



## A comparative study of the objective elements of crimes related to the illicit circulation of drugs

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### Abstract

One of the fundamental responsibilities of the public health sector is to ensure that the population is provided with medicines that are of high quality, safe, and effective. Unfortunately, alongside this legitimate system, the circulation and use of substandard and counterfeit medicines persist as a pervasive shadow and continue to infiltrate the lawful pharmaceutical market. Moreover, due to the high profitability of this sector, the illegal production, trade, import, and export of counterfeit and unauthorized medicines have been increasing. In Mongolia, the circulation of medicines of unknown origin, as well as unauthorized, unregistered, counterfeit, and substandard pharmaceutical products, has become increasingly prevalent. Accordingly, this paper aims to conduct a comparative analysis of the objective elements of crimes related to the illicit circulation of medicines by examining how such elements are regulated and defined in the relevant legislation of selected foreign countries. The study seeks to identify the distinctive characteristics of these crimes, reveal existing legal gaps, and propose further solutions and recommendations for improving the legal and regulatory framework.

**Keywords:** Drug, objective elements, act, omission, crime

### Introduction

The widespread practice of enterprises, organizations, and individuals engaging in the production and sale of drugs without authorization or regulatory oversight, importing pharmaceuticals without proper approval, and selling or distributing expired and unregistered medicines through informal channels has resulted in citizens suffering harm to their lives and health as a consequence of using counterfeit and substandard drugs.

In recent years, beyond medicines and medical devices, individuals and legal entities have increasingly been importing and trading pharmaceutical raw materials, biological products, and dietary supplements without any form of authorization, and reports have emerged indicating that the quality of such products is inadequate.

In this regard, Mongolia has criminalized offenses related to the illicit circulation of medicines under the current Criminal Code as “Illegal production, export, import, supply, and sale of medicines, pharmaceutical raw materials, biological products, and medical devices” (State Gazette, 2016, No. 07). Article 20.14 of the Criminal Code provides that:

Article 20.14. Illegal Production, Export, Import, Supply, and Sale of Medicines, Pharmaceutical Raw Materials, Biological Products, Medical Devices, and Health Supplements

1. If a person produces, exports, imports, supplies, sells, or distributes drugs, pharmaceutical raw materials, biological products, medical devices, or health supplements that are prohibited for use in human treatment, unauthorized, expired, or counterfeit, a fine equivalent to 2,700 to 14,000 units of the monetary unit, or a restriction of the right to travel for a period of six months to three years, or imprisonment for a period of six months to three years shall be imposed.
2. If a person carries out activities of producing, exporting, importing, supplying, selling, or distributing medicines, pharmaceutical raw materials, biological

products, or medical devices without the required authorization, a fine equivalent to 5,400 to 27,000 units of the monetary unit, or a restriction of the right to travel for a period of one to five years, or imprisonment for a period of one to five years shall be imposed.

3. If, as a result of this offense:  
3.1. serious harm to human health is caused or a human life is lost; or  
3.2. substantial damage is caused, a fine equivalent to 10,000 to 40,000 units of the monetary unit, or imprisonment for a period of two to eight years shall be imposed.
4. If the offenses specified in paragraphs 1 and 2 of this Article are committed on behalf of or in the interest of a legal entity, the legal entity shall be deprived of the right to engage in certain types of activities and shall be subject to a fine equivalent to 20,000 to 120,000 units of the monetary unit.
5. If the offense specified in paragraph 3 of this Article is committed on behalf of or in the interest of a legal entity, the legal entity shall be deprived of the right to engage in certain types of activities and shall be subject to a fine equivalent to 200,000 to 400,000 units of the monetary unit.

The concept of illicit circulation of medicines encompasses the production–export, import–supply, and sale of medicines, pharmaceutical raw materials, biological products, and medical devices.

The objective element of this crime consists of active conduct, namely the production–export, import–supply, sale, and distribution of medicines, pharmaceutical raw materials, biological products, medical devices, and health supplements that are prohibited for use in human treatment, unauthorized, expired, or counterfeit. The commission of any one of these acts is sufficient to complete the offense; the occurrence of harmful consequences is not required. Accordingly, this constitutes a formal offense (Criminal Law: Special Part, 2024).

## Comparative Analysis

In this regard, the legislation of states that have acceded to the Medicrime Convention on combating the illicit circulation of drugs has been examined to identify how the objective elements of this type of offense are defined. (Mongolia is not a party to this Convention.)

### 1. Republic of Albania: Criminal Code, Article 284/d

Production and Marketing of Counterfeit or Life and Health-Endangering Drugs and Medical Devices

This provision defines the objective element of the offense as the illegal production, possession for the purpose of sale, sale, offering for sale, distribution, export, or import of medicines, their active and excipient substances, as well as medical products and devices, accessories, components, and materials.

Paragraph 2 further specifies aggravating circumstances where such acts are committed in the course of professional activity, via the internet, jointly, or repeatedly. Paragraph 3 provides that where the acts cause serious harm to human life or health, enhanced liability applies (Albania, 2025).

A notable advantage of this provision, which is not reflected in Article 20.14 of the Criminal Code of Mongolia, is the criminalization of “possession” and “offering for sale” as independent acts, as well as the explicit inclusion of offenses committed in the course of professional activity, via the internet, jointly, or repeatedly. These elements demonstrate a modern and context-responsive legislative approach.

At present, illicit pharmaceutical trade in Mongolia is increasingly conducted through digital platforms, particularly by using Facebook as a primary means to facilitate such offenses. The absence, in Article 20.14 of the Criminal Code of Mongolia, of provisions addressing possession, offering for sale, and the commission of offenses via the internet, jointly, or repeatedly constitutes a notable legislative gap.

### 2. France: Public Health Code, Article L5421-13

This provision criminalizes the production, brokering, distribution, and advertising, offering for sale, sale, import, and export of counterfeit, substandard, or non-compliant medicines (France, 2025).

Paragraph 1 specifies that the offense is established where counterfeit, substandard, or non-compliant medicines pose a risk to human health.

Paragraph 4 further defines as an objective element the advertising, offering for sale, or selling of counterfeit, substandard, or non-compliant medicines through publicly accessible electronic communication networks, thereby explicitly addressing offenses committed via digital platforms.

The provision in French law that treats the commission of this offense through publicly accessible electronic communication networks as an aggravating circumstance represents a highly responsive and contemporary regulatory approach. In recent years, not only in Mongolia but also in most countries worldwide, such crimes have increasingly been committed through digital means, demonstrating that legislators have begun to incorporate specific provisions into their legal frameworks to address and combat this evolving mode of criminal conduct.

### 3. Republic of Türkiye: Criminal Code, Articles 186 and 187

**Article 186:** Sale of Food and Drugs that are Spoiled or Altered

1. The production, alteration, or sale of foodstuffs, beverages, or medicines in a manner that renders them spoiled or dangerous to human life or health (Türkiye, 2025).

**Article 187:** Production or Sale of Medicines Dangerous to Human Life or Health

1. The production or sale of medicines in a manner that poses a danger to the life or health of others (Türkiye, 2025).

In Türkiye, the law addresses food products and medicines jointly, criminalizing conduct where such products are altered or sold in a manner that endangers human life or health. By contrast, Article 20.14 of the Criminal Code of Mongolia adopts a broader scope by criminalizing a wider range of acts, including production–export, import–supply, sale, and distribution, which may be regarded as a legislative advantage.

### 4. Hungary: Criminal Code, Article 186

Counterfeiting of Health Products

- a. The counterfeiting of health products or the production of counterfeit health products;
- b. The supply, offering for sale, marketing, or use of counterfeit or falsified health products, as well as conducting activities involving health products not authorized in Hungary;
- c. The importation, exportation, transit, or unjustified acquisition or possession in large quantities of counterfeit or falsified health products;
- d. The unjustified acquisition or possession in large quantities, or the cross-border movement or transit of health products;
- e. The use of documentation related to health products for commercial purposes other than their intended purpose (Hungary, 2025).

(2) The acts specified in points (a) and (b) of paragraph (1) constitute aggravated offenses where:

- a) They result in the permanent loss of working capacity or serious harm to health; or b) They cause the death of a person.

(4) The widespread distribution to consumers of counterfeit or falsified health products, or of health products not authorized in Hungary, constitutes an aggravated form of the offense.

The Hungarian Criminal Code provides a highly detailed and comprehensive definition of the objective elements of offenses related to the illicit circulation of medicines. In contrast to Article 20.14 of the Criminal Code of Mongolia, it explicitly criminalizes acts such as transit, offering for sale, unjustified large-scale acquisition and possession, as well as consequences including the loss of working capacity, and the misuse of documentation related to health products for commercial purposes, thereby reflecting a broader and more nuanced legislative approach.

## 5. Republic of Belarus: Criminal Code, Articles 338.1 and 338.2

**Article 338.1:** Counterfeiting of Quality Documentation, Labels, and Packaging of Medicines and Medical Devices, Auxiliary Substances, Components, Materials, and Equipment

1. The use or production of counterfeit documents, the manufacture of counterfeit packaging, or the affixing of counterfeit labels, as well as the production of medicines, substances used in the manufacture of medicines, auxiliary substances, medical devices, their parts and components, consumable materials, and auxiliary medical equipment (Belarus, 2025).

**Article 338.2:** Production, Importation, Storage, or Sale of Counterfeit, Substandard, or Unregistered Medicines and Medical Devices

1. The production, importation into the Republic of Belarus, storage for the purpose of sale, or sale of counterfeit, substandard, or unregistered medicines and medical devices. Paragraph 3 provides that where the acts specified in paragraph (1) are committed by a group or result, through negligence, in serious bodily injury or death, enhanced criminal liability shall apply.

Under Article 338.1 of the Belarusian Criminal Code, the objective element consists of the counterfeiting or use of quality documentation, labels, and packaging of medicines and medical devices. Article 338.2(1), by contrast, criminalizes the production, importation, storage, and sale of counterfeit, substandard, and unregistered medicines and medical devices—acts that are not explicitly regulated under Mongolian law, thereby highlighting a notable legislative distinction.

## 6. Republic of Moldova: Criminal Code, Article 241-1 Production or Sale of Counterfeit Medicines

1. The production or sale of counterfeit medicines (Moldova, 2025).  
Paragraph 2 defines an aggravated form of the offense where the same acts cause serious or moderate harm to human health, or result in death.

While Article 241-1(1) of the Moldovan Criminal Code limits criminal liability to the production and sale of counterfeit medicines, Article 20.14 of the Criminal Code of Mongolia adopts a broader approach by criminalizing not only the production and sale of counterfeit medicines, but also the illegal production—export, import—supply, and sale of medicines, pharmaceutical raw materials, biological products, and medical devices, thereby encompassing a wider range of illicit conduct.

## 7. Republic of Croatia: Criminal Code, Article 185 Counterfeiting of Medicines and Medical Products

1. The production of counterfeit medicines, active substances, excipients, or medical products, or the alteration of genuine medicines, active substances, excipients, or medical products, including their components or devices (Croatia, 2025). Paragraph 2 criminalizes the act of selling as genuine, storing, importing, exporting, distributing, or supplying the items referred to in paragraph (1). Paragraph 3 extends criminal liability to the

counterfeiting or alteration of internal or external packaging, as well as the falsification of medicinal properties, instructions for use, or technical documentation.

Paragraph 4 further criminalizes the use of genuine packaging, instructions, or technical documentation for unlawful purposes, including their use in illegal supply chains.

Paragraph 5 provides an aggravated form of the offense where the acts specified in paragraphs (1)–(4) are committed by a manufacturer or supplier, or are disseminated to the public through information systems or the internet.

The Croatian Criminal Code adopts a distinctive and highly granular approach to defining the objective elements of this offense. Although the core of the *جرم* lies in the circulation of counterfeit medicines and medical products, the law further encompasses acts such as alteration, sale as genuine, storage, importation, exportation, distribution, falsification of packaging and documentation, and the misuse of authentic materials for unlawful purposes, thereby providing a comprehensive and modern legal framework.

## 8. Republic of Slovenia – Criminal Code, Article 183

Production and Sale of Medicines and Medical Products Dangerous to Health

1. The production, sale, or supply by other means of medicines or other medical products that may endanger public health (Slovenia, 2025).

Paragraph 2 criminalizes the production, preparation, or processing of medicines derived from blood or other tissues contaminated or infected with pathogens, including bacteria, viruses, or parasites.

Paragraph 4 provides that where the offenses specified in paragraphs 1–3 cause serious bodily injury or serious deterioration of health to one or more persons, aggravated criminal liability applies.

Paragraph 5 further aggravates liability where the offense results in the death of several persons.

The Criminal Code of Slovenia adopts a graduated and highly detailed structure in defining the objective elements of the offense, distinguishing between general endangerment, serious bodily harm, serious health deterioration, and fatal consequences.

Notably, Slovenian law explicitly criminalizes the production of auxiliary substances and medicines derived from infected blood or tissues contaminated with infectious agents such as bacteria, viruses, and parasites. By contrast, Article 20.14 of the Criminal Code of Mongolia formulates the offense in a more generalized manner, without a clearly defined graduated classification of consequences.

Furthermore, the inclusion of the phrase “supply by other means” reflects a broad legislative intent to encompass all possible methods of distribution, thereby extending criminal liability to any form of transmission or dissemination of dangerous medical products.

## 9. Republic of Tajikistan: Criminal Code, Article 210<sup>[1]</sup>

Illegal Importation, Production, and Circulation of Substandard, Counterfeit, Non-Compliant, or Expired Medicinal Products

1. The large-scale illegal importation, production, or circulation within the Republic of Tajikistan of substandard, counterfeit, non-compliant, or expired medicinal products (Tajikistan, 2025).

Paragraph 3 establishes aggravated forms of the offense where the act is committed:

- (b) on an especially large scale;
- (c) Negligently causing the death of a person or other serious harmful consequences.

This provision largely corresponds to Article 20.14 of the Criminal Code of Mongolia in criminalizing the production, large-scale importation, and circulation of expired or counterfeit medicines. However, its distinctive feature lies in the explicit legal characterization of medicines as “substandard,” thereby introducing a qualitative criterion for assessing the unlawfulness of medicinal products.

### 10. Republic of Uzbekistan: Criminal Code, Article 186-3

Production, Storage, Transportation, Sale, and Unauthorized Distribution of Substandard or Counterfeit Medicines and Medical Devices

This article criminalizes the production, storage, transportation, sale, distribution outside licensed pharmacies, and violations of pharmaceutical regulatory procedures in relation to substandard or counterfeit medicines and medical devices (Uzbekistan, 2025).

Aggravating circumstances include:

- Causing large-scale damage;
- Commission by a group of persons acting in prior conspiracy;
- Repeated commission of the offense;
- Abuse of official authority;
- Causing moderate or serious bodily injury;
- Falsification of quality documentation;
- Causing especially large-scale damage;
- Acting in the interests of an organized group;
- Causing the death of a person;
- Causing the death of multiple persons or other grave consequences;
- Violations of prescription requirements, including the sale of prescription-only or toxic medicines without proper authorization, particularly where the offender has previously been subject to administrative sanctions.

Unlike Mongolian law, which does not explicitly criminalize the transportation of illicit medicines, the Uzbek Criminal Code imposes criminal liability for the act of transportation itself.

Among the jurisdictions examined, Uzbekistan’s provision may be regarded as one of the broadest in scope, encompassing not only production and sale, but also purchase, storage, transportation, and unauthorized distribution outside pharmacies. This comprehensive approach significantly enhances the effectiveness of legal mechanisms aimed at combating the illicit circulation of medicines.

### Conclusion

Based on the present study, the following conclusions are advanced:

1. Article 20.14 of the Criminal Code of Mongolia encompasses the principal forms of the illegal

circulation of medicinal products, provides for a broad range of criminalized conduct, and establishes mechanisms for the criminal liability of legal entities, including sanctions such as fines and disqualification from certain activities.

2. However, in comparison with international legislative standards, Mongolian law lacks several key provisions that contemporary society increasingly demands. Specifically, it does not criminalize acts such as storage or offering for sale, nor does it address offenses committed through the internet, electronic communication technologies, organized or repeated conduct. Moreover, it does not clearly define a graduated classification of consequences, such as serious bodily injury, serious health deterioration, or death. The law also omits provisions concerning the misuse of documentation, unjustified large-scale possession, or transit of medicinal products.
3. The criminal legislation of Albania, France, Türkiye, Hungary, Belarus, Moldova, Croatia, Slovenia, Tajikistan, and Uzbekistan demonstrates a more granular and contemporary regulatory approach, explicitly criminalizing offenses committed through digital platforms and mass media, as well as organized, repeated, and large-scale conduct. These legal systems also adopt a graduated framework for defining harm to human health, thereby aligning criminal liability more closely with the severity of consequences.

### Recommendations

Based on the findings of this study, the following recommendations are proposed:

1. To incorporate into the Criminal Code of Mongolia provisions similar to those found in the legislation of France, Hungary, Belarus, Slovenia, and Tajikistan, particularly with regard to offenses committed through electronic communication networks and mass media, as well as repeated, organized, and seriously harmful conduct.
2. To introduce clear criteria for aggravation, including serious bodily injury, permanent loss of working capacity, death, and thresholds for large-scale and especially large-scale offenses, as well as repeat commission.
3. To criminalize the falsification and misuse of documentation and packaging related to medicinal products, as well as the use of such materials for purposes other than their intended function, and to explicitly regulate these acts within the relevant statutory provisions.

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