL)**

2017: **339 drugs added to NRDL**, which determines coverage by state insurance schemes. This was the first revision of the list since 2009. A further 13 drugs were added in July 2017, bringing the total to **2,548** medicines. In return, suppliers agreed to slash the average price of drugs on the list by 44% compared with 2016.

The number of drugs on the EDL was last increased in 2013, from 307 to **520**.
**BOX 3.2  Existing evidence of over-utilization of drugs and health interventions**

- **Over-prescription of drugs:** Average number of drugs per prescription (3) exceeds WHO rational drug use reference level (Yin, Chen, et al. 2015); 50 percent prescriptions were for antibiotics and 10–25 percent were for two or more types of antibiotics (Li, Xu et al, 2012; Yin, Song, 2013).

- **Over-use of intravenous injection drug:** Intravenous injection rate (53 percent) exceeds WHO rational drug use reference level (Yin, Chen, et al. 2015).

- **Over-use of surgical procedures:** Cesarean section rate in all deliveries is 46 percent, among which 50 percent were unnecessary (Liao, 2015).

- **Over-use of CT scan:** True positive rate of CT scan is only 10 percent, as compared with global average of 50 percent (Liao, 2015).

**Source:** Deepening Health Reform in China
Pharma cost control

- January 2017 the government unveiled a **two-invoice system**, whereby one invoice will be provided by a manufacturer to the distributor, which will in turn provide an invoice to the hospital. This system is to be piloted in select hospitals before being rolled out nationwide in 2018.

- National Development and Reform Commission (NDRC), lifted price caps on most pharmaceuticals from June 2015. Price controls on lower-cost medicines (250 Chinese patent drugs and 280 drugs made by Western companies) had already been lifted a year earlier.

- However, a pharmaceutical policy circular issued by the State Council in February 2017 stated that patented and branded medicines for which there is no generic must be priced no higher than in the country of origin or neighbouring countries.

- The 44% average price-cut agreed for NRDL drugs in 2017 also shows that government pressure on prices remains strong. The NRDL allows for up to 80% reimbursement of medicines, and establishes a price-monitoring system and will conduct investigations if it suspects profiteering.
Essential drugs, high quality and fairly priced

- Pharmaceutical distribution in China is changing rapidly as a result of hospital reforms, price cuts, the two-invoice system and the take-off of online sales. In 2016 there were 450,000 pharmacies in China, generating sales revenue of Rmb350bn, of which online stores accounted for just 3-4%.

- The EDL, recent anti-corruption investigations and reform of the drug mark-up system favour the use of generics. However, since 2013 local governments have been required to consider quality as well as cost for medicines on the EDL, benefiting branded drugs.

- A new drug-classification system introduced in 2015 requires proof of bioequivalence for generics. In March 2016 CFDA announced that bioequivalence would need to be on a par with branded pharmaceuticals.

- In February 2017 the State Council announced plans to raise drug quality, particularly for generics and vaccines, as well as improving the affordability of medicines and speeding up drug approval.
Recent cascade of policy announcements

• On September 22, the State Council announced to abolish administrative licensing requirements on 40 subject matters (《国务院关于取消一批行政许可事项的决定》), including (i) certification on qualification of medical device clinical trial institutions; (ii) registration for new drugs and imported drugs; (iii) registration of drug packaging materials; (iv) approval for on-line drug trading service providers; and (v) approval for import and export of human blood, tissues and organs.

• On September 29 the State Council issued a white paper “Development of China’s Public Health as an Essential Element of Human Rights”

• On October 8, the State Council issued a document titled Opinions on Deepening the Reform of the Evaluation & Approval System, and Encouraging Drug & Medical Device Innovation (《关于深化审评审批制度改革鼓励药品医疗器械创新的意见》)
• **Guidance for Quality and Efficacy Equivalence Assessment Application for Generics** (《仿制药质量和疗效一致性评价受理审查指南(需一致性评价品种)》), **Guidance for Equivalence Assessment Applications for Generics both Marketed and Manufactured in China and Developed Countries** (《仿制药质量和疗效一致性评价受理审查指南(境内共线生产并在欧美日上市品种)》), **Invoices for Quality and Efficacy Equivalence Assessment for Generics** (《仿制药质量和疗效一致性评价相关单据》), policy interpretations of last month’s **Circular on Certain Issues on Quality and Efficacy Equivalence Assessments for Generics** (《《关于仿制药质量和疗效一致性评价工作有关事项的公告》政策解读 》), **Provisional Technical Standards for Quality and Efficacy Equivalence Assessment Application Reviews** (《仿制药质量和疗效一致性评价申报资料立卷审查技术标准(暂行)》).

• September 1, CFDA published the **Circular on Implementing the Medical Device GMP on Class I and Class II Medical Device Manufacturers** (《总局办公厅关于第一类、第二类医疗器械生产企业实施医疗器械生产质量管理规范有关工作的通知》),
• On September 4, CFDA published the amended *Medical Device Classification Catalogue* (《医疗器械分类目录》), which will become effective on August 1, 2018.

• The amended catalogue consists of 22 sub-catalogues, developed based on product types, intended use, and product descriptions. The amended catalogue does not apply to IVD products and drug and device combination products.

• On the same date, the Agency also revealed the transition plan (《总局关于实施《医疗器械分类目录》有关事项的通告》) for the implementation of the amended catalogue, including that device registration applications received before August 1, 2018 will be reviewed according to the current catalogue.
Thank you!

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