



## PHARMACEUTICAL CRIMES IN IRANIAN LEGAL SYSTEM

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### ABSTRACT

Pharmaceutical crimes and disciplinary misconducts have recently changed into a serious threat to Iranian health policies. Different social and cultural problems pave the way for offenders to gain a lot of profit at the cost of endangering patients' lives. Familiarizing medical professions, researchers and students, the author believes, will help to shape or at least, to change professional, social and cultural viewpoints towards a direction that Iranian society generally, and Iranian medical society specially deserves. The purpose of this writing is to introduce pharmaceutical crimes, legal responses to such crimes and Iranian legislator's viewpoints concerning sanctions to prevent the crimes. The author has tried to analyze legal regulations, provisions and Guidelines related to medical and pharmaceutical affairs and occupations approved in 1994, 1955, 1988, and also Guidelines for Drugstores 1988 so generally and simply that readers with scant legal knowledge can take advantage of it and when necessary, he referred the readers to endnotes to learn more. Finally, the author concludes that there is no stable policy in decision making at administrative level in Iranian legal system. As such, continuous change in administrative policies is one of basic difficulties in public health policies and such instability has never brought a comprehensive and fruitful criminal policy for Iranian criminal justice system in combating against pharmaceutical crimes. To solve these problems, the author proposes some suggestions at the end of the article.

**Keywords:** Pharmaceutical crimes; disciplinary misconducts; punishments; pharmaceuticals; drugstores.

### INTRODUCTION

*When the so-called morals of the marketplace are applied to drugs that can be invaluable when used properly, the result is not only the prostitution of science, physicians and pharmacists are uninformed or misinformed, patients are needlessly harmed<sup>1</sup>.*

The above-mentioned sentence has been extracted from a book dedicated to the memory of people who had died from drugs prescribed for the treatment of minor ailments, including chloramphenicol, an antibiotic with the possible fatal side effect of aplastic anemia (bone marrow failure). Silverman<sup>1</sup> suggested that companies were "lying" when they claimed in their standard defense that they were not breaking any laws. His finding of a "double standard of drug advertising" was indicative of corporate practices in the absence of laws or their enforcement<sup>2</sup>. Smith and Quelch<sup>2</sup> also suggest that in proportion to its size, the pharmaceutical industry received more criticisms for its practices in the Third World and, indeed, the developed world, than most other industries. This was at least partially due to the nature of its business, so closely involved with life and death. The pharmaceutical industry claims to have invested US\$30.5 billion in research and development in 2001, which would make it the largest direct funder of medical research in the USA<sup>3</sup>. Increasing numbers of studies seem to be concerned with marketing issues—e.g., establishing equivalence with existing products rather than trying to develop superior drugs<sup>4</sup>. While the market for drugs has

drawn attention from those specializing in the study of organized crime and the development of a global criminal economy, such literature has dealt almost exclusively with prohibited narcotics, to the neglect of medicinal drugs<sup>5</sup>. This neglect is surprising, in that the social impact of such criminal activities is increasingly well documented<sup>6</sup>.

Access to medicines has no single clear definition, but it may be considered as a collection of different interrelated dimensions: accessibility, affordability, acceptability, and availability<sup>7</sup>. Accessibility refers to physical access to health facilities that deliver drug benefits; affordability refers to the composite measure of price, product mix, and actual volumes of consumption; availability refers to drug production, procurement, and distribution; and acceptability refers to quality, efficacy, and safety of medicines. Furthermore, High prices (in part attributable to inappropriately high taxes, mark-ups, and dispensing fees), poor purchasing and distribution programs, uncertain product quality (including counterfeit drugs), and inappropriate prescribing practices continue to undermine availability<sup>8</sup>. Evidence suggests that less choice or decision space from consolidation is associated with increases in performance of distribution logistics, while greater decision choice in planning and budgeting provides better performance and accountability<sup>9</sup>. In addition, consolidation of public supply chains will reduce the number of entry points for counterfeit, substandard drugs<sup>7</sup>. WHO defines a counterfeit pharmaceutical as:



*'One which is deliberately and fraudulently mislabeled with respect to identity or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging.'*

Thus counterfeit pharmaceuticals can include, for example, legitimate medicines that have been diluted or 'bulked out' with other substances, or those whose expiry date has been altered, thereby presenting them as still within their window of safe and effective use<sup>6</sup>. Both production and consumption are now globally distributed. Some 14% of drugs imported to the US are thought to be counterfeit<sup>11</sup>, with recent documented cases including antiretrovirals, antibiotics, and anti-anaemia drugs<sup>12</sup>. The production of counterfeit pharmaceuticals is globally differentiated; India, for example, is thought to account for some 35% of all counterfeit medicines production, with goods being exported to countries such as Bangladesh, Burma and neighboring former Soviet Republics such as Uzbekistan<sup>13</sup>. Nevertheless, it would be misleading to present pharmaceuticals counterfeiting as a problem confined to the developing world<sup>6</sup>. Yar<sup>6</sup> maintains that the prevalence of counterfeit pharmaceuticals is highly differentiated across countries and regions, with the highest rates being found in developing and least developed countries and the lowest in the advanced industrial nations. In Peru, for example, up to 80% of drugs are estimated to be counterfeit<sup>14</sup>. The circulation of counterfeits is also widespread in the former Soviet Republics, with rates estimated at 12% for Russia and 40% for Ukraine<sup>15</sup>. Such counterfeits are often introduced into legitimate pharmaceutical supply chains, and sold (wittingly or otherwise) via licensed pharmaceutical traders to both the public and health care providers such as hospitals<sup>16</sup>.

Drug counterfeiting is a globalised public health crisis<sup>17</sup>. The distribution and use of such counterfeits clearly indicates that they are responsible for a large, though often undetected, numbers of deaths and injuries<sup>6</sup>. The damage to patient health resulting from the use of such drugs is difficult to calculate, as non-effectiveness is likely to be attributed by physicians to the underlying disease or illness, rather than suspecting that the medicines themselves are defective<sup>16</sup>. Dora Akunyili, chief executive of Nigeria's National Agency for Food and Drug Administration and Control (NAFDAC) claims that the problem has reached such a scale in her country that counterfeit medicines now pose a threat more severe than those from malaria, HIV/AIDS and armed robbery combined<sup>15</sup>. On Nov 25, 2010 in Istanbul, Turkey, Ministers of Justice from Europe and around the world met. Many attended to sign up to the Council of Europe's MEDICRIME Convention, a proposed treaty to criminalize the manufacture and trade in counterfeited drugs and other medical products<sup>17</sup>. Recent years have seen concerted efforts to address the problem of pharmaceuticals counterfeiting at a number of levels<sup>6</sup>. As

well as strengthening legal provisions, there have been efforts to encourage better coordination, collaboration and information exchange between those national-level agencies which have an enforcement role – for example, drug regulators, police, customs, and professional organizations<sup>18</sup>. There now exists a burgeoning sector of the private security industry that specializes in hi-tech brand protection solutions, which are intended to enable ready discrimination between legitimate and counterfeit goods. These include the marking of legitimate products with:

- (a) Bi-dimensional bar coding, which enables products to carry 10 to 30 times the amount of information on a traditional bar code;
- (b) Holograms, similar to those already used on credit cards;
- (c) Ultraviolet inks, invisible to the naked eye, but detectable with a scanner;
- (d) Chemical protection systems, such as DNA coding;
- (f) Information-encoded micro-crystals and micro-particles;
- (j) RFID (radio frequency identification) comprising tiny microchips, encoded with product information, than can be fitted to the item<sup>19</sup>.

Despite of the above-mentioned measures, some problems remain: (a) the proposals for RFID tagging are on a voluntary rather than mandatory basis<sup>16</sup>; (b) even if measures such as RFID could be successfully implemented, they would likely be hampered by the unavailability of the tag-reading technologies in those poorest countries where the circulation of counterfeit drugs is highest; (c) the cost issues are likely to recur with new technological solutions<sup>20,21</sup> and so significantly increase unit production costs, which will be passed on to consumers; (d) technological solutions may only offer a temporary respite, as (to judge by past experience) counterfeiters have proven adept at finding means to circumvent anti-counterfeiting and IP (intellectual property) protection mechanism; there is ample evidence that pharmaceutical counterfeiters are becoming increasingly sophisticated in their ability to reproduce authentication devices, making it difficult to spot counterfeits even upon close examination<sup>22</sup>.

Intellectual property (IP) crimes, such as counterfeiting and trademark theft, are now estimated to make up 5% of total world trade, amounting to some \$450 billion per annum<sup>23,24</sup>. One area upon which focus has fallen is the burgeoning global trade in counterfeit pharmaceuticals – according to the World Health Organization (WHO), counterfeits now account for an estimated 10% of the global medicines market<sup>25</sup>. Intellectual property is a property right in an abstract object. Examples include copyright, trademarks and patents, which serve to mediate property relationships between individuals by objectifying an intangible<sup>26</sup>. Intellectual property rights are rule governed privileges that regulate the ownership



and exploitation of abstract objects<sup>27</sup>. Governments protect intellectual property through patents. Patents are also intended to benefit the community, by encouraging innovation and ensuring an affordable supply of the drug<sup>4</sup>. Internationally, exclusivity of production is protected through World Trade Organization (WTO) agreements on trade-related intellectual property (TRIPS)<sup>28</sup>. TRIPS agreements include safeguards, including the granting of compulsory licenses, which enable local production of drugs by non-patent-holders in the case of public-health emergencies or abuse of patent rights<sup>4</sup>.

Crime is defined as an act that the law makes punishable and it is known as the breach of legal duty treated as the subject matter of a criminal proceeding<sup>29</sup>. Accordingly, pharmaceutical crimes can be defined as any commissions or omissions<sup>1</sup> which cause disorder or interruption in the process of production, synthesis, distribution, buying, selling, and correct use of medicine and for which the legislator considers punishment or corrective measures. Commissions of each crime causes disruption in public order and society will react to such a disorder and this is usually referred to as public prosecution in criminal law. Public prosecutor is responsible to prosecute the offenders who breach public order. Most of the crimes have a public feature but some of them may also contain a private feature. In the later case, the victim has a right to sue the offender. As examples, some crimes such as vagrancy<sup>2</sup>, wine-drinking and forgery<sup>3</sup> will not inflict harm on individuals actually but some other crimes such as fraud, breach of trust, using a forged document, murder, theft and direct or indirect illegal interference in pharmaceutical issues will inflict harm on natural and legal persons<sup>4</sup>.

Hence, a crime can have both of the above-mentioned features and can be sued from two claims: public claim and private claim. The first claim is conducted to observe law and preserve public order but the latter aims to revive the victim's rights such as redress the harm inflicted by the offender. Pondering on Iranian criminal Acts related to pharmaceutical crimes, one can find out that such crimes have public claim and do not depend on a private claim. All behaviors related to deception in producing or disturbing medicine, without license, illegal export and import, buying and selling medicine, manipulating to sell counterfeit materials knowingly, overcharging the patient and refusing to offer or sell medicine. Concerning all above crimes, if the harm is inflicted on an individual, he/she has a right to bring an action to the court. If manslaughter<sup>5</sup> is committed through using fictitious medicine, victim's blood-wits<sup>6</sup> have a right to claim blood-money<sup>7</sup>. Like most of the crimes, pharmaceutical crimes can be studied from different Iranian legislator's viewpoints. Each of such crimes, like other crimes, has specific features and constituent elements. A constituent element is defined as an essential component of a crime or cause of action<sup>29</sup>. There are two constituent elements for a crime to be committed:

**Actus reus and mens rea:** The term *actus reus* [Latin "guilty act"] means "the act of a criminal". But simply committing a wrongful act does not mean that one has committed a crime. To fulfill the requirements of the criminal law, the actor must willfully commit a proscribed physical act or intentionally fail to act where the law requires a person to act (i.e. omission. The rationale for the *actus reus* requirement is to prevent a person from being guilty of a crime based on thoughts or intent alone. In most cases the *actus reus* will simply be an act (e.g. appropriation of property is the act of theft) accompanied by specific circumstances (e.g. that the property belongs to another)<sup>30,31</sup>. *Mens rea* [Latin "guilty mind"] is the state of mind that the prosecution, to secure a conviction, must prove that a defendant had when committing a crime, criminal intent or recklessness<sup>29</sup>. The *mens rea* for theft is the intent to deprive the rightful owner of the property. It is also termed mental element, criminal intent, and guilty mind. To constitute a crime, there must be a concurrence of the *actus reus* with the *mens rea* (i.e. a person's criminal intent)<sup>29</sup>. Also, intention can be categorized as general intent<sup>8</sup> and specific intent<sup>9</sup>.

It is necessary to categorize and introduce pharmaceutical crimes so that we can realize and distinguish them from other crimes. Followings are analysis of legal articles of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955<sup>32</sup>, the Governmental Discretionary Punishments Act for Health and Therapy Affairs 1988<sup>33</sup>, Guidelines for Drugstores 1988<sup>34</sup>, and Disciplinary Guidelines for Dealing with Trade and Occupational Misconducts of Personnel in Medical Occupations and Related Professions 1994<sup>35</sup>. In each case, the crime is introduced then the related article, applications, terms and conditions and criminal responses to the crime are described.

## 1. DISCIPLINARY MISCONDUCTS OF PHYSICIANS, CHEMISTS, AND MEDICINE DEALERS

A misconduct is defined as conducting a behavior against the law: Refusing to achieve a commitment or delaying in its achievement (criminal law); doing against what was stipulated as a provision (civil law); breaching administrative provisions when in duty by a government's officer or clerk (administrative law). Followings are main misconducts in medical professions related to medicine:

### 1.1. Prescribing narcotics to an extent that the patients become addicted

Based on article 9 of Disciplinary Guidelines for Dealing with Trade and Occupational Misconducts of Personnel in Medical Occupations and Related Professions 1994, narcotics should not be prescribed unless in emergency situations and when severe pains originated from lethal diseases. Emergency situations and/or severe pains are technical diagnoses which should be achieved by experts and preferably those who are specialized in forensic medicine.

### 1.2 Achieving misleading propaganda through mass



media and attaching advertisements in places and passages against the rules stipulated in medical system (article 14 of the above Disciplinary Guidelines).

1.3 Achieving commercial propaganda about medical and pharmaceutical goods and installing propagandistic advertisements with commercial aspects (article 14 of the above Disciplinary Guidelines).

1.4 Achieving misleading propaganda with the use of propagandistic means and through publishing medical articles and reports and describing technical and professional materials (article 15 of the above Disciplinary Guidelines).

It is worth mentioning that achieving misleading propaganda and deceiving patients are included in the crimes against professional status of medicine. Such crimes also inflict a lot of harm on physician-patient relationship and will finally result in patients' mistrust of medical society. Doing misleading propaganda is both a disciplinary misconduct based on articles 14 and 15 of the Disciplinary Guidelines for Dealing with Trade and Occupational Misconducts of Personnel in Medical Occupations and Related Professions 1994 and is a crime according to article 5 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955. *Actus reus* of this crime is to conduct misleading propaganda and *mens rea* is general intent and offender's motivation is not an effective factor. Regarding Iranian legislator's stipulation, the offender(s) can be natural or legal persons (See endnote no. 4) provided that they are realized as the owners of medical and pharmaceutical professions and/or medical institutes stipulated in article 1 of the above-mentioned Act.

1.5 Prescribing medicine which is not included in pharmaceutical collection of Iran (article 18 of the above Disciplinary Guidelines).

There are two important points in article 18: (a) The accusation is attributed to physicians whether medical doctors (MDs) or Attending doctors (ADs); (b) prescribed medicine should not be included in the approved list declared by the Ministry of Health and Medical Education.

1.6 Prescribing medicine which is not needed or not homogeneous and is out of technical and scientific regulations (article 21 of the above Disciplinary Guidelines).

It is an expert's duty to realize whether prescribed medicine is out of scientific and technical regulations or not and it needs an expert's opinion.

1.7 Selling medicine and medical equipments without receiving license (article 22 of the above Disciplinary Guidelines).

1.8 Refusing to write identifications of the drugstore or those of physician in the prescription and the way to use prescribed medicine in an understandable writing (article 23 of the above Disciplinary Guidelines).

1.9 Chemist's refusal of describing how to use medicine based on the physician's prescription. (article 23, clause II of the above Disciplinary Guidelines).

There are two important points concerning article 23: (a) physician's writing characteristics of medicine and how to use it in a prescription prevents a drugstore to make a mistake when delivering medicine and the patient will be sure and confident about the way to use medicine. Accordingly, if the physician's refusal to write characteristics of medicine and the way to consume it in the prescription or lack of legibility in writing cause some risks for the patient, these will result in both physician's civil or criminal responsibilities and disciplinary responsibility; (b) based on clause 11 of article 23, if the chemist does not describe how to use medicine, he/she will commit an omission which will result in disciplinary responsibility.

## 2. CRIMES STIPULATED IN THE ACT RELATED TO PROVISIONS OF MEDICAL AND PHARMACEUTICAL AFFAIRS AND EDIBLE AND DRINKABLE MATERIALS 1955

### 2.1 Unlicensed buying and selling medicine

Article 3 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 holds:

Everybody who deals with medicine, pharmacy, dentistry, laboratory affairs, physiotherapy, obstetrics without a license or founds one of medical institutes stipulated in article 1 of this Act without a license of the Ministry of Health and Medical Education or transfers his/her license to another person or uses other person's license, his/her institute or drugstore will be closed promptly by the Ministry of Health and Medical Education, and will be convicted from 6 months to 3 years discretionary [10] imprisonment and a fine of 5 million to 50 million rials and if the offender commits the crime again, he/she will be convicted to 2-10 years imprisonment and a fine of 5 million to 100 million rials or a price equal to 2 times that of the discovered medicine.

Clause II: if one of the authorities mentioned in article 3 and/or authorities responsible for producing, preparing, distributing and selling medicine, medical equipments and supplies buys and sells the above-mentioned items illegally and/or refuses to distribute them and to give service or causes disorder in pharmaceutical system of the country, he/she will be deprived of occupation in pharmaceutical professions in addition to punishments stipulated in article 3.

Here *actus reus* is to buy and to sell medicine. *Mens rea* is the intention to buy and to sell without any licenses. This crime needs no specific intent. By the phrase "buys and sells medicine illegally", Iranian legislator stipulated that the mere buying or selling is not a crime but commission of two conducts is the provision of committing a crime. Hence, if a physician buys medicine for his/her use or



another person's, he/she does not commit a crime. But if a physician buys medicine illegally and sells it to another person, he/she will commit a crime even if he/she sells medicine to his/her patients, family members, relatives and friends. If Iranian legislator used the conjunction "or" instead of "and" each conduct (whether buying or selling) would be a crime and the offender would be punished for each crime separately.

### 2.2. Refusing to distribute medicine or to offer pharmaceutical services

Concerning this crime, article 3 (clause II) is applied. *Actus reus* is to avoid distributing medicine or giving services which manifests as omission. *Mens rea* is general intent. The crime will be committed as soon as the conduct is achieved regardless of offender's motivation to gain property or profit. Suppose a person who refers to a drugstore, presents a prescription and demands medicine, and pharmacist avoid giving him/her the medicine while there is some medicine. This conduct will be considered as both a crime and a disciplinary misconduct.

### 2.3 Causing disorder in a pharmaceutical distributing system

Here again article 3 (clause II) is applied. *Actus reus* is any conduct which causes disorder in a pharmaceutical distributing system. *Mens rea* is general intent. Offender's motivation, whether to cause disorder in a pharmaceutical distributing system or not, is not a provision to commit a crime but the conduct should be one that actually causes disorder. Iranian legislator did not stipulate any definition of disorder and did not refer to some manifestations either. This is a legal gap which paves the way for the judges and lawyers to apply their own subjective and discretionary decisions (See endnote no. 10). This should be amended and any ambiguities should be removed. It is deduced from article 3 when one of the authorities responsible for producing, preparing, distributing and selling medicine achieve a conduct which makes the usual and sound process of distributing medicine slow, the crime will be committed. Iranian legislator deprived the offender to take a pharmaceutical occupation in addition to the punishments considered in article 3.

### 2.4 Managing technical affairs of pharmaceutical institute by individuals without technical and legal capacity

Article 4 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 holds:

*Every medical and pharmaceutical institute whose technical affairs are managed by individuals without technical and legal capacity will be closed by the Ministry of Health and Medical Education and the owner of the institute will not have a right to reopen it for one year if it is his/her first commission of the crime and if it is the second commission, the offender cannot reopen it for two years legally even under another person's title, and the*

*offender(s) will be convicted to punishments stipulated in article 3 of this Act.*

Here the *actus reus* is to manage the institute by individuals without technical and legal capacity. *Mens rea* is general intent. The conduct will be a crime whether it results in selling pharmaceutical items and gaining profit or not. Based on article 21 of Guidelines for Drugstores 1988 and article 24 of Disciplinary Guidelines for Dealing with Trade and Occupational Misconducts of Personnel in Medical Occupations and Related Professions 1994, technical affairs of a drugstore should be managed by a technical expert and his/her presence is necessary when selling or buying medicine. According to article 4 of Guidelines for Drugstores 1988, technical expert of a drugstore can transfer a part of his/her duties to a capable chemist who is present at the drugstore. Nevertheless, this will not remove technical expert's legal responsibilities concerning what happens at the drugstore.

### 2.5 Changing the date of use on medicine by authorities of pharmaceutical affairs and owners of drugstores

Article 5 (clause II) of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 holds:

*Each of the authorities of pharmaceutical affairs and the owners of the drugstores who changes the date of use on medicine or increases the price of medicine or frauds in rating prices of prescriptions, regarding the offender's terms, conditions and facilities and times of commission the crime, he/she will be convicted to a fine of 10,000 to 100,000 rials and/or to 3 months up to 6 months imprisonment.*

Here, the *Actus reus* is to change the date of use on medicine. *Mens rea* is general intent. This conduct is a crime regardless to whether the medicine is sold or individuals who bought it used medicine or not. This crime may be considered as one of the manifestations of forgery (See endnote no. 3) which increases the severity of punishment. It is necessary to pay a special attention to this crime because different and numerous gangs use developed equipments to produce counterfeit medicine or change the date of use on pharmaceutical products which are decayed or have no shelf life and finally, inflicts a great harm and loss on individuals' lives.

### 2.6 Misconduct in ranking prices of prescriptions by authorities

In this crime, *actus reus* is a misconduct which increases the price of medicine and any conduct which is considered as ranking prices of prescriptions. The mere increase in price or ranking against provisions stipulated in article 5 (clause II) is considered as a crime regardless of selling medicine with high price. Iranian legislator also stipulated clause II of article 5 to prevent overcharging. Furthermore, according to article 19 of the Governmental Discretionary Punishments Act for Health and Therapy



Affairs 1988, supplying medicine with informal or unauthorized prices is a crime.

### 2.7 Distributing decayed medicine or those with short-term date of use or with no shelf life

*Actus reus* is to distribute decayed medicine or those with no shelf life with the above-mentioned terms and conditions. Regarding the word "distributing", if medicine is preserved in a place even with the intention of distribution, the crime has not yet been committed. Distribution can be achieved in drugstores or black market. The word "distributing" is generally used and there is no difference to distribute such medicine legally or illegally. Accordingly, individuals' use of such medicine is not a provision to commit the crime. It seems that the reason behind Iranian legislator's mention of medicine with short-term date of use besides decayed medicine and those with no shelf life is that a period of time will lapse in the process of supply and demand and patients' use and this causes expiration of appropriate date. As people in Iran have confidence in drugstores, they usually do not pay attention to date of use on medicine. Accordingly, it is likely that a decayed medicine or the one with no shelf life is used and Iranian legislator mentioned medicine with short-term date of use besides decayed medicine and those with no shelf life.

### 2.8 Overcharging customers/patients by distributing companies.

According to Acts and Guidelines related to medicine, each kind of medicine has a fixed and authorized price. Accordingly, companies which distribute, produce or import medicine are obliged to sell all medicine with their fixed and authorized prices and do not have a right to increase prices. To reach this aim, Iranian legislator criminalized<sup>11</sup> overcharging customers/patients by distributing companies based on article 14 (clause IV) of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955.

### 2.9 Unlicensed importing medicine by importers, producers, pharmaceutical companies and medical institutes.

Amended article 15 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 maintains:

*Those who import or produce pharmaceutical materials and/or biological products stipulated in article 14 [of this Act] in the country, regarding the offender's terms, conditions and facilities, times of commission of the crimes, and processes of correction, above-mentioned materials will be seized for the benefit of the Ministry of Health and Medical Education and if necessary, medicine will be demolished and the offenders will be convicted to a fine of 500 thousand to 5 million rials for the first time and 5 million to 10 million rials for the second time and if they commit the crime again, they will be convicted to*

*the most severe pecuniary penalty in addition to cancellation of their license.*

Here, *actus reus* is unlicensed import of medicine and *mens rea* doesn't need specific intent and offender's intention to import medicine is enough to commit the crime. By the pronoun "those" in the first part of the above article, Iranian legislator meant natural persons (i.e. individuals) but the second part of the article refers to importers, producers and pharmaceutical companies and institutes which are considered legal persons (See endnote no. 4). Article 3 (clause I) of the same Act has the same content about unlicensed imports and exports but the above-mentioned article refers only to imports and does not include exports.

### 2.10 Unlicensed producing medicine by distributing companies

*Actus reus* is unlicensed production of medicine. *Mens rea* is general intent; that is, the mere unlicensed production is enough for the crime to be committed regardless of using such medicine by patients. The phrase "produce...in the country" refers to a principle according to which criminal provisions stipulated in article 3 of Islamic penal Act 1991<sup>36</sup> are applied in Iran. This article holds: "Criminal Acts are applied to all those who commit offences in sovereignty of Islamic Republic of Iran; whether land, sea or air, unless other formalities are done based on law". Accordingly, if medicine is produced out of Iran the conduct is not a crime even if its production is unlicensed. But unlicensed importing such medicine to Iran is a crime.

### 2.11 Manipulating formula or composition or shape or packing of medicine or biological productions by chemists before receiving license

Amended article 16 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 maintains:

*Chemists who produce medicine and biological productions under the license, have no right to change formula and composition and shape and/or packing medicine or biological process and/or manipulate them before receiving another license from the Ministry of Health and Medical Education. In the case of committing such a crime, the offender will be convicted to punishments stipulated in article 15 [of this Act] concerning each crime.*

*Actus reus* is to manipulate formula or composition or shape or packing of medicine or biological productions. *Mens rea* is general intent and there is no need of criminal intent for the crime to be committed. Manipulating means any conduct which changes the early state of medicine whether the change occurs to shape, packing, and appearance or to nature and usefulness.



### 3. CRIMES STIPULATED IN THE GOVERNMENTAL DISCRETIONARY PUNISHMENTS ACT FOR HEALTH AND THERAPY AFFAIRS 1988

The above-mentioned Act contains 4 chapters, 44 articles and 9 clauses. Its second chapter is dedicated to pharmaceutical crimes. Followings are the crimes stipulated in this Act.

#### 3.1 *Supplying and selling medicine without license of production or license of entrance to a drugstore*

Basically, medicine which are supplied and sold enjoy one of the following conditions: (a) medicine may be produced in Iran and distributed by distributing companies; (b) medicine may also be imported directly from abroad. According to article 14 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 and article 4 (clause III) of Exports and Imports Act 1987<sup>37</sup> and related guidelines, importers and exporters are obliged to agree to the terms and conditions of the Ministry of Health and Medical Education. According to article 1 (paragraph 17) of the Act for Establishments and Duties of the Ministry of Health and Medical Education 1988<sup>38</sup>, standards related to import, production, preservation, export, consumption and demolition of pharmaceutical productions are all included in the duties of the above-mentioned ministry.

Also, based on article 7 (paragraphs 5 & 6) of the same Act, the above-mentioned ministry can establish producing companies to provide medicine, rough materials and biological materials and distributing companies to distribute medicine. According to amended article 3 (clause III) of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955, only medicine whose names has been registered in the list of Iranian licensed medicine are allowed to be imported.

Article 13 of the Governmental Discretionary Punishments Act for Health and Therapy Affairs 1988 holds: "Medicine should be subjected to a license to be produced or imported which is issued by the Ministry of Health and Medical Education and supplying and selling medicine without license of production or import by a drugstore will be considered a crime..." As this article maintains, preserving medicine mentioned in the article is not a crime but it is deduced that supplying and selling medicine separately is considered a crime. Accordingly, if a person supplies such medicine so that clients can buy it and he/she sells the medicine, two crimes will be committed. But if a person hides the medicine in a place and sells it to the clients, mere selling the medicine without license of production and import is considered a crime. Punishment stipulated for this crime is to collect the unlicensed medicine. There are two legal gaps here: First, the authority which is responsible to collect medicine has not been identified; second, nothing has been mentioned whether collected medicine should be seized, demolished or returned back to the offender. Here, we should refer to article 10 of Islamic Penal Act

1991 and make a decision about the medicine seized.

#### 3.2 *Founding a drugstore without a license*

Article 14 of the Governmental Discretionary Punishments Act for Health and Therapy Affairs 1988 maintains: "Supplying and selling medicine should be achieved when the chief technical expert is present and in the case of disobedience, the crime is committed and the drugstore will promptly be closed." Here the *actus reus* is to found a drugstore and *mens rea* is general intent. The crime will be committed as soon as the drugstore is founded and is inaugurated without any license and then selling medicine is not a provision of the crime. This crime is also mentioned in amended article 3 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955. Suspension of work is a punishment rather than a preventive measure.

#### 3.3 *Technical chief's absence in a drugstore during working hours*

Based on article 25 of Guidelines for Drugstores 1988, some of a technical chief's duties are as follows: (a) supplying and selling medicine, controlling, sealing, and signing all prescriptions; (b) writing the way of consuming medicine on packages or pockets of prescribed medicine according to physician's advices and reminding the patient/customer what is necessary; (c) counseling with the physician who treated the patient if there is some ambiguities in the prescription; (d) offering medicines with no prescription based on list and rules declared by the Ministry of Health and Medical Education; (e) supervising the way of preserving medicines, their physical shapes, qualities and shelf life. Pharmaceuticals may be subjected to technical problems and enjoy a special importance since they are integrally related to patients' rights. Furthermore, patients do not know anything about usefulness of kinds of medicine, interferences, harmfulness and side effects of medicine. Accordingly, it is very necessary that the prescription be read by a chemist. It is likely that some medical mistakes are committed in writing a prescription and such mistakes should be realized and removed to prevent any harmful results arisen from mistakes. Accordingly, technical chief's presence during all working hours of a drugstore is necessary.

#### 3.4 *Providing medicine from an unlicensed network by a drugstore*

Article 20 (clause III) of Guidelines for Drugstores 1988 holds:

*Companies which distribute medicine are obliged to deliver produced and/or imported medicine to drugstores or other competent centers based on rules. Also, drugstores are obliged to provide their medicine from licensed distributing companies which are determined and whose names are declared by the Ministry of Health and Medical Education.*

Also, the opinion issued by the Legal General Department



of Iranian Judicial System No. 7. 6325 – 29.10.72 holds:

*If an individual, who provides medicine, has a formal license, but provides medicine from somewhere except distributing networks of medicine determined by the Ministry of Health and Medical Education, his/her conduct will be subjected to article 17 of the Governmental Discretionary Punishments Act for Health and Therapy Affairs 1988.*

By the words "a drugstore" in article 17 above, Iranian legislator means "the technical chief of a drugstore" because a drugstore is a legal person (See endnote no. 4). If an individual without formal license provides and supplies medicine to sell, his/her conduct will be subjected to article 3 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955

### 3.5 Delivering medicine without receiving any prescriptions

The only clause of article 18 holds: "the Ministry of Health and Medical Education declares the list of medicine which can be legally sold without receiving physician's prescription". Also, opinion issued by Legal General Department of Iranian Judicial System No. 7. 222–6.3.1369 maintains:

*According to article 18 of the Governmental Discretionary Punishments Act for Health and Therapy Affairs 1988, medicine should be delivered when receiving physician's prescription and delivering medicine without a prescription is subjected to a discretionary punishment and some punishments are considered for it. For those who found a drugstore without receiving any license in article 3 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955, imprisonment and compensation are considered as punishments. Accordingly, since unlicensed selling medicine is forbidden, the above-mentioned punishments are also considered for peddler sellers and they can be sued according to article 3 of the same Act.*

A drugstore is obliged to deliver all items of medicine merely when receiving prescriptions. The principle is that no medicine can be offered and sold without receiving a prescription unless its selling is licensed based on the declaration of the Ministry of Health and Medical Education. Accordingly, a technical chief of a drugstore cannot take the responsibility of selling medicine under the pretext that she/he did not know the prohibition of selling a specific medicine without receiving a prescription.

### 3.6 Offering medicine for an unapproved price

Basically, every kind of medicine has an approved price and a drugstore cannot consider the price of black market as ranking price for medicine. Article 19 considered the mere offering medicine for and unapproved price a crime. Accordingly, if a person offers medicine for an unapproved price in a drugstore and then sells it, he/she

will commit two crimes each of which deserves an independent punishment. Also, these are considered disciplinary misconducts.

### 3.7 Refusing to write approved prices in prescriptions

According to article 19, approved prices of medicine should be written in prescriptions. Hence, refusing to write approved prices in prescriptions is a crime even if all medicine is sold for approved prices. Iranian legislator obliged all drugstores to write approved prices of medicine in prescriptions to prevent overcharging patients.

### 3.8 Refusing to seal and to write approved prices in the second sheet of Therapeutic Services Insurance Organization

Concerning article 19, all these crimes will be committed through omissions (See endnote no. 1) and as soon as the prescription is given back to the patient the crime will be committed. It seems that these are deliberate crimes. So, if these are committed negligently, the crime will not be committed. Iranian legislator's emphasis on sealing prescriptions indicates that realizing the offender is very important.

### 3.9 Preserving or offering and/or selling decayed medicines and/or those with no shelf life (article 20 of the Act mentioned in title 3)

Each of the conducts (i.e. preserving, offering or selling) concerning decayed medicines and/or those with no shelf life is considered a separate crime. Accordingly, if a chief of a drugstore supplies decayed medicine and/or those with no shelf life in a drugstore, offers them to the patients and then sells them when demanded, he/she commits three separate crimes. Based on article 47 of Islamic Penal Act 1991, each of these crimes has separate punishments. Regarding the last part of article 20, this crime is dedicated to a drugstore but article 14 (clause IV) is related to companies which distribute medicine.

### 3.10 Refusing to offer medicine

A drugstore is obliged to offer all medicine bought lawfully and are included in the list of licensed medicine and must not hide rare medicine to sell in black market or based on any other motivations. Based on article 7 of the same Act (mentioned in title 3 above), the mere hiding medicine and refusing to offer it are not crimes but these conducts should be done based on motivations to overcharge or discriminate in selling them (i.e. to sell to a specific person and not to others). But in article 23 the mere refusing to offer or to sell is considered a crime and does not need a specific malice or intention.

### 3.11 Providing medicine by distributing companies from unauthorized companies

Providing medicine contains any deal which results in transferring ownership from an unauthorized company or an unauthorized importer to a distributing company. The distributing company should be one of authorized and





competent companies but this is not a provision for unauthorized producing and importing companies. The provision to commit the crime is that the medicine should be produced or imported with governmental currency. The adverse meaning<sup>12</sup> of this provision is that if a kind of medicine is produced or imported with other currencies and without governmental support, it will not be subjected to article 28.

### 3.12 Unauthorized centers' access to medicine by distributing companies

Distributing companies are obliged to provide medicine from authorized and competent companies. With regard to distributing medicine, distributing companies are also obliged to access authorized centers to medicine. Accordingly, the crime will be committed through accessing an unauthorized company to medicine whether the medicine is sold or not.

### 3.13 Distributing companies' refusal to deliver an invoice

This crime is committed through omission and it is a deliberate crime. Pharmaceutical companies are obliged to deliver the invoice of distributed medicine to drugstores and authorized centers.

## 4. UNAUTHORIZED INTERVENTION IN PHARMACEUTICAL AFFAIRS

These crimes are defined as dealing with a medical or pharmaceutical occupation illegally or fraudulently by incapacitate individuals without receiving any license. The crime can be manifested in different conducts. Followings are some important ones:

### 4.1 Unlicensed importing and exporting medicine

Article 3 (clause I) of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 holds: "Importing and exporting and buying and selling medicine without receiving a license from the Ministry of Health and Medical Education is a crime and the offender will be convicted to punishments stipulated in article 3 of the same Act". *Actus reus* of this crime is four conducts mentioned at the beginning of the clause which are connected to each other with conjunction "and". Here, Iranian legislator should use conjunctions "and/or" together to cover these four conducts (i.e. importing, exporting, buying and selling) together and also either of them separately. This is a deliberate crime and its *mens rea* is general intent. Also, according to article 4 (clause III) of the Exports and Imports Act 1987, importing medicine (pharmaceutical products, raw and subordinate materials) should be achieved through mere agreement of the Ministry of Health and Medical Education.

### 4.2 Unlicensed buying and selling medicine

Article 3 (clause I) is applicable to this crime. Mere buying or mere selling is not a crime but coincidence of these two conducts is the provision to commit the crime. Accordingly, if a person provides medicine from

unlicensed centers for personal use, he/she will not commit a crime. The same is when a person sells medicine which he/she does not need or based on his/her financial need. The author of this article suggests the severity of punishments for this crime because it covers a large part of criminal conducts in medical law such as selling counterfeit medicine, those with no shelf life and/or the kinds of medicine which are not produced based on standard criteria. Moreover, a large portion of people can be the target of offenders especially when they do not have any access to rare medicine especially in the cases of lethal diseases.

### 4.3 Fraud in providing pharmaceutical materials

Article 18 of the Act Related to Provisions of Medical and Pharmaceutical Affairs and Edible and Drinkable Materials 1955 maintains:

*Individuals who commit fraud in providing pharmaceutical materials in any way such as presenting one material for another and/or mixing them with other materials and also preparing or offering materials for sale with the knowledge that they are counterfeit materials and/or delivering one kind of medicine for another will be sentenced to the following punishments...*

Iranian legislator did not define fraud concerning the above materials rather he/she mentioned its manifestations: (a) presenting one kind of material for another; (b) mixing one kind of material with other kinds. In this case, the offender usually adds other kinds of materials to the original one which do not change its appearance but decrease its quality and make it useless. Added materials seem to be legally prohibited. The offender decreases the volume of the original material through adding extra materials and in this way he/she gains a lot of profit; (c) selling one kind of medicine for another kind. Iranian legislator considered preparing to sell, offering and/or selling decayed and counterfeit medicine knowingly fraud<sup>13</sup>. Changing the date of use is likely to be another kind of fraud. *Mens rea* in this crime is general intent and the conduct is a crime regardless of offender's intention. The severity of punishment for this crime depends on whether the victim used medicine or not and whether the used medicine results in victim's death, lethal disease or amputation.

Punishments stipulated in the above article for the crime are capital punishment, life imprisonment, temporary imprisonment, fine, detaining equipments used to produce medicine for the benefit of government. In addition, the offender is obliged to redress the inflicted harm to plaintiff<sup>14</sup>. If the offender's occupation is one of pharmaceutical professions, he/she will be sentenced to deprivation of his/her occupation. If counterfeit materials are discovered, they will be demolished after issuing the final decree<sup>15</sup> from a criminal court. In addition to punishments stipulated in the above article, if using counterfeit medicine causes harm or death, the court is obliged to issue a decree to pay blood money (See endnote no. 7) based on victim's demand or that of



his/her legal guardians. If murder is realized as intentional, according to article 206 of Islamic Penal Act 1991, the offender will be convicted to retaliation (i.e. capital punishment).

*4.4 If counterfeit medicine is serum or vaccine and/or antibiotic, the severest punishment should be considered for the offender.*

*4.5 Since the crime is so sensitive and has harmful consequences, Iranian legislator both determined obligations for judges and the court to proceed the case promptly and out of turn, and also obliged interrogator<sup>16</sup> to detain the accused.*

## CONCLUSION

Medicine has always been paid attention to in government's policies and statesmen have focused on it due to political, economic and social benefits related to medicine. It affects citizens' health directly and lack of management and lawful regulation in the processes of production, distribution, buying, selling, imports and exports of pharmaceuticals may threaten citizens' lives seriously. There are still some dealers who endanger quite a lot of people's lives through their unauthorized intervention in pharmaceutical affairs. The author of the present article believes that Iranian legal system doesn't have a legislative policy which is appropriate with values and needs of the society in legislation and there is no stable policy in decision making in administrative level. As such, continuous change in administrative policies is one of basic difficulties in public policies and this instability has never brought a comprehensive and fruitful criminal policy for Iranian legal system. Accordingly, dealing with pharmaceutical crimes and misconducts specially organized crimes in medicine has sometimes been failed. Legislative, administrative, judicial and criminal policies should always be coordinated and adapted with each other to focus all measures taken on these domains to solve the problems.

Three decades fighting against disorder in distributing system of medicine and judicial-police approach show that such treatments have not been successful so much to overcome existing problems. Using successful experiences of some countries and programs enforced by United Nations in respect of fighting against pharmaceutical crimes and making use of new and efficient mechanisms of criminal policy can solve a lot of existing problems.

It seems that Iranian judiciary can prevent committing pharmaceutical crimes and misconducts through determining strong and weak points of statutes and provisions related to medicine in Iranian criminal justice. Such a goal can be reached at through finding out disorders in production, distribution, imports and exports. The author of this article suggests following solutions to be considered by authorities in pharmaceutical affairs: (a) Relying on an efficient criminal policy which is related to pharmaceutical crimes in Iranian criminal justice system;

(b) dedicating a part of police force to combat against pharmaceutical crimes and misconducts; (c) using a criminal policy with the approach of specializing judicial authorities; (d) upgrading judges' knowledge, and employing judges specialized in medical law for special cases which deal with pharmaceutical crimes and misconducts; (f) reforming executive policies and moving towards non-criminal preventions; (g) involving citizens and Non-Governmental Organizations (NGOs) in situational and social preventions; (g) making offenders' punishments more severe and considering imprisonment due to the threat pharmaceutical crimes expose on Iranian citizens; (h) delivering enough information through mass media to increase awareness in Iranian society; (i) familiarizing those involved in medical professions with their legal duties and Acts and provisions through holding conferences and congresses; (j) familiarizing students of medicine with the subject through holding seminars and presenting courses; (k) using special sheets when issuing formal medical licenses so that individuals cannot fake them easily; (l) conducting criminological researches concerning pharmaceutical crimes and offenders' characters and motivations to take preventive measures more efficiently. Hopefully this article will be the first and a small step towards familiarizing medical professionals, researchers, students and those interested in medical law.

## ENDNOTES

1. Commissions or omissions: Commission is the act of doing or perpetrating (as a crime). (Garner, 2004, P. 286). Omission: 1. a failure to do something; especially; a neglect of duty; 2. The act of leaving something out; 3. The state of having been left out or of not having been done; 4. Something that is left out, left undone or otherwise neglected (Garner, 2004, P. 1121).
2. Vagrancy is the state or condition of wandering from place to place (Garner, 2004, P. 1585).
3. Forgery: 1. the act of fraudulently making a false document or altering a real one to be used as if genuine; 2. a false or altered document made to look genuine by someone with the intent to deceive (Garner, 2004, P. 677).
4. Natural and legal persons: Natural persons are human beings (Garner, 2004, P. 1176). A legal person also an artificial person: an entity such as corporation, created by law and given certain legal rights and duties of a human being; a being, real or imaginary who for the purpose of legal reasoning is treated more or less as a human being (Garner, 2004, P. 1178).
5. Manslaughter is the unlawful killing of a human being without malice aforethought (criminal intent) (Garner, 2004, P. 983).
6. Blood-wits are the descendants of the killed person who have a lawful right to demand retaliation or to forgive the offender. The offenders of unintentional



murder and manslaughter should pay the blood money (See endnote no. 7).

7. Blood-money is a sum of money which Islamic law determined and the offender is obliged to pay to the blood-wits (see endnote no. 6).

8. General intent is the intent to perform an act even though the actor does not desire the consequences that result. This is the state of mind required for the commission of certain common-law crimes not requiring a specific intent or not imposing strict liability. General intent usually takes the form of recklessness (involving actual awareness of a risk and the culpable taking of that risk) or negligence (involving blameworthy inadvertence) (Garner, 2004, PP. 825-6).

9. Specific intent is the intent to accomplish the precise criminal act that one is later charged. At common law, the specific-intent crimes were robbery, assault, larceny, forgery, false pretenses, embezzlement, attempt, solicitation and conspiracy (Garner, 2004, P. 826).

10. Discretionary: (of an act or duty) involving an exercise of judgment and choice, not an implementation of a hard-and-fast rule. Such an act by a court may be overturned only after a showing of abuse of discretion (Garner, 2004, P. 499).

11. The act or an instance of making a previously lawful act criminal, usually by passing a statute (Garner, 2004, P. 402).

12. Adverse meaning is the one which is deduced in a reverse order of a situation. Here, the author means all other situations which are not mentioned directly but can be inferred from the text.

13. Fraud is (1) a knowing misrepresentation of the truth or concealment of a material fact to induce another [person] to act to his or her detriment; (2) a misrepresentation made recklessly without belief in its truth to induce another person to act (Garner, 2004, P. 685).

14. Plaintiff is the party who brings a civil [or a criminal] suit in a court of law (Garner, 2004, P. 1188).

15. Decree is a court's final judgment (Garner, 2004, P. 440).

16. Interrogator is the one who poses questions to another (Garner, 2004, P. 838).

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