

China's response to fraudulent medicines

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**China has developed strict legal scheme
for combat against the fraudulent
medicines**



In 1984, “Drug Administration Law of the PRC” was stipulated

amended largely in 2001



The amendment was put into effect on December 1, 2001



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

increased the penalties against production and sales of fraudulent medicines

expanded the definition of making/selling fraudulent medicines

enlarged the punishment extension of violations

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 fraudulent medicines

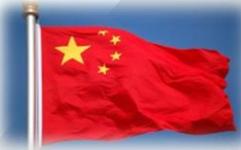


The definition of fraudulent medicines:

Article 48, The amendment to the Drug Administration Law of the PRC

- (1) the ingredients in the drug are different from those specified by the national drug standards; or
- (2) a non-drug substance is simulated as a drug or one drug is simulated as another.

- (1) its use is prohibited by the regulations of the drug regulatory department under the State Council;
- (2) it is produced or imported without approval, or marketed without being tested, as required by this Law;
- (3) it is deteriorated;
- (4) it is contaminated;
- (5) it is produced by using drug substances without approval number as required by this Law; or
- (6) the indications or functions indicated are beyond the specified scope.



In 2011, The amendment VIII to the Criminal Law of the PRC

- Paragraph 1 of Article 141 of the Criminal Law is amended to read: "Whoever manufactures or sells fraudulent medicines shall be sentenced to fixed-term imprisonment of not more three years or criminal detention and be concurrently given a fine. Where serious harm to human health is caused or there are other grave circumstances, he/she shall be sentenced to fixed-term imprisonment of not less than three years but not more than ten years and be concurrently given a fine. If death is caused to another person or there are other especially serious circumstances, he/she shall be sentenced to fixed-term imprisonment of not less than ten years, life imprisonment or death penalty and be concurrently subject to a fine or confiscation of property.
- fraudulent medicines as mentioned in this Article refer to medicines or any non-medical substances that fall under the category of or are regarded as fraudulent medicines under the Drug Administration Law of the PRC.



In addition, China 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”

“Drug Distribution Supervision Measures”

provided legal basis for comprehensive fighting against fraudulent medicines

In May 2009 China Supreme People’s Court and Supreme People’s Procuratorate issued

a Judicial Interpretation for handling criminal cases of fraudulent medicines manufacture & distribution

strengthened the crackdown of fraudulent medicines crimes



China has established a multi-ministerial cooperation taskforce for fighting against fraudulent medicines, and engaged close collaboration with local government to combat fraudulent medicines



In April 2009 China State Council approved the establishment of an inter-ministerial cooperative taskforce for fighting against fraudulent medicines.

- 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
- China Postal Office.

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 fraudulent medicines.

In addition, we mobilized the public to participate in fighting against fraudulent medicines effort to strengthen social supervision.



The taskforce cleared fraudulent medicines websites and illegal drug advertisements, cracked down underground factories, disrupted networks of fraudulent medicines distribution and deterred fraudulent medicines transport through express.

The taskforce outlined enforcement system and improved laws and regulations concerning fraudulent medicines 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.

Through education campaigns, we raised consumers' awareness of drug-related legal knowledge

consumers' ability in identification of fraudulent medicines

SFDA at all levels opened mail box, hotline, email and website for fraudulent medicine complaints.

Award was granted to fraudulent medicine information providers.



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, prefecture level and county level. We also trained a large number of drug inspectors

equipped all counties with portable inspection kit, totally 4,000 sets. China government allocated US\$7000, and provided local SFDA with 400 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.

The nation-wide drug sampling, regular drug quality bulletin

drug distribution supervision

drug advertisement supervision

SFDA at all levels also exposed fraudulent medicines on SFDA website to warn and educate public so they purchase drugs from legitimate supply channels



China also attach high importance in international cooperation and bear the responsibilities of combating fraudulent medicines around the world



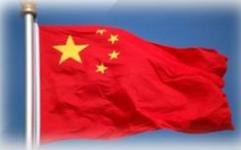
SFDA staff training

bilateral or multilateral 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 fraudulent medicines globally. Closely cooperating with WHO and other governments, we were engaged in fighting against fraudulent medicines

information sharing

joint investigation with international units



As for the supervision of import and export drugs, China adopted the same principle and practice of the international society, firmly combat import/export fraudulent medicines

- China provided “Drug Distribution Permit” to exported drugs as WHO requires

export

import

- 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 fraudulent medicines control measures China government has taken in the past years and numerous successful fraudulent medicines crackdowns deliver a strong message to the world, that is, combating fraudulent medicines, China has put a lot of efforts and achieved tremendous successes.





新年快乐

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