TO THE EDITOR

Targeting epidermal growth factor receptor (EGFR) mutation and anaplastic lymphoma kinase (ALK) fusion has become a milestone in lung cancer treatment.\(^1,2\) Targeted drugs have become the first choice for most patients because they can significantly prolong survival and are less toxic and easier to administer. To identify the use of targeted drugs by patients with lung cancer, we carried out a two-phase, 36-week investigation at Guangdong Lung Cancer Institute and Guangdong General Hospital. Between 2014 and 2015, we enrolled 98 patients who had EGFR mutation and 100 with ALK mutation. Of these, 19.4% (19 of 98) with EGFR mutation and 32.0% (32 of 100) with ALK mutation had ever taken at least one kind of pirated targeted medicine, and 16 patients either had the wild-type gene or were missing genotype information.

What was a pirated drug in our survey? We considered three categories of drugs. First, there are generic drugs, which are similar to patented drugs in terms of dosage, safety, and effectiveness. Generics originate mainly from India, the so-called world pharmacy, and their average price is less than 20% to 40% of the price of patented drugs, owing to the absence of royalties. Second, there are crude drugs, which consist of the active pharmaceutical ingredient (API). These lack US Food and Drug Administration (FDA) approval and have been restricted to animal experiments and clinical trials. Third, there are drugs for which neither the composition nor efficacy is clear. Such “fake drugs” are sold as “generics” or the “API” simply to make a profit with no regard to their effectiveness. The sources of pirated medicines are complex, and it is difficult to guarantee quality. Although our small survey was limited to outpatients, our data also imply that pirated targeted-drug abuse has become a serious social issue in China.

Why Is Pirated Drug Abuse So Severe in China?

Targeted drugs have been approved slowly in China because of delayed clinical trials and the complex drug-approval process. A typical example is erlotinib, which was approved as a first-line treatment for EGFR-mutant lung cancer in 2013 by the FDA and the European Medicines Agency but has yet to be approved by the Chinese FDA, although the clinical trials have been completed.\(^3\) In general, a 3- to 5-year delay in approval is common in China.

Even if the targeted drugs were listed, Chinese patients with lung cancer still cannot afford these drugs, which are often not on the reimbursement drug list, and patients must pay the full cost. In our survey, patented medicines such as gefitinib, erlotinib, and crizotinib are extremely expensive at 15,000 to 50,000 yuan per month; even icotinib, an EGFR tyrosine kinase inhibitor produced by a Chinese company, costs 12,000 yuan per month. These prices are more than three- to 12-fold the per capita monthly income of surveyed patients, whereas the pirated drugs are much less expensive at 500 to 5,000 yuan per month.

Why are innovative drugs so expensive in China? In addition to the high research and development costs, drugs cannot be sold directly to Chinese hospitals. After the government sets the price, the drug must pass along a chain of dealers, and each link generates additional costs. Finally, according to the figures released by the European Federation of Pharmaceutical Industries and Associations in 2014, the value-added tax rate on drugs in China is 17%, which is far higher than the average 8.8% in European countries and 0% in the United States, Australia, and some other countries.

Group psychology in cancer treatment is another important reason for the abuse of pirated drugs. In China, numerous patients are active on online anticancer bulletin-board systems where they share their anticancer experiences and encourage each other. To extend their lives, patients who hear about a drug from a benefit group will blindly attempt the miracle cure regardless of their genotype. Owing to imperfect network monitoring, patients can easily acquire these medicines from ward-mates or purchasing agents. These factors all result in rapid circulation of domestic pirated drugs.
What Should We Do to Deal With the Misuse of the Farraginous Pirated Drugs?

Everyone has the right to health, and every patient has the right to use a drug that is capable of extending his or her life. The law should not be a weapon to deprive patients of survival rights. We need an effective policy to improve drug accessibility that should accelerate drug approval and clinical trials to ensure timely access to needed drugs and promote drug-pricing reform so that more patients can afford patent drugs. Drug-pricing reform is a global problem. Regarding the current situation, domestic reform can draw on lessons from the experiences of Taiwan and Western countries. Linking drug marketing with insurance coverage to shorten the time to reimbursement is a good idea. Determining the price via a negotiating mechanism is also worth learning.

Health is a basic right, and it is encouraging to see that our government has a positive attitude toward this. The Chinese National Development and Reform Commission, National Health and Family Planning Commission, and five other departments recently issued a joint notice titled “Ways to Promote the Reform of Drug Prices.” This declared that most drugs will no longer be priced by the government after June 1, 2015, and that the price of patent drugs would be determined by a new, transparent, multistakeholder negotiation mechanism. This means that the control of drug prices will be transferred from the government to the market, and that the costs incurred through the dealer chain will be eliminated. Unfortunately, specific negotiation strategies and reform policies have not yet been introduced.

There is a fable about a hungry dog hunting a rabbit. When asked why the rabbit escaped, the dog explained that the rabbit was running for its life, whereas the dog was just looking for a meal. Like the rabbit in the fable, patients are in a race against death. Therefore, it is easy to understand why the current policy has difficulty meeting patient needs. The misuse of pirated drugs is an instinctive reaction. This is a complex issue that involves human rights and the right to health. The attitude toward this issue reflects the sentiment and spirit of a country. We hope that the Chinese government ultimately helps, rather than hinders, this issue.

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Hui-wen Sun
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Yi-Long Wu
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