China (People’s Republic of China)

1. The Principal laws
The principal laws governing the counterfeiting of pharmaceuticals (counterfeit medicines) in China (People’s Republic of China) are the Criminal Law (Adopted on July 1, 1979 and Amended on October 1, 1997)\(^1\); the Drug Administration Law (Adopted in 1984 and Amended on February 28, 2001 and effective as of December 1, 2001)\(^2\) and the Regulations for Implementation of the Drug Administration Law (Promulgated on August 4, 2002, and effective as of September 15, 2002)\(^3\).

Pharmaceutical Affairs Act (Enacted by the Act No. 300 of 1953 and effective as of January 28, 1954 and Lastly Amended by Act No. 12,450 of 2014 and as effective as of March 18, 2014)\(^1\); the Act on Special Measures for the Control of Public Health Crimes (Enacted by the Act No. 2, 137 of 1969 and Lastly Amended by the Act 11,690 of 2013 and as effective as of March 23, 2013)\(^2\) and the Enforcement Decree of the Act on Special Measures for the Control of Public Health Crimes (Enacted by the Presidential Decree No. 4326, Nov. 27, 1969 and Lastly Amended by the Presidential Decree No. 22075, March 15, 2010)\(^3\).

2. Legislation Links
(1) Criminal Law

(2) Drug Administration Law
http://eng.sfda.gov.cn/WS03/CL0766/61638.html (English) (Chinese government- Food and Drug Administration)

(3) Regulations for Implementation of the Drug Administration Law
http://english.gov.cn/laws/2005-07/25/content_16953.htm (English) (Chinese Government)

3. Extracts of legislation related to combat the counterfeit medicines:

(1) Criminal Law
Article 141
Whoever produces or sells fake medicines that are harmful enough to seriously endanger human health shall be sentenced to fixed-term imprisonment of not more than three years or criminal detention and shall also, or shall only, be fined not less than half but not more than two times the amount of earnings from sales; if human health is seriously harmed, he shall be sentenced to fixed-term imprisonment of not less than three years but not more than 10 years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if death is caused to another person or especially serious harm is done to human health, he shall be sentenced to fixed-term imprisonment of not less than 10 years, life imprisonment or
death, and shall also be fined not less than half but not more than two times the amount of earnings from sales or be sentenced to confiscation of property.
Fake medicines as mentioned in this Article refer to medicines or any non-medical substances that fall under the category of or are regarded as fake medicines under the Pharmaceutical Administration Law of the People’s Republic of China.

Article 142
Whoever produces or sells medicines of inferior quality and thereby causes serious harm to human health shall be sentenced to fixed-term imprisonment of not less than three years but not more than 10 years and shall also be fined not less than half but not more than two times the amount of earnings from sales; if the consequences are especially serious, he shall be sentenced to fixed-term imprisonment of not less than 10 years or life imprisonment, and shall also be fined not less than half but not more than two times the amount of earnings from sales or be sentenced to confiscation of property.
Medicines of inferior quality as mentioned in this Article refer to medicines that fall under the category of medicines of inferior quality under the Pharmaceutical Administration Law of the People’s Republic of China.

(2) Drug Administration Law

Chapter V
Control over Drugs
Article 48
Production (including dispensing, the same below) and distribution of counterfeit drugs are prohibited.
A drug is a counterfeit drug in any of the following cases:
(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.
A drug shall be treated as a counterfeit drug in any of the following cases:
(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.
**Article 49**
Production and distribution of substandard drugs are prohibited.  
A drug with content not up to the national drug standards is a substandard drug.  
A drug shall be treated as a substandard drug in any of the following cases;  
(1) the date of expiry is not indicated or is altered;  
(2) the batch number is not indicated or is altered;  
(3) it is beyond the date of expiry;  
(4) no approval is obtained for the immediate packaging material or container;  
(5) colorants, preservatives, spices, flavorings or other excipients are added without authorization; or  
(6) other cases where the drug standard are not conformed.

**Chapter IX**
**Legal Liabilities**

**Article 74**
Where counterfeit drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than two times but not more than five times the value of the said drugs shall be imposed. The approval documents, if any, shall be withdrawn and an order shall be given to suspend production or business operation for rectification. If the circumstances are serious, the Drug Manufacturing Certificate, Drug Supply Certificate or Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 75**
Where substandard drugs are produced or sold, the drugs illegally produced or sold and the illegal gains shall be confiscated, and a fine not less than, but not more than three times, the value of the said drugs shall also be imposed. If the circumstances are serious, an order shall be given to suspend production or business operation for rectification, or the drug approval documents shall be withdrawn and the Drug Manufacturing Certificate, the Drug supply Certificate, or the Pharmaceutical Preparation Certificate for Medical Institution shall be revoked. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

**Article 76**
Where enterprises or other institutions are engaged in production or sale of counterfeit or substandard drugs, if the circumstances are serious, the persons directly in charge
and the other persons directly responsible shall be prohibited from engaging in the drug production or distribution within 10 years.

The drug substances, excipients, packaging materials and manufacturing equipment specially used for producing counterfeit or substandard drugs by any producer shall be confiscated.

Article 77
Anyone who knows or should know that the drugs are counterfeit or substandard drugs provides conveniences such as transportation, keeping or storage of the drugs, all the earnings therefrom shall be confiscated, and a fine not less than 50 per cent of, but not more than 3 times, the amount of the illegal earnings shall also be imposed. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.

Article 78
The quality testing results provided by the drug testing institution shall be contained in the penalty notification regarding counterfeit and substandard drugs, except in cases specified in the provisions of Subparagraphs (1), (2), (5) and (6) of the third paragraph of Article 48 and the third paragraph of Article 49 of this Law.

Article 97
Drug regulatory departments shall, in accordance with law, perform their duties of supervision and inspection and shall see to it that the enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate engage in drug production or drug distribution in accordance with the provisions of this Law.

Where enterprises holding the Drug Manufacturing Certificate or Drug Supply Certificate produce or sell counterfeit or substandard drugs, the legal liabilities of such enterprises shall be investigated and, in addition, the persons directly in charge and the other persons directly responsible of the drug regulatory departments who neglect their duty or commit dereliction of duty shall be given administrative sanctions in accordance with law. If a crime is constituted, criminal liabilities shall be investigated in accordance with law.