Related Analysis of Changes in Import Policy of Antitumor Drugs in China

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Abstract

According to the National Cancer report of China issued by the National Cancer Center, cancer has become one of the major public health problems that seriously threaten the health of the China's people. antitumor drugs are the hope of cancer patients and their families. However, in recent years, because foreign antitumor drugs have the strong competitive advantage , and the import policy of antitumor drugs in China is not consummate, cancer patients in China have to choose to use a large number of expensive imported antitumor drugs. Therefore, China has carried on the extremely necessary reform to the import antitumor drug policy, so this paper mainly analyzes the reasons, the concrete contents, the influence of China's antitumor drug import policy reform, and puts forward some relevant countermeasures which can make the new policy play the highest effect and stabilize the domestic antitumor drug market in China.

Keywords

Antitumor drugs; Zero tariff Policy.

1. Reasons for the Reform of China′s antitumor Drug Import Policy

1.1 The Problems of China′s antitumor Drug Market

1.1.1 Spread of illegal antitumor drugs in China

Illegal antitumor drugs are not entirely equivalent to fake drugs, because some genuine drugs are included in them. However, according to the laws of China, drugs that are not approved for the sale of imported drugs in China are the fake drugs. The main reason for these illegal drugs flooding is that they are cheaper for patients than normal antitumor drugs, and they contain high profits for illegal sellers. The main ways for domestic cancer patients to buy antitumor drugs are roughly divided into two categories: one is to buy at physical drugstore(physical drug retailers and formal hospitals); the other is to purchase online(online legal drug retail enterprises and self-owned stores,called Daigou in China), while most illegal antitumor drugs are purchased online. Pharmaceutical products belong to special commodities. All countries have strict management on the sales of prescription drugs, which can only be purchased according to the prescription of local doctors. Therefore, the channel of buying and selling foreign antitumor drugs through online stores is very suspicious, the drug quality cannot be guaranteed, and the formal online drugstore will not establish such business. According to the past cases handling experience of a China's local drug supervision department, about 75% of the overseas antitumor drugs purchased online have been proved to be fake drugs.After taking such fake antitumor drugs, the cancer patients may not be cured forever, what’s worse, some of those may even die.

In addition, in recent years, with the increase of demand for antitumor drugs, China's antitumor drug purchasing market has gradually formed a gray sub-purchase chain because antitumor drugs are in cheaper prices in some other countries such as India etc. Lu Yong, who suffered from leukemia, accidentally learned that the antitumor drugs produced by India were almost the same as those of Imatinib Mesylate Tablets in Switzerland. After testing, the similarity of the drugs between the two countries was 99.9%, but the price of a box of drugs in India was much lower than 2/3 of the price of China.

1.1.2 The speed of China's generic antitumor drugs coming to market is slow, and the quality of some drugs is poor

The generic drug is an imitation of the same amount, safety and efficacy, quality, effect, and indication of the drug product. The patent medicine needs a large amount of manpower, material resources, and the capital investment.At the same time, the R&D time is extremely long,and the risk is also great. Once the R&D fail, the companies that invest for the item will face a lot of loss. In the past, it is generally considered that the cost of R & D of an imported antitumor drugs needs to be around $1 billion. But a data suggests that the cost of developing a new drug is far more than that, such as the Novartis Pharma Ltd, which has spent about $836 billion in R&D between 1997 and 2011, while only 21 new drugs have been approved during the period, with an average of $4 billion for each new drug. It also contains a lot of R&D failures. In recent years, international R&D on antitumor drugs have made a breakthrough.

The quality of the generic drug is in fact the same as that of the patent drug, except that the generic drug only needs to be explored and purified, and the development time is short. And the international pharmaceutical company will apply for patent in China after R & D of new medicine, but according to the patent law of our country, as long as the patent medicine developed by the international pharmaceutical enterprise is still in the patent protection period, China's pharmaceutical enterprises can't "copy" and imitate. As a result, there will be a shortage of antitumor drugs in the country, and there is no place for the patient to find a drug. According to IMS Health Consulting, the annual growth rate of generics in China will exceed 25%. According to the data of the State Administration of Drug Administration, there are only 16,000 drug-listed drugs in our country,138 kinds of antitumor drugs have been listed. However, in our country's tumor drug market, Nearly half of the market is divided up by imported drugs, and the relatively high-end targeting drugs are basically dependent on the import. The majority of the drugs in domestic medicine are generics. However, the production of them is basically after the international antitumor drug patent has been overdue, and the imitation is two or more times, the treatment effect is not good. In these generic drug companies, there are some small businesses that simplify the process of drug production in order to gain more profits and to simplify the drug production process, and the drug effect of the generic drugs produced by such enterprises is worse.

1.2 The import price of antitumor drugs in China is too high

Due to the influence of "the importance of many imported new drugs to China's patients is deliberately exaggerated by foreign pharmaceutical companies" [1] and some other similar factors, the import prices of major antitumor drugs in China's mainland are too high. Such a price makes the majority of cancer patients dare not use medicine, and can't afford to use the medicine.

The following is a comparison table between the import prices of several antitumor drugs in the mainland and those in Hong Kong (Table 1.1). We can see that the import prices of antitumor drugs in the mainland of China are too high compared with those in Hong Kong. First of all, this is closely related to Hong Kong's drug import policy. Hong Kong is a port city with zero tariffs on imported drugs. According to People's Daily, public hospitals in Hong Kong buy drugs from the national Hospital Authority without commission. The cost of drugs is born by the government and the drugs are sold at the original price. Secondly, cheap drug prices in Hong Kong benefit from a very simple chain of sales between drug manufacturers and patients.

Therefore, it can be seen that it is very necessary to reform the import policy of antitumor drugs in order to slow down the high import price of antitumor drugs in mainland China.

Table 1.1 comparison of mainland and Hong Kong prices of several common antitumor drugs (monetary unit: RMB)

Drugs	Drug	Manufacture	For the	Mainland	HongKong Price	

Name	Specification	Factory	Disease	Price		Price Differences
Herceptin	440 mg	Roche Pharmaceutical Ltd	Mammary cancer	24500 yuan	About15200yuan	9300 yuan
Cetuximab	100mg/50mg	Merck	Colorectal cancer	4698 yuan	About3200 yuan	1498 yuan
Sorafenib Tosylate Tablets	200mg / tablet 60table/box	Baye	Clear-cell carcinoma	24267 yuan （0.2g）	About17500yuan	6667 yuan
Velcade	3.5mg/bottle	Janssen (America)	myeloma	13635 yuan	About11136yuan	2499 yuan
Imatinib Mesylate Tablets	0.1 g/bottle	Novartis Pharma Ltd	CML	25500 yuan （120 Grain / box）	About17760yuan	7740 yuan

Data source: People's Daily

2. Major changes in China's Import Policy of antitumor drugs in recent years

2.1 Zero tariff policy on the import of antitumor drugs

"The high R&D of the antitumor drugs, the monopolization of the market and the innovation of the market make most of the antitumor drugs expensive and bring great economic burden to our patients. In recent years, our country will adjust the import duty of drugs as one of the important measures to promote the rationalization of drug price."[2] On April 12,2018, the executive meeting of the State Council takes the "Internet add health care" as the subject, and determines the development measures to reduce the economic burden on the patients, especially the medicine cost of the cancer patients, so that the patients have more medicines to select. The meeting decided that the import duty of China's patent medicine, including cancer drugs, all common drugs, Bio-alkaloids antitumor drugs and Traditional Chinese Medicine Patent Prescription which are actually imported, were zero from May 1, and zero tariffs on all the imported antitumor drugs in our country were made. The VAT for production and import of antitumor drugs will be significantly reduced. The reduction of the import duty of the antitumor drugs to zero means that the cost of the import of the antitumor drugs in the country is greatly reduced, and the purchasing burden of the patients and their families is reduced. The zero-tariff policy can truly realize the phenomenon that the people use the low-price antitumor medicine to relieve the difficulty of a single medicine.

2.2 VAT reduction policy

The Ministry of Finance announced that with effect from March 1, 2019, VAT general taxpayers who produce, sell, and retail rare disease drugs may choose to pay VAT in accordance with the simple measures according to the 3% collection rate; for imported rare disease drugs, the VAT on import links shall be reduced by 3%. According to the latest tariff rate adjustment of the Ministry of Finance in 2017, the VAT on imported drugs in China is as high as 17%. On the basis of zero tariff on the import of antitumor drugs, the reduction of VAT will improve the effect of domestic antitumor drug price reduction brought by zero tariff to a greater extent.

2.3 Zero tariff policy on import of antitumor drug raw materials

In 2019, the Ministry of Finance announced that China will impose zero tariffs on some raw materials for drug production. The new raw materials for drug production include more than 50 kinds of antitumor drug raw materials, such as Triptorelin Acetate, Formetan, Exemestane Tablets,Vinorelbine bitartrate, Vincristine Sulphate, iritican hydrochloric acid, the tax rate is reduced from 4% to 0, and the tax rate of antineoplastic raw materials has been directly reduced from 9% to 0. In addition, the tax rates of Lenalidomide, Penicillamine, Riluzole Tablets and Bosentan were reduced directly from 6.5% to 0. 5%, and pirfenidone was reduced from 9% to 0. 5%.

3. The impact of the reform of the import policy of antitumor drugs in china

3.1 Positive influence

3.1.1 Benefiting the patients and purifying the China′s antitumor drug market environment

The reduction of zero tariff and value added tax in China is directly caused by the significant decline in the import price of antitumor drugs. In August 2018, Chang Feng, deputy director of the Medical Security Policy Research Center of China University of Pharmacy, pointed out that the zero tariff policy on the import of antitumor drugs has been implemented for three months, the price of related drugs has fallen by 3.30% to 51.62%, and the average price reduction of antitumor drugs has reached 7.51%. At the same time, according to the data of the State Medical Insurance Administration, 17 kinds of antitumor drugs were included in the medical insurance reimbursement catalogue in 2018, and the average payment standard of negotiated drugs reached 56.7%. The payment standards of most imported drugs were lower than the market prices of neighboring countries or regions, with an average of 36% lower, which greatly reduced the drug use burden of tumor patients. "[3]

" From the point of view of the sick population, At present, the sick population in our country is generally insufficient to pay for the high cost of antitumor drugs, only from the price of antitumor drugs, the control of the price of antitumor drugs can alleviate the pressure on the purchase of antitumor drugs. "[4] the decline in the price of antitumor drugs has once again made cancer patients see the hope of survival, cancer patients do not have to seek antitumor drugs through illegal ways such as purchasing agents. It not only benefits the sick population, but also greatly reduces the possibility of the continued spread of counterfeit drugs, and relatively purifies the environment of the antitumor drug market in China.

3.1.2 Promoting the Development of multinational antitumor Drug Import Enterprises

The tumor drug market is large in the global drug market, and this pattern is expected to continue. Fig. 3.1 shows the changes in the scale and the growth trend of the tumor market in China in recent years. The figure shows that the market size is expected to reach $23.4 billion in 2018, and the size of the antitumor market in China will continue to expand gradually in the future. (data source: IMS China Business Industry Research Institute). With the continuous expansion of China's antitumor market, transnational antitumor drug importing enterprises are also facing the possibility of expansion, and the policy reform has obviously provided greater convenience for the import of antitumor drugs. The import of antitumor drugs is much lower than before, and the import volume of transnational antitumor drug importing enterprises will gradually increase. To a certain extent, it alleviates the dangerous situation of high import cost and low profit of some transnational antitumor drug importing enterprises before the implementation of the policy. At the same time, the implementation of the policy will also enhance the business confidence of this kind of enterprises and improve their economic development speed.

At present, some varieties of imported drugs are sold by the branches of imported enterprises in China, and most of them are introduced through domestic company agents. Therefore, the zero tariff policy will be conducive to imported drug agents and distributors, such as Shanghai Medicine, traditional China's Medicine holding, China Resources Pharmaceutical and so on.

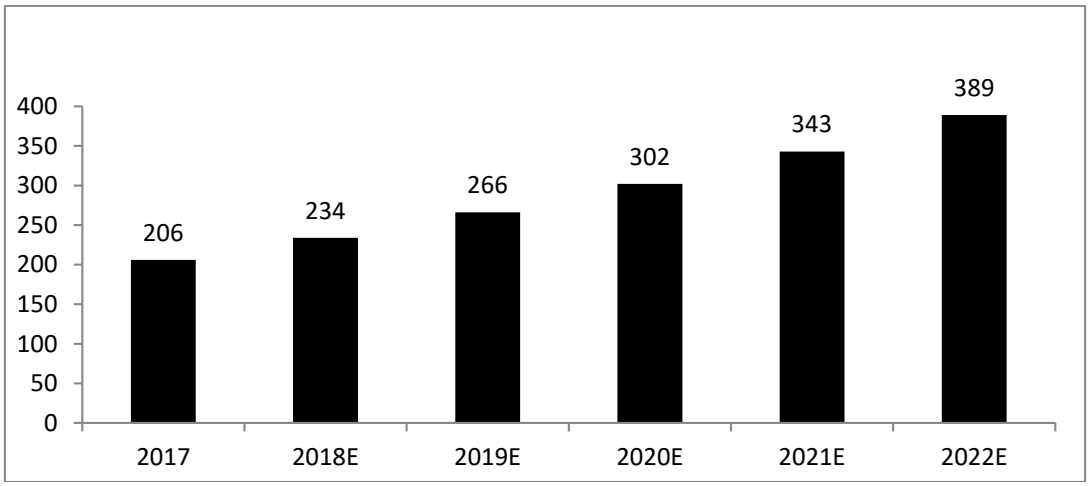

Figure 3.1 Prediction of the scale of tumor drug market in China

Picture source: prospective Industrial Research Institute

3.2 Negative influence

3.2.1 The Competitiveness of domestic Drug Enterprises in the International antitumor Drug Market is reduced

Generic drugs have always been the main object of production and sales in China, but compared with the world, the investment in new drug R&D in China has been at a low level. As can be seen from figure 3. 1, until 2018, the proportion of R & D investment of pharmaceutical enterprises in the world has just exceeded 10%. On the one hand, the reason for this situation is "in reality, the new drug examination and approval cycle is too long, the drug purchase passes through the customs layer by layer, and the road card is set up, resulting in the domestic original new drug can not quickly enter the medical insurance catalogue and hospital purchase list." [5] It takes a long time to develop new drugs at the same time, the cost is large, the risk is high, and the probability from determining the molecular structure to successfully pushing to the market is very low. In contrast, generic drug investment is lower, time is shorter, the risk is smaller, its success rate can be said to be very different from innovative drugs; on the other hand, in R & D funds, R & D technology and other aspects, there are great differences between China's pharmaceutical enterprises and international pharmaceutical enterprises, and many China's pharmaceutical innovative enterprises have just started, compared with multinational pharmaceutical enterprises with a hundred years of basic industry, the difference in strength is too wide. Therefore, if the emerging local drug companies in China want to maximize their profits, compared with the R&D and production of innovative drugs, the production of generic drugs is undoubtedly their best choice. But pile-up production of generic drugs may greatly undermine the international competitiveness of local drug companies in China.

3.2.2 Causing extreme instability in the domestic antitumor drug market

The import tariff of antitumor drugs and the sharp adjustment of VAT (VAT) will inevitably make the imported antitumor drugs, which have plummeted prices, become the first choice for more cancer patients, or even rely entirely on imported antitumor drugs. Domestic antitumor drugs, especially domestic antitumor generics, will gradually fade out of their sight. This will make the domestic antitumor drug market more and more demand for antitumor drugs, domestic antitumor generics manufacturers are facing an unprecedented crisis and possible depression, some domestic antitumor drugs imitation pharmaceutical manufacturers may take high-risk stop-loss measures that have to be transformed into imported drug enterprises, resulting in unbalanced development of domestic antitumor drugs market.

However, the contradiction with the above problems is that while the price of imported antitumor drugs is greatly reduced, some imported antitumor raw materials also implement a zero-tariff policy. With the approval of the State Council, the “2019 Provisional tax rate Adjustment Plan for Import and Export” has been implemented since January 1, 2019. The program imposes zero tariffs on

important raw materials for domestic production and treatment of cancer, rare diseases, diabetes, hepatitis B, acute leukemia and other drugs that need to be imported. The head of the Customs Department of the General Administration of Customs said that taking capecitabine tablets for the treatment of gastric cancer and colorectal cancer as an example, the tariff rate of xeloda, the raw drug, xeloda was reduced from 6.5 percent to 0, and it is expected that the tariff cost will be saved by more than 42 million yuan in 2019. It can be seen that on the basis of the reduction of import tariffs and VAT on antitumor drugs, the implementation of this scheme will reduce the production cost of drugs by a greater extent. From the point of view of drug companies, the lower import cost of raw drugs will increase the profits after the sale of finished antitumor drugs, and the expected increase in profits will stimulate more domestic drug companies to participate in the imitation of such antitumor drugs. After the same kind of domestic antitumor drugs are listed, the price will inevitably be lower than that of completely pure imported drugs, and it will also have an impact on the imported drug market, inhibit the development of domestic drug importing enterprises, and force domestic imported drug enterprises to reduce the price of the finished preparations of imported antitumor drugs. Therefore, whether the domestic antitumor drug imitation pharmaceutical production enterprises want to transform, whether the antitumor drug import enterprises can still obtain the maximum profit, will there be vicious competition between enterprises and other unknown factors will cause the instability of the domestic antitumor drug market, at the same time, it may also lead to the unstable development of domestic drug enterprises at the present stage, bankruptcy due to the mistakes in the formulation of future development decisions, and the problem of vicious competition in the market.

3.2.3 Affect the market growth rate of antitumor proprietary China's medicine in China

The implementation of zero tariff import of antitumor drugs will lead to more effective targeted drugs pouring into the China's market, and the growth rate of China's proprietary drugs for tumors in China will be further curbed or even declined. Because most of the proprietary drugs in tumor treatment play the role of promoting blood circulation and removing blood stasis, and so on, they can only be in the position of auxiliary treatment and can not play a real role in healing. In recent years, the quality and quality of antitumor proprietary China's medicines in China have also declined, so since 2015, many control measures, such as monitoring and using drugs, catalogue of auxiliary drugs, regulation and control of national drug prices, proportion of drugs, centralized bidding and procurement, have been issued one after another, and the sale of antitumor proprietary China's medicines, especially injections, has been greatly affected.

Generally speaking, where to go for domestic drugs and where China's drug companies should go is one of the important problems that the relevant departments of state medicine should face and solve after the change of China's antitumor drug import policy.

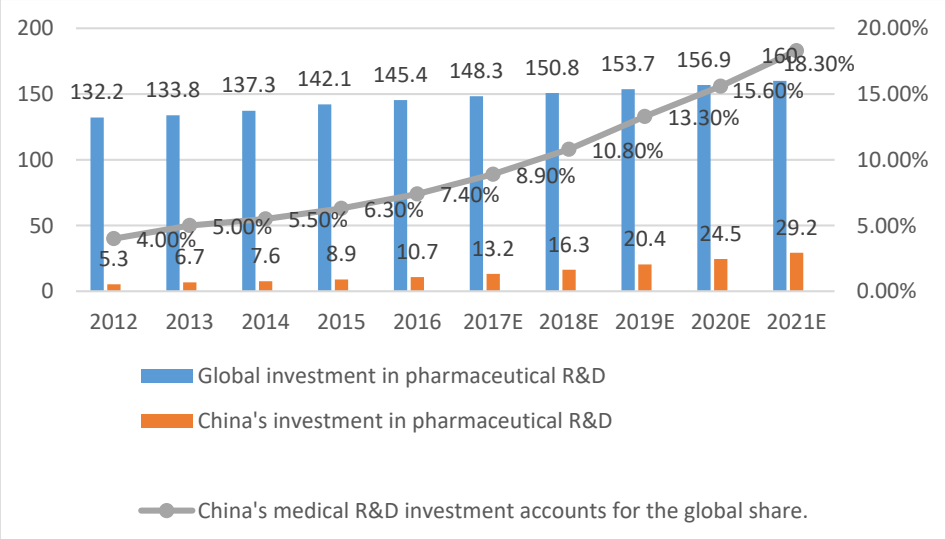

Figure 3.1 Global medicinal R & D investment and China's pharmaceutical R & D investment ratio (2012-2021E)

4. Related countermeasures

4.1 We will intensify R&D of new antitumor drugs

In order to improve the international competitiveness of domestic antitumor innovative drugs, the state should increase the R&D of innovative antitumor drugs in domestic drug enterprises. For enterprises with difficulties in R & D funds, the local government should give allowance or help policies. At the same time, we should strengthen the training of developers, make them have more professional R & D technology, properly introduce advanced R & D machinery and equipment, reduce R & D time as much as possible, and improve the probability of R & D success. For the qualified antitumor drugs developed, we should encourage domestic doctors to give priority to prescription drugs, gradually expand the scope of use of domestic antitumor innovative drugs, and include them in the scope of national medical insurance, so as to reduce the burden of patients as much as possible without loss. Of course, we should also consider putting them on the international market, raising international popularity, improving international competitiveness, and reducing the adverse situation of the spread of antitumor generic drugs in China.

4.2 Strengthening the flexibility of policy formulation and the innovation and integrity of mechanisms

In view of the instability of the domestic antitumor drug market, the government should adjust the corresponding policy appropriately to ensure the flexibility of the policy at all times. If the proportion of domestic antitumor generics enterprises in the domestic antitumor drug market is large, or even show the trend of monopoly, the policy of importing some raw materials should be moderately tightened, and the related policies for most of the imported antitumor drugs should be relaxed moderately. This will relatively increase the pharmaceutical cost of domestic antitumor generics and increase their drug prices.

At the same time, the reduction of the price of imported antitumor drugs will make consumers who previously inclined to buy domestic generics gradually switch to buy relatively cheap imported antitumor drugs, which is conducive to maintaining the relative stability and balance of the domestic antitumor drug market. At the same time, in order to speed up the marketing of domestic innovative drugs and their proportion in the domestic antitumor drug market, the state or related institutions should also actively carry out innovative reform and revision of the institutional mechanism related to domestic innovative drugs. "Drug regulatory agencies can deepen regulatory scientific research, optimize policy tools, strengthen the construction of new drug R & D technical guidance system, improve communication mechanism, provide R & D and registration guidance for enterprises, form a review and approval mechanism to stimulate innovation vitality, and speed up the listing of innovative drugs through cooperation with the industry, university and research circles." [6]

4.3 Improving the quality of Antitumor proprietary China's Medicine

Antineoplastic drugs are essentially different from antitumor drugs with strong therapeutic function, but only play an auxiliary function. After the zero tariff policy, a large number of antitumor targeted drugs flow into the domestic market, and the price is lower than before, because patients gradually reduce the purchase of antitumor drugs, but this is only an external factor, the most important and fundamental factor is the decline in the quality of proprietary China's medicines. It is necessary to formalize the purchase channels, strictly standardize the production standards, standardize the raw materials used, maximize the auxiliary function of antitumor proprietary China's medicines, optimize the quality of drugs, make patients regain their confidence in antitumor proprietary China's medicines, restore the market vitality of domestic antitumor proprietary China's medicines, and improve their growth rate.

5. Conclusion

The prevalence of illegal antitumor drugs in China's antitumor drug market, the slow listing of antitumor generics in China, the poor quality of some drugs, the insufficient R&D of antitumor generics in China and the high import price of antitumor drugs in China are the main reasons for the reform of China's antitumor drug import policy. The reform of zero tariff adjustment and reduction of import value added tax will not only bring about the decrease of import price of antitumor drugs and the positive influence of promoting the development of multinational antitumor drug importing enterprises, but also reduce the competitiveness of domestic drug enterprises in the international antitumor drug market, the extremely unstable market of domestic antitumor drugs and the negative effect of affecting the market growth rate of domestic cancer proprietary drugs.

If we want to minimize these negative effects, our country should strengthen the R&D of new antitumor drugs to prevent the proliferation of antitumor generic drugs in China, strengthen the flexibility and moderation of policy formulation in order to maintain the balance of the domestic antitumor drug market as much as possible and improve the quality of antitumor proprietary China's medicines in order to restore the market vitality of antitumor proprietary drugs in China.

No matter what the impact of the reform of China's antitumor drug import policy, I believe the starting point of the reform is to benefit cancer patients in China and give them more hope, and I firmly believe that in the future, countless China's cancer patients will be more and more likely to be cured and their future will be full of sunshine.

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