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Drug policy in China: pharmaceutical distribution in rural areas

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Abstract

In 1978, China decided to reform its economy and since then has gradually opened up to the world. The economy has grown rapidly at an average of 9.8% per year from 1978 to 1994. Medical expenditure, especially for drugs, has grown even more rapidly. The increase in medical expenditure can be attributed to changing disease patterns, a higher proportion of older people in the population and fee-for-service incentives for hospitals. Due to the changing economic system and higher cost of health care, the Chinese government has reformed its health care system, including its health and drug policy. The drug policy reform has led to more comprehensive policy elements, including registration, production, distribution, utilization and administration. As a part of drug policy reform, the drug distribution network has also been changed, from a centrally controlled supply system (push system) to a market-oriented demand system (pull system). Hospitals can now purchase drugs directly from drug companies, factories and retailers, leading to increased price competition. Patients have easier access to drugs as more drugs are available on the market. At the same time, this has also entailed negative effects. The old drug administrative system is not suitable for the new drug distribution network. It is easy for people to get drugs on the market and this can lead to overuse and misuse. Marketing factors have influenced drug distribution so strongly that there is a risk of fake or low quality drugs being distributed. The government has taken some measures to fight these negative effects. This paper describes the drug policy reform in China, particularly the distribution of drugs to health care facilities. © 1999 Elsevier Science Ltd. All rights reserved.

Keywords: Drug distribution; China; Drugs policy; Pharmaceuticals; Health sector reform; Markets

1. Introduction

In 1978, the Chinese government decided to reform its economy, and since then the Chinese market has gradually opened up. The economy has grown rapidly although there have been regional variations. The gross national product (GNP) annual growth rate, adjusted for inflation, from 1978 to 1994 was 9.8%

(State Statistical Bureau, 1995). The GNP per capita in the more developed coastal areas is nearly five times that of the lesser developed interior provinces of south-west China. Within the provinces there are increasing gaps between urban and rural areas. The average per capita income in urban areas in 1989 was 2.7 times that in rural areas. According to the report of the national health services survey, the average per capita income in rural areas in 1993 was 747 yuan and in urban areas 2256 yuan, about three times as much (Ministry of Health, 1994).

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With economic growth, medical expenditure, especially for drugs, has increased rapidly. This is due to the changing disease patterns, a changed age structure with a higher percentage of older people and also the 'fee-for-service' incentives for the hospitals. According to the reports of more than 200 hospitals in 1993, the growth of medical expenditure exceeded that of the national economy and of residents' income (Ministry of Health, 1994). In 1986, the average medical fee per visit to outpatient departments was 4.4 yuan, but in 1993 it was 23.3 yuan, a mean annual growth rate of 28%. The same year the average inpatient medical fee per admission was 167 yuan, increasing in 1993 to 1021 yuan, a mean annual growth rate of 30%. Adjusted for inflation (10%–11%), the annual growth rate would be about 15%, which was higher than the annual national financial income (income from general tax) growth of 10% and the individual income increase of 6%. Over 70% of out-patient medical expenditures and over 55% of in-patient medical expenditures are for drugs (Ministry of Health, 1994). According to available information fee-for-service revenue has contributed from 85.5% to 90.3% of the total health services funding in two relatively well-off Chinese counties in 1992 (Bogg, 1995).

The reform of the Chinese economy from a planned to a market orientation has greatly influenced the health system. Economic reform and the higher growth in health care costs and medical expenditure have required the Chinese government to change its health and drug policy. Since 1980, the government has reformed and changed the system of reimbursement for health care facilities. Previously, the government financed the whole budget of county and township health care facilities, including salaries, supplies and equipment. Currently, the government only finances 60% of salaries. The remaining 40% of the salaries, cost of equipment and supplies are to be funded from fee-for-service revenue, including drug sales (Chinese Health Year Book Editing Commission, 1984–1989; Jiang, 1994).

At the same time, the payment mechanism for health providers has also been changed. Before, providers just received monthly salaries, nothing more. Now providers can earn their salary and a bonus as well. The salary level is determined according to their professional titles and years of experience, the bonus level is set according to the workload and especially in relation to the revenue from their drug prescriptions. In addition to the salary and the bonus, they also have other sources of income, e.g., drug sales commissions. China has maintained low prices for most health services and the prices are not established in relation to cost, except for drugs and 'new', high-technology services. For those elements and services, the price is set at a higher level than the actual cost, to allow for a profit margin.

Health care providers are allowed to mark up their drugs by 15% above the wholesale price for modern drugs, 16% for Chinese herbal preparations and 30% for Chinese herbs (Haiao, 1995; Dong, 1997).

The changes in reimbursement, pricing structure, and payment mechanism for providers are obviously one of the explanatory factors behind the rise in the cost of services, as well as contributing to over-prescribing and polypharmacy, since hospitals and health professionals throughout the system are dependent on the profit from drugs and high-technology services for their income.

As part of the health reform, the drug distribution network has been changed, from a centrally controlled supply system to a market-oriented demand system. Since the reform, hospitals can purchase drugs from drug companies, factories and retailers (Dong and Zhan, 1995). This has given patients easier access to drugs, as more drugs are available on the market. Previously, more than 90% of the county hospitals' drugs and nearly 100% of township hospitals' drugs were supplied by the county drug company, while 100% of village health stations' drugs came from their township hospitals. Now the system for drug procurement has changed to a demand-oriented one.

2. Reform of drug policy

In recent years the World Health Organization (WHO) has been active in the field of drugs and drug policy. In the 1960s and early 1970s, the WHO was largely concerned about the safety and efficacy of drugs. Since the mid-1970s, the WHO has changed its focus and started to emphasize the importance of countries having a national drug policy (NDP). Under the effort of the Drug Policies and Management (DPM) Unit and the Action Program for Essential Drugs (DAP), the WHO has set up an action program embracing all aspects of a NDP including drug selection, legislation, supply, procurement and distribution, the feasibility of regularly supplying rural areas in developing countries, quality control, research, and the dissemination of information on essential drugs (Najmi et al., 1992).

Compared with the drug policy before 1980, China's drug policy is now more comprehensive and detailed. Its elements include drug production, drug quality, distribution, supply, utilization, drug advertising; research on new drugs, including clinical trials, examination and approval, production and registration; and the pricing and management of 'special' and imported drugs.

(a) *Drug production.* Previously, the government made a drug production plan (types of drugs and quantity), but now drug factories can make their own production plans and adjust them according to the

government's guiding plan and the drug market. Thus, the plan links production to market demand.

(b) *Registration of a new drug.* The document 'Methods for examining and approving new drugs' (Chinese Health Year Book Editing Commission, 1984–1989) published in 1985 is more detailed and strict than before. It specifies a detailed procedure required for new drug selection, naming the drug, establishing the period of clinical trials, selecting the hospital for the trials, sets the test sample size and also specifies the procedure for examination and approval. The new rules make the drug registration procedure more formal and difficult than before.

(c) *Drug distribution.* Previously, the government organized a network for the supply and distribution of all drugs. In this system, the factories produced the drugs, and the business sectors (drug distributors or companies) sold the drugs. But now both distributors and factories can sell drugs (Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995). This change has formed a link between factory and market. It may also reduce the length of the chain between producer and user; which may in turn reduce costs by way of less linkage and competition. From 1983 to 1984, the cost of drugs decreased by 3.2% (Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995).

(d) After the WHO publication of the essential drugs list, China prepared its own essential drugs list according to the principles of safety, efficacy, appropriate use in Chinese conditions, easy availability of raw materials, and reasonable prices. The criteria also included that the drugs should be possible to produce in China, and should be included in the national pharmacopoeia. The list was submitted to the Ministry of Health (MoH) in August 1981 and officially approved in 1982 (Yang, 1986; Chen, 1991). Health care facilities were asked to promote and encourage the use of essential drugs. The pharmaceutical manufacturers and distributors were requested to ensure production and supply. In 1984, the MoH published a manual, National Essential Drugs of China (Yang, 1986; Chen, 1991), in order to give doctors basic information about the rational use of the essential drugs. In the manual, the drug categories were dealt with in terms of effect, adverse reactions, precautions, pharmacokinetics, administration, interactions, uses, dosage, formulations and storage. Although the essential drugs list has been officially approved for 15 years, the effects of the list on the production, distribution and utilization of drugs have not yet been evaluated in detail.

(e) *Regulating pharmaceutical manufacturers.* Guidelines and quality control are the two methods to be used to regulate the drug factories. Every year the government makes production guidelines for the drug manufacturers according to the essential drugs list.

Drug factories make their own plans according to the guidelines and the demand of the market. In order to strengthen drug quality control, China has revised and republished its pharmacopoeias, including the national pharmacopoeia, the MoH pharmacopoeia and local pharmacopoeias. The pharmacopoeias provide the quality standards for the production and testing methods of drugs. The national pharmacopoeia provides the criteria for the drugs which are already in use in China. The MoH pharmacopoeia provides the criteria for new drugs produced in China, anesthetic drugs, radiopharmaceuticals which are not yet produced in China, Chinese herbal preparations and contraceptive drugs. Local pharmacopoeias provide the criteria for the drugs which are not included in national pharmacopoeia, but are already in use in local areas.

The pharmacopoeias defined the standards for selecting drugs for production before the introduction of the essential drugs list. Nowadays, these pharmacopoeias, together with the essential drugs list, provide the standards for selecting the drugs for production, distribution, quality control, management and utilization. Quality control is enforced by drug quality control institutions at central, provincial, prefectural and county level. They collect drug samples from the market, test the content of drugs according to relevant criteria and publish the test results. China has published the drug test results every year since 1985. For example, in 1987 MoH published the test results four times (Chinese Health Year Book Editing Commission, 1984–1989).

(f) *Drug marketing administration.* In September 1984, 'The Drug Administration Law of the P.R. of China' was declared and on July 1, 1985 it took effect (Chinese Health Year Book Editing Commission, 1984–1989). The declaration of the law means that China has begun to use legislation tool to regulate the production, distribution, advertising, sale and utilization of drugs. Since 1985, the Chinese government has used the law to regulate the drug manufacturers and to restructure the drug market, e.g. by inspecting 300,000 drug factories or distributors and processing 2000 illegal cases in 1987 (Chinese Health Year Book Editing Commission, 1984–1989). Table 1 summarizes the key drug policy reforms since 1980 in China.

3. Availability of drugs

Since 1949, the production of drugs in China has continuously increased. During the 1950s, most antibiotics in China were imported. In 1978, China was able to produce 41.0 million kilos of chemicals for pharmaceuticals (Chinese Economy Year Book Editing Commission, 1984–1986, 1988, 1989, 1993). In 1981,

Table 1
The key reforms or events of drug policy in China since 1980

Key reforms or events	Date
Drug production plan (centrally controlled planning to market-oriented demand planning)	1982
National essential drugs list	1982
Drug distribution (centrally controlled supply system to market-oriented demand system)	1983
Revised and republishing the national pharmacopoeia	1985
More detailed new drug registration methods	1985
Drug administration law	1985
Enforced drug quality control	1985
Enforced regulating drug market	1985

China produced more than 95% of the drugs it needed (Liu, 1982). In 1982, it produced over 1100 types of chemicals, over 3000 kinds of pharmaceutical preparations, and in excess of 3000 kinds of Chinese medicines (Chinese Health Year Book Editing Commission, 1984–1989). In 1990, China had a production of 84.8 million kilos of chemicals for pharmaceuticals (Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995). Table 2 shows the production of chemicals and Chinese herbal preparations. From 1978 to 1990, the production of chemicals increased at a rate of 6.2% per year.

From 1981 to 1985, the gross production of the medical and pharmaceutical industry grew by 15% per year, and sales increased by 8.6% per year. In 1985, the production of chemicals reached 57.6 million kilos, and Chinese medicine 156.2 million kilos. The con-

sumption of new drugs and imported items increased considerably. The consumption of drugs in hospital and in the cities also increased, while decreasing in the countryside (Chinese Health Year Book Editing Commission, 1984–1989). From 1986 to 1990, the gross sales of drugs increased at the rate of 18.4% per year, and the quality of the drugs improved. More than 300 new chemicals were supplied on the market and the number of short-supply-drugs decreased year by year, with the exception of some anti-cancer drugs and drugs for children. Other drugs have met the demand of the market. In 1990, the production of chemicals increased so much that there was an over-production. Since 1989, some drugs which used to be in short supply are now over-supplied. Currently, the production of drugs, including chemicals and Chinese herbs, is enough for the demands of the market.

Some drugs are exported to other countries. From 1985 to 1992, the production of chemicals exported to other countries increased by 16.8% annually, from 19.0 to 56.3 million kilos; the value of chemicals exported to other countries increased at the rate of 36.0% per year, from 540 to 4642 million USD. Only a few kinds of drugs are now in short supply, such as anti-cancer drugs and children's drugs as already mentioned (Chinese Economy Year Book Editing Commission, 1984–1986, 1988, 1989, 1993; Chinese Health Year Book Editing Commission, 1984–1989; Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995).

Table 2
Production of chemicals and Chinese herbal preparations from 1978 to 1992 in China

Year	Chemicals			Chinese herbal preparations		
	production ^a	products value ^b	sales value ^b	production ^a	products value ^b	sales value ^b
1978	41.0	4960.0	3900.0	78.0	800.0	790.0
1981	35.7	5625.4	4405.5	103.9	1140.0	–
1982	42.0	6818.0	5098.9	122.8	1408.0	–
1983	47.7	7610.0	5670.0	141.0	1690.0	1830.0
1984	52.3	9096.0	5922.0	136.6	1906.0	2017.0
1985	57.6	10700.0	6128.0	156.2	2298.0	2170.0
1986	63.5	12546.0	7423.0	179.4	2841.0	2711.0
1987	65.4	15270.0	9170.0	195.7	3890.0	3410.0
1988	72.0	19100.0	11900.0	227.0	5140.0	4530.0
1990	84.8	27510.5	14567.7	–	–	–
1991	–	–	–	254.2	9442.5	7922.2
1992	–	–	–	269.5	11653.0	9486.0

Sources: Chinese Economy Year Book Editing Commission, 1984–1986, 1988, 1989, 1993; Chinese Health Year Book Editing Commission, 1984–1989; Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995.

^a Million kgs.

^b Million Chinese yuan, current price.

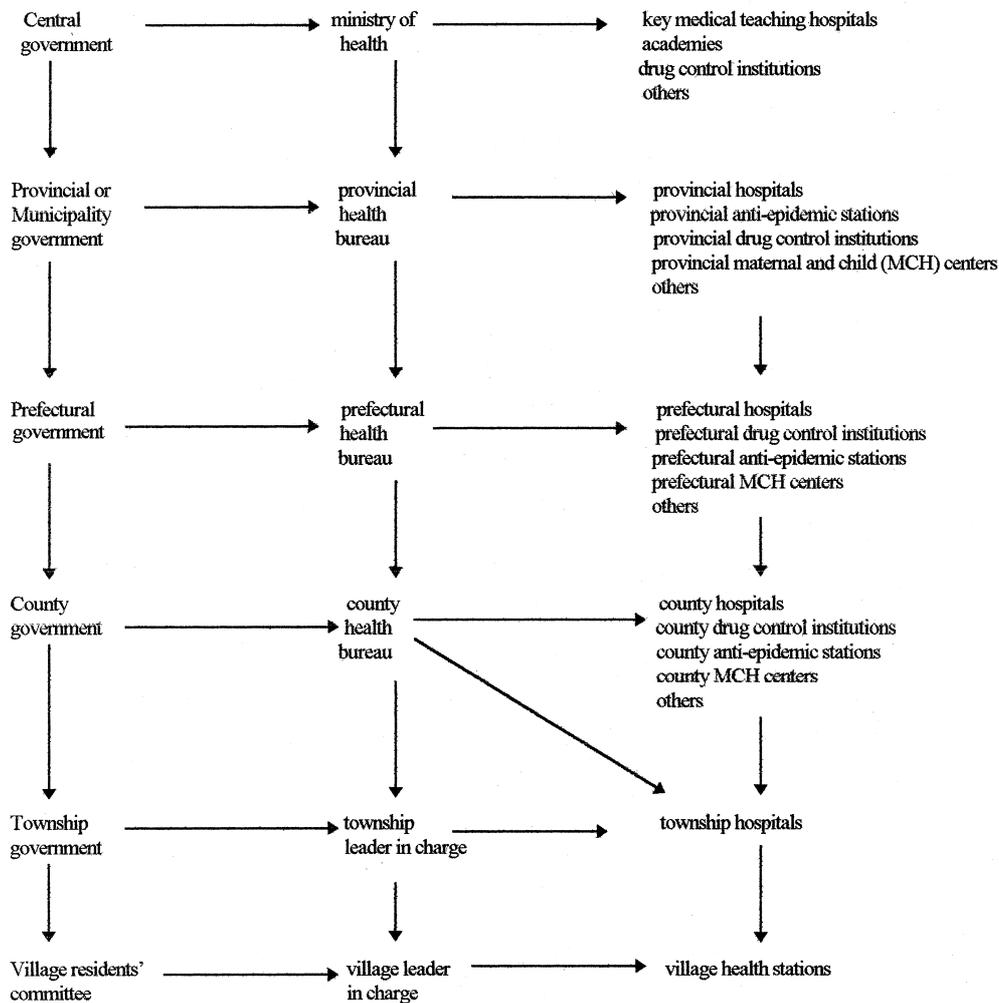


Fig. 1. China's health care structure.

4. Change of drug distribution

The distribution network of drugs is related to the structure of health care which in turn is related to the structure of the health administration and the structure of government. Fig. 1 shows the six-tiered structure of government, health administration and health care. From county to village the health service system is a so-called rural three-tier health care system.

The drug distribution network has changed considerably since the health system reform. In the past, over 90% of the county hospital drugs and nearly 100% of township hospital drugs came from county drug wholesale stations, whereas village health station drugs came from the township hospitals. But the old distribution network was not flexible enough. If the county drug wholesale station could not meet the demand, there would be a shortage of drugs in the hospitals. Now, the drug distribution system has been changed;

hospitals can buy drugs not only from drug wholesale stations at different levels, but also from other sources, such as pharmaceutical manufacturers, salespersons, etc. The hospital chooses the sources of drugs according to its own criteria.

Although this kind of drug market is able to meet the demand of hospitals, drug quality has become an important problem. Sometimes, hospitals purchase low quality drugs in order to earn more or for other personal reasons, e.g. sales commissions (Dong and Zhan, 1995).

5. The old drug distribution network

Fig. 2 shows the old pharmaceutical distribution network. There was a simple and clear drug distribution network from pharmaceutical manufacturers to patients. Like with other products in the planned

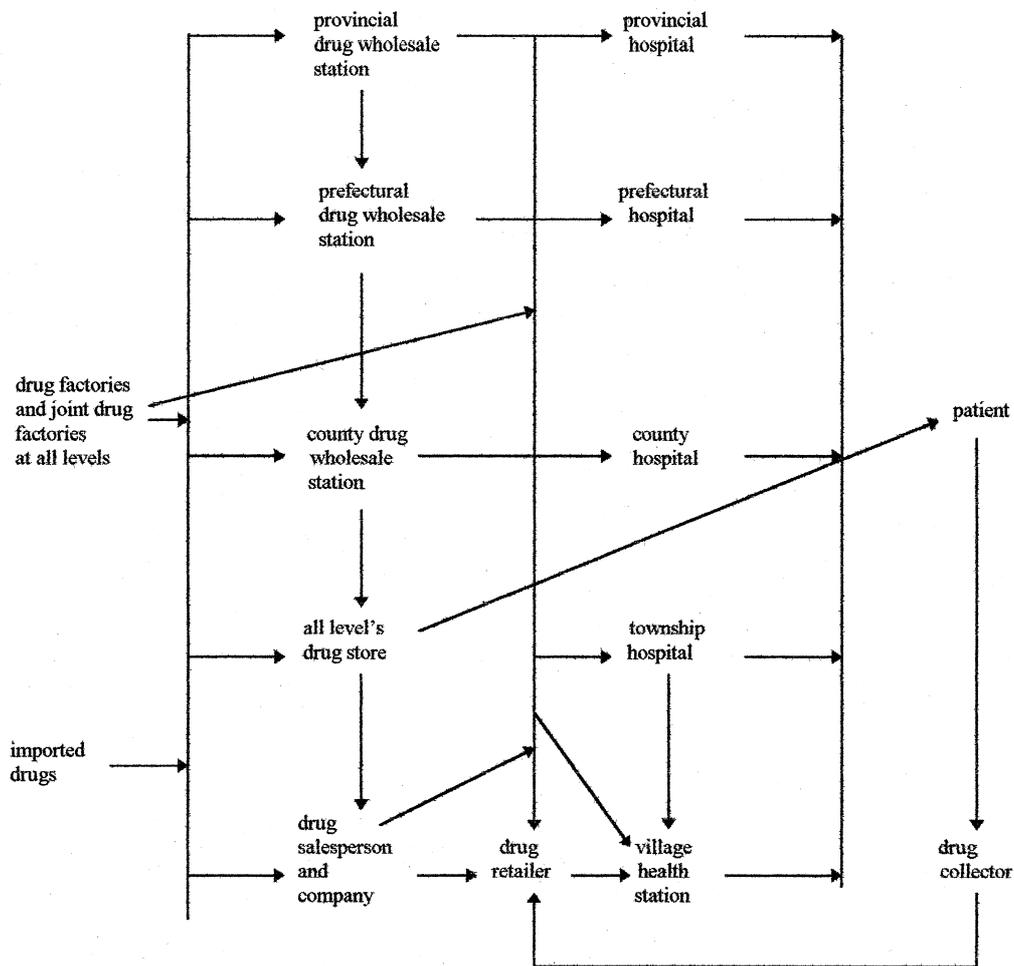


Fig. 3. The new distribution network of pharmaceuticals.

factories and the hospitals or the patients. This makes drug distribution more competitive.

In this new distribution network, pharmaceutical factories can sell their products, not only to the government drug wholesale stations, but also directly to hospitals, drug stores and other drug companies. Usually, they sell drugs in large quantities and do not allow credits. Higher level drug wholesale stations actively sell their drugs not only to the higher level hospitals but also to the lower level hospitals or small hospitals. Neighboring drug wholesale stations can also compete on the local market. Salespersons can, on behalf of the drug factories or drug companies, directly contact hospitals to promote the sale of their products with lower prices than those in the government drug wholesale stations. Salespersons can also directly contact doctors to persuade them to prescribe their products and to give gifts or commissions to them. A strange phenomenon of the new distribution network

is the emergence of illegal drug collectors who collect drugs from families at a lower price and then sell them again to low level hospitals or drug retailers.

The result of a recent survey shows that county hospitals purchase more and more drugs from pharmaceutical factories, provincial and prefectural drug stations and less drugs from county drug stations, because they have the ability to purchase a large quantity of drugs at one time (Dong and Zhan, 1995). For township hospitals and village health stations, drugs are mainly purchased at local county drug stations although a percentage of drugs come from higher level drug wholesale stations or pharmaceutical factories. Township hospitals and village health stations have less ability to purchase large quantities at one time; and if they buy small quantities of drugs from higher level drug wholesale station at lower prices, they have to go to the large city and pay the transportation fees. The total expenditure will be higher. Most of the

health care facilities do not purchase drugs from drug retailers because of doubts about the drug quality.

The main advantage of the new distribution network is that the competitive mechanism has been introduced into the drug market, which improves the availability of drugs and reduces the cost, benefiting manufacturers, hospitals and patients alike. The manufacturers earn more and achieve cost recovery faster; the hospitals purchase drugs at competitive, usually low prices; the patients obtain better care. In order to improve their competitiveness, the government drug wholesale stations have changed their work style, and have taken measures to promote the sale of drugs; e.g., by improving their internal management, reducing the wholesale price, actively delivering drugs to the hospitals and allowing buyers credits. Small health care facilities like township hospitals or village health stations can benefit from the measures because, sometimes, they are short of funds (Dong and Zhan, 1995). Other advantages of this new distribution network are that it increases the sources of drug supply and decreases the risks of short supply, especially in remote rural areas.

The disadvantage of the new drug distribution network is that it is very difficult for the government to regulate the production, distribution and marketing of drugs:

(a) Some factories produce fake or low quality drugs, some individuals even start drug factories without government approval, forge drug approval documents, and print fake trade marks. According to the results of drug quality tests, about 22% (range 6.7 to 38.5%) of tested drugs failed to meet the quality criteria from 1980 to 1987. But the data showed that the unqualified rate of drugs decreased year by year (Chinese Health Year Book Editing Commission, 1984–1989). A typical example of fake drugs is the notorious 'Jinjiang fake drugs' occurrence in Fujian province in the 1980s. From 1983 to 1985, at Jinjiang, Nanan counties and Qianzhou city in Jinjiang prefecture, Fujian province, 58 fake drug factories forged over 170 drug approval documents and printed over 100 thousand boxes of fake trade marks. Over 700 people worked outside Jinjiang prefecture to promote the sale of their products to thousands of hospitals or other units in 29 provinces and cities using unethical measures. The total sales value was over 35 million yuan. In Hankou village, Jinjiang county, 22 fake drug factories were built, the sales value reaching 20 million yuan, and 80% of farmers in this village were employed in this business (Chinese Health Year Book Editing Commission, 1984–1989).

The government has taken strong measures to combat this undesirable phenomenon by banning fake drug factories, strengthening production control and market surveillance, publishing drug quality test results including names of pharmaceutical manufacturers and

the names of the drugs, and by punishing the manufacturers who produced fake or low quality products.

(b) In 1990, there were 33,857 formal or informal drug wholesale companies or stations, 14 times as many as in the early 1980s. Of these, 22,003 (65%) were owned by collectives and individuals. A legitimate drug company must have licenses from the sectors of drug administration, health administration, and industrial and commercial administration. Of all companies, 23% (7658), however, had not managed to get all the three licenses, 32% (10,946) had not got any of the licenses. In all, 55% of drug wholesale companies were informal. This situation has interfered with the distribution of drugs and with the business of the formal drug companies (Chinese Pharmacy Year Book Editing Commission, 1985, 1987, 1992, 1995). The government has also taken strong measures to ban informal businesses in order to reorganize the market. The central and local health administrative sectors have issued a document requesting health providers to purchase drugs via formal channels.

(c) Marketing factors have influenced drug distribution, choice and use. In an interview with health providers in rural China, we found that some physicians prescribed more drugs than necessary because of marketing activities or patient demand (Dong et al., a). This is also suggested by some of the literature on drug use. Information from drug companies about their products, as well as sales commission or gifts to prescribers, can also influence the provider behavior (Avorn et al., 1987), and the drug chosen by prescribers and patients (Avorn et al., 1982). As a result of institutional and direct consumer advertising, some prescribers are influenced to write prescriptions they would not issue otherwise (Poulsen, 1992). The incentives of sales commission for hospitals and prescribers can result in hospitals purchasing low quality or expensive drugs, improper prescribing or over-prescribing, and polypharmacy.

7. Discussion

From the above description, it is evident that China's economic reform has indeed resulted in a change in health policy, including drug policy. The reform of the drug distribution system has entailed several benefits for health providers and consumers; but has also had many negative effects. The old drug administrative system does not work with the new drug distribution network. It is too easy for people to obtain drugs on the market that might be dangerous for their health. In a study of households at six counties in central China, we found that 75% of the individuals interviewed had bought modern medicines without prescriptions during the previous two weeks,

implying that the drug administration was not effective and could potentially harm people's health (Dong et al., b). In China, there are no strict definitions of over-the-counter medicines and prescription medicines.

In order to sell more of their products, the drug suppliers, in the new 'drug market', do their best to develop a relationship with the purchasers. They use many methods such as, connections with old friends and leaders, reducing the prices and/or paying sales commissions to promote their products. Some competitive methods used in the market are not fair. Unequal competition can result in cheating, low quality and fake drugs because some hospitals purchase drugs not based on the quality but depending on the price and the sales commissions.

The Chinese government has recently paid more attention to combating the fake drugs and has also taken strong measures to fight fraud in the drug market. Since 1985, the government and the people have used the Drug Administrative Law to fight fraud in the health services. All levels of government have used the law to strengthen the administration of the drug market, i.e. by publishing drug quality test results including names of pharmaceutical manufacturers and drugs, and by punishing the manufacturers producing fake or low quality products. The measures have made great progress, but there is still much fraud going on in the drug market. The drug administration at all levels should adapt to changes in drug distribution, especially in the rural areas, where people have less education, less knowledge about health and drugs, and the government has less qualified drug administrators and drug testing facilities.

Many factors influence the production and distribution of drugs including, in addition to drug policy and regulations, self-medication and health financing systems. The Chinese people have a tradition of taking tonics, such as ginseng, especially in the winter. This has greatly influenced the production and distribution of traditional Chinese medicines. Chinese living overseas also have the same tradition. A study showed that self-medication was a common and universal practice by Hong Kong Chinese with a prevalence of 32.5% in two weeks, Chinese tonics being the most frequently used, although, overall, Western medicines were used as often as Chinese medicines in the self-treatment of illnesses. But people lacked knowledge of the possible side effects in over 96% of the cases of self-medication (Lam et al., 1994). In our study we found that the prevalence rate of self-medication in rural China was lower, and it was easy to buy drugs (most were antibiotics) without prescription (Dong et al., b).

Health financing systems are another factor influencing the production, distribution and use of drugs. In China there are two main forms of insurance, government health insurance and labor health insurance.

Both have a policy limiting the kinds of drugs and the use of drugs, which may influence the production plan of drug factories. General speaking, insured people have more access to health care and a higher ability to pay for health care than uninsured people. We found that insured patients had more expensive drugs, higher drug expenditure and medical expenditure per visit than uninsured patients (Dong et al., c). Taking into consideration the reform of the reimbursement system for health care facilities, the change of payment mechanisms for health providers, the mark-up on drugs and the coverage of insurance, this may imply that insured people are particularly targeted for overprescribing and polypharmacy. The influence of health financing systems and self-medication on the production, distribution and utilization of drugs needs to be studied further.

In conclusion, the changed drug distribution network has given health care providers more sources from which to purchase drugs at competitive prices, including not only drug companies but also drug factories directly. The reform has also afforded patients easier access to drugs as more drugs are available on the market. However, it has also had some negative effects. The old drug administrative system is not suitable for the new drug distribution network. It is easy for people to over-use and misuse drugs. Marketing factors have also strongly influenced drug distribution so that there is a risk of fake or low quality drugs being distributed on the market. The government has taken some measures to combat these negative effects.

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