South Korea (Republic of Korea)

1. The Principal laws
The principal laws governing the counterfeiting of pharmaceuticals (counterfeit medicines) in South Korea (Republic of Korea) are the 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) Pharmaceutical Affairs Act

- Pharmaceutical Affairs Act (Lastly Amended by Act No. 12,450 of 2014 and as effective as of March 18, 2014)
  http://www.law.go.kr/lsInfoP.do?lsiSeq=152038&efYd=20140318#AJAX (Korean)

- Pharmaceutical Affairs Act (Amended by the Act No. 10,788 of 2011)
  http://www.moleg.go.kr/english/korLawEng?pstSeq=58356&rcptPstCnt=3&searchCondition=AllButCsfCd&searchKeyword=PHAR (English)

(2) Act on Special Measures for the Control of Public Health Crimes

- Act on Special Measures for the Control of Public Health Crimes (Lastly Amended by the Act 11,690 of 2013 and as effective as of March 23, 2013)
  http://www.law.go.kr/lsInfoP.do?lsiSeq=136678&efYd=20130323#0000 (Korean)

- Act on Special Measures for the Control of Public Health Crimes (Amended by At No. 10,579 of 2011)
  https://elaw.klri.re.kr/kor_service/main.do (English)

(3) 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)
  http://www.law.go.kr/lsInfoP.do?lsiSeq=103228#0000 (Korean)
  https://elaw.klri.re.kr/kor_service/main.do (English)

3. Extracts of legislation related to the counterfeit medicines:

(1) Pharmaceutical Affairs Act

Article 60 (Labelling Prohibited from being Stated)
The following matters shall not be stated on leaflets, containers or packages of drugs:
<Amended by Act No. 8643, Oct. 17, 2007>
1. False matters or those apprehended to be misunderstood with regard to the drug concerned;
2. Indication which has not been permitted or reported pursuant to Article 31 (2) and (3) or 41 (1);
3. Direction, dosage or period of use which is dangerous to public health and sanitation.

Article 61 (Prohibition of Distribution, etc.)
(1) No one shall sell, or store or display the following drugs for sale: <Amended by Act No. 8643, October 17, 2007, Act No. 10788, June. 7, 2011>
1. Drugs in violation of the provisions of Articles 56 through 60 or fake drugs;
2. Drugs manufactured or imported in violation of Articles 31 (2) and (3), 41 (1), 42 (1) and (3), and 43 (1).
(2) No one shall put a mark on a container, package or leaflet, which is apprehended to make a product, other than drugs, misunderstood as having medical indication, or shall put an advertisement of these contents, sell a product indicated or advertised like drugs, store or display them for sale.

Article 62 (Prohibition of Manufacturing, etc.)
No one shall sell the following drugs or manufacture, import, store or display them for sale: <Amended by Act No. 8643, Oct. 17, 2007, Act No. 10788, Jun. 7, 2011, Act No. 11690, March 23, 2013 >
2. Drugs which are permitted or reported under Articles 31 (2) and (3) and 41 (1), but whose ingredients or quantities (if active ingredients are not clear, the essence thereof or outline of manufacturing methods) are different from the details permitted or reported;
10. Drugs whose containers or packages might make users misunderstand the method of using them.

Article 93 (Penal Provisions)
(1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than five years, or by a fine not exceeding twenty million won: <Amended by Act No. 8643, Oct. 17, 2007>
10. A person who violates Article 61 (including cases applicable mutatis mutandis in Article 66).
(2) As for the punishment referred to in paragraph (1), imprisonment and fines may be imposed concurrently.

Article 94 (Penal Provisions)
(1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than three years, or by a fine not exceeding ten million won: However, any person who has violated Article 87 (1) may be charged only when an accusation is filed against him/her: <Amended by Act No. 8643, Oct. 17, 2007; Act No. 10788, Jun. 7, 2011>
9. A person who sells, manufactures, imports, stores or displays drugs, in violation of Article 62 (including cases applicable mutatis mutandis in Article 66)
(2) As for the punishment referred to in paragraph (1), imprisonment and fines may be imposed concurrently.

Article 95 (Penal Provisions)
(1) A person who falls under any of the following subparagraphs shall be punished by imprisonment for not more than one year, or by a fine not exceeding three million won: <Amended by Act No. 8558, Jul. 27, 2007; Act No. 8643, Oct. 17, 2007; Act No. 10324, May 27, 2010; Act No. 10788, Jun. 7, 2011>
10. A person who violates Article 60, 64 (1) or 68.
As for the punishment referred to in paragraph (1), imprisonment and fines may be imposed concurrently.

**Article 97 (Joint Penal Provisions)**

Where a representative of a corporation, or an agent, employee or other servant of the corporation or an individual commits an offence under Articles 93, 94, 94-2, 95, 95-2 and 96 in connection with the business of the corporation or the individual, in addition to the punishment of such offender, the corporation or the individual shall be punished by a fine under each relevant Article: Provided, That where such corporation or individual has not been negligent in giving due attention and supervision concerning the relevant duties to prevent such violation, this shall not apply.

(2) Act on Special Measures for the Control of Public Health Crimes

**Article 3 (Punishment for Manufacturing Illegal Medicines, etc.)**

(1) A person who manufactures medicines without permission under Article 31(1) of the Pharmaceutical Affairs Act, a person who, knowingly, sells or acquires them for the purpose of sale and arranges the sale or a person who purchases them for the purpose of medical treatments, a person who substitutes the efficacy of entirely different ingredients for that of primary ones in violation of subparagraph 2 of Article 62 of the same Act, or makes sensibly more deficient contents than licensed ones, a person who knowingly sells or acquires them for the purpose of sale and arranges the sale or a person who purchases for the purpose of medical treatment, a person who counterfeits something similar to the already licensed medicines, a person who, knowingly, sells or acquires them for the purpose of sale and arranges the sale, or a person who purchases them for the purpose of medical treatment, shall be punished in accordance with the following classifications:

1. Where medicines are seriously harmful to the human body, or medicines prescribed by Presidential Decree from among state-authorized medicines as prescribed for in Article 53 of the Pharmaceutical Affairs Act fall far short of (or considerably lack) the designated efficacy or contents, imprisonment for life or for not less than five years shall be sentenced;
2. Where the value of medicines at retail amounts to not less than 10 million won per annum, imprisonment for life or for not less than three years shall be sentenced;
3. Where a crime listed in subparagraph 1 is committed causing the death or injury of another, he/she shall be sentenced to death penalty, imprisonment for life or for not less than five years.

(2) In case of paragraph (1), a fine equivalent to not less than double but not more than quintuple of the retail value of the products manufactured, processed, counterfeited, altered, acquired, purchased, sold or offered good offices for sale shall be concurrently imposed.

(This Article Wholly Amended by Act No. 10579, April 12, 2011)

**Article 3-2 (Special Aggravation for Second Offenders)**

In cases where a person who was punished with a crime listed in Article 2 or 3 re-commits a crime listed in Article 2 (1) 1 or 3 (1) 1 within three years after the date on which the execution of the punishment has been completed or remitted, he/she shall be sentenced to death penalty, imprisonment for life or for not less than five years.

**Article 6 (Joint Penal Provisions)**

When a representative of a corporation, or an agent, employer or any other employee of a corporation or individual commits any act in violation of Article 2, 3, 4 or 5 in connection with the business of the corporation or individual, the corporation or individual shall be punished by a fine not exceeding 100 million won, in addition to the punishment of the offender: Provided, That
the same shall not apply where the corporation or individual has not neglected to give a due attention and supervision to the affairs in order to prevent such violation.
(This Article Wholly Amended by Act No.9840, Dec 29, 2009)

Article 7(Revocation of License)
(1) In respect of business which has been punished under this Act, or business whose products are harmful to the human body in violation of the standards and specifications, or business whose products are certified by the Korea Food and Drug Administration to considerably lack the efficacy and contents, the head of agency which has control over the license, authorization or registration shall revoke such license authorization or registration upon request of the Minister of Health and Welfare, the Commissioner of the Korea Food and Drug Administration or the Minister of Environment. (Amended by the Act 11,690, March 23, 2013)
(2) In the case of paragraph (1), no person whose business has been revoked in accordance with this Act shall engage in the same business for a period of five years after the date of its revocation (no person shall engage in the same business for a period of five years after the date of its revocation (no person who has been punished shall engage in the same business for a period of five years after the date on which that the execution of punishment has been completed or remitted)
(This Article Wholly Amended by Act No. 10579, April 12, 2011)

Article 8 (Standards for Harmfulness, etc.)
The standards for “seriously harmful” or “considerably lack: mentioned in Articles 2, 3, 4 and 7 shall be determined by Presidential Decree.
(This Article Wholly Amended by Act No. 10579, April 12, 2011)

Enforcement Decree of the Act on Special Measures for the Control of Public Health Crimes
Article 5 (Standards for Harmfulness of Illegal Medicines, etc.)
(1) The standards for “being seriously harmful to human body” in Article 3(1) 1 of the Act means those medicines for which the maximum doses of their ingredients are indicated on their authentic certificates designated by the Korean Pharmacopoeia or the Minister of Health and Welfare, and refers to cases where the maximum doses are exceeded. (Amended by Presidential Decree No. 14446, Dec 23, 1994; Presidential Decree No. 20679, Feb. 29, 2008; Presidential Decree No. 20679, Feb 29, 2008I Presidential Decree No. 22075, March 15, 2010)
(2) The standards for “considerably lack the efficacy and contents” in Articles 3 (1) 1 and 7(1) of the Act means cases where the total content of the primary ingredients of medicines or cosmetics measured at the time of their production fall short of the minimum effective dose.