

Pharmaceutical Market Failure, Subsequent Policy, and its Obstacles in China

By Walter Liu

Author Bio:

Yanling (Walter) Liu is a 10th grade student at the Episcopal High School in Alexandria, Virginia. He has a great passion for history and social studies, being the founder and president of his school's history club. He is also a correspondent in the Spectrum Club of his school, where they discuss social issues such as race and gender. Additionally, he is part of the government club, which enriched his knowledge of the U.S government while staying well-informed, civic, open-minded, and empathetic. His research paper on "The Battle of Macau in 1622" is currently under review at the *Concord Review*. He was cited in a *Washington Post* article about the Critical Race Theory Controversy, in which he contributed a personal perspective informed by his family history.

Abstract

There is a perception today among many Chinese people that domestically produced drugs are inferior in quality to foreign ones, which is partly true considering that China is not researching and developing its own medicine at a high enough rate. The economic issue of the pharmaceutical market in China is that foreign drugs require high-cost and out-of-pocket payment because the medical insurance from the government only pays for domestic medicine, which doesn't cover certain diseases due to issues such as a slow drug approval period and low R&D investment. In order to deal with this problem, in October of 2017, the Chinese government implemented a policy that allowed importing of foreign medication and medical tools that are urgently needed by Chinese people through an easier procedure. However, this policy is hard to implement since it disadvantages domestic pharmaceutical producers and regulatory authorities, generating voices of opposition.

Considering the obstacles, this paper argues that the optimal policy is to reimburse the cost of more foreign drugs until the quality of Chinese drugs improves through R&D. The money for R&D will come from government tax breaks, especially for private companies, which constitute 70% of the industry. In order to make up for the money lost in tax breaks, the government should spend less in other sectors, considering the importance of healthcare to citizens. With a larger healthcare budget, more money can be invested in state-owned pharmaceutical companies in China, who are also responsible for producing domestic medicine.

Keywords: Pharmaceutical market, pharmaceuticals in China, healthcare, research and development, healthcare cost

Introduction

During the 2000s, there were many counterfeit pharmaceutical drugs produced in China, which resulted in harm or even death of patients who took them. Consequently, there is a perception today among Chinese people that domestically produced drugs are inferior in quality to foreign ones, which is partly true considering that China is not researching and developing its own medicine at a high enough rate. The economic issue¹ (See endnotes) of the pharmaceutical market in China is that foreign drugs require high-cost out-of-pocket payment because medical insurance from the government only pays for domestic medicine, which still doesn't cover certain diseases due to issues such as slow drug approval period and low R&D investment.²

The Golden Horse award-winning movie *Dying to Survive* is exemplary of this issue and talks about a shopkeeper in China who illegally smuggled medicine for leukemia from India. This medicine costs 5000 USD per bottle in the hospital, which is unaffordable for most Chinese citizens.³ The shopkeeper sells it at a much lower price and receives plenty of customers. In the end, this shopkeeper gets caught by the government but the hospitals end up recognizing the high cost of this leukemia medicine and lowering their prices. This movie successfully portrays how China's pharmaceutical system is not able to provide medicines for certain diseases because it hasn't opened up its drug industry for foreign enterprises and that its domestic industry is underdeveloped in some areas.

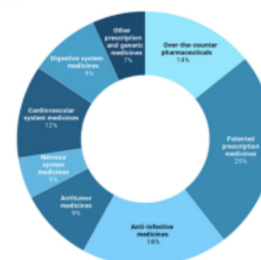
In order to deal with this problem, in October 2017, the Chinese government implemented a policy that allowed importing of foreign medication and medical tools that are urgently needed by Chinese people through an easier procedure. Part of the policy includes relying on foreign clinical trial data to decide if a drug should be approved and used in the domestic market. According to the state-run *People's Daily* newspaper, this policy change significantly expedited the process of reviewing a medication before it comes out; previously, overseas medications required more than six years for Chinese regulators to test and approve, thus delaying the time for patients to access them.⁴

However, this policy is hard to implement since it disadvantages domestic pharmaceutical producers and regulatory authorities, creating opposition. For example, the Chinese government provided special economic zones (SEZs) for its domestic manufacturers and companies in order to economically favor them over foreign operations. But by permitting overseas influence entering the Chinese market, the original advantage for the domestic industry will diminish. Domestic drugs will be in competition with multinational ones, and Chinese consumers would prefer foreign drugs due to the belief that they are higher in effectiveness and safety. Domestic enterprises made this policy a challenge to implement, even though the policy is there to fix China's pharmaceutical market.⁵

China's Pharmaceutical Market

It is important to acknowledge China's market because of its substantial size given its 1.4 billion potential consumers. China's drug market is an ever-growing one, with the trend beginning in recent times. Estimates suggest that by 2023, it will reach \$161.8 billion and account for 30 percent of the global market. In 2018, China's pharmaceutical market stood at \$134.6 billion, ranking second in the world.⁶ Of the total market value, generic drugs (out of patent) take up \$85.3 billion, the largest fraction of all. Over-the-counter (OTC) medicines in pharmacies add up to 18.4 billion, constituting 13.6% of the whole. This shows that because of cultural norms, only a small fraction of Chinese consumers choose self-medication (buying medicines from a pharmacy) instead of going to the doctor. Finally, patented drugs, which are much more common in Western countries, created \$30 billion of revenue in 2018, making up 22.9% of the total portion.⁷

China's Pharmaceutical Industry Products, % of total industry revenue



Distribution of China's pharmaceutical market, as mentioned above: Table 1⁸

As a result, many of the largest transnational pharmaceutical businesses have been increasingly locking their eyes on China and establishing R&D facilities, as they see a lot of potential in its market. China's 1.4 billion population provides many consumers. This large demand for drugs greatly incentivizes domestic and international pharmaceutical companies to innovate and produce medicines. Because of China's aging population and rapid urbanization, there will be more diseases and public health needs appearing, leading to a growth in the drug market. On top of its sizable market, China is also a very strong manufacturer. Manufacturing drugs in China is cheaper than in developed countries because China has a large workforce to perform cheap labor. Actually, China's reputation for being a secondary economic sector exceeds pharmaceutical goods, as it is common to see different products made in China.⁹

Currently, there is a policy in China called "zero markup", stating that public hospitals should obtain all drugs on the essential drug list composed by the government. These essential drugs are to be sold without a price difference between the producer and the hospital, so that it can be more affordable for consumers. Drugs that do not make the list (mainly foreign ones) are not required to be in stock. Patented medications are mostly used by China's upper class since it is more expensive, and its cost is rarely covered by the government.¹⁰ Considering both the large pharmaceutical market and manufacturing ability of China, more transnational pharmaceutical companies will enter China if the government allows, and in turn, people's healthcare would improve significantly, not just the upper class.

The Exclusion of Foreign Medicines in the National Drug List

The National Reimbursement Drug List is the same as the Essential Drug List mentioned above. Before more western drugs were added to the list in the past five years, most drugs on the list were domestic. The two main considerations by the Chinese government to do so is:

1. Build a competitive domestic pharmaceutical industry and not depend on foreign imports
2. High levels of distrust in overseas industries entering China¹¹

The reason why China's pharmaceutical system favors its domestic players so much is because it is highly controlled by the government. The role of a government is usually to support and balance its domestic enterprises with foreign competitors. And in China's case, the government has a strong will to develop its domestic drug industry into a world-leading one. President Xi Jinping once said to make China "masters of its own technologies", which includes the pharmaceutical industry. The promotion of domestic pharmaceuticals is also part of a national plan called "Made in China 2025", meaning to make China self-sustainable in every industry by 2025. Therefore, it can be concluded that the main motives for China to only reimburse its domestic medicines are strengthening its own technologies and improving its national image.¹²

Distrust in international companies is a main motive for the Chinese government to reimburse foreign drugs. Because there have been cases of bribery happening in multinational pharmaceutical companies, the Chinese government decided to place stricter surveillance on them. The anti-corruption department in China has taken action on these overseas industries, adding regulations such as anti-commercial bribing and anti-unfair competition law. As a result, foreign enterprises are working under heavy scrutiny in China, with many restrictions to expand its influence.¹³

Market Failure

Even though China's pharmaceutical market is growing, many citizens are still unable to obtain the medications they need at an acceptable price, just like in the movie *Dying to Survive*. Three key reasons for this problem are:

1. Harsh restrictions on foreign medicine
2. The beneficial results of China's research and development (R&D) investment in its domestic drugs are not evident enough
3. Overly-strict regulations for reviewing new medicines

There is a paradox in China's approach to improving its pharmaceutical system. The goal of the government is to expand its own pharmaceutical industry and make China self-sustainable, not relying on foreign products. On one hand, foreign medicines are deliberately set at a sky-high price by the government, so most patients will choose domestic ones instead due to economic concerns. On the other hand, however, China's pharmaceutical industry still comes with flaws, the most notable of which are stated in points 2 and 3 above.

While the Chinese government wants to minimize foreign influences in its pharmaceutical market, their R&D sector requires refining in order to match the level of foreign medicines. "Although the Chinese pharmaceutical industry has been developing fast in terms of market size and revenue volumes, the scale of Chinese pharmaceutical companies remains relatively small with a low market concentration. Therefore, local pharmaceutical companies with higher Research and Development (R&D) input are generally less profitable. Although there have been increases in the number of patented drugs in the pharmaceutical industry in China, patents have made relatively low contributions to the industrial values."¹⁴ Additionally, the intellectual property (IP) of pharmaceutical firms in China are not able to compete with foreign enterprises. This is because Chinese drugs are mainly generic and out of patent, creating less incentive to produce better medicine.

Apart from weaknesses in R&D investment, the process for assessing new drugs is also too extensive, lengthening the time for patients to access them, and increasing the cost. For example, the government set new regulations for the manufacturing process of medicine and for handling chemical waste in drug factories. As a result, this improved the quality of drugs, but also increased its cost for patients because there are more steps involved in making the medicine. Secondly, because there are strict standards for registering new drugs and licensing existing ones, many new drug developments have been hindered by the government. As Table 2 shows, different drugs (y-axis) have undergone longer review times over the years (x-axis).¹⁵ To sum up, China is overly circumspect in regulating its domestic pharmaceuticals, leading to delays.

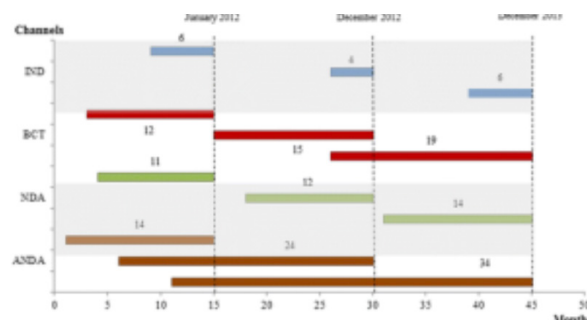


Table 2: Average waiting time for technical review of chemical drugs ¹⁶

Other evident problems are in areas like price caps and market entry. The government is restricting drug spendings on companies by using price caps and profit-margin regulations. With these restrictions, companies in the innovation, manufacturing, and distributing sector will have little market incentive to produce higher-quality medicine, because they wouldn't profit enough from consumers. Even with these regulations, medicine still makes up for half of the total health spending by the government, 43 percent of which are used for patients staying in hospitals (inpatient), and 51 percent for those who leave after checking with the doctor (outpatient). The greatest problem is that China currently lacks the technology to produce certain medicines and has many medicines in the market whose effectiveness are unknown, because not enough investment is made by the government.¹⁷

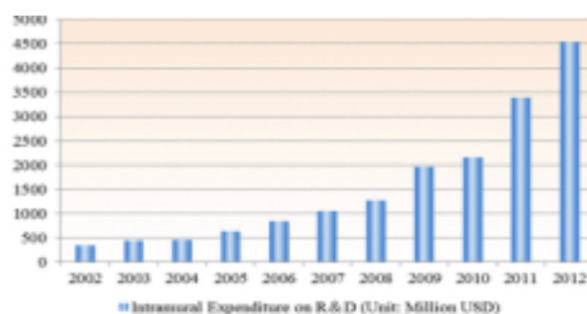


Table 3: An increase in R&D government spending ¹⁸

In general, there are many areas to improve in China's innovation in the pharmaceutical industry. Limitations in industrial, financial, institutional, and academic sectors are the main sources that impede the progress of domestic medicine innovation. However, China's strengths lie in its ever-growing drug market and increasing R&D fundings (Table 3). But for

China's pharmaceutical system to be well-rounded and stronger, the sector needs to invest more in developing new drugs and at the same time, embrace the "global value-chain" of drug production by contributing their own strengths.¹⁹

Government Intervention Through Policy

Recognizing the problems with its pharmaceutical system, the Chinese government implemented a policy to solve them. This policy loosened the grip on foreign medications and sped up the process for drug regulators. In terms of foreign pharmaceuticals, there is an upward trend of foreign pharmaceutical investments and overseas medicines entering Chinese markets. After joining the International Council for Harmonization in 2017, China announced plans to integrate international regulatory guidelines into its own industry, regulating system, and R&D. In consequence, these implementations helped China better connect with the global community in terms of regulation standards, and also allowed Chinese people to better access foreign medicine.²⁰

In 2017, China followed its plan and added more than 100 foreign drugs such as AstraZeneca's Brilinta (ticagrelor), and cancer treatments like Roche's Herceptin (trastuzumab), MabThera/Rituxan (rituximab), Avastin (bevacizumab) and Tarceva (erlotinib), so people can use these drugs without paying because it's covered by the government. Before these medicines were added, some diseases were untreatable because the domestic medicines for them were underdeveloped. By adding western medicines to the market, which are generally higher in quality, people could finally access the treatments they need. In 2018, new cancer treatment methods also became part of the healthcare insurance list.²¹

In addition to the policy's goal of making foreign medication more accessible, China has been making efforts to match its vast array of drug demands by updating its regulation and licensing process for overseas enterprises. In 2019, the Center for Drug Evaluation and the Chinese Food and Drug Administration (CFDA) decreased the time for reviewing domestic and international medicines, making the addition of new drugs quicker than in the past (Table 4). Furthermore, in order to speed up the time for drugs to be released, authorities also removed the need for clinical trials prior to the release of medicines. What used to slow down the availability of Chinese market drugs is now eliminated. China now accepts foreign drugs that have been approved in their respective countries, and these drugs will only need to undergo fast-track review in China without conducting further testing. Hence, the National Medical Products Administration (NMPA) changed its testing obligations concerning the quality of non-patent drugs (generic) so that industry standards are increased and foreign drugs can be reviewed faster.²² Since people are getting the medicines they need more ²³ quickly, this policy is helpful for China's citizens.

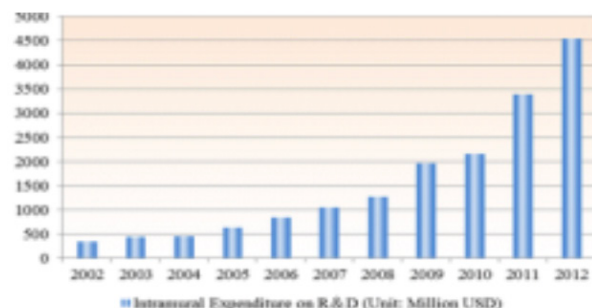


Table 4: Number of approved new medications by the CFDA, 2009-2012.²⁴

Category 1.1 (blue): Medicines that have not been approved in any country

Category 3 (Orange): Medicines that are only sold in foreign countries

Category 4 (Green): Medicine with changes in its component but is already sold in China

Category 5 (Green): Medicine already being sold in China but with a changed dose method

Category 6 (Green): Medicines that completely follow Chinese standards

China has been working on a plan to provide better healthcare for every citizen, originally to be completed by 2020. The main goals of the plan are making sure drugs are safe to take, effective at fighting the disease, easily accessible, and within the affordable range. All of these goals are part of the larger National Pharmaceutical Policy. Actions such as regulating the production process of drugs (manufacturing, distribution, safety monitoring) have been taken by the China Food and Drug Administration. Because the prices for medicine are heavily regulated in hospitals, there is less economic incentive for the sellers (Table 5). To solve this problem, the National Development and Reform Commission eliminated price caps in June 2015. Additionally, there will be more drugs supplied to retail pharmacies instead of hospital pharmacies, in order to decrease the burden in hospitals and help people with common illnesses get their medicines faster and easier. Currently, pharmacists in China are not playing an important role in healthcare. However, this possible transition to retail pharmacies will require a change in lifestyle, as most Chinese citizens are used to going to the hospital to treat issues with their body, no matter big or small.²⁵

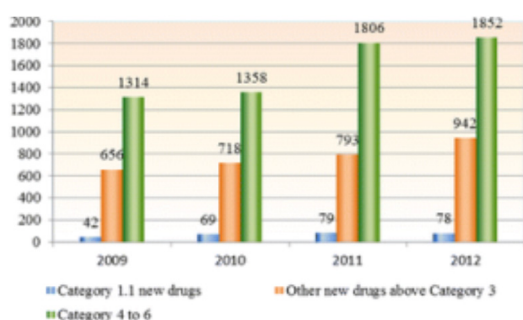


Table 5: The number of patented medicines and licensing percentage throughout the years²⁶

Obstacles to the Policy

China is a one-party nation with a government-dominated pharmaceutical industry, where instructions from central authorities are mostly followed without much explicit political resistance. Even so, there are still barriers for the government to implement a certain policy. In this case, the two main challenges for the government are:

1. Dissatisfaction from domestic companies since the policy benefitted foreign products.
2. The problem of domestic R&D inefficiency lingers due to lack of cooperation between research and industrial sectors; importing more foreign drugs is a short-term solution, but China still needs to improve its innovation sector in order to fulfill the “Made in China 2025” plan, and make China more self-sustaining in the long run.

China’s domestic pharmaceutical industry is mainly composed of individual distributors and producers scattered all around the country, large in number but varying in size. In 2012, the total number of manufacturers was 4500, with 14,000 distributors. Out of the drugs they produce, 32% are traditional Chinese medicine, which foreign companies do not make. This means that because of the implementation of this policy, 68% of domestic drugs will be in competition with foreign medications, where foreign ones have a better reputation among patients of being more refined in quality. This poses a direct threat to domestic Chinese companies, who have gotten used to developing under a privileged environment created by the Chinese government, as the government needs to boost its pharmaceutical economy.²⁷ This is an example of politics interfering in the economy.

Among domestic Chinese companies, the ones that will be harmed the most from this policy are the small-scale ones. As of 2012, 70% of China’s domestic medicine distributors were small-scale (Table 6) who supplied to their local region. These distributors usually only had under 300 employees with around \$3 million US of market value.²⁸ Wholesalers (large retail merchants), on the other hand, only constitute one third of the total distribution market. However, more and more wholesalers, some of which are foreign, are starting to merge with these

small-scale distributors and acquire them under the wholesaler's name. The reason behind this is that the Chinese government has been encouraging these mergers, with the goal of improving distribution efficiency, compressing supply lines, making regulation easier, and raising the market value of pharmaceuticals in different regions. Thus, the losers in this situation are clearly the small-scaled distributors, who are losing their companies and getting eaten by bigger fish.²⁹ As this policy opens the door for more overseas companies, who are obviously not small-scaled local distributors but instead wholesalers and multinational corporations, the domestic small-scaled distributors will be unhappy and stand up to oppose this policy.

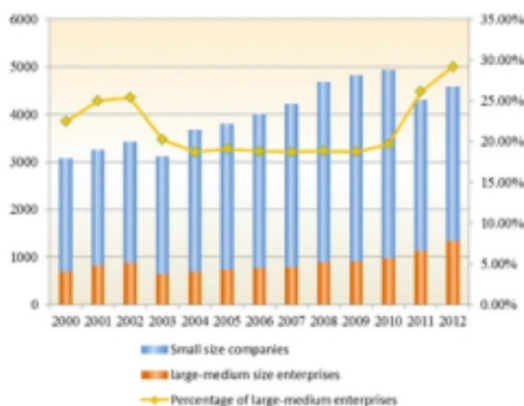


Table 6: The total number of Chinese drug companies, differentiated by size.³⁰

On top of the obstacles created by domestic small-scale businesses, R&D in pharmaceuticals remains a weakness for China. This policy hasn't addressed the fact that China's own medicines need to be of higher effectiveness and safety. The current approach to conducting R&D is a combined effort between colleges, research institutes, and enterprises, in order to ensure maximum commitment and results. Nevertheless, this three-way partnership is hard to manage, because it crosses between academic and industrial sectors.

While experts from universities and other research institutions are focusing on the scientific nuances of pharmaceuticals, companies are considering how to present them to consumers in society. There is constantly a gap between these multiple parties, as the research done in laboratories "does not usually take into consideration the overall development of the

pharmaceutical industry. Consequently, the research work may not fully address and respond to the challenges and changing demands of the industry." To sum up, universities and businesses³¹ companies have different purposes and goals in society, and these two entities have clashing interests in China.

Another problem in the domestic research sector that this policy has not addressed is the quality of scientific papers and patents in Chinese universities. The main motivation for Chinese scholars is to publish on the Science Citation Index (SCI), so that they receive promotions in work. Incentivised by personal achievement, many scholars publish dozens of SCI papers a year and apply for patents non-stop thus lowering the quality of each piece of research. Hence, most Chinese patents don't last very long due to their low quality. With fewer long-lived patents, the incentive for industries and enterprises will decrease, widening the gap between research and development. All of these factors result in China's innovation output falling behind Western countries who have both a strong foundation and effective method in pharmaceutical R&D. Therefore, the Chinese government should set a new policy to improve the domestic R&D situation and catch up with foreign medications.³²

Conclusion

Looking at the bigger picture, the policy implemented by the Chinese government in October 2017 is mostly positive. The main beneficiary are patients in China, who had foreign medicines added to their healthcare insurance list, and who can now increase their chances of surviving with more effective medicines. Moreover, as part of the policy required the shortening of the regulation process, patients can receive new drugs faster, thus treating their diseases sooner. However, the risk of deregulation is that some imported medicines might be crude in quality and worsen the users' health. Nevertheless, these occurrences are rare because patented medicines are usually thoroughly reviewed in their respective companies and countries, so they are mostly safe to use. Therefore, this policy benefits the mass population of China who are common patients that need appropriate medications. While Chinese citizens benefited from the reimbursement of more foreign drugs, it undermined the importance of domestic

companies, especially for local-scale ones, and the policy did not propose solutions to this problem. Domestic companies would only benefit if they had a large share of the domestic market, which creates the main source of profit. Once they get in competition with foreign drugs which are better in quality, fewer people will purchase their products.

Hence, the current policy is considered Pareto efficient. The definition of Pareto efficiency is that no entity can be better off without making another entity worse. In this case, the government took away part of the advantage held by domestic pharmaceutical companies and gave it to foreign enterprises. Specifically, the government gave foreign companies a greater share of the Chinese drug market, as an increasing number of Chinese consumers will choose foreign over domestic products in the reimbursement list knowing that domestic medicines lack the ability to treat a range of illnesses. This in turn will decrease the profit gained by the domestic industry, which is damaging. With less money, people working in domestic companies may lose their jobs, making it a negative externality of the current policy.

The plan I believe the government should follow is to reimburse more foreign drugs until the quality of Chinese drugs improves through R&D. While the current policy only addresses the former, it doesn't explain how China could improve its domestic technology in order to reach the "Made in China 2025" goal. The job of the government is to give patients the most effective medicines possible, and for the foreseeable future, foreign medicines are generally higher in quality, so hospitals should use them more until they can be replaced by domestic ones. But in order to reimburse foreign drugs and conduct R&D for domestic drugs at the same time, the national healthcare expenditure ought to be increased. In 2017, only 13.7 out of 2959.5 billion dollars from China's national spending were on healthcare, which is around 0.4%. Although it is a 50.3% increase from the previous year (2016), more money should be allocated for public health considering the significance of this sector.

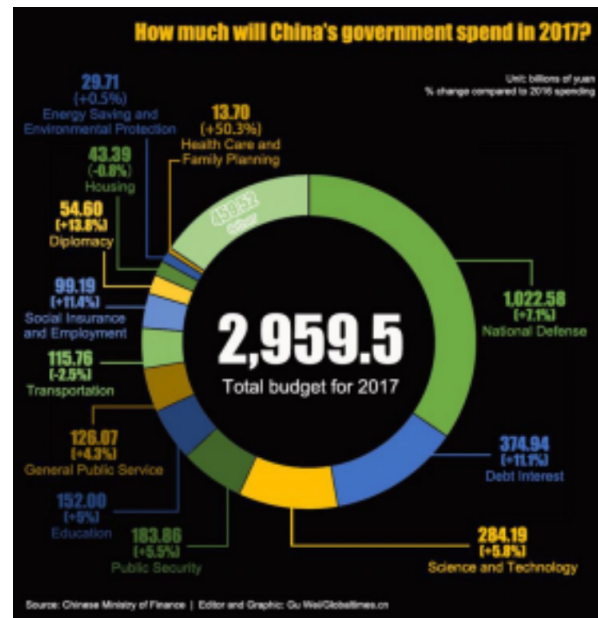


Table 7: Pie chart of government budget in 2017³³

As of today, 4 years after the policy has been implemented, some foreign drugs are still challenging to access for Chinese patients. My grandma, for example, lives in Chengdu and has had Alzheimer's for 3 years already. In the case of Alzheimer's, only domestic medicines are reimbursed by the government. There are German-made Alzheimer medicines available in the hospital, but they require out-of-pocket payment and are too expensive for my grandma to afford in the long term. Therefore, my grandma decided to take the domestically produced one, which even the doctor admitted was less effective. As a result, her condition gets worse year by year, and our family has no choice but to trust the development of Chinese drugs.

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