Advances in Social Science, Education and Humanities Research, volume 594
Proceedings of the 2021 3rd International Conference on Literature, Art and Human Development (ICLAHD 2021)

Cancer Drugs in China: Unaffordability and Policy Solutions

Yining Liu

University of North Carolina at Chapel Hill
Email: angelayn@ad.unc.edu

ABSTRACT
The high cost and unaffordability of cancer drugs present serious challenges to treatment access and cancer outcomes. This issue is particularly salient in developing countries, where health care provision is limited and patients are themselves responsible for a large portion of treatment costs. What are the various reasons for the high cost of cancer drugs? How do different countries respond to this challenge differently? What policies are already in place to address this challenge, and what additional issues remain to be addressed in the long term? This paper discusses these topics in the context of China through an economic and public-policy lens and suggests a few long-term solutions.

Keywords: *cancer drug, China, affordability, policy, human welfare*

1. INTRODUCTION

Dying to Survive, a 2018 Chinese film about the plight of poor patients suffering cancer, sparked a wave of public debates on the high cost of cancer drugs in China and inspired efforts to find solutions. It shows that, despite recent improvements in healthcare coverage, cancer patients in China still face insurmountable challenges in obtaining affordable drugs. According to a study by the National Cancer Center, the treatment cost per cancer patient in China is US $9,739 in 2016, exceeding the average household income of US $8,607 in the same year [1]. In addition, the percentage of out-of-pocket expenses in China (28.6%) is still high compared to most developed countries [2]. This unaffordability issue, despite being recognized and widely discussed among the public, is rarely systematically analyzed. This paper seeks to fill this gap by systematically reviewing factors affecting drug costs (Section 2), as well as policies that have been enacted around the world (Section 3) and in China (Section 4) to reduce drug costs and improve affordability.

2. WHY ARE CANCER DRUGS SO COSTLY?

The high cost of cancer drugs results from a variety of factors across multiple agencies and interest groups. This section identifies a few most crucial reasons.

First, cancer drug research and development (R&D) entails large financial and time investments. In the U.S., it takes on average $650 million and 7.3 years to develop a drug [3] Additionally, new cancer drugs face particularly high risks of failure during clinical trials: on average, only 3.4% of cancer drugs are approved, compared to 33% for other drugs [4]. These risks are amplified by complexities relating to the approval and registration processes, which normally take 1 to 2 years in the U.S. [5] and 3 to 5 years in China [6]. Given these challenges, pharmaceutical companies have to sell cancer drugs at high prices in order to cover all the costs and make profits.

Second, cancer drugs for the most part are not operated under a free market economy. Compared to other drugs (e.g. over-the-counter antibiotics) that are much easier to invent and produce, each newly-approved cancer drug represents a virtual monopoly that obtains its exclusivity through patent protection. While such protection is crucial for innovation, it creates barriers for competition and enables patent holders to sell the drugs at exuberant prices.

Third, the retail price of cancer drugs does not reflect the cost of production; rather, it is an artificially high price resulting from a chain of transactions among suppliers, regulators, hospitals, distributors, and doctors. The retail profit – the large difference between the retail price and the cost of production – can be attributed to the profits separately earned by each party in the circulation

of drugs . In China, doctors earn the greatest share of the profit (37%); hospitals (15%), distributors (17%), and suppliers (4%) earn substantial share of the profits, as well [7].

Fourth, many cancer drugs are not covered by the national health insurance. Furthermore, the government has limited bargaining power against the drugmakers when it comes to setting the drug prices. With more drugs included in insurances and more pricing regulations in place, patients would be more able to afford the drugs; however, these approaches reduce the value of pharmaceutical projects and curtail the resources available for firms to carry them out, leading to adverse consequences on pharmaceutical innovation, which eventually harms the patient.

Lastly, while China produces its own cancer drugs, many effective drugs are still expensive foreign imports. As of now, China lacks the ability to produce original or generic drugs of sufficiently high quality to adequately meet market demand.

3. POLICY COMPARISONS

Pharmaceutical policies vary enormously across countries. This section discusses and compares cancer drug policies in China and the United Kingdom (UK) in the areas of pricing, insurance coverage, and R&D. The UK has one of the most equitable health care systems in the world and has recently introduced a series of reforms in cancer drug policies. Therefore, understanding the UK policies may provide important insights for China, albeit the different demographic challenges faced by the two countries. This section also compares generic drug policy in China and India - the leading country in the world's generic drugs market.

Drug pricing is an important area of policy comparison. After all, affordability would greatly improve if drugs were cheaper. The UK resorts to two main schemes to control drug prices: the Pharmaceutical Pricing Regulation Scheme (PPRS) for patent drugs and the Maximum Pricing Scheme (MPS) for off-patent drugs. The PPRS is a voluntary scheme negotiated between the government and pharmaceutical companies every five years in the U.K. The scheme sets a limit to the profit that pharmaceutical companies can make (usually 25%); on their part, participating companies in compliance with the rule could have their affordable drugs listed in the insurance-eligible catalog by the government [8]. The MPS is essentially a price ceiling. A downside of these two pricing schemes is that restraining the drug prices within a certain range might result in supply shortage. In China, drug pricing is determined through either tendering for off-patent drugs or direct negotiations for patent drugs, with the National Health and Family Planning Commission (NHFPC) as a lead. Unlike the UK, where drug prices are largely determined by market supply and demand (with some additional price regulation), the Chinese government unilaterally determines a price range, within which the tendering or the negotiation process takes place. While tendering has been successful at decreasing prices, concerns about quality have arisen, for such a "race to the bottom" likely yields low-quality products at low costs [9]. Therefore, tendering remains an imperfect mechanism, given the current level of pharmaceutical manufacturing in China.

Source of funding and access schemes are another main area of policy discussion. In the UK, the National Health Service (NHS) established a special Cancer Drug Fund (CDF) in 2011 to facilitate the development of innovative cancer drugs. With an initial capital of 200 million pounds, this fund supports effective drugs that are not formally funded by NHS. In the beginning, the CDF ran into a series of problems due to a lack of clarity in inclusion criteria and poor budget management. Over the years, CDF clarified its evaluation criteria, standardized the approval process, and improved its risk management. As a result, it now supports innovative cancer drugs in a much more efficient and sustainable way. In China, there is not a fund designated for the development of cancer drugs. But just as certain drugs are selected to be included in the CDF, good-quality drugs with great potential are selected to be included in the Chinese health insurance program, which guarantees large sale of drugs and better affordability for the patient, as the cost of the drug are partially (if not entirely) subsidized by the government and insurance companies.

Drug affordability is also improved through the development of better independent (domestic) research and development (R&D) capabilities. The United Kingdom is a leading producer of pharmaceuticals: over 40% of the pharmaceutical products produced in the UK are exported to other countries. It is also an important pharmaceutical research and development center. Pharmaceutical R&D accounts for 27% of all UK manufacturing R&D in 2018, and over 30% of the UK pharmaceutical industry employment focuses on R&D [10]. In comparison, China invests less in domestic R&D and is less experienced in producing its own drugs. Relying on foreign drugs at a tariff of zero is a temporary solution, but is not sustainable in the long term.

Finally, a comparison of generic drug policies in India and China sheds important light. The year 1995 witnessed the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) among members of the World Trade Organization. It is considered highly beneficial to protecting pharmaceutical inventions. For this and other reasons, the agreement has been strictly followed by most nations in the world [11] The one exception is India, which insisted on its own interests and decided not to protect the medicine itself (but only its production processes) until the amended Patent Act of 2005 came into effect. Because of this delay in patent

protection period, generic drugs in India enjoyed an advantage in the earlier development stage and continued to be a very strong industry today. Even after 2005, the revised Act only protects selected drugs. Thanks to these policies and its heavy investment in high-quality generic drug development, India was able to cover most of its domestic needs by 2007 and has become a major exporter of generic drugs for other developing countries in need of these affordable drugs. By contrast, China has been a faithful taker of TRIPS Agreement, producing generic drugs only after the protection period has passed. Due to the country's limited production capacity, the quality of those drugs remains relatively low. In recent years, China has begun investing more in the development of high-quality generic drugs. For example, the government announced a list of generic drugs in 2019 and encouraged pharmaceutical companies to research and product them.

4. PROGRESS MADE AND LONG-TERM SOLUTIONS

In the last five years, the Chinese government has implemented a series of policies with the aim of improving the affordability of cancer drugs. This section reviews major policies implemented during these years as well as their effects on drug accessibility.

A major policy focus has been to expand the list of drugs eligible for medical insurance. In August 2018, China's National Medical Insurance Administration appointed 70 experts from 20 provinces to negotiate with pharmaceutical firms. As a result of this negotiation, 17 cancer drugs from 12 firms were incorporated into the insurance-eligible list. The prices of these drugs went down by 57% on average, and the sales of these drugs have greatly increased [12]. This policy, along with similar negotiations in 2016, 2017, 2019 and 2020, shows the government's consistent effort to reduce drug prices by expanding insurance coverage (see Figure 1).

The government also sought to increase the accessibility of cancer drugs through centralized purchasing and direct price adjustment [15]. For example, in December 2018, the 4+7 drug volume-based purchasing pilot program was launched in Shanghai. After the implementation of the policy, the prices of 25 selected drugs were lowered by an average of 52% compared to the minimum purchase prices of the same drugs in 11 pilot cities in 2017 [16].

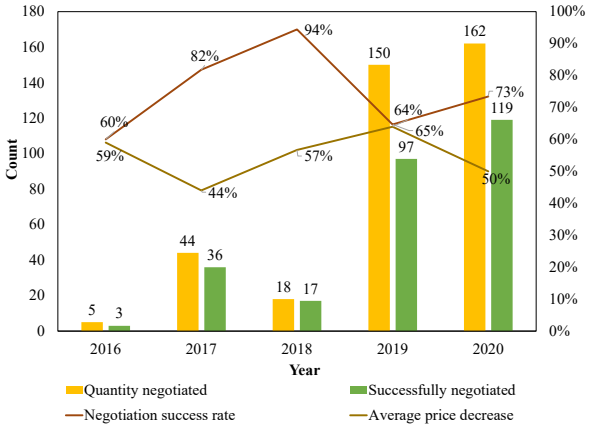

Figure 1 Medicines Negotiated in China from 2016 to 2020. *Data source*: NHSA (National Health Security Administration), China News [13] and Tang et al (2019) [14]. *Notes*: The quantities in the chart reflect total number of drugs negotiated. Cancer drugs are a portion of them. For example, in 2019, 22 of the 97 successfully negotiated drugs are cancer drugs.

On May 1st, 2018, following the State Council's executive meeting, a decision was made to eliminate the tariffs of all imported cancer drugs. Also significantly reduced was the value-added tax (VAT) rate on cancer drugs. Such reductions in tariff and tax rates led to an increase in drug imports at cheaper costs, which greatly improved the accessibility of cancer drugs

In addition, the government took several measures to strengthen regulation and ensure fair and efficient drug transactions. For example, in August 2018, nine Ministries and Commissions jointly issued a statement, laying out penalties for misconduct such as bribery, collusion, and other types of anti-competitive behaviors [17]. Later in November 2018, another document was issued that reinstated the "public" nature of public hospitals – public hospitals that contract or lease pharmacies for profit would thereafter be penalized.

Lastly, several policies were also implemented to encourage the production of high-quality generic drugs. In April 2018, for example, the State Council proposed to refine the evaluation criteria of generic drugs and speed up the evaluation process. A decision was made to include equivalently effective alternatives in the catalog of standard generic drugs.

In addition to the areas mentioned above, several other polices are worth considering in the long term. First, China needs to develop indigenous capabilities that allow it to develop and first-to-the-world drugs. To achieve this, China should continue to invest more in the R&D and build up core technology, in order to produce a larger variety of drugs at greater efficiency. Greater supply of domestic drugs will improve the affordability of domestic drugs and reduce reliance on expensive foreign alternatives. Secondly, the experience and lessons of

CDF in the rapid access to innovative cancer drugs is a noteworthy reference for China. It may be useful for to create a designated fund for cancer drugs, establish drug-access and withdrawal mechanisms, and explore a reasonable budget management model under scientific risk-sharing principles. Thirdly, in addition to government funding, it is advisable to expand funding sources by mobilizing investments from the private sector to support the production of domestic drugs. Fourth, the government should streamline and accelerate the approval process for both domestically-produced and imported drugs, so that more drugs will be approved within shorter time frames at lower costs. Last but not the least, it is necessary to avoid financial waste in the healthcare system overall, in order to better leverage existing resources for medical development.

5. CONCLUSION

In China, the short supply and high cost of cancer drugs have been a longstanding public concern. Compared to developed countries such as the U.K., such problems are graver in China where population is larger and average income is lower. The high cost of cancer drugs results from a variety of factors, from the large risks and investment associated with the production process to exclusivity protection, to high administrative costs and limited insurance coverage. To alleviate these concerns, the Chinese government has introduced a number of policies to improve the affordability of cancer drugs, including price negotiation, centralized purchasing, and measures taken to ensure fairer and more efficient transactions. These policies have reduced the prices of cancer drugs to a great extent.

It is worth noting, however, that reducing the price and accessibility of the drugs is not sufficient to improve cancer outcomes and human welfare. Another important approach would be to develop more effective drugs to increase the effectiveness of every treatment, and thereby shortening the overall treatment time and cost for patients. Moreover, it is necessary to evaluate the effects of drug price reduction on patients' recovering rate and death rate in order to adjust prices and adapt policies accordingly. Since drugs are not the only resource within the entire healthcare system that cancer patients receive, whether the change in one factor could improve the overall treatment result remains to be determined. A better solution would be to promote patient centered care, where patients have the opportunity to choose treatments and drugs based on scientific explanations from doctors.

REFERENCES

[1] Huang, H. Y., Shi, J. F., Guo, L. W., Zhu, X. Y., Wang, L., Liao, X. Z., ... & Dai, M. (2016). Expenditure and financial burden for common cancers in China: a hospital-based multicentre cross-sectional study. *The Lancet*, *388*, S10.

[2] Sorgato, A. (2021). China. In *Global legal insights: Pricing & reimbursement*. essay, GLOBAL LEGAL GROUP LTD.

[3] Prasad, V., & Mailankody, S. (2017). Research and development spending to bring a single cancer drug to market and revenues after approval. *JAMA internal medicine*, *177*(11), 1569-1575. DOI: 10.1001/jamainternmed.2017.3601

[4] Wong, C. H., Siah, K. W., & Lo, A. W. (2019). Estimation of clinical trial success rates and related parameters. *Biostatistics*, *20*(2), 273-286. DOI: 10.1093/biostatistics/kxx069

[5] U.S. Food & Drug Administration (2019). Development and Approval Process. Available at: https://www.fda.gov/drugs/development-approval-process-drugs

[6] Xie, D., Li, X., Li, A., (2019). The Rewards of Regulatory Change – Launching Innovative Biopharma in China. *Deloitte Insight*. Available at: https://www2.deloitte.com/content/dam/Deloitte/cn/Documents/life-sciences-health-care/deloitte-cn-lshc-the-rewards-of-regulatory-change-en-190530.pdf

[7] Wang, J. (2014). From Pharma Factory to Patient: Profits in Drug Circulation. *China Pharmacy*.

[8] Lü, L., and Yu, L. (2019), Comparative Study of Sino-British Cancer Drug Policies. *Chinese Journal of Health Policy*, 12(2), 15-21.

[9] Sun, Q., Santoro, M. A., Meng, Q., Liu, C., & Eggleston, K. (2008). Pharmaceutical policy in China. *Health affairs*, *27*(4), 1042-1050. DOI: 10.1377/hlthaff.27.4.1042

[10] *The UK pharmaceutical sector, An Overview. Enterprise Ireland. Evolve UK* - Global Ambition. Available at: https://globalambition.ie/wp-content/uploads/2020/03/Enterprise-Ireland-Report-UK-Pharmaceutical-Manufacturing-Sector-Overview.pdf.

[11] Nayyar, D. (1992). Intellectual property rights and LDCs: some strategic issues. *Economic and Political Weekly*, 271-274.

[12] Zhou, C. (2018). The First Anti-cancer Drug Negotiation by the National Medical Insurance Administration: 17 Drugs Entered the Medical Insurance at a Price Cut. Available at: http://www.nbd.com.cn/articles/2018-10-14/1262798.html

[13] Li, X. (2021) National Medical Insurance Catalogue 2021 - the Sixth Round of Negotiation. Chinanews. https://www.chinanews.com/gn/2021/06-09/9496338.shtml

[14] Tang, M., Song, P., & He, J. (2019). Progress on drug pricing negotiations in China. *Bioscience trends*, *13*(6), 464-468. DOI: 10.5582/bst.2019.01339

[15] Liu, B., Li, J., & Wang, T. (2021). *Embracing the change: Strategizing on volume-based procurement in China*. Available at: https://www.simon-kucher.com/en-us/blog/embracing-change-strategizing-volume-based-procurement-china

[16] Tang, M., He, J., Chen, M., Cong, L., Xu, Y., Yang, Y., ... & Jin, C. (2019). " 4+ 7" city drug volume-based purchasing and using pilot program in China and its impact. *Drug discoveries & therapeutics*, *13*(6), 365-369. DOI: 10.5582/ddt.2019.01093

[17] State Counsil of China (2018). Notice on Correcting Unhealthy Practices in the Field of Medicine Purchase and Sale and Medical Services. http://www.gov.cn/zhengce/zhengceku/2020-11/18/content_5562297.htm