Anti-counterfeiting Situation in China

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Drug counterfeiting is a global problem. Counterfeit drugs appear in all countries, deceive our patients, making them believe the “medication” they are taking will help them recover, though in fact, it is causing deterioration or even more seriously, death.
According to WHO report, as the development and complexity of counterfeiting techniques, counterfeit pharmaceuticals have been infiltrating into legitimate global supply chains, and shaping an independent distribution network. Counterfeit pharmaceuticals are endangering human health and safety world-wide. As pharmaceutical industry and different governments reported, manufacture, distribution and sales of counterfeit drugs are developing rapidly, this increased the difficulties of drug supervision and counterfeit drug control.
In order to safeguard public medication security, China government has always put drug anti-counterfeiting one of their top priorities, and has taken a series of measures to combat counterfeit drugs.
1. China has developed strict legal scheme for drug anti-counterfeiting
1. In 1984, “Drug Administration Law of the PRC” was stipulated, later amended largely in 2001. The amendment was put into effect on December 1, 2001.

2. “Implemental Statutes for Drug Administration Law” was issued on September 15, 2002.

3. The stipulation and implementation of the amended “Drug Administration Law” increased the penalties against production and sales of counterfeit drugs, expanded the definition of making/selling counterfeit drug, enlarged the punishment extension of violations and added the penalty of deprivation of qualification for manufacturing.

   The amendment not only adapted to the need of drug supervision, but also represented the public will; moreover, it reflected China’s determination in combating counterfeit drugs.
In addition, SFDA issued and executed other rules and regulations, including “Drug Supervision & Administrative Penalty Procedure”, “Drug Import & Export Administration Measures”, “Drug Registration Measures”, “Chinese Medicines Production Administration Measures” and “Drug Distribution Supervision Measures”. The above regulations provided legal basis for comprehensive drug anti-counterfeiting activities.

In May 2009 China Supreme People’s Court and Supreme People’s Procuratorate issued a Judicial Interpretation for handling criminal cases of counterfeit drug manufacture & distribution, which strengthened the crackdown of counterfeit drug crimes.
2. China has established a multi-ministerial cooperation taskforce for drug anti-counterfeiting, and engaged close collaboration with local government to combat counterfeit drugs.
New problems on the network

As some report, 50% drugs sold on the internet were counterfeit, some had no APIs, some even contained toxic substances. It is a new model of counterfeit drug trade following the rapid development of internet. It is transnational, covert, and a new challenge for all countries government regulatory departments.
In April 2009 China State Council approved the establishment of an inter-ministerial cooperative taskforce for combating counterfeit drugs. The taskforce was composed of Ministry of Health, SFDA, Ministry of Industry & Information Technology, Ministry of Public Security, Ministry of Supervision, Ministry of Finance, Ministry of Commerce, China Customs, State Administration of Industry and Commerce, Administration of Broadcast & Television, Bank Supervision Committee, Legal Office of State Council and China Postal Office.
The taskforce cleared counterfeit drug websites and illegal drug advertisements, cracked down underground factories, disrupted networks of counterfeit drug distribution and deterred counterfeit drug transport through express couriers.

The taskforce outlined enforcement system and improved laws and regulations concerning counterfeit drug advertisement and sales on the internet.

The taskforce initiated public education programs to raise the awareness of basic medical and medication knowledge, and guided the public to acquire medical treatment through legitimate channels.
Meantime supported by local government, local SFDA actively cooperated with Public Security Bureau, Postal Office, local Customs, local AIC and Quality Supervision Bureau to combat counterfeit drugs. Judicial units also enhanced their rulings against counterfeit drug crimes.
In addition, we mobilized the public to participate in anti-counterfeiting effort to strengthen social supervision. Through education campaigns, we raised consumers’ awareness of drug-related legal knowledge, and consumers’ ability in identification of counterfeit drugs. SFDA at all levels opened mail box, hotline, email and website for counterfeit drug complaints. Award was granted to counterfeit drug information providers.
3. China has enhanced SFDA technical capacity and increased routine inspections and sampling.
SFDA established nation-wide four-level inspection teams, including state level, provincial level, municipal level and county level. We also trained a large number of drug inspectors, equipped all counties with portable inspection kit, totally 4,000 sets. Central government allocated 280 million RMB plus 44 million RMB from local government, we provided local SFDA with mobile drug testing labs to assure suspicious drugs identified quickly during enforcement actions. The scientific testing method and results provided reliable basis for enforcement, improved the efficiency and quality of drug testing, ensured punishments to violations and increased anti-counterfeiting deterrent force.
The nation-wide drug sampling, regular drug quality bulletin, drug distribution supervision and drug advertisement supervision all enhanced our market control. SFDA at all levels also exposed counterfeit drugs on SFDA website to warn and educate public so they purchase drugs from legitimate supply channels.
4. China also attach high importance in international cooperation and bear the responsibilities of combating counterfeit drugs around the world.
High importance in international cooperation

China government not only safeguards domestic drug safety, but also collaborates with international organizations, other countries and regions to fulfill the responsibilities of combating counterfeit drug globally.

Closely cooperating with WHO and other governments, we were engaged in drug anti-counterfeiting activities, SFDA staff training, bilateral or multilateral cooperation, information sharing and joint investigation with international units. We demonstrated SFDA willingness and confidence in working with international society to combat counterfeit drug crimes.
Cooperation with the United States

At the end of 2007, China and USA signed a MOU to enhance the supervision of drugs and medical devices. According to the Agreement, both sides chose 18 items including drugs, medical devices for stricter supervision through registration documentation, product manufacturer recordation, product approval data, and adverse effect reports, etc.

Two sides set a good example for international drug supervision and cooperation.
Cooperation with the United Kingdom

Similar case reflected in Sino-UK cooperation. In January 2009, UK “Observer” reported Chinese counterfeit drug JinPuSa entering into UK market. Through the bilateral cooperation channel established with UK Drug & Healthcare Product Administration Bureau, China was able to reach UK regulatory agency and collect leads and facts in a timely manner, which won us valuable time for solution and media response.
As for the supervision of import and export drugs, China adopted the same principle and practice of the international society, firmly combat import/export counterfeit and substandard drugs. On one hand, China provided “Drug Distribution Permit” to exported drugs as WHO requires, on the other hand, China has strict administration rules for imported drugs, which requires the importer to provide complete credential documents, and pass the procedure of registration, testing and approval.
In summary, various anti-counterfeiting measures SFDA has taken in the past years and numerous successful counterfeit drug crackdowns deliver a strong message to the world, that is, combating counterfeit drugs, China has put a lot of efforts and achieved tremendous successes.
Summary

With China’s rapid economic growth, public need for quality and safe medical services also increased. As a developing country, China is also facing the threat and harm caused by counterfeit drugs. To confront the challenge, we follow scientific development perspective, analyze and judge food and drug safety situation objectively, summarize the experiences and lessons we learn from drug supervision work, put forward requests for scientific supervision concept, and fully address the overall, fundamental and directional issues relating to food and drug supervision.
Counterfeit drugs have a long history. One of the main causes is the high profit generated by counterfeit drug trade. It is thorny to tackle the problem thoroughly. Drug regulatory agencies in western countries have adopted some high-tech measures, such as RFID or bar codes on the packaging. However these measures all have certain limitations in implementation due to infrastructure shortage.

In fact, raised awareness of patients, lower price of drugs, policy support from drug regulatory units and using effective legal tools are all effective solutions for the rampant counterfeit drugs in the market. In high risk countries, seeking closer international cooperation is an additional way to combat the counterfeits.
Following economic globalization and free trade, drug industry extended to all corners of the world, drug supervision and public healthcare business became transnational. For that reason, we must adjust our traditional supervision model to face the challenge, and increase international cooperation and communication for information sharing and coordination, so as to meet the increasing needs of public for drug safety.

Facing rapidly updated technology, globalization of drugs, pressures from public and media, we must collaborate and congregate limited manpower and financial resources to overcome the challenge in the new era.
THANKS!