

## Procedures and controls of narcotics and psychotropic substances



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## **Procedures and controls of narcotics and psychotropic substances**



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## **Introduction:**

In pursuit of Saudi Food and Drug Authority represented by the administration of controlled laboratories in the development and improvement of procedures and controls of narcotics and psychotropic substances procedures and controls have been updated based on the observations and suggestions by the authorities dealing with narcotics and psychotropic substances in accordance with modern computerized systems and services

Referring to the electronic Narcotics Program (NDS), it has become mandatory for all institutions that dealing with narcotics and psychotropic substances to register in it and to adhere to the restriction of all operations through it. Also, they can check the user guide through the authority's website to get more information.

In order to contribute to facilitating the procedures and controls of narcotics and psychotropic substances, we are pleased to receive your queries and suggestions through direct contact with the Controlled Laboratories Section in the drugs sector via phone (0112038222) transfers (5147-5322-5717) or via e-mail ([narcotic.drug@sfda.gov.sa](mailto:narcotic.drug@sfda.gov.sa))

# Ant-Narcotics and psychotropic Substances Law

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# The Anti-Narcotics and Psychotropic Substances Law

## Definitions

### ◆ 1 Article:

All words and phrases that stated in this law shall be contain the following meaning unless the context requires otherwise.

Narcotic drugs:

Every natural, composite or manufactured substance mentioned in the table 1

Annexes to this law.

Psychotropic substances:

Each natural, composite or manufactured material in the Psychotropic that listed in Table 2 accompanying this law.

Precursor Chemicals:

Substances used in illicit drug manufacture or psychotropic substances that listed in table 3(accompanying this law).

Import: bringing narcotics and psychotropic substances to Kingdom of Saudi Arabia.

Export: sending out narcotics and psychotropic substances abroad Kingdom of Saudi Arabia.

Smuggling: Everything considered smuggling in accordance with the customs regulations.

Production: Separation of narcotic drug and psychotropic substances from their plant origin.

Manufacturing: all non-productive processes by which narcotics or psychotropic substances

are obtained, including purification, extraction and conversion of drugs to other drugs, psychotropic to other psychotropic substances, prepare that are not composed or formed by pharmacies on prescription.

Extraction: analysis of a narcotics or a psychoactive substance and separation of their constituent elements for them to have the narcotics or psychoactive substance.

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Possession: seizure of narcotics or psychotropic substances for ownership or jurisdiction purposes.

Preservation: The acquisition of narcotics or psychotropic substances for any purpose.

Mediation: mediation between parties who are dealing with narcotics or psychotropic substances in return or without charge, to get the parties acquainted with each other and bring them closer together to complete the deal.

Technical expertise and physical evidence: conduct laboratory analysis at the certified laboratories to inspect the seized substance and prove its positive relation to the narcotics or psychoactive substance or not.

Profits: any financial assets or money obtained directly or indirectly as a result of committing the crimes that provided for in this law.

Funds: assets of any kind movable or immovable (transferred or non-transferred), material or otherwise, and documents or instruments proving ownership of such assets or any right related thereto.

Money-laundering: any act committed directly or indirectly (by intermediation) to acquire funds, rights or property as a result of committing any offence in this system, transfer, hide its truth, source, location, movement, or related rights or ownership, or contribute in an original or consequential manner to such acts with the purpose of concealing or disguising the unlawful source of funds or with the intention of assisting any person involved in such crimes to enable him/her to launder money and avoid punishments.

Preventive detention: The temporary seizure decision, which issued by a court or competent authority to the owner of materials and funds related to the foreseeable case to prohibit the disposing or transferring those funds and materials.



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Seizing: Transferring of objects, funds or part of them into state's ownership by court judgement, due to their relevance to an offence that is subjected to law or derived from it.

Regulation: implementing regulation of this law.

◆ 2 Article:

It is legal to bring, export of specific quantities of medications containing narcotic drug or psychotropic substances through transport means such as ships and planes to face emergency situations and first aid, if it is authorized in the country whose flag or nationality is carried by the transport upon arrival and departure from Saudi Arabia. The responsible person is responsible for the declaration of the shipment mode of transport shall declare any such substances. In addition, the regulations specify the transports involved in this exception, the maximum amount of drug or product shall be carried and the amount of narcotic drug and psychotropic substances. Besides, the controls required to prevent the diversion from the transport as soon as they are inside Saudi Arabian territory. These drugs and products are defined as narcotic drug or psychotropic substances approved to pass through Saudi Arabia.

## Criminal Acts

◆ 3 Article:

The following considered as criminal acts:

1. Illegal import of narcotic drug and psychotropic substances or receiving them from smugglers.
2. Import, export, manufacture, extraction, transfer, acquisition, sale, purchase, distribution, delivery, transfer or trade-off, used, cared for, facilitated, calmed, financed or supplied the narcotics or psychotropic substances, except in the circumstances that stated it in the law and in accordance with the conditions and procedures provided therein.

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3. Cultivate plant included in table (4) which mentioned in this law or import, export, possession, acquisition or disposal of such plants. Besides, their entire record growth and seeds trade or participate in any such act aside in the circumstances stated it in the law that according to approved. Also, growers are all those who have done the necessary work to grow seeds or seedlings or oversee planting until they have matured and harvested.
  4. Manufacture, sale, transport or distribution of equipment or substance for illegal purpose in cultivation, production or manufacture of narcotics and psychotropic substances.
  5. Laundering the money which obtained as a result of the crimes mentioned in this law.
  6. Participation or aiding in any of acts stated it in paragraph (1- 2-3-4- 5) of this Article.
  7. Attempt to commit any of the acts stated it in paragraph (1 -2-3 -4-5 -6) of this Article.

## Judicial Competence

### 4 Article:

Any person who commit one of the crimes which included in this regulation will subjected and monitored by the competent authorities of Saudi Arabia in the following situations:

1. If the crime is committed within the territory of Saudi Arabia or as a result of the crime or effects.
2. If the crime occurs in a ship that rises Saudi Arabia flag.
3. If the crime is committed in a foreign ship while it is in the territorial sea of Saudi Arabia or its effects and consequences are extended to Saudi's territory.
4. If requested by the captain of the ship, representative of the diplomat or a consular officer of country flag apart from assisted by local authorities to adopting processes against Illicit of narcotics or psychotropic substances according to what stated it in (27) Article in addition, the agreement of the United Nations Convention on the Law of Sea.
5. If crime occurred, on board of an airplane that rises Saudi Arabian flag.

### 5 Article:

The competent authorities in Saudi Arabia could request assistance of other countries in controlling smuggling or illegal trafficking of narcotics and psychotropic substances. Besides, on a ship at sea when there are reasons to believe that ship is Saudi Arabia flag. Moreover, the country that will assist the Kingdom shall adopt necessary action against ship, persons or goods carrying it after coordination with competent authorities of Saudi Arabia.

## **Article 6:**

The rules of jurisdiction in the Articles (4) and (17) of the United Nations Convention 1988 on jurisdiction to prosecute narcotics and psychotropic substances crimes on ships and airplane they are complementary to and set out the jurisdiction rules provided for in this law in any case.

## **Article 7:**

1. The competent authority of Saudi Arabia shall be prosecuting and punish any Saudi national who has committed- outside Saudi Arabia- an offence provided for in this law Article (3). Also, crime committed was punishable in country which it was committed was not prosecuted or punished by country government.
2. Paragraph (1) of this Article shall be apply the provisions of the convention officials of Saudi Arabian diplomatic service consular corps outside Saudi Arabia. If they are prevented from pursuing immunity enjoyed by countries to which they are accredited.

## **Article 8:**

The competent authority of Saudi Arabia shall be prosecuting persons whom are accused of criminal complicity involvement and original or dependent contribution or through aiding by interfering, abetting, preparing or attempting to commit an offence be subjected to Article 3 of law outside territory of Saudi Arabia. Besides, intent of accused is to initiate or facilitate the commission of one such offence within Saudi Arabia.

## Judicial Assistance

### ◆ Article 9:

Saudi Arabia competent authority are obliged to provide mutual legal assistance in accordance with the regulations and agreements to which Saudi Arabia is a part, as well as the principle of reciprocity.

### ◆ Article 10:

The Regulations specify the authorized sector to consider, form, contents, respond to, reject or postpone conditions for their use.

## Controlled Deliveries

### ◆ Article 11:

1) The competent authorities in Saudi Arabia can allow a quantity of narcotics and psychotropic substances or other substances to enter or pass through or exiting territory of Saudi Arabia. In coordination, with country's related authorities in order to detect and arrest persons involved smuggling and trafficking such substances which including:

A – An agreement with authorities of other countries to inspect the approved shipments to subject them to controlled delivery.

B- An agreement with authorities of other countries to replace narcotics or psychotropic substances of approved shipments with similar substances for fear that they will leak during transport. In addition, this considers, where necessary, the agreement on financial cost for the implementation of controlled delivery procedures.

2) Decisions on controlled delivery shall be done on a case-by-case basis.

## Licensing of the import or Trade in Narcotics or Psychotropic Substances for Legitimate Purposes

### ◆ Article 12:

Narcotics or psychotropic substances shall not be imported or exported for lawful purposes without an import or export license issued by Ministry of Health. Although, license is granted for a renewable period of one year, including data on licensee, narcotics or psychotropic substances in their details as specified in regulations.

### ◆ Article 13:

The license for import or export of narcotics or psychotropic substances shall be restricted to following establishments:

- 1) Pharmaceutical companies and agents.
- 2) Wholesale drug warehouses.
- 3) State and private therapeutic establishments and scientific research institutes and centers where the use of narcotic drugs and psychotropic substances is essential.
- 4) Chemical, industrial, microbial, food or other laboratories whose work requires the use of narcotic drug or psychotropic substances.
- 5) Licensed manufacturer drugs, which include narcotic drug or psychotropic substances

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◆ Article 14:

Narcotics or psychotropic substances may not be imported or exported except in sealed package. Although, with a statement specifying the name, quantity, concentration and dosage form of substance even if it is samples. Besides, parcel for these substances shall not be contain any other.

◆ Article 15:

Ministry of Health shall be reviewing the quantity to be imported or exported for approval, modification or rejection in accordance with regulations.

◆ Article 16:

A permit issued by Ministry of Health must be obtained to deliver the narcotics or psychotropic substances when they arrived at customs. Such license shall be returned after the clearance procedures is completed.

◆ Article 17:

The Minister of the Interior shall be authorize government authorities, departments, institutes and scientific research centers to import and grow plant seeds listed in table (4) of law for medical and scientific research purposes, subject to the prescribed regulations.

◆ Article 18:

The controls and conditions specified in the regulation are required when transporting the narcotics or psychotropic substances inside Saudi Arabia.



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◆ Article 19:

In accordance with regulations, The Ministry of Interior, in coordination with customs, shall be authorize the transit of narcotics or psychotropic substances from Saudi Arabia to another country.

◆ Article 20:

- 1) The Ministry of Health shall be authorizing the trade in narcotics or psychotropic substances for medical and scientific use within the Kingdom of Saudi Arabia for supply depot, pharmaceutical manufacturer and pharmacies. In addition, establish is managed by a Saudi pharmacist has pharmacist licensed.
- 2) The owner of a pharmaceutical establishes licensed to trade in narcotics or psychotropic substances shall not be dispose of establish until approval of the Ministry of Health.

◆ Article 21:

A Saudi pharmacist or a Saudi technician shall be responsible of narcotics or psychotropic substances in warehouses, pharmaceutical establishments and therapeutic institutions. Also, the Head of Nursing or a member of the internal departments of therapeutic establishment is responsible for narcotics and psychotropic substances.

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#### ◆ Article 22:

The following shall not be appointed as a responsible person for narcotics drugs and psychotropic substances in the licensed establishments:

1. Who sentenced of drinking alcohol.
2. Sentenced of an offence related to narcotics and psychotropic substances.
3. Sentenced him/her to a crime of dishonesty or moral.
4. Had been previously dismissed from public service on disciplinary reasons of dishonesty or moral.

#### ◆ Article 23:

The narcotics and psychotropic substances must be registered and monitored their dispense by Every pharmaceutical, treatment or research establishments which are authorized to import, export, acquire or trade them. In addition, they are required to submit registration substances to Ministry of Health as specified in the regulations.

#### ◆ Article 24:

1. Only licensed pharmaceutical establishments and therapeutic institutions shall sell narcoticsor psychotropic substances in bulk.
2. Treatment institutions shall not dispense their narcotics and psychotropic substances to other entities until approved by Ministry of Health.
3. Narcotics or psychotropic substances which has been sold shall only be delivered to pharmacists or technicians responsible for license trafficking and shall be by official receipt.
- 4.

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## Licensing in the Manufacture of Medicinal products Containing Narcotics or Psychotropic Substances

### ◆ Article 25:

The establishment of manufacturer or laboratories to manufacture narcotics or psychotropic substances for scientific or commercial purposes shall be authorized by a decision of the Council of Ministers.

### ◆ Article 26:

Pharmaceutical manufacturers, which licensed to manufacture medical preparations that has narcotic or psychotropic substances components, are required to earn a license from Ministry of Health. Although, the license applicant shall be qualified and be licensed to trade in narcotic drug.

### ◆ Article 27:

Licensed manufactures may not be disposing of use narcotics or psychotropic substances except in the manufacture of medical products specified in the license and shall follow the provisions and regulations of these regulations concerning the registration, disposal and control of such substances.

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## Conservation and Disposal of Narcotics or Psychotropic Substances

### ◆ Article 28:

Narcotics or psychotropic substances are kept in licensed establishments in their own inside their original container to protect it from being misused or changing their quantity, composition, weight or concentration. The regulations specify the conditions.

### ◆ Article 29:

The pharmacist shall not prescribe drugs that specified by Ministry of Health for containing narcotics or psychotropic substances unless the prescription is approved by a physician, veterinarian or dentist whom are authorized to practice in Saudi Arabia. Besides, regulations specify condition, date and validity of the recipe.

### ◆ Article 30:

The prescription for narcotics or psychotropic substances shall be saved after contents dispensing in the pharmacy. The prescription shall have the date of drug dispensing and its number of registers in the prescription registry. Moreover, the pharmacy's seal to dispensing must stamp the prescription. Regulation specifies the duration of these prescriptions.

### ◆ Article 31:

The pharmacist and pharmacy technician shall be restricted to all drugs containing narcotics or psychotropic substances received in the pharmacy and what is going in registry as specified in regulation.

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◆ Article 32:

Every therapeutic establishment shall be from time to time review the procedures for prescription and disbursement of narcotics or psychotropic substances. Moreover, to verify the reasons for description and disbursement as required by recognized medical assets and report to the Ministry of Health when any abuse is detected.

### Authorization of Possession of Narcotics or Psychotropic Substances and Uses in Treatment

◆ Article 33:

1. Doctors are authorized to possess, prescribe and release narcotics or psychotropic substances from own clinics in accordance with controls by the regulations.
2. In accordance with the regulation's controls, Specialist paramedics have the possession and delivery of certain emergency drugs containing narcotics or psychotropic substances only in ambulatory cases.

◆ Article 34:

It is prohibited for a doctor to dispense a pharmaceutical product for himself/herself or a family member that contain narcotics or psychotropic substances in any amount.

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## Authorization for Patients to Possess and use Narcotics or Psychotropic Substances

◆ Article 35:

1. Unauthorized person should not possess narcotics or psychotropic substances unless prescribed by a licensed doctor in accordance with provisions of regulations. Furthermore, shall not be waive narcotics or psychotropic substances obtained for treatment purpose in any form or any person and shall be returned when it is not used anymore.
2. The products must be returned to the dispenser pharmacy if the patient died.

◆ Article 36:

It is illegal to import chemicals precursor listed in table 3 accompanying law, as well as export, manufacture, trade, abuse, renunciation or possession of such chemicals with out conditions and procedures mentioned in this regulations. The regulation determine the competent monitor authority and how to monitor such products.

## Penalties

### First, Original Penalties

#### ◆ Article 37:

**Firstly, with Consideration of the provisions in term 2 of this Article, any person who has been legally proved for committing any of the following acts shall be executed:**

1. Smuggling of narcotics or psychotropic substances.
2. Receiving narcotics or psychotropic substances from contrabandist (drug smuggler).
3. Import, export, manufacture, production, transfer, extraction, cultivation or receipt of narcotics or psychotropic substances intention of promotion in circumstances, which are not authorized by the regulations.
4. Participating in any of the acts that mentioned in the previous paragraph.
5. Promotion of narcotics or psychotropic substances for the second time for sale, gift, distribution, delivery, receipt or transfer, subject to a previous conviction for the first time.
6. Promotion for the first time, provided convicted of one of the acts stipulated in paragraph (1-2-3) of this Article.

**Secondly: The Court may, for discretion reasons, commute the penalty of execution to imprisonment of not less than fifteen years, flogging of not more than fifty lashes with a fine not less than 100,000 S.R.**

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**Thirdly, if offender is applying to the following cases and has not sentenced to discretionary penalty stipulated in clause (1) of this article. Although, penalty is imprisonment at least twenty-five years and lashing up to fifty lashes each time. Also, a fine of at least one hundred and fifty thousand Riyals. These cases are:**

1. If the offender re-commits one of these offences after being sentenced for committing one of them, the penalty shall be based according to this Article.
2. If the offender is a public servant, employee or is responsible for implementing the provisions of this law and involved in Law of Combating Narcotics and psychotropic Substances of their handling or possession.
3. If the offender is a member in an organized gang which smuggling the narcotics or psychotropic substances into Kingdom of Saudi Arabia or trafficking them. Also, if linked to an international crime such as smuggling, counterfeiting or terrorism.
4. The perpetrator was armed or used a weapon during the execution of crime.

◆ Article 38:

1. whoever possesses a drug, seed or plant that produces narcotics or psychotropic substances or sold, purchased, financed, acquired, delivered, transferred or traded or cashed or mediating in any capacity. This was for the purpose of trafficking or promotion in payment or for non-payment, other than the conditions authorized in this law, the sentenced to a minimum of five years in prison and not more than fifteen years. Also, no more than 50 lashes each time and with a fine of 1,000 to 50,000 Saudi Riyals. Although,.

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2. The penalties provided in paragraph (1) of this Article shall be increased in the following cases:

- A. If the offender has one of the cases which are mentioned in Article 37, clause 3 of the law.
- B. If the offender commits an offence or part of it in a mosque, schools or correctional institution as defined by law.
- C. Narcotics or psychotropic substances contain of cocaine or any similar substance of the same seriousness based on a technical report approved by Ministry of Health, it shall be included in the table accompanying this law.
- D. If the offender is used to commit an offence by a person who is raising or has an effective authority over him/her, sell or provide drugs to a minor or a push him/her to use it by any means of intimidation.
- E. Anyone who has created a place for or managed to use narcotics or psychotropic substances.

◆ Article 39:

Any person who has acquired, transported, delivered or received narcotics or psychotropic substances inadvertently for trafficking, promotion or personal use in a way that does not meet the terms of this law shall be punished with an imprisonment of two to five years and a term of up to fifty lashes at a time shall be imposed. Moreover, a fine of not less than three thousand Riyals and not more than thirty thousand Riyals.



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◆ Article 40:

1. The penalty is imprisonment not less than three years and not more than ten years and flogging not more than fifty flog each time and with a fine of at least 50,000 Saudi Riyals. Every person has committed the act stipulated in paragraph (5) of Article 3 of this law. The Court shall be severe tempo if there are good reasons for the case.
2. Punishable by a fine of at least 300.000 Riyals, any company, institution or establish and even if it is unlicensed to operate, the director or a member of the court shall be find guilty of the act provided in Article 3, paragraph 5, of the law if it is establishment committed the act for its own interest.
3. If this act is punishable under this and another law, the severe penalty shall be applied.

◆ Article 41:

1. Shall be punishable by a minimum of six months and not more than two years, and anyone commits one of criminal acts steadied in Articles 37 of law shall be sentenced to a minimum of six months and not more than two years and the purpose of personal use or use in other circumstances licensed by a law.
2. The penalty shall increase in the following cases:
  - A. If the abusers oversee Law of Combating Narcotics and psychotropic Substances, control, possession or handling and those who are functionally related to any type of narcotics or psychotropic substances.
  - B. If the narcotics or psychotropic substances is used or under its influence when performing his/her work.

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◆ Article 42:

1. The prosecution cannot be brought for use or addiction of narcotics or psychotropic substances the offender of one of these acts if he/she submits him/herself or one of assets or branches or husband /wife or a relative seeking treatment. Besides, this requires that narcotic drug or psychotropic substances, if any, be handed over to the user or the drug addict or guide to the place.
1. The investigation cases of use narcotics or psychotropic substances shall be filed at the first time if the following are achieved:
  - A. The accused is not more than 20 years old.
  - B. The offence of use or abuse shall not be accompanied by a criminal offence that warrants legitimate consideration.
  - C. The offence of use or abuse shall not be accompanied by a traffic accident which resulted in deaths and in which special rights were granted.
  - D. When seized, the accused shall not have issued any severe resistance that would cause harm to the arresting authority or others.

◆ Article 43:

Instead of imposing the punishment, the addict of narcotic drug or psychotropic substances can be hospitalized in one of the clinics that designated to treat the drug addiction. The regulations specify the cases in which an addict could be placed in a sanitarium and which sector orders his/her treatment and conditions for the release.

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#### ◆ Article 44:

A committee decided by the minister of the interior in agreement with the Minister of Health is called the committee for the consideration of cases of addiction and regulation specifies its task, competencies, membership and procedures.

#### ◆ Article 45:

If during the period of treatment, the detainee commits any of the offences provided in this law the prison sentence imposed on him/her shall be served after deducting the length of time they spent in the institution from that sentence.

#### ◆ Article 46:

1. Shall be punished with imprisonment for a term not exceeding three months or with no more than fifty lashes anyone who has been seized visiting frequently a place that prepared for the use of narcotics or psychotropic substances during their abuse with knowledge of what is going on in that place.
2. The provisions of this Article shall not apply to a spouse who has prepared the said place for the use of narcotics or psychotropic substances, to his/her relatives, brothers, or to a resident of the mentioned place, unless they have participated in the crime.

#### ◆ Article 47:

The Minister of Interior -or an official authorized by him – has the authority to deport the addict of narcotics or psychotropic substances who submitted a Hajj or Umrah visa and in possession of narcotics or psychotropic substances does not exceed his/her need and personal use and regulations specify the type and quantity of such substances.

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#### ◆ Article 48:

Any person who violates the Article 36 law shall be punished with imprisonment not exceeding six months and by a fine not exceeding three thousand Riyals, or one of these penalties.

#### ◆ Article 49:

1. Without prejudice to the provisions of the previous Articles shall be punished with a fine of not more than twenty thousand Saudi Riyals:
  - A. Anyone who is licensed to possess or trade in narcotics or psychotropic substances and violates the provisions of the 23, 30 and 31 Articles of this law.
  - B. Any person who manages a pharmacy or shop that authorized to trade in narcotics or psychotropic substances and who violates Article 23 of this law.
  - C. Any person who is authorized to possess narcotic drugs, psychotropic substances, plants or seeds referred to in tables (1-2-4) which mentioned in this law and acquired in bona fide (in good faith) quantities that exceed his/her actual need.
2. The penalty for violator shall be doubled in the case of reoffending to commit a similar act of the violations provided for in paragraph (1) of this Article before serving three years from date of the previous sentence in addition to the closure of the shop.

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## The Obligation of an Addict to visit a Psychiatric Clinic

### ◆ Article 50:

Instead of imposing the penalty provided in the Article 41 of this law, the addicted person will be obligated to visit a psychiatric clinic dedicated to this purpose to help him/her heal from addiction. Besides, those who decide to release him/her from the sanatorium are required to review the psychiatric clinic ascertain his recovery. Besides, the doctor of the clinic in charge of assisting the addict shall submit a report on his/her condition to the committee for the consideration cases of addiction within three months from the date of the treatment beginning at psychiatric clinic in order to decide to stop visiting the clinic or keeping on the treatment plan.

### ◆ Article 51:

The addict is treated confidentially, and his/her identity and any personal information shall be kept secret. Moreover, anyone who discloses this information at any stage of the case shall be punished by imprisonment for a period of not more than three months or a fine which is not more than thirty thousand Riyals.

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## Secondly, Supplementary Penalties

◆ Article 52:

1. Seized narcotics and psychotropic substances all that were manufacture, acquisition, sale or used illegally shall be confiscated, if these substances do not belong to the accused or have not led to his/ her conviction.
2. Narcotics or psychotropic substances confiscated or delivered in whole or part of them to any government sector for use in scientific, industrial or medical purposes as determined by the regulation shall be destroyed.

◆ Article 53:

**Without prejudice to the rights of others bona fide (good faith), the following shall be seized by court order:**

1. Machinery, instruments and means of transportation that used in the crime.
2. Money and objects derived from, or derived directly or indirectly from, commission of crime, even though they are concealed, owned or disguised.
3. Proceeds resulting from criminal acts punishable by the law are converted into money of another kind.
4. Equivalent to the estimated value of illicit proceeds if such proceeds are mixed with money acquired from legitimate sources.
5. The land planted with the plants listed in listed in the table 4 accompanying the law, if it is owned by the offender if it is not owned by owner, the court shall be consider terminating the deed of tenure.



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◆ Article 54:

The competent court on its own motion or at the request of the investigating body at any stage or if the case is considered on compelling reasons that govern conduct preventive seizure of transferred and non-transferred assets of drug smugglers traffickers, business, money to their husbands/ wives, their minor children or other people who born inside or outside Saudi Arabia. Although, until the case is decided if evidence indicates that source of this or some of money is one of criminal acts mentioned in Article 3 of this law.

◆ Article 55:

1. Eliminates the license of establishment trade in substances for trading the narcotics and psychotropic substances for medical or scientific purposes, if the offender or the responsible personal is responsible for committing the criminal act which were provided in article 3 of this law.
2. Shall be deprived of the sentenced practitioner's duration of no more than a sentence of imprisonment. Also, shall be sentenced to temporarily close the shop for a period of not more than one year or closed permanently in case of repeating one of criminal acts which provided in Article 3 of this law.



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◆ Article 56:

1. A Saudi national who is convicted of committing one of the criminal acts provided in Article 3 of this law shall be prohibited from traveling outside Saudi Arabia after the end of prison sentence for a period that is similar to his/her period in prison, provided that the ban period should not be less than two years. The Minister of Interior has the right to authorize the travel for necessity during the prohibition period.
2. The non-Saudi will be deported from Saudi Arabia after carrying out his/her sentence and shall not be allowed to return except for the Hajj and Umrah under conditions.

◆ Article 57:

1. The license to engage in the profession shall be revoked to anyone who is sentenced for committing an offence provided in Article 3 of this law.
2. The license for trafficking in narcotics or psychotropic substances granted to the pharmaceutical establishment shall be revoked, if one of the offences provided in Article 3 of this law occur by the owner of establishment or repeated one of its officials.
3. The private Treatment Institution shall be prohibited from acquiring narcotics or psychotropic substances in it is possession if one of the offences provided for in Article 3 of the law is repeated by the its employee who is responsible for such substances.

## General Provisions

### ◆ Article 58:

Punishment for same offence the same penalty shall be imposed on anyone who participates in committing one of the acts provided in Article 3, paragraphs 1.2.3.4.5, of this law whether by agreement, incitement or assistance.

### ◆ Article 59:

1. Attempt to commit any of offences provided for in paragraph 1 of Article 38 of this law shall be punished by imprisonment for a term not exceeding ten years and a fine not exceeding fifty thousand Riyals.
2. Attempts to commit any other offence shall be punished by up to half of the maximum penalty of imprisonment and fine provided for this law for the total offence.
3. In addition to paragraphs 1.2 of this Article, court shall be sentence the lashing penalty which it seems appropriate in all circumstances.

### ◆ Article 60:

1. The court and for reasonable reasons, or if it comes from morality of the convict, can reduce the minimum prison sentence which provided in articles 37,38,39,40 and 41 of this law according to his past, age, the personal circumstances, the circumstances in which the crime was committed or if it is reasonable to believe the accused person will not return to violate the provisions of this law.

Moreover, court shall be suspending sentence of imprisonment in accordance with Article 48 of this statute for the same reasons unless he/she has already been sentenced and commit the same offense again. Although, reasons on which judgment was based shall be set out in all circumstances.

2. If the convicted person returns to commit an offence which is punishable under law within a period of three years from date of suspension sentence, court will revocation of the suspended and order it is enforcement without prejudice to penalty prescribed for new offence.
3. If suspended sentence expires without return of convicted person for commission of one of offences punishable in law. Although, suspended sentence counts as if it had not been, and all excitement had passed.

#### ◆ Article 61:

Exemption from the penalties prescribed for offences provided for in Article 3 of law, each of offenders, unless he/she is an instigator of crime, shall be report the crime to public authorities before they become aware of it. If the report of the crime came to attention of the authorities, exemption shall be led to arrest of remaining perpetrators if possible.

◆ Article 62:

1. If he/she commits several offences punishable under law before a final verdict on any of them shall he/she had to be tried for the offence with maximum penalty and sentenced to penalty otherwise.
2. If offence is punishable under this and another law, the maximum penalty shall be applied.

◆ Article 63:

Penalties are limited by a fine and do not require seizure.

◆ Article 64:

Penalties may overlap strengthening flogging only if the judge sees otherwise will he/ she be found guilty of each offence.

◆ Article 65:

Articles 27 and 28 of Criminal Procedure Law shall apply to the seizure of the offences provided for in this law.

◆ Article 66:

In accordance with Article 26 of Criminal Procedure Law to Law of Combating Narcotics managers, officers and non-commissioned officers have criminal seizure status throughout Saudi Arabia for offences provided for law such as investigating the crimes and their perpetrators.

Collection of evidence for the investigation of these crimes, and seizure and storage of suspicious substances.

◆ Article 67:

Specialists in Ministry of Health have criminal seizure status in implementation of provisions of law and entering drug stores and warehouses of trafficking in narcotics or psychotropic substances, hospitals, dispensaries, pharmacies, pharmaceutical manufactory and chemical analysis laboratories using narcotics or psychotropic substances. Moreover, they have access to books and registry on the disposition n of narcotics and psychotropic substances.

◆ Article 68:

Customs specialists, border guards, the Saudi Central Bank and the Ministry of Agriculture have criminal seizure status relates to the provisions of the law. In addition, they are coordinated with the criminal seizure officers of security agencies, security bodies and relevant investigative bodies in counter-narcotics cases.

## Final provisions

### ◆ Article 69:

The implementing regulations for law are prepared by Ministry of Interior, Ministry of Justice and Ministry of Health within a hundred and eighty days after implementation of this law. Besides, it is issued by decision of the Council of Ministers and published in the official gazette.

### ◆ Article 70:

The Minister of Health may amend tables which accompanying this law by adding new articles to them, deleting some of articles mentioned therein, or making a change in order or descent. Moreover, such amendments must be published in official gazette.

### ◆ Article 71:

The accompanying tables and amendments are an integral part of law.

### ◆ Article 72:

The sentence shall not affect the penalties provided for law shall not affect which is a legitimate right of others.

### ◆ Article 73:

This regime abolishes the regime for prevention of trafficking in narcotics or psychotropic substances issued by supreme order No. 3318 and date 9.4.1123 AH, and all provisions that conflict with it.

### ◆ Article 74:

Publish in the official gazette and is in operation after ninety days from the date of bulletin.

**Implementing regulation  
Law of Combating Narcotics  
and Psychotropic Substances**

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## Implementing regulations Law of Combating Narcotics and psychotropic Substances approved by decision No. 201 of the Council of Ministers dated 10-6-1431 AH.

### ◆ Article 1:

1. The Ministry of Health shall be identified laboratories accredited to perform laboratory analyses of narcotics and psychotropic substances and samples from accused.
2. The laboratory analysis adopts the following two experts:
  - A. As a result of the detection of the identity of the seized substance and the proof of its positivity or passivity and the seriousness of the substance.
  - B. Result analysis of samples from accused persons.
3. Ministry of Health prepares and adopts laboratory analysis modules in coordination with the Ministry of Justice.
4. Ministry of Health shall be determining sampling and quantity required for analysis in coordination with Ministry of Interior.

### ◆ Article 2:

#### **1. Modes of transport are:**

- A. Ships      B. Airplanes.      C. Trains

#### **2. Controls on carrying of drugs that containing narcotics or psychotropic substances in transportation are:**

**First, non-Saudi means of transport inside Saudi Arabia's territory:**

1. Declaration shall be including names and quantities of these drugs and proportion of narcotics or psychoactive substances.
2. The Transport official declares the name of the person responsible for the custody of these drugs.
3. If any violations appears to the competent customs officer during his inspections or checks of the custody records of medical drugs containing narcotics or psychotropic substances, an official record will be prepared along with notifying the Ministry of the Interior to take the necessary action.
4. If transport means need to supply medical medicines containing narcotics or psychotropic substances because of a shortage, it shall apply a request to the competent administration of the arrival station. Moreover, explain the reason for request, names of drugs and quantities required of them, but not more than those originally authorized in country that carries the flag or nationality, customs department must be notified.
5. The department of medical services of each military body is responsible to take the above-mentioned measures regarding foreign military means of transport.

**Secondly, Saudi Arabian Transport:**

1. Transportation organizations raise submit their annual requirement for drugs that containing narcotics or psychotropic substances to be approved, certified or rejectedwith explanation of cause by Saudi Food and Drug Authority.
2. Medical drugs containing narcotics or substances shall be kept in conformity with Article 28 of Combating Narcotics and psychotropic Substances Law and this regulation.

3. Medical drugs containing narcotics or psychotropic substances shall be handed over to person responsible for means of transportation or to his assistant (deputy) unless they have a pharmacist or a doctor among their staff.

4. Medical drugs containing narcotics or psychotropic substances may be carried in means of transport are:

Name of drug and proportion of substance that is narcotic or psychoactive	
10mg/2ml amp	Diazepam
10mg/ml amp	Morphine
2mg/ml amp	Lorazepam
100mg/2ml amp	Tramadol
50mg/ml amp	Pethidine
15mg/3ml amp	Midazolam

5. Quantities of drugs listed in table above are determined based on number of passengers and duration of journey. In addition, considering the nature of trip and presence of a doctor on mean of transport or not, as follows:

number of passengers	Maximum drugs ampoule (amp)			
	Less than 3 days.	From 3 to 10 days	From 10 to 30 days	More than 30 days
Less than 100 passengers	5	10	15	20
From 100 to less than 500 passengers	10	15	20	25
From 500 to less than 1,500 passengers	20	25	30	35
More than 1,500 passengers and double the number.	30	35	40	45

6. These drugs shall be injected drugs that only used once. The means of transportation may secure all or part of these drugs according to its need.
7. Compliance with requirements and controls governing use of narcotics or psychotropic substances contained in the Law of Combating Narcotics and psychotropic Substances shall be in this regulation.
8. If any violations appear during the inspection or checks of the records of the custody of medical drugs containing narcotics or psychotropic substances, the incident shall be seized according to its form.
9. Administration of medical services of each military body is competent to take above-mentioned measures about Saudi military means of transport and their provisions.
10. Executive chairman of Saudi Food and Drug Authority has the right to amend the list of drugs containing narcotics or psychotropic substances, permitted transport, quantities and dosage forms.

**3. The use of drugs containing narcotics or psychotropic substances is restricted within means of transportation.**

◆ Article 3:

1. Competent authorities to monitor perpetrators of offences provided in Law of Combating Narcotics and psychotropic Substances are the General Directorate of Narcotics Control and each body with jurisdiction over location and crime location.
2. Competent authorities to prosecute perpetrators of offences provided for in law for control of narcotics or psychotropic substances everybody has status of criminal control or carries out criminal seizure all matters relating to performance of functions. In accordance with law on Law of Combating Narcotics and psychotropic Substances the regulations and the criminal procedure law.

◆ Article 4:

Competent authorities to request the assistance of other countries in controlling smuggling or illegal traffic in narcotics and psychotropic substances on a ship at sea:

1. General Directorate of Narcotics Control
2. International Police Liaison Department (Interpol)

◆ Article 5:

1. Competent authorities to prosecute and punish any Saudi has committed an offence outside Saudi Arabia provided for in this Article 3 of the Law of Combating Narcotics and psychotropic Substances General Directorate of Narcotics Control, the bureau of Investigation and public prosecution and prosecution authority and competent courts.
2. Proceedings shall be initiated by an official request of competent authorities of country where the crime has been committed or issued statement by official bodies request or statement shall be accompanied by a certified copy of documents on which accusation is based including facts, descriptions and evidence of crime.

◆ Article 6:

1. Competent authorities has the right to pursue any person who is accused of complicity in commission of one of offences provided for in Article 3 of Combating Narcotics and psychotropic Substances Law outside Saudi Arabia are:
  - A. General Directorate of Narcotics Control.
  - B. International Police Liaison Department (Interpol).
2. Measures referred to in Article 8 of Law of Combating Narcotics and psychotropic Substances shall be consider the requirements of international conventions.

◆ Article 7:

1. The sector which is responsible to consider for assistance are mutual legal assistance committee of the Ministry of Interior, to which all requests for legal assistance are transferred.
2. Requests for assistance, form, content, response, refusal or postponement and use conditions which provided in the 1988 United Nations Convention against illegal traffic of narcotics and psychotropic substances and its implementing regulations.

◆ Article 8:

1. Competent authorities to permit entry, transit through or exit of narcotics, psychotropic substances or substituted substances from Saudi Arabia are General Directorate of Narcotics Control and the customs service.

2. Controlled delivery controls and conditions:

A. If the shipment will be shipped to Saudi Arabia:

1. Request shall be in Arabic language.
2. Request shall be including available information on source and carrier of shipment, means of transport, type of narcotics or psychoactive substance and persons involved in commission of crime within territory of Saudi Arabia.
3. The requestor is obligated to control the source of the shipment and other interested parties whether the people involved within the territory of Saudi Arabia have been reached or not for any reason and provide competent body in Saudi Arabia with results of investigations and trial in the case.

4. The competent bodies in Saudi Arabia are required to seizure with their obligations to investigate accuracy of their seizure procedures and to verify that there is no incitement or lure. Moreover, whenever there is evidence of this, they shall initiate the suspension or cancellation of the proceedings and inform the requesting country authorities.
5. Presence of narcotics or psychotropic substances in controlled delivery or a portion of quantity in case the agreement to replace them.
6. The request shall be containing an agreement on the shipment delivery shop and means of transport, whether or not those involved are seized.
7. Customs and drug enforcement administration (DEA) verify shipments approved to be subject to controlled delivery through which shipment will pass under a joint record. Although, after an inventory with means of transport, if any, is delivered to the DEA to complete the rest of the procedure.

**B. If the shipment is required to pass through Saudi Arabia territory into the territory of other countries:**

1. If the request is in Arabic language.
2. Customs shall verify the presence of the narcotic or psychotropic substance in place of delivery or the substances that have taken their place in accordance with the request for extradition.
3. Drug enforcement administration (DEA), in coordination with any competent body within Saudi Arabia, shall monitor shipment until it is released from territory of Saudi Arabia and handed over to the authorities of other countries.
4. Request shall be containing complete information on shipment as well as consent of destination counters. However, pass through the territories of several countries after exiting from territory of Saudi Arabia. Although, competent authority of requesting countries shall coordinate with those countries and obtain their consent and prospects.

**C. If the shipment is discovered within the territory of Saudi Arabia and is on its way to the territory of another countries:**

1. The request shall be in Arabic language.
2. The competent authorities of Saudi Arabia shall approve with authorities of the country in question to send or replace the shipment.
3. If it is approved shipment of narcotics or psychotropic substances shall be sent without replacement, samples of the quantity shall be deducted.
4. The request shall be containing a concordance in respect of cargo in question and means of transport, whether or not those involved are seized.
  
3. In all cases and if shipment contains any prohibited substance other than narcotics or psychotropic substances. Although, drug enforcement administration (DEA) shall be coordinate with relevant competent bodies before proceeding with any of cases of controlled delivery referred to.
4. The actions described in the preceding paragraphs shall be agreement by Minister of Interior or of the commissioner to coordinate with customs in respect thereof.
5. The Minister of Interior or who is deputy in such cases as deems, commissioner may exclude from these controls and conditions. Although, competent authorities shall be verifying existence of narcotics or psychotropic substances and where are hidden and just watching and not searching.

◆ Article 9:

1. Ministry of Health and Saudi Food and Drug Authority should authorize private establishment that desire to import narcotics or psychotropic substances for legitimate purposes.
2. The government or private establishment shall have an annual requirement approved by Saudi Food and Drug Authority.
3. Import license shall be granted for a maximum period of one year, which shall be expire at end of requirement's year.
4. Conditions for renewal of the import license:
  - A. License of private establishment shall be valid.
  - B. The applicant shall has a requirement approved by Saudi Food and Drug Authority for year during which it is to be renewed, covering quantity to be imported.
  - C. In case of import delay, establishment shall be providing proof that delay was for adequate reasons.
5. The applicant shall be submitting a valid import permit from intended export country includes the following:
  - A. Name and address of the importer, beneficiary and manufacturer and exporter
  - B. Product generic and commercial name, dosage form, concentration, size, packaging, quantity and pure weight.
6. An export license shall be granted for a period similar to validity of an import permit issued by countries to be exported, but not exceeding one year.

7. Conditions for renewal of the export license:

- A. License of the private enterprise shall be valid.
- B. The body applicant has a Saudi Food and Drug Authority approved requirement for year to be renewed, covering the quantity to be exported.
- C. Import license issued by countries to be exported shall be valid and in conformity with data of export license.

8. Import or export license shall be including the following data:

- A. Name and address of the importer, beneficiary and manufacturer and exporter.
- B. Product's generic and commercial name, dosage form, concentration, size, packaging, quantity and pure weight.
- C. License instructions defining by Saudi Food and Drug Authority.

9. Import of narcotics and psychotropic substances by air transport and Saudi Food and Drug Authority, in agreement with Ministry of Interior, may permit use of other means of transport. Moreover, importer shall be complying with conditions and specifications for transport and shipment of narcotics and psychotropic substances established by manufacturer and the conditions provided for in international agreements and law in Saudi Arabia.

10. Samples of narcotics or psychotropic substances may be imported only for registration.



◆ Article 10:

**Quantity to be imported or exported shall be reduced in accordance with following controls:**

1. The quantity to be imported shall not be exceed the amount required by the establishment adopted by Saudi Food and Drug Authority.
2. The data and quantity of substance to be exported shall be identical to that of substance or part of the quantity in import license issued by countries to be issued.
3. Quantity to be exported shall not be exceed annual requirement of countries to be exported from International narcotics control board.

◆ Article 11:

1. A clearance license issued by Saudi Food and Drug Authority before the date of arrival in Saudi Arabia is required a releasing permit for the narcotics and psychotropic substances arriving at customs. Exception is drugs containing narcotics or psychotropic substances that are in possession of patients arriving in or leaving Saudi Arabia for personal use and in accordance with procedures and controls approved by president of Food and Drug Authority, in coordination with the Minister of Health.
2. Narcotics and psychotropic substances shall be kept at customs in accordance with conditions provided in Article 19 and 10 of these regulations.
3. The clearance license shall be including on instructions which specified by Saudi Food and Drug Authority.

◆ Article12:

1. The body which desire to import the seeds of plants listed in Law of Combating Narcotics and psychotropic Substances (table No. 4 ) should submit an application containing type, quantity and purpose of the seed.
2. This request is addressed to the Ministry of Interior and will be analyzed by a committee composed of Ministry of Interior, the Ministry of Health, the Ministry of Education, the Ministry of Environment water and Agriculture in addition to Saudi Food and Drug Authority.
3. The import license shall be valid for one year from the date of it is issuance.
4. The import license includes the following data:
  - A. Name, type and quantity of seeds.
  - B. Beneficiary's name and address.
  - C. Name and address of importer and exporter.
  - D. Purpose of import.
  - E. Date of validity of import license.
  - F. License instructions determined by Ministry of Interior.
5. Seeds arriving at customs may only be delivered under a clearance license issued by Ministry of Interior license shall be returned to it after the end of clearance. The Minister of Interior clearance license is required to be issued before the seeds arrival date.
6. Seeds may only be imported within sealed packages that specified the name and quantities substance. Moreover, packages shall not contain any other substance.

7. Seeds shall be in the custody of a person designated by the applicant body for the application compliance with Article 23 of Law of Combating Narcotics and psychotropic Substances.
  8. Beneficiary shall be obliged to prove consumption of the quantity purpose for which it was requested. Moreover, this is in accordance with a statement that it maintains and provides to Ministry of Internal with copy.
  9. If quantity is not consumed, rest shall be handed over to combating narcotics administration under a statement. In addition, a statement of provisions contained in Article 52 law of combating narcotics and psychotropic substances shall apply this regulation.
10. The license for agriculture requires:
- A. Determine the location and duration of agriculture.
  - B. Location which prepared for agriculture is surrounded by a security fence and under the security of beneficiary, only authorized personal is permitted.
  - C. Beneficiary is obliged to preserve production of seeds and other plants in order to ensure that they are not leaked or used for unauthorized purpose. Besides, control and inspection procedures are implemented by the beneficiary body to verify this.
  - D. Destroy remains of cultivation and production, if any, in accordance with Article 52 of law of combating narcotics and psychotropic substances and regulation.

◆ Article 13:

Controls and conditions for transfer and delivery of narcotics or psychotropic substances within Saudi Arabia:

1. Transport shall be in closed containers sealed with a serial number seal that registered in an original statement of the container, along with a copy of both supplier body and beneficiary body.
2. Delivery of narcotics or psychotropic substances from the warehouse to a container or vice versa under a statement signed by the custody holder in the warehouse and officer who escorts the container.
3. Delivery statement shall be including on substances name, size, packaging and quantities in number and in writing. Also, name and address of body recipient and date of receipt and seal must be included.
4. During period of transport, delivery, the container shall be under a security guard authorized and approved by Ministry of Interior.
5. If narcotics and psychotropic substances are transported by a private transport company, it shall be licensed by the Ministry of Interior.
6. When transporting drugs containing narcotics or psychotropic substances, the following conditions:
  - A. Storage during transport shall be in accordance with storage specifications approved by manufacturer.
  - B. The officer accompanying package is a pharmacist or technician.
  - C. The delivery statement shall be including on dosage form, concentration, lot number and validity.

7. When transferring samples sent to laboratories for analysis shall be inside an airtight package and in a letter explaining the substances name and quantity by number or weight. Besides, the package shall be accompanied by a letter addressed to the laboratory, requesting analysis and indicating the sample's secret number.

◆ Article 14:

1. Customs does not permit transit of narcotics or psychotropic substances through territory of Saudi Arabia except with an authorization issued by the Minister of Interior or his deputy.

2. The passage of narcotics or psychotropic substances through the territory of Saudi Arabia requires:

- A. Obtaining a license from the importing and the exporting country.
- B. Determine the means of transportation, route and departure port.
- C. Identification of substance, name, quantity and proportion of the narcotic psychoactive substance.
- D. These substances shall be subject security guard determined by Ministry of Interior.

3. Customs shall be verifying the conditions for the transit of narcotics and psychotropic substances through the territory of Saudi Arabia in accordance with law, regulations and instructions.

4. Customs verify the exit of narcotics or psychotropic substances from territory of Saudi Arabia through designated exit point within prescribed period. Moreover, if it do not leave, inform drug enforcement administration (DEA) immediately to complete necessary according to jurisdiction and inform the customs of what has been done in this regard.



◆ Article 15:

The president of Saudi Food and Drug Authority shall be in agreement with Minister of Health adopt procedures and controls for delivery custody of narcotics or psychotropic substances in warehouses, pharmaceutical manufacturer and therapeutic establishments.

◆ Article 16:

1. The statement of registration of narcotics or psychotropic substances in pharmaceutical establishments and therapeutic or research institutions authorized to use narcotics or psychotropic substances shall include the following:

- A. Periodic register number (periodic) and date.
- B. Product generic name, dosage form, concentration, size and packaging of narcotics or psychoactive substance.
- C. The remaining amount of the previous periodic registry.
- D. Quantity received.
- E. Receiver
- F. Grand total
- G. Quantity spent.
- H. Data on who you spent the amount for.
- I. Amount Left.  
Custodial responsibility name and signature of narcotics or psychotropic substances.
- J. Name of establishment manager or behalf and signature.
- K. Official seal of the establishment

2. The data of periodic registration shall be submitted every six months to Ministry of health or Saudi Food and Drug Authority, each according to its competence and saved a copy of it at establishment.

3. The Executive Chairman of Saudi Food and Drug Authority shall be adopting, in agreement with Minister of Health, procedures for exchange control procedures and controls.

◆ Article 17:

The Executive Chairman of Saudi Food and Drug Authority, in coordination with Minister of Health, shall be adopting procedures and controls for sale, delivery and disposal of narcotics and psychotropic substances in pharmaceutical establishments and therapeutic institutions.

◆ Article 18:

1. The license applications to establish factories or laboratories to manufacture narcotics or psychotropic substances separation, manufacturing them for scientific or commercial purposes shall be submitted to Saudi Food and Drug Authority.

2. A standing committee with the participation of the Ministry of Interior, the Ministry of commerce, Ministry Industry and Ministry of Resources and the Ministry of Health shall be established within Saudi Food and Drug Authority directly the following missions:

A. conditions and procedures for the granting of licenses for manufacturing and laboratories referred to in paragraph 1 above, and how to monitor.

B. Study of applications for authorization in paragraph 1 Above, and appropriateness of approval.

3. Saudi Food and Drug Authority shall be submitting applications for authorization approved by the standing committee to council of ministers for appropriate necessary action.

◆ Article 19:

1. Preservation requirements for narcotics and psychotropic substances in licensed establishments:
  - A. Preservation shall be done in compliance with the storage specifications and conditions established by the manufacturer.
  - B. The storage shall be in a treasury or warehouse in the authorized establishment.
  - C. This treasury or warehouse is intended to store only narcotics and psychotropic substances.
  - D. The treasury or warehouse shall be sealed and not be left to be removed, broken or moved and provided with a security alarm system for protection.
2. Saudi Food and Drug Authority, in coordination with Ministry of Health, shall be verify safety and security of modern techniques for conservation of narcotics and psychotropic substances, ensuring their conservation character and meeting previous requirements before approving their use.
3. The president of Saudi Food and Drug Authority, in coordination with Minister of Health, shall be adopt procedures and controls for preservation and destruction of damaged taps and empty packaging of narcotics and psychotropic substances.
4. In cases of excess, loss, deficiency or damage to narcotics or psychotropic substances, the following actions shall be taken:
  - A. Custodial responsibility shall be obliged to preserve it and report to head of command without touching or changing its status. Moreover, the official shall put an immediate guard on the place and reservation everything.
  - B. If the loss, deficiency or damage resulted from a robbery or there was a suspicion of theft and evidence of attempted robbery establishment director shall be reporting the incident to police department and drug enforcement administration (DEA).

C. If the loss, deficiency, damage or increase is not accompanied by an assault or robbery or there is no suspicion of theft, the following shall be taken:

1. The manager of establishment shall be forming a committee of inquiry formed by at least three members, one of whom shall be from inventory control of establishment to perform the following tasks:
  - A. Inventory of items in place where increase, deficiency, loss or damage occurred to account for excess, deficiency, missing or combination thereof and quantities.
  - B. Investigation of causes of excess, loss, deficiency or damage. Whether this is result of negligence or any other incidental emergency with limitation of liability of defaulter or cause of negligence.
2. Manager of establishment shall be submitting the report of the committee to Ministry of Health or Saudi Food and Drug Authority in accordance with competence to take necessary action and shall be saved a copy thereof in registry of covenant.
3. If competent officer of Ministry of Health or Saudi Food and Drug Authority with criminal seizure status finds that increase, loss, deficiency or damage results from a criminal act. Moreover, a report of the incident is prepared. and informs DEA, Bureau of Investigation and Public Prosecution.

◆ Article 20:

1. Prescription conditions are:

- A. The prescription shall be containing only one drug.
- B. The prescription consists of an original written in a red font (restricted substances) and two copy written on it (non-expendable)
- C. The original of prescription is saved in pharmacy, patient is given a copy and other copy is saved in prescription book.
- D. Paper shall be written link in indelible ink and be free of deletion or modification.

2) Prescription data are:

- A. Name and address of establishment.
- B. The patient's name is quadriplegic, age, gender and nationality.
- C. Patient file number and identification number.
- D. Prescription number and date
- E. Diagnosis.
- F. Name of scientific drug, dosage form, prescribed dose, duration of treatment, a number and a writing.
- G. Doctor's name, business card number and signature.
- H. Name of pharmacist in custodial responsibility, business card number and signature.
- I. prescription instructions by Ministry of Health in coordination with Saudi Food and Drug Authority.
- J. Seal establishment.

3. Be access from the date of issue as follows:

- A. Only one day in ambulatory situations.
- B. Seven days for clinic patients and out-of-hospital patients.

4. Minister of Health, in coordination with the president of SaudiFood and Drug Authority, shall be amend conditions, data and validity mentioned in preceding paragraphs of this Article.

5. Ministry of Health, in coordination with the Saudi Food and Drug Authority, is verifying availability of modern prescription writing techniques. Besides, to ensure they comply with foregoing conditions before agreeing to use.

◆ Article 21:

- 1. Saves Origin of the prescription for three years.
- 2. Every pharmacy shall be maintaining a prescription register for five years.
- 3. The prescription and registry prescription shall be destroyed after expiration of period of time for preservation by a three-member committee by a decision of manager of establish or by whistleblower and a report shall be prepared.

◆ Article 22:

- 1. Shall be a special register in pharmacy establish for every drug narcotic or psychoactive substance.
- 2. Registry pages shall be serially numbered.
- 3. Registry in pharmacies and warehouses shall be include the following data:

- A. Name of scientific drug and dosage form and concentration and size.
- B. Previous balance.
- C. Incoming quantity, lot number and validity date.
- D. Body and date of receipt.
- E. Grand total.
- F. Quantity spent, lot number, date of exchange, name of discharge and signature.
- G. Body name and address for (warehouses only).
- H. Patient's name, age, identification number, medical file, prescription number and name of (pharmacy description only)
- I. Quantity remaining

4. Register shall be written in indelible ink, and upon modification signs it.

5. At the end of each year, registry shall have name of custodial responsibility of narcotics or psychotropic substances and signature. Besides, name of establishment manager or his/her deputy and his /her signature and seal registry with the official seal of the establish.

6. Saving the registers for ten years.

7. Register shall be destroyed after expiration of specified period of preservation by a committee composed of three members by decision of manger of establishment or a deputy and prepare record.

8. Saudi Food and Drug Authority, in coordination with Ministry of Health, shall be verify modern technique available for registering all information received by pharmacy or warehouse in order to ensure that it respects the above requirements.

◆ Article 23:

1. Minister of Health, in coordination with the Executive chairman of Saudi Food and Drug Authority procedures and controls for prescribing narcotics or psychotropic substances in therapeutic institutions.
2. The minister of Health adopts procedures and controls to verify the commitment of therapeutic institutions and stated in this Article and evidence.

◆ Article 24:

1. Doctors are authorized to possess, prescribe and dispense narcotics and psychotropic substances from their own clinics in accordance with the following regulations:
  - A. The clinic license which issued by the Ministry of Health shall be valid.
  - B. The clinic has an annual requirement approved by Saudi Food and Drug Authority.
  - C. Narcotics or psychotropic substances shall be below supervision and responsibility of the physician in the clinic or under his /her reign a Saudi pharmacist or a Saudi technician works in the clinic.
  - D. Possession is limited to ambulatory medications prescribed by the minister of Health.
  - E. The description and disbursement at the private doctors' clinic are subject to the regulations provided for in Articles (20- 21- 22- 23) of this regulation.
2. Controls on the possession and delivery of drugs containing narcotics or psychotropic substances in ambulatory cases.
  - A. Manager of Ambulance station is responsible for paramedical drugs containing narcotics or psychotropic substances in ambulatory centers.  
If there is no Saudi pharmacist or Saudi technician in the center.

- B. The head of the ambulatory chamber is responsible for custody of ambulatory drugs containing narcotics or psychotropic substances in ambulance transport.
- C. The Minister of Health shall be adopting ambulatory drugs containing narcotics or psychotropic substances, their quantities and dosage forms of permitted in ambulatory cases.
- D. Ambulatory drugs containing narcotics or psychoactive substances are given in ambulatory cases according to the following:
  - 1. Paramedic drugs are given to injured by paramedics after taking the doctor's approval and determining the drugs and quantity.
  - 2. The empty package of drugs is returned to body of the drugs name of patient, name of doctor, time of contact, date, name of drug, the quantity, time of discharge, name of patient and signature of the patient are registry in custody register.
  - 3. If the prescribed amount of the infected person is less than one injection the paramedic administered drug and head of ambulance team supervised it had to destroy remaining amount and sign it in ambulance report.

◆ Article 25:

Family members are parents, children, brothers/sisters and husbands/wives.

◆ Article 26:

The minister of health shall be issues controls and instructions on the return and disposition of drugs containing narcotics or psychotropic substances, including narcotics and psychotropic substances that are administered from a government or private therapeutic institution.

◆ Article 27:

1. Application of provisions of chemical import and management law and implementing regulations to chemical precursors listed in table No. 3 to Law of Combating Narcotics and psychotropic Substances. Moreover, regarding to conditions and procedures for their import, export, manufacture, trade, abuse, renunciation or possession and control and competent bodies.
2. Competent bodies referred to in preceding paragraph of this Article shall be provide Ministry of the Interior general directorate of narcotic and psychotropic substances of with following:
  - A. Annual estimates of annual needs - Gregorian year -legitimate requirements for chemical precursors determined by Ministry of the Interior (general directorateof narcotic and psychotropic substances)
  - B. Copy from import & clearance License.
  - C. Purpose of these precursor chemicals and approximate amount required for this purpose.
  - D. Data and reports every three months on the following:
    1. Quantities consumed and the rest.
    2. Quantities produced and consumed.
    3. quantities damaged.
    4. Names and quantities of substances produced names of beneficiaries' body and their addresses and quantity of each body and for purpose of using these substances at each body.
    5. These quantities shall be in weight (kg, grams) or in size (liters, milliliters)

E. A statement at the end of each Gregorian year:

1. Total imported quantities (clearance) by weight or size and importing countries.
2. Total quantities exported by weight or size and country to which it is exported weight shall be net and does not include the weight of packaging or container.

F. A copy of violations reports for chemicals imports and its implementing regulation.

3. In addition to competent authorities provided for in chemical import law and its management coordinates Ministry of Interior (Directorate General for control of narcotics and psychotropic substances) with Saudi Food and Drug Authority, to control precursor chemicals and validation the data referred to paragraph (2) in Article (27) of this regulation.

4. Responsible for the custody of chemical precursors listed in table (3) Law of Combating Narcotics and psychotropic Substances Saudi pharmacist, Saudi chemist or Saudi technician or Saudi chemical technician.

◆ Article 28:

1. It is based on previous provisions before issuance of the narcotics or psychotropic substances regime in indictment and prosecution of crimes provided for in paragraphs (5-6) of clause (1) of Article (37) of Law of Combating Narcotics and psychotropic Substances.

2. Provision shall be including determination of criminal description and narcotic or psychotropic substance.



◆ Article 29:

1. The mosque shall be provided with a service establishments.
2. Considering sanctity and sanctity of the Two Holy Mosques.
3. Emphasis includes all places designed for education or training and activities arranged as well as affiliated establish and adjacent places.
4. Includes correctional institutions:
  - A. Role of timing.
  - B. Youth detention centers (juvenile correctional facilities) and prisons.
  - C. Role of guidance, observation and social care centers for girls.

◆ Article 30:

If judge decides to imprison the abuser of narcotics or psychotropic substances by, penalty shall not be exceeding maximum penalty provided in Article 41, paragraph (1), of Law of Combating Narcotics and psychotropic Substances.

◆ Article 31:

1. Hands over possession with abuse or addicts of narcotics of psychotropic substances to bodies to which he/she is applying. Although, seizure is confirmed if an official report prepared and handed over to DEA.
2. If drug abuse or addict's possession has not been handed over, he/she will be guided to the place and it is seized by police if there isn't DEA department.

3. Includes issues of narcotics or psychotropic substances - contained in paragraph (2) of the Article (42) of Law of Combating Narcotics and psychotropic Substances. Moreover, offences punishable under Article (41) of the same law If this is for abuse or personal use.
4. Investigation of use or possession of narcotics or psychotropic substances with intent to abuse or personal use at first time shall be preserved. This is in accordance with provisions of law of criminal procedure.
5. The body responsible for filing the investigation is obliged to inform DEA in region to register cases that are saved in a special register in accordance with paragraph (2) of Article (42) of DEA.

◆ Article 32:

1. An addict who proves his/her addiction with a medical report from a designated sanatorium.
2. Cases in which it is permissible to order the placement of the addict in the sanatorium:
  - A. Addict found guilty of offence of narcotics or psychotropic substances, but not accompanied by any other offence.
  - B. The addict who acquired, obtained, purchased or received narcotics or psychotropic substances intended only for use. Besides, do not over his/her need or for personal use.
  - C. Addict who captured by competent authorities based on a report or complaint.

3. The institution shall determine the duration of placement through a medical report as required by condition of therapy of addict, but not less than fifteen days.
4. The Addiction Commission submits its report on the addict to Law of the Bureau of Investigation and Public Prosecution including his/her social and health status and the length of medication he/she needs.
5. The Bureau of Investigation and Public Prosecution shall submit public case to competent court, including report of committee for consideration of addiction cases.
6. The addict is placed in the sanatorium by court order after the guilty verdict is issued.
7. Minimum duration of treatment is six months and not more than two years and the court may dispute the minimum period for fair reasons.
8. The filing does not benefit the following cases:
  - A. The addict who has already been to the sanitarium twice by court order.
  - B. A drug addict who has committed a crime during a period of in-house treatment, any of the crimes prescribed in the drug and psychotropic drug control system.
  - C. Excluded from Paragraph (A) from the last order of deposit three years ago.
9. Conditions of release:
  - A. The sanatorium releases the applicant after condition has been determined by a medical report, provided that commission for consideration of addiction status in writing.
  - B. If the applicant's condition requires an extension of the period of treatment, the sanatorium submits to the committee for the consideration of addiction cases a report on the case well before the end of the treatment period.
  - C. An extension order for a period or other period is issued by the judge, the source of the depositing order.

10. The order of treatment is revoked by the court at the request of Bureau of Investigation and Prosecution the basis of a report from the commission. This is done in the following cases:

- A. Lack of treatment.
- B. Violation of the duties imposed for treatment in the sanatorium.
- C. Violation of the sanatorium regulations and instructions.
- D. If the depositor commits any of the prescribed offences during the deposit Combating Narcotics Drug and Psychotropic Substances

◆ Article 33:

1. Tasks and terms of reference of the committee for the consideration of cases of addiction:

- A. Formation of sub-committees and define their tasks, terms of reference and procedures for the progress of work in them.
- B. Study the reports submitted by the subcommittees on cases of addiction and make recommendations to the National Narcotics Control Committee.
- C. Follow up on the performance of sub-committees and evaluate.
- D. Identify the authorized bodies to receive requests for treatment of addiction, whether from the addict himself / herself or one of the assets, branches, wife or husband or a relative. Controls on receiving such requests.
- E. Set the necessary controls to maintain the confidentiality of information as provided for in Article (51) of Combating Narcotics Drug and Psychotropic Substances.

2. The committee shall include in its membership representatives of the following bodies:

- A. Ministry of Interior.
- B. Ministry of Health.
- C. The Ministry of Social Affairs.
- D. The Bureau of Investigation and Public Prosecution.
- E. National Narcotics Control Commission.

3-Proceedings of the committee:

- A. The commission shall have a secretariat to coordinate the work.
- B. The venue of this committee shall be the headquarters of the National Narcotic Control Commission.
- C. The committee shall have a president for a period of three years, renewable only once, alternating between the Ministry of Interior and the Ministry of Health, and a Minister of Interior chooses the president in agreement with Minister of Health.
- D. Taking place this committee periodically every three months and may be convened at the request of the president when needed.
- E. Decisions of the committee shall be made by majority.
- F. The committee may seek the assistance of all those it sees as specialists in this matter.
- G. The general secretariat of the National Narcotics Control Commission supports work of the commission and its sub-committees' substance and technically.
- H. The committee has the right to add deems to facilitate the work.

◆ Article 34:

Narcotic drug and psychotropic substances referred to in Article ( 47 ) of Combating Narcotics Drug and Psychotropic Substances are the following substances and quantities.

Maximum allowable amount	Substance Name	
100 mg	Papaver Somniferum (Opium)	1
100 mg	Cannabis and Cannabis resin	2
1000 mg	Catha edulis (KHAT)	3
10 mg	Fentanyl	4
225 mg	Hydrocodone	5
150 mg	Hydromorphone	6
1 g	Methadone	7
1.5 g	Morphine	8
0.5 g	Oxycodone	9
6 g	Pethidine	10
6 g	Codeine	11
3 g	Dextropropoxyphen	12
6 g	Dihydrocodeine	13
0.5 g	Dronabinol	14
1 g	Methylphenidate	15
150 mg	Buprenorphine	16
0.5 g	Butalbital	17

Maximum allowance amount	Substance Name	
15 mg	Flunitrazepam	18
3 g	Pentazocine	19
1.5 g	Pentobarbital	20
7.5 g	Barbital	21
0.5 g	Chlordiazepoxide	22
300 mg	Clorazepate	23
150 mg	Diazepam	24
37.5 mg	Lorazepam	25
300 mg	Medazepam	26
20 g	Meprobamate	27
0.75 g	Oxazepam	28
1.5 g	Phenobarbital	29
0.5 g	Prazepam	30
300 mg	Temazepam	31
1.5 g	Tetrazepam	32
Ten tablets	AMPHETAMINES	33

2. The Ministry of the interior, in coordination with Minister of Health to amend the types and quantities of narcotic drug or psychotropic substances listed in the table contained in Paragraph (1) Above.

◆ Article 35:

The Ministry of Health, in coordination with the committee for the consideration of cases of addiction, determines the psychiatric clinics referred to in Article (50) Law of Combating Narcotics and psychotropic Substances.

◆ Article 36:

1. Confiscated substances mentioned in Paragraph (1) of Article (52) of the Combating Narcotics and Psychotropic Substances as adjust them to prove seizure report.

2. The Minister of Interior may remain in the control of the illegal narcotic drug or psychotropic substances seized until the date of their destruction or delivery to the Narcotics Control Department.

3. Formation of one or more committees according to Minister of Interior to destroy narcotic drugs or psychotropic substances confiscation involving a delegate from both:

1.Emirate region.

2.DEA

3. Court.

4.The Bureau of Investigation and Public prosecution

5.The body handled the seizure.

B. Controls and procedures for the destruction of confiscated narcotics or psychotropic substances shall be determined by Minister of Interior.

C- The Council of Ministers may reward members of the commission of destruction.

4. All or part of the confiscated narcotics or psychotropic substances may be handed over to any government body for scientific, industrial or medical purposes, in accordance with regulations issued by Minister of Interior.

◆ Article 37:

The competent executive bodies shall take the necessary measures to implement the provisions of Articles (55, 56 and 57) of the Law of Combating Narcotics and Psychotropic Substances.

◆ Article 38:

Exemption provided for in Article (61) of the Combating Narcotics and Psychotropic Substances shall be issued reasoned decision by the head of the Bureau of Investigation and Public Prosecution.

◆ Article 39:

Narcotic Drug and Psychotropic Substances Control managers, officers and Non-Commissioned Officers in the military sectors have the status of criminal restraint in the crimes provided for in the Law of Combating Narcotics and Psychotropic Substances within the sectors and establishment thereof. Although, to coordinate between them and the officials of criminal control and investigation in the competent authorities in drugs cases.

◆ Article 40:

Published these regulations in the Official Gazette and after thirty days from the date of publication.

## Procedures and Controls of Narcotics and Psychotropic Substances

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Article 1:

Procedures, and controls the registration of establishments for electronicsystem pharmaceuticals narcotic drug and psychotropic substances of Saudi Food and Drug Authority.

1. All licensed bodies import, export, acquire or trade narcotic drug or psychotropic substances by registering in the electronic system of narcotic drug and psychotropic substances of Saudi Food and Drug Authority through the internet as described in the user manual of the electronicsystem of narcotic drug and psychotropic substances and attached to these procedures and work under it.
2. In case that access to the electronicsystem for narcotic drug and psychotropic substances is not possible, all operations of narcotic drug or psychotropic substances are dealt with on paper until the return of the service.
3. All health bodies reinsert all operations of narcotic drug or psychotropic substances in the electronicsystem of narcotic drug and psychotropic substances during the period of interruption of electronic services.

Article 2:

**Procedures and controls for approving the annual requirement for narcotic drug and psychotropic substances:**

The annual requirement for narcotic drug or psychotropic substances is approved for the government and private sectors for the coming Gregorian year using the electronicsystem of narcotic drug and psychotropic substances based on the rotators entered into the electronicsystem.

In case of a request for a narcotic drug or a psychotropic substance that is not part of the annual need or in amounts greater than previously entered information, the justification for the addition or increase is clarified.

If you cannot access the electronic system for narcotics and psychotropicsubstances, the following steps are followed:

- 1.** All health bodies in Saudi Arabia for the public and private sectors raise their needs for the coming Gregorian year of narcotic drug or psychotropic substances to Saudi Food and Authority as indicated in paragraphs (2) to (3) of this Article, during the period from the beginning of January to the end of May of each year.
- 2.** The raising of the annual need estimate shall be as follows:

**A - Submission of a statement containing the following:**

1. Product generic name of narcotic or psychotropic effect, pharmaceutical form, concentration, size, required quantity and pure weight of the substance.
2. Trade name and packaging (only suppliers of narcotic drug and psychotropic substancesregistered and priced and licensed by Saudi Food and Drug Authority)
3. Names of products to be manufactured, quantities and pure weight of each substances manufactured (only for local pharmaceutical manufacture licensed by Saudi Food and Drug Authority)
4. Number of working families in the therapeutic institution.
5. Number of doctors and their specialties in the therapeutic institution.
6. Number of pharmacists.
7. Number of pharmacies affiliated to the establishment.

**B- The pure weight of the narcotic or the psychoactive substance in grams is calculated as follows:**

(Quantity × concentration in grams × (size in milliliters + packing coefficient) substances coefficient / 1000

(The substance is the coefficient of the file or ethers or Thio: any content property anhydrous pure as reported in the existing yellow or green International Narcotics Control Board) and

)The size and packing coefficient only for liquid substances)

**C- Attached to the request of need are the following:**

1. If the applicant is a government body:

The name of responsible for the custody of narcotic drug and psychotropic substances in the applicant must be determined, whether a pharmacist or a pharmaceutical technician and nationality.

2. In case the applicant is a private body:

- A. License issued by the Ministry of health or Saudi Food and Drug Authority or license issued by the Ministry of Environment Water and Agriculture. In case the substances required veterinary drugs containing narcotic drug or psychotropic substances.
- B. License pharmacist or pharmacist technician is a Saudi responsible for the custody of narcotic drug and psychotropic substances.
- C. If the requesting body is a warehouse or manufactory, the valid license shall be attached to both:
  1. The company imported from the Saudi Food and Drug Authority.
  2. Saudi pharmacist is the manager of the establishment in wholesale drug warehouses, pharmaceutical manufactures or pharmacies.
  3. Pharmacist or Pharmaceutical technician a Saudi responsible for the custody of narcotic drug and psychotropic substances.

3. Procedures and submitting the annual need estimation as follows:

- A. The establishments of the Ministry of Health, which are supervised by the General administration of medical supply, raise the estimates of their annual needs for narcotic drug or psychotropic substances to the medical supply department in the region or province. Although, to be audited and then submitted to the General Directorate of medical supply at the Ministry of Health, which, after its audit, sends the total of these needs to Saudi Food and Drug Authority.
- B. Pharmacy establishments and private therapeutic institutions licensed by the Ministry of Health raise their annual needs estimates of narcotic drug and psychotropic substances to the health Investment Development Department of Health Affairs in the region or province.
- C. The steroid pharmacy licensed and not from Saudi Food and Drug Authority and amphetamine-government non-Ministry of Health, and government establishment of the Ministry of Health and supervised by the General Administration of medical supply in the ministry and government establishment veterinary. In addition, raise estimates of its annual demand of narcotic drug or psychotropic substances to the branch of Saudi Food and Drug Authority in region or province (or Saudi Food and Drug Authority if there is not a branch of the Authority in region or province)
- D. Agents of narcotics and psychotropic substances registered and licensed by Saudi Food and Drug Authority submit their annual needs estimates to cover the demand of the local market (specifying quantities in case they are in favor of government bodies) to Saudi Food and Drug Authority.
- E. Local pharmaceutical plants licensed by Saudi Food and Drug Authority submit their annual needs estimates of narcotic drug and psychotropic substances used in manufacturing to Saudi Food and Drug Authority.

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- F. Veterinary private establishments are increasing their requirements for veterinary drugs containing narcotic drug or psychotropic substances to General administration of Livestock Services at Ministry of Environment Water and Agriculture region or province and scrutinize the needs approved requirements to branch of Saudi Food and Drug Authority in the region or province (or Saudi Food and Drug if there is not branch of the Authority in the region or in the province)
  - G. Saudi Arabian means of transport - contained in Article 2 of the regime for the Combating Narcotics Drug and Psychotropic Substances and its implementing regulations. By increasing its annual requirements for medical drugs containing narcotic drug or psychotropic substances for emergency and first aid to the government body responsible for the means of transport, to scrutinize and approve then to uploads total of these requirements. As well as the total projected requirements for non-Saudi Arabian transport requests to Saudi Food and Drug Authority.
4. The health Investment development department of the region, province or the branch of Saudi Food and Drug Authority in region or province after receipt of data on their respective needs to the following:
- A. Scrutinize these requirements and ensure that applicant's Rotators for the year prior to the year in which the requirement is circulated are complete.
  - B. Keeping the origin of need letter in registry.
  - C. Send a copy of the needs of narcotic drug and psychotropic substances to Saudi Food and Drug Authority.
  - D. Clarification of its opinion on the applicant's regularity and quantity.
  - E. If the governmental or private body has several health establishments, a separate requirement shall be raised for each establishment.

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5. After receiving the needs data from the concerned bodies above Saudi Food and Drug Authority reviews needs and compares them with annual consumption records. In order to ascertain the actual requirements, the applicant's Rotators for the year prior to the year in which the requirement is circulated are complete. Moreover, all these data are then kept as official documents on the needs of Saudi Arabia health services. The bodies are responded to in quantities that have been approved for them in the next year's requirements.
  
  6. Saudi Food and Drug Authority shall be transmitting to the International Narcotics Control Board (INCB) the total needs of Saudi Arabia not later than end of June of each Gregorian year.
  
  7. Saudi Food and Drug Authority and the Health Investment Development Department of region or province the Department of Health Affairs of the requesting body. Moreover, they have the right to accept request for need, to reject it or modify with an explanation the reason.
  
  8. Saudi Food and Drug Authority has opportunity to allow a government body to upload the total requirements of establishments.

◆ Article 3:

**Procedures and controls for issuing an import license for narcotic drug and psychotropic substances:**

The requesting bodies (beneficiaries) request the import of their approved needs from the beginning of January of the year of requirement until the end of September of the same year. the application is submitted through the electronicsystem of narcotic drug and psychotropic substances as explained in the User's manual for the electronicsystem for narcotic drug and psychotropic substances, annexed to these procedures.

2 . If you cannot access the electronicsystem for narcotic drug and psychotropic substances, the following steps are followed:

- A. The requesting bodies (beneficiaries) request the import of their approved needs from the beginning of January of the year of need until the end of September of the same year the application is submitted as usual in raising the need provided that application includes the following:
  1. Letter from the body applicant (beneficiary)
  2. To state in the letter the following:
    - A. Scientific and commercial name of narcotic drug or psychoactive substance, pharmaceutical form, concentration, size, quantity required and pure weight of the substance.
    - B. Name and address of the manufacturer and exporter in Arabic and English languages.
    - C. Name and address of the company imported in Arabic and English languages.
    - D. The address shall be Include the name of the country, city, neighborhood or district, street and building number.
  3. The request for the issuance of the import license is accompanied by the following:
    1. In case the applicant is a government body:
      - A. The name of the custodian of narcotic drug and psychotropic substances shall be specified in the requesting body and shall be a pharmacist or technician Saudi and his/her nationality.
      - B. If the import is through an importing company, the valid license is attached to:
        1. The company imported issued by Saudi Food and Drug Authority.

2. Saudi pharmacist is the manager of the establishment in the warehouses selling drugs wholesale.
3. Pharmacist or pharmacist technician Saudi responsible for the custody of narcotic drug and psychotropic substances in the company imported.

2 - In case the applicant is a private body:

- A. License issued by Ministry of health or Saudi Food and Drug Authority or the establishment license issued by the Ministry of Environment Water and Agriculture in case that substances required veterinary drugs containing narcotic drug or psychotropic substances.
  - B. Licensing of the pharmacist or pharmaceutical technician Saudi responsible for custody of narcotic drug and psychotropic substances.
  - C. If the requesting body is a warehouse or manufacturer, the valid license shall be attached to:
    1. The company imported issued by the Saudi Food and Drug Authority.
    2. Saudi pharmacist director of establishment in wholesale drug warehouses or pharmaceutical manufacturer or pharmacies.
    3. Pharmacist or pharmacist technician Saudi responsible for custody of narcotics and psychotropic substances.
3. The import license may be issued after September under the following conditions:
    - A. Import shall be done before the end of the year - end of validity of import license-
    - B. Shall not be clearance if substances arrive the exception to this is paragraph ( E ) of No. 1 in Article ( 5 ) of these procedures and controls.

C. The remaining substances to be imported are not sufficient to cover the consumption of the establishment until the end of the year of the required need, based on the monthly consumption rate.

4. The import license may be issued for approved annual requirement prior to its commencement under the following conditions:

- A. Submit the application - as the practice of submitting need - after the end of October for the year prior to need and explain justification for the request.
- B. The applicant shall be applied in full for the year prior to the need.
- C. The remaining substances required to be imported are not sufficient to cover the consumption of establishment until end of the first month of year of the need, based on monthly consumption adjustment.
- D. Import shall be done at the beginning of the validity of the import license.
- E. The validity of the import license is from the beginning of the year of need and not from the date of issuance.
- F. Shall not be clearance in the substances of access to customs prior to the entry into force of the import license.

5. An import license may be issued in full or part of the approved requirement and for all or some clause.

6. Narcotics or psychotropic substances contained in the import license may be imported in several batches and for all or certain clause unless otherwise indicated in the license.

7. An import license may be issued for a narcotic drug or psychoactive substance in a dosage form or in a concentration or size. Although is not include the approved annual need of the establishment under the following conditions:

- A. Clarification of the rationale for the request.
  - B. The establishment shall have a certified need for the same product generic name of the required substance and a sufficient weight to deduct the required amount of it.
8. The import license for narcotics and psychotropic substances is granted to registered and reputable drugs agents approved by Saudi Food and Drug Authority. In case the authorized agent is unable or not required to supply narcotic drug or psychoactive substances, the beneficiaries bodies may request the import of such drugs in accordance with the following:
- A. Submission of the agent's letter of apology or proof of non-compliance with the provision of registered and priced drugs.
  - B. There's not alternative product registered in Saudi Food and Drugs Authority.
  - C. The required product to import must be registered and marketed in the country of origin.
  - D. The manufacturer company is recorded in Saudi Food and Drug Authority. Failing that manufacturer's registration requirement may be waived approval of the executive vice president of the pharmaceutical sector at Saudi Food and Drug Authority.
  - E. Trafficking in imported unregistered preparations is prohibited. Moreover, it may not be loaned, exchanged or ceded to the importer except after receiving the approval of Saudi Food and Drug Authority.
9. In case of loss or damage of the import license, the applicant body shall be explaining the reasons of loss or damage and bring the original of license if possible. Moreover, pledge to return the lost license as soon as it is found and when accompanying the application, it is issued a license instead of the lost.

10. In case of requesting compensation for withdrawn, recovered, damaged or re-exported quantities from Saudi Arabia the applicant body shall attach proof. Upon approval of the application an import license is issued in the required compensatory quantity which is referred to in license.

11. In case of completion of the reasons and conditions of the import license application. It issues a license to import narcotic drug or psychotropic substances. In the name of director of controlled products department at Saudi Food and Drug Authority.

12. In case the beneficiary body cancels the import request. Moreover, it shall report this to Saudi Food and Drug Authority in a maximum period of two weeks from date of cancellation via e-mail management products controlled by Saudi Food and Drug Authority and return origin of the license to be revoked if possible.

13. The import license instructions shall be determined by Saudi Food and Drug Authority and shall be printed in the license.

14. Requests for the import of standard substances containing narcotic drug or psychoactive substances shall be dealt with governmental and private sector treatment of narcotic drug and psychotropic substances.

15. Saudi Food and Drug Authority and Health Investment Development Department in region or province of applicant body. Besides, right to accept an application for the issuance of an import license or rejection or suspension, with explanation of the reason.

16. The bodies listed in article (second) of the implementing regulations on the control of narcotics and psychotropic substances insurance of its needs for medical drugs containing narcotic drug or psychotropic substances in its transport.

Emergency response and first aid through direct purchase from the pharmaceutical agent or local pharmaceutical manufacturer licensed by Saudi Food and Drug Authority as stated in paragraph (K) of No. 2 in Article (7) of these procedures and controls.

◆ Article 4:

**Procedures and controls for issuing an export license for narcotic drug and psychotropic substances:**

1. The applicant body shall be submitting the request to Saudi Food and Drug Authority which shall include:

- A. Clarification of the purpose of export.
- B. Origin of valid import authorization issued by country to be exported.
- C. Provide a copy of valid license issued by Saudi Food and Drug Authority for each of the:
  1. Special establishment issued by Saudi Food and Drug Authority.
  2. Saudi pharmacist establishment manager.
  3. Pharmacist or technician pharmacist Saudi responsible for the custody of narcotic drug and psychotropic substances.

2. If the reasons and conditions of the export license application are complete. Besides, license is issued in the name of director of the controlled product department at Saudi Food and Drug Authority

3. The instructions of the export license shall be specified by Saudi Food and Drug Authority to be printed in the license.

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4. May the export of narcotic drug and psychotropic substances contained in import license issued by the country to export. In several instalments and for all or certain clause unless otherwise indicated in the license.
  5. Applications for export of standard substances containing narcotic drug or psychoactive substance for governmental and private sectors shall be treated as narcotics and psychotropic substances.
  6. Requests for re-export shall be treated in accordance with the following:
    - A. Justification for re-export request.
    - B. Return to the same destination in the exporting country.
    - C. Submission by the competent bodies of the exporting country of a mechanism for approving re-export.
    - D. It is a non-corrupt and undeterred drug.
    - E. Remove any logo or information pertaining to the registration or price in Saudi Arabia.
  7. Export license is only granted to pharmaceutical agents and local pharmaceutical manufacturer and warehouses selling drugs wholesale only. Exception the head of Saudi Food and Drug Authority to permit the export of any establishment listed in article (thirteen) of Combating Narcotics Drug and Psychotropic Substances Law when the need arises.
  8. The sector which issue permission should clarify reasons for loss and damage, and bring original license if possible. Also, pledge of returning license to the missing if it found. Besides, when an application approved, it re-issues the lost license.

9. In case of request for compensation for withdrawn, recovered, damaged or re-exported quantities to Saudi Arabia the applicant body shall attach proof of this. Moreover, upon approval of the application, the applicant body shall issue an export license for the required amount of compensation, which shall be indicated in the license.
10. Saudi Food and Drug Authority has right to accept the request to export license, reject it or modify it with an explanation.

◆ Article 5:

**Procedures and controls for the issuance of clearance license for narcotics and psychotropic substances and export authorization:**

**1. Clearance of imported narcotics and psychotropic substances:**

- A. Upon receiving of narcotics and psychotropic substances to the customs one of the airports in Saudi Arabia. In addition, importers apply for clearance through the electronic system for narcotics and psychotropic substances as described in the user manual of the electronic system and attached to these procedures.
- B. If the electronic system is not accessible for narcotics and psychotropic substances, the following steps are followed:
  1. Upon receipt of narcotics and psychotropic substances to the customs one of airports in Saudi Arabia importing body shall submit the clearance application to the branch of Saudi Food and Drug Authority in the customs, the request is accompanied by the following:
    - A. Import copy license and a copy of the export license issued by the exporting country if any

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- B. Bill of lading copy indicating the policy number, date, source country and the name of the arrival customs port.
  - C. Origin certificate establishing (or a copy of the certificate establishing that bring original copy within thirty days from the date of issuance of license clearance) signed, sealed and certified by the Saudi Embassy or Chamber of Commerce in the country of establishment. Moreover, stating the name and address of the manufacturer and exported and data for narcotic drug or psychoactive substance contained in the import license, operational number, production date and validity if possible, the invoice number and date.
  - D. The invoice original (or shall be brought a copy within thirty days from the date of issuance of clearance license) signed, sealed and certified by the Saudi Embassy or the Chamber of Commerce in the export country indicating the following:
    - 1. Invoice number and date.
    - 2. Name and address of manufacturer and exporter.
    - 3. Scientific and commercial name of narcotic drug or psychoactive substance pharmaceutical form, concentration, size, packaging and quantity.
    - 4. Lot Number, production date and validity, the remaining validity shall be at least two thirds of the validity period.
    - 5. Price of narcotics or psychotropic substance registered with the Saudi Food and Drug Authority. In case the substances are for the benefit of pharmaceutical agents to cover the demands of the local market

- E. Shall be submit a letter agreeing to accept the receipt of the narcotic drug or psychoactive substance from the beneficiary body when the remainder of the validity is less than two thirds of the validity period. In addition, narcotic drug and psychotropic substance registered and priced to cover local market applications shall be at least two thirds of the validity period. Saudi Food and Drug Authority may descend the minimum period remaining in validity whenever the need arises.
- F. Upon approval of the application, the clearance license shall be issued in the under-branch director of Saudi Food and Drug Authority at the customs port. Then the original license is returned to Saudi Food and Drug Authority without this license, narcotic drug or psychotropic substances may not be released.
- G. The clearance license may be issued for substances that reach the customs port after a maximum of two weeks from the expiration date of the import license. In addition, provided the export license and the certificate of establishment have been issued by responsible authorities in country of export before the expiration date of the import license.

## **2 - Export authorization for narcotics and psychotropic substances.**

- A. The exporting body shall submit the request for export authorization. The branch of Saudi Food and Drug Authority shall submit the customs port through which to export (or Saudi Food and Drug Authority if there is not a branch of Authority in the region or prefecture) the application is accompanied by the following:

1. Export license copy approved by Saudi Food and Drug Authority.
2. Bill of lading copy indicating the number of bills, its date and arrival customs in the exporting country.
3. The original invoice is signed and sealed with the following:
  - A. Invoice number and date.
  - B. Name and address of manufacturer and exporter.
  - C. Product generic and trade name of narcotic or psychoactive substance, dosage form, concentration, size, packaging, quantity and pure weight of substance.
  - D. Batch Number, production date and validity.
4. If the request is re-export, the approval of Saudi Food and Drug Authority to re-export shall be attached.  
B. After approval of the application, export authorization under branch director of Saudi Food and Drug Authority at customs port (or the Saudi Food and Drug Authority if there is not Authority branch in region or province). It is sent to the Customs Administration, which does the notation actual issuer then returns the origin of the license to Saudi Food and Drug Authority. Moreover, without this permission, narcotic drug or psychotropic substances may not be exported.

### **3- General procedures and controls:**

- A. The validity of the clearance license and export license is three months from the date of issue.
- B. The instructions for the clearance license and export authorization shall be specified by Saudi Food and Drug Authority and to be printed in the license.

- C. Applications for clearance and export of standard substances containing narcotic drug or psychoactive substance for the government and private sectors shall deal with narcotics and psychotropic substances.
- D. In case of loss or damage of the license or export permit, the requesting parties shall explain the cause of loss or damage, bring the original license or permission if possible or pledge to return it once found. If the application is approved, clearance license or export permit is issued as a lost allowance.
- E. In case of request for clearance license renewal or export permit for expiry of clearance license or export permit the applicant shall be explain the reasons for renewal application and bring original license. Moreover, upon approval of the request, issued clearance license or exported only once and for only one month.
- F. Saudi Food and Drug Authority has the right to accept, reject or modify the application for issuance of clearance license or export permit with an explanation of the reason.

◆ Article 6:

**Procedures and controls for the clearance of drugs containing narcotics or psychotropic substances in the possession of patients coming to or leaving Saudi Arabia for personal use or in the possession of Hajj missions and official government bodies (only) coming to Saudi Arabia or departing from them for the use of patients who are belonging to the mission:**

- 1. International and local prohibited substances must not granted the clearance.

2. It is forbidden to allow the drugs clearance in category (D) in table (1) , and category (a) in table (2)of the Law Combating Narcotics Drug and Psychotropic Substances tables . Moreover, the substances referred to in paragraph (4) of psychotropic substances in the tables of the regime Law Combating Narcotics Drugs and Psychotropic Substances.

3. A request for clearance shall be submitted to branch of Saudi Food and Drug Authority at the customs port, which shall arrive through (or Saudi Food and Drug Authority if there are not a branch of the Authority in the region or province).

4. Drugs containing narcotics or psychotropic substances shall be disclosed to incoming patients.

5. Drugs in possession of patients arriving in Saudi Arabia shall be allowed for personal use under the following conditions:

A. Attach a detailed and certified medical report from the institution in which the patient is treated not more than six months have passed since the date of its publication, the report should include the following:

1. Personal information about the patient.
2. Medical diagnosis.
3. Treatment plan and duration.
4. Medical recommendations.
5. Product generic name of the drug, dosage form and prescribed dosage.

B. The other condition is attaching a prescription in the patient's name approved by the same therapeutic institution. Moreover, it has not been issued for more than six months and include the following information:

1. Patient diagnosis.
  2. Product generic name of the drug, dosage form and prescribed dosage.
  3. Method of use and duration of treatment.
  4. treatment institution sealed.
- C. Pledge to use drugs only on the patient and on his/her responsibility and attaching a copy of the patient's identity.
- 6.The drug clearance is approved in an sufficient amount for thirty days maximum or duration of a patient's stay in Saudi Arabia whichever is less. Besides, Authority has the right to waive the condition requirement in case the required drug or alternative is not available in local market. The validity date of the drug shall be valid, and shall take into account the following:
- A. If the amount of the drug is exhausted, the patient shall be consulting a specialist doctor to practice the profession in a therapeutic institution to make sure that he/she needs to continue on the same drugs.
  - B. In case the doctor confirms that the patient needs to continue the same treatment, a medical file is opened for him/her at the same therapeutic institution the appropriate drug is prescribed by a prescription approved by the same therapeutic institution and dispensed from a local pharmacy. Although, if the drug is trade in the local market for the required time and the patient continues to review the same therapeutic institution to continue to obtain the drugs if his / her medical condition so requires.
  - C. If the required drugs or a suit is not provided on the local market, the treatment institution in which the patient is reviewed may secure this treatment through the drug distributors after receiving Saudi Food and Drug Authority approval.

7. If the drug is in the form of an injection, clearance is approved supervised by a local therapeutic institution in the patient's name. Although, the drug shall be registered within the hospital registry for personal use according to the applicable system of these drugs.

8. If the amount of clearance drug required exceeds the patient's need, the remaining amount will be destroyed.

9. Patients leaving Saudi Arabia shall be treated as incoming patients in accordance with paragraphs 1, 2 and 5 of this Article. Moreover, in sufficient quantity for a maximum of ninety days, subject to the requirements and regulations of the countries to be visited.

10. If the drugs are not in the possession of the patient, but in the possession of a relative (parents, children, brothers, husband/ wife) have a copy of his/her identification. Although, if it is in the possession of a person on his/her behalf shall be attach proof that patient agreed to bring drugs and have a copy of identification.

11. If drugs containing narcotics or psychotropic substances are in the possession of Hajj missions or only official government bodies coming to Saudi Arabia for use of mission patients, they are treated as follows:

- A. The mission will submit a clearance request to Saudi Food and Drug Authority branch at customs port where the drugs will arrive.
  - B. Identification the head name of mission and the name of the pharmacist or pharmaceutical technician accompanying the mission responsible for the custody of narcotic drug and psychotropic substances and if not, the custody shall be under the name of doctor accompanying the mission.
  - C. Determination of the number of mission personnel.
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D. Attached to the application is the following:

1. Statement of application drugs, approved by competent authorities of the mission countries including the product generic name of the narcotics and psychotropic substances, pharmaceutical form, concentration, size and quantity required.
2. Pledge to limit the use of drugs only to mission personnel and their responsibility and will not be sold or disposed of in any way and the remaining damaged or used and all packaging will be returned with the mission upon return. Moreover, provide the statement of the expense and the reason for the exchange and the remaining and damaged before the mission leaves Saudi Arabia to Saudi Food and Drug Authority branch at the customs port.

E. The mission shall contain a medical center or doctor and the application drugs shall be under the responsibility of head of mission.

F. The application drugs shall be free from internationally or locally prohibited substances in Saudi Arabia.

G. Import of drugs containing narcotics or psychotropic substances by air transportation only.

12. Upon approval of application, the clearance license is issued from Saudi Food and Drug Authority branch at customs port.

13. Saudi Food and Drug Authority branch in the region or province which the drugs will arrive at customs port. Besides, Authority has the right to accept reject or modify the application with explanation of reason.

14. At the time of mission's departure from Saudi Arabia shall be provide copy of expense statement, the reason for the exchange and the remaining and damaged.

◆ Article 7 :

**Procedures and controls for the sale and delivering of narcotics and psychotropic substances:**

**1. Procedures and controls for the delivery of narcotic drug and narcotic substances to the customs port as follows:**

- A. If it is imported directly by the beneficiary body, it receives the substances from the customs under clearance license.
- B. If the import by a pharmaceutical agent or an importing company for the benefit of another body receives substances from customs under clearance license. Besides, to be transferred to beneficiary body in a maximum period of fifteen days from the date of receipt of the substances from customs port. The branch of Saudi Food and Drug Authority in the region or province shall provide beneficiary body (or Saudi Food and Drug Authority if there is not a branch of Authority in region or province). In the form of a seizure report of the substances delivery to the beneficiary body may receive drugs directly from customs if it desired, subject to approval of the importer.
- C. Receives narcotics and psychotropic substances at customs port custodial responsibility of narcotics and psychotropic substances, pharmacist or pharmaceutical technician of Saudi Arabia authorized body to import or beneficiary.
- D. If narcotics or psychotropic substances have been received at the customs port without an import license, such substances shall be confiscated and dealt with in accordance with Article (52) of Law of Combating Narcotics and Psychotropic Substances.

And Article (36) of implementing regulation and Article (17) of these procedures and controls and apply to the importer incoming provisions in Law of Combating Narcotics and psychotropic Substances and implementing regulation.

E. In case substances are narcotics or psychotropic substances it was received to customs port before the import license to expire or after the expiration of the imports license except as aforesaid in paragraph (5) of No. (1) in Article (59) of these procedures and controls, they are re-exported or destroyed in accordance with the destruction procedures contained in Article (16) of these procedures and controls.

The Saudi Food and Drug Authority may allow the clearance of these substances and grant them to a governmental body designated by the Authority. The body shall be provided with a copy of the record of the delivery of such substances to the government body within two weeks of the date of approval.

H. In the case of narcotics or psychotropic substances received by the customs port or clearance and delivered by the importer to the beneficiary body the damaged or expired or in an incomplete or excessive amount or not conforming to the specifications and conditions approved by Saudi Food and Drug Authority. Moreover, not conforming to the specifications and the conditions under the beneficiary body was ordained shall be subject to the following actions:

1. Report signed by the customs who represent Saudi Food and Drug Authority branch at the customs port is responsible for criminal control and Saudi pharmacist or Saudi technician responsible for custody of narcotics and psychotropic substances in the importing body. Although, substances are delivered to the importer body to provide Saudi Food and Drug Authority.

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A copy of report. In case the substances are delivered by the importing body to the beneficiary seizure report are signed by the pharmacist or technician who is authorized to accompany the container a pharmacist or technician Saudi is responsible for the custody of narcotics and psychotropic substances in the beneficiary establishment.

2. The importer body shall be obliged to:

- A. Damaged or expired substances will be destroyed by a regulator methods of destruction, Saudi Food and Drug Authority shall be provide with a copy of the destruction report.
- B. Excess quantities or substances not in conformity with specifications and conditions approved by Saudi Food and Drug Authority or which does not comply with the requirements and conditions established for the beneficiary body. Although, it may only be disposed of after the approval of Saudi Food and Drugs Authority, which has the right to require the granting of such substances to a governmental body designated, re-exported or damaged or cleared according to the rules followed. The Authority shall be entitled to export excess quantities and treat them in accordance with Article (Fifty-second) of the Law of Combating Narcotics and Psychotropic Substances, Article (thirty-sixth) of implementing regulation and Article (seventeenth) of these procedures and controls.

**2. Procedures and controls for the sale of registered and priced narcotics and psychotropic substances from pharmaceutical agents or local pharmaceutical manufacturing licensed by the Saudi Food and Drug Authority to other establishments, as follows:**

- A. The drugs agent or the local pharmaceutical manufacturer shall submit the application for approval of the sale and transfer of narcotics and psychotropic substances to the beneficiary establishment.

The electronic system of narcotics and psychotropic substances as described in the user manual of the system attached to these procedures.

B. If it cannot log in the electronic system for narcotics and psychotropic substances, the following steps are followed:

1. The beneficiary establishment shall submit application for approval of the purchase from the drugs agent or the local pharmaceutical manufacturer to the branch of the Saudi Food and Drug Authority in the region or province affiliated to the application body (or Saudi Food and Drug Authority if there are not a branch of the Authority in the region or province). Moreover, pharmacy establishments and private therapeutic institutions licensed by the Ministry of Health submit the application to the health Investment Development Department region or province.

2. Attached to the request is a copy of the valid licenses for:

- A. Pharmaceutical establishment or private therapeutic institution issued by the Ministry of Health or Saudi Food and Drug Authority or the establishment license issued by the Ministry of Environment Water and Agriculture in case the required substances contain narcotic drug or psychotropic substances.
- B. Pharmacist or technician Saudi responsible for the custody of narcotic drug and psychotropic substances the government bodies mention the name and qualification of the pharmacist or pharmaceutical technician a Saudi responsible for the custody of narcotic drug and psychotropic substances.

C .Saudi pharmacist manager of the selling establishment (drug agent or local pharmaceutical manufacturer) and the pharmacist or technician pharmacy Saudi responsible for the custody of narcotics and psychotropic substances.

**3 -** The application shall state the following:

- A. The name of the local pharmaceutical manufacturer or the drug agent to be purchased from.
  - B. Scientific and commercial name of narcotic drug, psychoactive substance, pharmaceutical form, concentration, size and packaging.
  - C. Quantity to be purchased.
4. The establishment shall have an annual requirement approved by Saudi Food and Drug Authority that covers the quantity to be purchased.
  5. In case of approval of the purchase, the requesting body shall hand over the approval to the drug agent or the local pharmaceutical manufacturer and keep a copy of it in the custody record.
  6. The validity period of the approval of purchase is three months from the date of issue.
  7. Quantities approved for purchase are deducted from the beneficiary body annual requirement.
  8. In case the beneficiary body is a government establishment, the number and price of the substances drug printed on the packages shall be written off and prove it in the delivery signed by custodial responsibility of the seller and custodial responsibility of beneficiary body. Although, Saudi Food and Drug Authority branch in the region or province shall provide the beneficiary body (or Saudi Food and Drugs Authority if there is not a branch of Authority in region or province)

A copy of this statement in two weeks from the date of purchase and the original is preserved in the custody record in the seller's establishment and a copy of it in the custody record in the beneficiary body.

9. Injections of narcotics and psychotropic substances may not be sold to local pharmacies licensed for retail trade by the Ministry of Health.

10. The means of transport, which are contained in Article 2 of Law of Combating Narcotics and psychotropic Substances and its implementing regulation, shall not apply for approval of the purchase of medical drugs containing narcotics or psychotropic substances in its transport emergency response and first aid or local pharmaceutical manufacturer. Moreover, to submit the application to Saudi Food and Drug Authority branch in the region or province (or Saudi Food and Drug Authority if there is not branch of Authority in the region or province). Besides, the refuse the request of the approval letter from the government body responsible for modes of transport, including the names of the drugs and the quantities and discount amounts sold protest the government body in charge of modes of transport.

11. Shall be provide the branch of Saudi Food and Drug Authority (or Saudi Food and Drug Authority if there is not a branch of Authority the region or province) or Department of Health Investment Development in the region or province affiliated to the requesting body. Besides, each regarding a copy of the sales invoice from the drug agent or the local pharmaceutical manufacturer, and a copy of the official delivery record including the data of the drug sold, its operation number, date of production, validity, name and signature of the recipient and the seal of the requesting body, within two weeks from the date of purchase.

12 .The health Investment Development Department conducts health affairs in each region or province provide general administration of mental health and social basis of the approval of the purchase of psychotropic substances only.

13. Saudi Food and Drug Authority, and the Department of Health Investment Development in the health affairs of the region or province, all in respect of, the right to accept, reject or modify the application with an explanation of the reason.

**3 - The procedures and controls for the delivery of narcotics and psychotropic substances registered and priced from drug agents or local pharmaceutical manufacturer licensed by Saudi Food and Drug Authority to the beneficiary body are as follows:**

- A. In case the beneficiary body is the one who will receive the substances directly from the drug agent or the local pharmaceutical manufacturer, the substances will be disbursed to the beneficiary body in accordance with the procedures and exchange controls contained in paragraph (9) of Article (13) of these procedures and controls.
- B. In case that the local drug agent or pharmaceutical manufacturer will deliver the substances to the beneficiary body directly, it is when the delivery of narcotics or psychotropic substances or when there is a damaged or expired or in excess quantity or not conforming to the specifications and conditions approved by Saudi Food and Drug Authority or not conforming to the specifications and conditions that have been docked in the beneficiary body shall take the following measures:
  - 1. - A document signed by a pharmacist or technician authorized and accompanying the container, and from pharmacist or technical a Saudi in custodial responsibility of narcotics and psychotropic substances in the establishment.

Beneficiaries. Saudi Food and Drug Authority branch of its region or province provides the beneficiary body (or Saudi Food and Drug Authority if there is not a branch of a Authority in the region or province) with a copy of the record.

2. Substance damaged or expired or excess or non-conformity with the specifications and conditions of the treaty being Saudi Food and Drug Authority or shoddy and conditions that have been demarcation by the recipient, sent back to the agent of drug or pharmaceutical manufacturer local.
3. The local pharmaceutical agent or manufacturer must comply with the following:
  - A. Broken, damaged or expired substances are destroyed according to the systematic methods of destruction.
  - B. Substances non-conformity with the specifications and conditions approved by Saudi Food and Drugs Authority shall not be disposed of only after approval from Saudi Food and Drugs Authority which is not right in the requirement for the granting of such substances to a governmental body challenging or destroyed by the practice Law. The Authority has the right to confiscate excess quantities and treat them in accordance Article (Fifty-second) of the Law of Combating Narcotics and Psychotropic Substances, Article (thirty-sixth) of implementing regulations and Article (seventeenth) of these procedures and controls.
  - C. Excess quantities or substance that are not in accordance with the specifications and conditions have been awarded to the beneficiary body, the agent or the local pharmaceutical manufacturer may dispose of them according to the regular methods.

**4 - Procedures and controls the sale of drugs, narcotics and psychotropic substances registered and quoted in private pharmacies licensed by the Ministry of Health and allowed to sell drugs, narcotics or psychotropic substances, as follows:**

- A. The management of development and investment, Health Affairs health in each region or province for approving applications for private pharmacies licensed to allow for sell narcotics and psychotropic substances.
- B. Upon approval of the license application, the health Investment Development Department of Health Affairs in the region or province shall provide the Saudi Food and Drug Authority with license copy.
- C. Sale in licensed private pharmacies is limited only to narcotic drug and psychotropic substances registered and priced as determined by Saudi Food and Drug Authority.
- D. The sale is only for patients with systemic prescriptions.
- E. Before dispensing drugs to the patient, the pharmacist shall be fill in all the required data in the dispensing of narcotics and psychotropic substances for patients and the electronic system for narcotics and psychotropic substances shall be inquire about the patient before that to make sure the patient has never been disbursed the same drugs or that he/she remained on the end of the treatment period of the previous prescription disbursed to the patient more than seven days.
- F. Injections of narcotics or psychotropic substances shall not be sold.
- G. The dispensing of drugs to the patient is carried out in accordance with the procedures and controls contained in paragraph (6) of Article (13) of these procedures and controls.

◆ Article 8:

Procedures and controls for the disposal of narcotics and psychotropic substances in the therapeutic institution:

1. The disposition of narcotics and psychotropic substances is limited to loan, waiver or replacement between therapeutic institutions only. Through an electronic system for pharmaceutical narcotics and psychotropic substances as described in the user manual attached to this procedure.
2. If the establishment is liquidated, sold or temporarily closed, the establishment may then dispose of narcotics and psychotropic substances in accordance with Paragraph ( 8 ) of this Article.
3. If the electronic system for narcotics and psychotropic substances cannot be accessed, the request for loan, waiver or replacement shall be submitted by the beneficiary establishment to the Competent Authority of the region or province affiliate. The Competent Authority has the right to accept, reject or modify the application, explaining the reason for this according to the following steps:
  1. The Competent Authorities in considering the request for loan, waiver or replacement are:
    - A. Investment Development Department for Health Affairs in the region or provinces and specializes in applications between pharmacy establishments and private therapeutic institutions licensed by the establishments.
    - B. The General Administration of medical supply at the Ministry of Health specializes in the applications between the government establishment supervised by Ministry of Health.

- C. The branch of Saudi Food and Drug Authority of region or province (or Saudi Food and Drug Authority if there is not a branch of the Authority in the region or province) and all other requests between establishments of the region or province affiliate.
- 4. Saudi Food and Drug Authority - whenever the need arises - allow a government body to approve requests for borrowings, waivers or replacements between establishment.
- 5. The procedures and controls for submitting a loan, waiver or replacement request are as follows:
  - A. Submit the consent request including the following:
    - 1. Explain the reasons for requesting a loan, waiver or replacement.
    - 2. The application shall be including the following data:
      - A. Scientific and commercial name of the drug.
      - B. The dosage form of the drug.
      - C. Concentration and size of the drug packaging.
      - D. Lot number, production date and validity.
  - 3. Official letter of approval from the authorized, ceded or substituted establishment to the requesting establishment indicating the substances and quantities approved.
  - 4. Letter of consent of the Competent Authority of the authorized, ceded or substituted. In case that the two establishment do not belong to the same Competent Authority.
  - 5. In case the applicant is a government body, the name and qualification of the pharmacist or technician a Saudi responsible for the custody of narcotics and psychotropic substances shall be attached.

6. If one of two establishments are a private, the application shall be accompanied by:

- A. A copy of the valid license issued by Ministry of health or Saudi Food and Drug Authority or the license issued by Ministry of Environment Water and Agriculture in case the required substances veterinary drugs contain narcotic drug or psychotropic substances.
- B. A copy of the valid license of a Saudi pharmacist or technician responsible for the custody of narcotics or psychotropic substances.
- C. A copy of the purchase order for narcotics or psychotropic substances loaned or waived, indicating the price.

7. Submit a letter of approval from General Administration of Livestock Services at the Ministry of Environment Water and Agriculture in region or province in case substances the required veterinary drugs contain narcotics or psychotropic substances.

- A. The requesting establishment shall have applied for the import of its approved requirement.
- B. The amount to be borrowed or assigned shall not exceed 25 % of the approved requirement of the requesting establishment.
- C. The remainder of the required substances to be borrowed or waived is not enough to cover the consumption of the requesting establishment for a month based on the monthly consumption rate.
- D. In case of approval of the loan application or waiver and replacement, its validity is only one month.
- E. Provide the Competent Authority of both establishments with a copy of the delivery seizure report, and a copy of the delivery report to return the loaned quantities when returning them to the authorized establishment.

- D. In case the borrowed, ceded, replaced or returned substances are not registered and priced in Saudi Food and Drug Authority the private establishment shall be sell the drug at the same price as the purchase order of the loaned, waived or replaced establishment.
  - E. The establishment may not dispose of drugs borrowed, replaced or assigned to any other body when does not need them. Although, they are damaged in accordance with Article (16) of these procedures and controls.
  - F. The borrowed quantities shall be returned to the loaned establishment within a period of not more than six months from the date of receipt of the borrowed quantity.
  - G. The loaned establishment may replace the loaned substances with other in the same quantity or in a different quantity after receiving the approval of the loaned establishment and Competent Authority both establishments.
  - H. The loan, assignment or replacement shall not be for money.
  - I. The data of loaned, ceded or substituted substances shall be restricted in the registers and records of both establishments.
  - J. If one of the two establishments is a private licensed by Ministry of Health, the General Administration of mental and social health shall be provided with a form of approval for loan, waiver or replacement.
6. In the case of excess quantities or stagnant items-the balance of which has continued without movement for a year - of narcotics and psychotropic substances, the following follows:

- A. The establishment coordinates with the affiliated establishments or other health body or circulates them to the health bodies in Saudi Arabia.
- B. In the case of a demand for these stagnant, they are treated as loan, assignment or exchange requests based on the agreement between the two establishments.
- C. Re - circulate every six months until the entire amount is disbursed or becomes damaged according to the Article (16) of these procedures and controls.

7 - The approval of Saudi Food and Drug Authority shall be taken before approving an application in the following cases:

- A. Repeat the request for loan, return, replacement or waiver for more than twice a year in either of the two establishments.
- B. If the required quantity is more than 25 % of the approved requirement.
- C. There is no annual requirement for the required clauses in either establishment.

8. In case of liquidation or temporary closure of establishment, the inventory of narcotics and psychotropic substances an inventory record by a committee constituted for a resolution by branch director of Saudi Food and Drug Authority in region or province of the establishment or the deputy (or, executive vice president of Saudi Food and Drug Authority, or the delegate if there is not Authority branchy in region or province). Although, the pharmaceutical establishments and private therapeutic institutions licensed by the Ministry of Health, the resolution shall be by director of health Investment Development Department in the health affairs of the region, or the province affiliated to the establishment or from the deputy and the inventory committee shall be composed of:

- A. Establishment manager or deputy.
- B. Responsible for the custody of narcotics and psychotropic substances.
- C. Delegate from the Department of Health Investment Development in the health affairs of region or province.

These substances are disposed of in one of the following ways:

- 1 - Transferred to the custody of another establishment of the same body.
- 2 - Return it to the agent warehouse or the local manufacturer supplying these drugs after submitting approval.
- 3 - If the requesting establishment is a warehouse or drug agent or a local pharmaceutical manufacturer, it can be re-exported to the importer after submitting a formal approval letter from Competent Health Authorities in the exporting country.
- 4 - Sell it promptly to a government therapeutic institution or sell it to a pharmacy or a private therapeutic institution provided that these drugs are registered and priced, provided that amount is deducted from the need of the beneficiary body.
- 5 - Loan it to any government or private medical institution licensed in accordance with the borrowing procedures provided the reason for submitting the application is not for purpose of liquidation of the establishment.
- 6 - Donate to any government body.
- 7 - Destroy them as per the Law.
- 8 - In case of the sale of the establishment, the custody shall be transferred to custodial responsibility of the new establishment in accordance with the procedures contained in Article (9) of these.

Procedures and controls.

9.The committee constituted in paragraph (8) of Article has the right to accept, reject or modification the application with an explanation of the reason.

10.The Department of Health Investment Development in the health affairs of the region or province of Ministry of Health provides the Department of compliance with the health affairs of region or province of establishment and Saudi Food and Drug Authority an inventory copy of pharmacy establishments and private therapeutic establishments licensed by them and liquidate regulation copy or temporarily close the establishment.

◆ Article 9:

**Procedures and controls received the custody of narcotics and psychotropic substances:**

1. Upon appointment, transfer or termination of service of custodial responsibility, the custody shall be handed over to the new recipient by a committee formed by the decision of the director of establishment or a deputy whose members shall be as follows:

**A - In the establishment of the Ministry of Health, which are supervised by general administration of medical supply at the ministry:**

1. Principal Officer of Custody.
2. New recipient.
3. Delegate from the establishment inventory control administration.
4. Delegate from the administration of medical supply in the region or province, as for the warehouses of Ministry's Cabinet, the delegate is from the general administration of medical supply in the ministry.

**B - In pharmacy establishment and private therapeutic institutions licensed by the Ministry of Health:**

1. Principal Officer of Custody.
2. New recipient.
3. A representative from the inventory control administration or representative in the establishment.
4. Delegate from the health Investment Development Department in the health affairs of the region or province.

**C - In other government and private establishment:**

1. Principal Officer of Custody.
2. New recipient.
3. A representative from the inventory control administration or representative in the establishment.
4. Representative of the branch of Saudi Food and Drugs Authority in the region or its portfolio established (or Saudi Food and Drugs Authority if there is not a branch of the authority in the region or province)

**D - In case of custody in the modes of transport mentioned in Article (2) of the narcotics and psychotropic substances regime and implementing regulations. Moreover, a representative from government body responsible for the mode of transport is added to the commission.**

**E - In case that custody is veterinary medicines containing narcotics or psychotropic substances in a private establishment licensed by the Ministry of Environment Water and Agriculture, it is added to the delegate to commission of the general administration of services of Livestock, Ministry of Environment Water and Agriculture in the region or province.**

2. In the case of handing over custody to the alternates in the internal departments of hospitals, ambulance departments or ambulance transport. Although, the custody is delivered to the alternate at the beginning of the shift from the custody officer and the delivery is recorded in a record allocated for this and signed by both of them containing the name of the drug, the dosage form, concentration, size , packaging, quantity, the name of the recipient and the time and date of delivery.
- 3.Delivery and receipt procedures include making a record clarify the result custody inventory and matching the actual present with the balance recorded in custody record. Moreover, the new recipient will sign with the members of the committee, stating the receipt of custody.
4. If there are not custodial responsibility, the formed commission shall inventory the custody and hand over the actual existing of the custody to the new commitment this is explained in the record without regard to the final party's eviction of the principal officer of custody.
- 5.In case of leave or assignment to the custody officer for a period of not more than three months, the actual present is handed over from the custody by a committee formed by the regulation of the establishment manager or deputy. Although, the commission shall include both the custody officer and the new recipient and shall be kept in accordance with an official record and shall indicate this in register is not considered to be final eviction of custodial responsibility.
- 6.The new recipient of the custody shall be submit a copy Law of Combating Narcotics and psychotropic Substances and implementing regulations, a copy of these procedures and controls, and a copy of the user manual of the electronicsystem for narcotics and psychotropic substances, which is attached to these procedures under an official record sign it or sign a label with these systems as soon as they exist the other members of the committee sign it and a copy of the record is preserved in the custody register and the original.

Saves Investment Management Health Affairs Health Administration medical supply or the branch of Saudi Food and Drug Authority of the region or province affiliate (or the Saudi Food and Drug Authority if there is not Authority branch in region or province). Although, a copy is given to the rest of the committee members, and the Department of Health Investment Development provides the Department of commitment to health affairs of the region or province established a copy of the record.

7 - Inventory of custody shall be every six months by a committee formed by the decision of the establishment director or a deputy one of them from the Inventory Control Administration of the establishment or similar a copy to save it in a record in custody register and original at the inventory control or represents.

8 - In case of excess, loss, deficiency or damage in the custody of narcotics and psychotropic substances it follows the procedures contained in paragraph (4) of Article (19) of implementing regulations of the Law of Combating Narcotics and Psychotropic Substances. Although, establishment shall be submitting a report to the health Investment Development Administration in health affairs or the medical supply department or Saudi Food and Drug Authority branch (or Saudi Food and Drug Authority if there is not Authority branch in region or province). Moreover, the Department of Health Investment Administration provides the Department of Health Investment Development to provide the Administration of commitment to health affairs in region or province established a copy of the report.

◆ Article 10:

**Procedures and controls for prescribing narcotics and psychotropic substances in therapeutic institutions:**

1. The prescription of narcotics and psychotropic substances is limited to the pathological conditions estimated by the attending physician according to scientific evidence.
2. Procedures and controls for prescribing narcotic drugs.
  - A. The prescription of narcotics is limited to the following categories of licensed physicians:
    1. Consultant physician, first deputy and deputy in other specialties in the case of treatment of patients related to their specialty and that of inpatient, clinic patients and outpatient patients from the therapeutic institution.
    2. Resident physician when prescribed to inpatient patients only, provided this is be subjected to the supervision and responsibility of the consultant physician, first deputy or competent deputy.
    3. All doctors when treating severe pain cases in emergencies only.
    4. Doctors who have obtained a qualification and a license recognized by Ministry of Health to prescribe narcotics only for cases for which they have been qualified.
  - B. Narcotics are prescribed to patients of clinics and out-patients of the therapeutic institution for a period not exceeding sixty days.
  - C. Narcotics are prescribed to ambulatory patients for a period of not more than three days only, after which the patient shall be referred to the authorized specialist doctor for longer periods if the need arises.

### 3 - Procedures and controls for prescribing psychotropic substances:

- A. A - The prescribing of psychotropic substances is limited to the following categories of licensed physicians:
  - 1. Consultant physician, first deputy and deputy in psychiatry.
  - 2. Consultant physician and first deputy and deputy in other specialties in the case of treatment of patients related to their specialty for inpatient, clinic patients and outpatient patients from the therapeutic institution.
  - 3. In case of a psychiatric condition, the patient shall be referred to a psychiatrist.
  - 4. The resident physician when prescribing to inpatients provided that is be subjects to supervision and responsibility of consultant physician, first deputy or competent deputy.
  - 5. All doctors in ambulatory cases.
- B. Prescribed psychotropic substances for clinics and patients emerging from the treatment institution for a period not exceeding thirty days, except prescribed psychotropic substances to treat epilepsy and Parkinson's disease, hyperactivity, attention deficit peripheral, central nerve pain and for the treatment of cases of fibromyalgia, the consultant physician or first deputy or deputy may prescribe for a maximum of ninety days.
- C. Psychotropic substances are prescribed to ambulatory patients for a period of not more than three days only, after which the patient shall be referred to the authorized specialist doctor for longer periods if the need arises.
- D. The pathological diagnosis is written in the recipe, according to the international classification.

4 - General procedures and controls:

1 - Narcotics and psychotropic substances in all their different pharmaceutical forms are prescribed to inpatient patients in the therapeutic institution.

2 - Narcotics and psychotropic substances in various pharmaceutical forms (except injections) are prescribed to clinic patients and outpatient patients of the therapeutic institution.

3 - Injections of narcotics and psychotropic substances are prescribed to non-hypnotic patients in the therapeutic institution if the supervision of administration the drug to the patient trained health teams for government sector or technicians or specialists licensed in the private health institutions and for no more than two days. Moreover, the patient shall be examined by the specialist every ten days.

4 - Narcotics and psychotropic substances are prescribed to inpatients for a period of about seven days and the prescription may be repeated if necessary.

5 - Narcotics and psychotropic substances may be prescribed to unidentified patients in ambulatory and inpatient cases only, provided the competent security bodies are informed of this, and the file number is written in the poison and nationality box with the addition of the phrase (anonymous) in the prescription and file.

6 - Narcotics and psychotropic substances may be re-prescribed at the request of the attending physician, the treatment or dosage changes or in the following cases:

- A. Not more than seven days before the end of the treatment which prescribed in the previous prescription.

- B. If the prescription damaged before its dispense, the damaged prescription is returned to attending physician.
- C. If the prescription or drugs is lost or there is a shortage amount of drugs spent or damaged, according to paragraph (5) of Article (11) of these procedures and controls.

5 - The attending physician may prescribe narcotics and psychotropic substances to inpatients in the prescription of inpatients (medical order sheet) as follows:

A – Conditions of prescription of inpatients (medical order sheet):

- 1. The prescription may contain more than one drug.
- 2. The recipe consists of an original written at the top in red font (restricted substances) and two copy written on it (non-exchangeable)
- 3. The original of the prescription is save in the patient's file and a copy of the pharmacy in the prescription book and a copy with the department.
- 4. The recipe shall be written in indelible ink and free of deletion or modification.
- 5. The validity of the recipe is only forty-eight hours from the date of issuance.

B - The prescription of inpatients (medical order sheet) shall be containing the following data:

- 1. Address of the therapeutic institution.
- 2. Triple the patient's age, gender and nationality.
- 3. Patient file number.
- 4. Prescription number and date.

5. Diagnosis.
  6. The name of the scientific drug, the pharmaceutical form, the prescribed dosage and the duration of treatment are numbered and written.
  7. The name of the attending physician, seal, a classification number of the Saudi Commission for Health Specialties and a signature.
  8. The name of the custody pharmacist, business card number and signature.
  9. Nurse's name, business card number and signature.
6. The attending physician will write the required narcotics and psychotropic substances in the patient's file, indicating the name of the scientific drug and the pharmaceutical form, the prescribed dosage and duration of treatment number and writing, and the diagnosis of the disease.
7. Oral orders are accepted by attending physician in ambulatory cases only, and the nurse writes the medical order, the doctor's name, time and date of contact with him/her. After that, it is signed by the nurse and the head of Nursing on duty in the department, provided that the doctor signs this order within twenty-four hours of being written.
8. The recipe for non-hypnotic patients consists of an original written at the top in red (restricted substances) and two copy written on it (non-exchangeable) the prescription for non-sleeping patients shall be include the following instructions:
- A. The drugs prescribed in this prescription shall not be waived in any way to any person and the remainder of this drugs shall be returned in case of non-use to therapeutic institution that dispensed it and obtain proof of it.
  - B. These drugs shall be saved in a safe place and in accordance with the manufacturer's conditions.

- C. These drugs shall be saved of reach of children.
- D. The misuse of this prescription or drugs prescribed in this prescription leads to accountability and systemic penalties.
- E. The prescription is considered cancelled when there is any write-off or modification.
- F. Validity of the recipe only seven days from the date of issue.
- G. If this recipe is found, it shall be returned to the same therapeutic institution that issued it.
- H. The patient has the right to dispense this prescription outside the therapeutic institution issued within Saudi Arabia.
- I. Pharmaceutical establishments and therapeutic institutions authorized to trade narcotics and psychotropic substances shall be dispense any restricted regular prescription even if it is outside the therapeutic institution issued in Saudi Arabia.

9- If veterinary drugs containing narcotics or psychotropic substances are prescribed:

- A. Prescribing veterinary drugs that contain narcotics or psychotropic substances is limited to veterinarians only.
- B. Write the name of the owner of the animal and its identification number in the recipe instead of (name of the patient tetra, age, gender and nationality).
- C. Write the animal health card number in the recipe instead of (patient file number and ID number)

◆ Article 11:

**Procedures and controls for dispensing narcotics and psychotropic substances in therapeutic institutions:**

1 - Conditions for dispensing narcotics and psychotropic substances:

A - narcotics and psychotropic substances will be dispensed after counting and confirming the amount given to the patient and the pharmacist writes the amount spent on the prescription and the signature of the patient or the recipient by receiving the drug, the date of receipt , the identification number and the name and signature of the pharmacist who dispensed the drug, and then label appropriate packaging with a card containing the following data :

1. Patient name and file number.
2. The name of the drug, its concentration, size, pharmaceutical form, quantity, dosage and duration of treatment.
3. Exchange date, transaction number and expiration date.
4. Pharmacist's instructions for the patient and the method of preservation.

B - Before dispensing medicines to the patient in private therapeutic institutions, the pharmacist shall be fill in all the required data in a form (dispensing narcotics and psychotropic substances to patients) of the electronic system of narcotics and psychotropic substances in Saudi Food and Drug Authority. Prior to this, the patient shall be inquiring to confirm that the patient has never been given the same drugs or that has remained on the end of the treatment period of the previous prescription issued to the patient more than seven days.

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C – Shall not dismiss the prescription drugs, narcotics and psychotropic substances to once only, or prescription inpatients (medical order sheet) is expended be subject to copy for a period of seven days the doctor or nurse shall be sign the receipt each time, stating the time and date, and a reservation with custodial responsibility.

D - The hypnotized patient in the therapeutic institution is given a narcotic drug or psychoactive substances supervision by a doctor or nurse. After the patient in the hospital is given the Medication Recorded Administration drug registry (Medication Administration Record MAR) it is useful to give the nurse prescribed drugs and signed by the doctor or nurse who gave the drugs, and the other doctor or nurse supervised it.

E – A narcotic drug or psychoactive substances may not be delivered in the case of clinic patients or outpatient patients from the therapeutic institution only to the person who has prescribed to him/her or a relative (parents, children, brothers, husband and wife) after confirmation of his/her identity by the pharmacist. If the recipient is a person on his/ her behalf, it is necessary to attach proof of the patient's consent to bring him/her a drug, after confirming his/her identity and that is the intended person.

F - The injection of narcotic drug and psychotropic substances for clinics patients and outpatients of the therapeutic institution, except as stated in paragraph (C) NO. (4) of Article (10) of these procedures and controls.

G- The prescription of patients may not be discharged outside the therapeutic institution issued by them.

2- If there is a re-prescription, the patient's guardian or representative may receive narcotics or psychotropic substances after submitting a medical report on the patient's condition which should be certified from a healthcare institution every 6 months.

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3 - If the re-description is due to a change of treatment, shall be return the remaining amount of drug previous to the institution that spent before the disbursement of the new drugs, these returned drugs will be treated in accordance with paragraph (4) of this Article. If the re-prescribing is due to the change of the therapeutic dose, the remaining amount of the previously spent amount shall be calculated and then disburse only the amount difference, which is sufficient for the duration of the treatment of the new prescription.

4 – If the patient does not use the dispensed narcotics and psychotropic substances or if the Patient is dead, the following steps shall be taken:

- A. The remaining of these drugs shall be returned to the therapeutic institution that dispensed it to be destroyed in accordance with the destruction procedures contained in Article (16) of the procedures and controls.
- B. The patient or the person who returned the drug is given a receipt copy of these drugs indicating the name of the drug, the dosage form, concentration, size and quantity name, identification number and the signature of the recipient. Also, the date of delivery, and save the original data in a special register at the therapeutic institution.
- C. Re-use of narcotics and psychotropic substances returned from patients may be evaluated in government therapeutic institutions only. Besides, a committee formed by the decision of establishment director or deputy, component of pharmacy director or deputy and custodial responsibility of narcotics and psychotropic substances and sign on their resolution in the minutes. This shall be recorded in the custody record if the resolution is re-use. In the case of destruction, the destruction procedures contained in Article (16) of these procedures and controls shall be followed.

- D. These drugs can not be exchanged or returned for a money.
5. If a complaint from the patient about the loss of prescription, drugs and decrease in the amount of drugs spent or damaged a committee is formed by a resolution of the therapeutic institution director or a deputy, composed of the attending physician and the custodial responsibility of the narcotic drug and psychotropic substances to do the following:
- A. Study the patient's case to determine the possibility of re-prescribing the drug to the patient.
  - B. Conduct an official report and sign it by the patient and the members of the committee, then approve it from the therapeutic institution director or deputy and seal by therapeutic seal institution and save the original of the minutes in the patient's file and a copy of it in the custody record.
  - C. If recurrence from the patient or suspected the administration of therapeutic institution inform the administration of health commitment or the branch of Saudi Food and Drug Authority, the region or province affiliate (or Saudi Food and Drug Authority if there is not a branch of the Authority at the region or province)
  - D. If the specialist of Ministry of health or Saudi Food and Drug Authority, which has the status of criminal seizure, finds loss, deficiency or damage, is caused by a criminal act then conduct a record of seizure and inform the Drug Enforcement Administration and the Public Prosecution thereof.
6. If the drug is not available in sufficient quantities at the therapeutic institution, it is possible whenever the need to disburse the drug in a partial amount and necessary to write the entire amount described, the actual amount spent and the remaining amount of the patient on the original and copy of the prescription and save the original in the pharmacy. Moreover, the remaining amount shall be disbursed while the drug is available provided the patient's treatment plan is not compromised.

7. The pharmacist shall have non-prescription drugs, narcotics and psychotropic substances in the following cases:

- A. Violation of the prescription of the regulations and instructions in Law of Combating Narcotics and Psychotropic Substances and implementing regulation or these procedures and controls.
- B. The patient previous prescribed prescription and treatment period shall be more than seven days.
- C. Unsuitable drug for the patient or there is a conflict with other drugs after consultation with attending physician.
- D. If there is not write-off, modification or any sign of forgery and notification of the patient due to non-exchange.

8. In the case of dispensing veterinary drugs containing narcotics or psychotropic substances:

- A. The veterinary drugs should not be containing narcotics and psychotropic substances outside the therapeutic institution.
- B. In case the ambulatory condition of the animal requires the use of the drug outside the therapeutic institution the drug is delivered to attending veterinarian only and is in his/her care and treated as follows:
  1. The empty drugs package is returned to the body dispensed the drug, and the name of the doctor, the name of the drug disbursed, the amount and time of disbursement and the name of the disbursement and signature are recorded in the custody register.
  2. If the prescribed amount is less than the capacity of one injection, the doctor gives the drug shall be destroy the remaining amount and sign it in the emergency report.

C - The animal is given a narcotics or psychoactive substances by the veterinarian only.

9 - Narcotics and psychotropic substances are dispensed from the hospital pharmacy to the internal departments in accordance with paragraph (3) of Article (13) of these procedures and controls.

10 - The register of prescriptions in therapeutic institutions shall be include the following data:

A - Prescription number and date.

B - Patient name and ID number (or inpatient medical file number)

C - Drug name, dosage form, concentration and size.

D - The prescribed amount in the prescription and the amount spent.

E - The name and signature of the person who exchange and the date of it.

#### ◆ 12 Article:

**Procedures and controls the obligation of therapeutic institutions to review the procedures and prescribing of narcotics or psychotropic substances and their disbursement to verify the validity of the reasons for their prescribing and disbursement as required by the recognized medical assets:**

1 - Each treatment institution shall be do the following:

A - Formation of an internal committee resolutions by therapeutic institution director or deputy composed at least two doctors and a pharmacist to review the procedures for prescribing narcotics and psychotropic substances. Moreover, to verify the validity of the reasons for prescribing them as required by the recognized medical assets.

At least once a year and prepare a report of the results of the audit and save it in a special record. If any excess is detected in this regard, it shall be informed Administration of Health Commitment or Medical Supply Administration (or Saudi Food and Drug Authority if there is not Authority branch in the region or province) The region or province the necessary action on the commitment administration to provide the health Investment Development Department with a copy of is reached.

B - The formation of an internal committee resolution by therapeutic institution director or a deputy composed of - at least – two doctors and pharmacists, one of whom is custodial responsibility of narcotics and psychotropic substances. Moreover, to review the procedures for dispensing narcotics and psychotropic substances to verify the validity of their disbursements as required the medical assed. Although, it shall be at least once a year and report the audit results and save them in a special record. If any infringement is detected in this regard, it shall be informed medical supply Administration, or medical supply administration or Saudi Food and Drugs Authority branch (or Saudi Food and Drugs Authority if there is not Authority branch in the region or province). Besides, the region or province conduct necessary action the Commitment Development Administration shall provide the health Investment Development Department with a picture of is reached.

C - Therapeutic institutions that do not have a pharmacist, all members of the committee are doctors.

2. If the specialist of Ministry of health or Saudi Food and Drug Authority who has the status of seizure criminal finds the transgression is the result of a criminal act, a record of seizure criminal and inform the Drug Enforcement Administration and the Public Prosecution thereof.

◆ 13 Article:

**Exchange control procedures for narcotics and psychotropic substances:**

**1 - In the government warehouses follow the procedures stipulated in the rules and procedures warehouses, government issued by Finance Minister and national economy No. (21/ 420) date 11/08/1404 H.A**

**2 - Dispensing of narcotics and psychotropic substances in special establishment from central warehouses to sub-warehouses, or from the warehouse to the therapeutic institution or pharmacy affiliated to the same establishment is as follows:**

A - The custodian of the requesting establishment submits the request for the disbursement of substances and is approved by immediate line manager and establishment director (or deputy) and explains the following request:

1. Order number and date.
2. Product generic name of the substance, dosage form, concentration, size, packaging and quantity required of each substance by number and writing.

B. The application shall be a copy and the original shall be save with custodial responsibility in the warehouse and copy for custodial responsibility in the requesting establishment.

C. Delivery shall be under a delivery record indicating the date of receipt, lot number and date of validity and signed by custodial responsibility in the warehouse.

warehouse manager (or deputy) and the recipient of the custody in the requesting establishment, and the original of receipt minutes is preserved with the custodial responsibility in the warehouse and a copy with the recipient of the custody in the requested establishment.

**3 - Disbursement narcotics and psychotropic substances in the medical institutions of the pharmacy institution to the health centers or departments of internal affiliate is as follows:**

A -custodial responsibility in the center or department provides the applicant with a request to disbursement substances and is certified by immediate line manager and the establishment director (or deputy) application explains the following:

1. Order number and date.
2. Product generic name of the substance, dosage form, concentration, size and quantity required of each substance by number and writing.

B - The application shall be origin and copy. Also, the original shall be save at custodial responsibility in the pharmacy and the copy for custodial responsibility in the center or applicant department.

C - Shall be delivery under the drug disbursement form as follows:

1. The dispensing form shall be containing the following data:
  - A. Quantity received, lot number, validity date, date of receipt, name and signature of the custody recipient in the center or department, and signature of custodial responsibility,
  - B. Patient name, dose and medical file number.
  - C. The amount spent, the amount damaged, the signature of the person who disbursed or destroyed and the remaining amount.

2.Upon delivery, the data of the quantity received, lot number, validity date, the date of receipt, the name and signature of the recipient of the custody in the center or department and the signature of custodial responsibility in dispensing drugs form and save a copy with custodial responsibility in the pharmacy, and the original with the custody recipient in the center or department and become a personal custody on him/her.

3.The center or department of the therapeutic institution will fill in the data of the patient's name, dose, medical file number, the amount spent, the amount destroyed, the signature of the person who spent or destroyed and the remaining amount in the drug disbursement form. If the quantity is done, a copy of it is saved with custody recipient at the center or department and the original with the custodial responsibility at the pharmacy.

D - The pharmacy has a file for each center or department that has custody of narcotics or psychotropic substances, and the file includes disbursement requests and any papers related to the custody it will be a reference to indicate the movement of substances in departments and health centers and register prescriptions in a special register.

E - The recipient registry the quantity and specifications in his / her custody record. After that, custody record shall be in the treasury and kept in a safe place.

**4 - The disbursement of ambulatory drugs containing narcotics or psychotropic substances from the ambulatory centers to the means of ambulance transport is as follows:**

A. The custodial responsibility (head of the ambulance team) submits the request for dispensing drugs and is approved by immediate line manager and center director (or deputy) the application explains the following:

1. Order number and date.

Product generic name of the drug, dosage form, concentration, size and quantity.

- B. The application shall be of origin and copy. Also, the original shall be saved with custodial responsibility in the ambulance center and the copy for custodial responsibility in the ambulance transport.
- C. Shall be delivery according to a delivery minutes indicating the date of receipt, lot number and the date of validity and signed by custodial responsibility in the ambulance center and the custody recipient in the ambulance transport. Moreover, the original of the receipt shall be saved with custodial responsibility in the center and a copy for custody recipient in the ambulance transport and shall become personal custody.
- D. The center has a file for each ambulance transport vehicle that has a drug or psychotropic drugs custody, and this file includes disbursement requests and any custody papers. Although, it is a reference to indicate the movement of drugs in the ambulance transport in a special register.
- E. The recipient registry the quantity and specifications in his / her custody record and then placed inside treasury, also record is saved in a safe place.
- F. In case of damage to narcotics or psychotropic substances or needless to use them, the custodian of the ambulance transport shall return these drugs to the body that disbursed them and deliver under a delivery order. Besides, custodial responsibility in the ambulance transport and the recipient in the body that disbursed the drug and save the original to the custodial responsibility in the ambulance transport and a copy for the recipient.

**5 - Dispensing narcotics and psychotropic substances in local pharmaceutical manufacturer licensed by Saudi Food and Drug Authority make the medical products that include in their composition narcotics or psychotropic substances from the warehouse to the manufacturerdepartments is as follows:**

- A. The substance disbursement request is submitted by the department and the substance request is approved by the head of the department and manufacturer manager (or deputy) the application explains the following:
  - 1. Order number and date.
  - 2. Reason for ordering.
  - 3. Name and signature of the competent employee concerned.
  - 4. The product generic name of the substance, dosage form (concentration and size if possible) and the required quantity of each substance by number and writing.
- B. The application shall be original and copy also the original shall be saved with custodial responsibility in the warehouse and copy at the application department.
- C. Shall be delivery according to the delivery minutes indicating the date of receipt, lot number and the date of validity and signed by the custodian in the warehouse, the warehouse director (or deputy) and the custody recipient in the department a request for substances. The original copy of the minutes shall be saved at the custodial responsibility in the warehouse and a copy at the application department.
- D. The recipient registry the quantity and its descriptions in his / her custody record and then it is placed inside the treasury, and the record saved in a safe place.
- E. Conduct a statement is for each operation on narcotics and psychotropic substances in the department includes the following data:

1. Operation name and date.
  2. Used quantity, produced, remaining and damaged.
  3. Name and signature of the competent employee, immediate line manager and department manager.
- F. F - The remaining quantities, damaged or used in the quality choices in the department, shall be returned to the warehouse and delivered under a delivery statement signed by the custodian of the warehouse and the competent officer of the department. Besides, the quantities produced are sent to the warehouse of the substances produced and kept in a designated place and below the responsibility of the custody of the manufactory.
- G. J - The substances are delivered between the departments under an official receipt and delivery statement that preserves the original with the delivered department and a copy with the received department the statement includes the following:
1. Name of the delivered department and date of delivery.
  2. Name and signature of the competent employee and delivered department manager.
  3. Received department name and date of receipt.
  4. Name and signature of the competent employee and department manager received.
  5. Reason for ordering substances.
  6. Product generic name of the substance, dosage form (concentration and size - if possible), quantity of each item number, writing, operation number and date of validity.
- H. F - In all cases, the manufactures shall be adhere to the principles of good manufacturing of pharmaceutical products (Good Manufacturing Practices – GMP) approved by Saudi Food and Drugs Authority.

**6. Exchange narcotics or psychotropic substances in private pharmacies licensed trafficking in narcotics and psychotropic substances and convention center in medical institutions, government and hospitals are greeted patients and their treatment in return it is done as follows:**

A. Dispensing narcotics and psychotropic substances after counting and confirming the amount given to the patient and the pharmacist writing the amount spent on prescription the signature of the patient or the recipient of the drug receipt, the date of receipt, the identification number, the name and signature of the pharmacist who dispensed the drug, and then put it in appropriate packages with a label containing the following data:

1. Patient name and file number.
2. The name of the drug, its concentration, size, dosage form, quantity, dose and treatment duration.
3. Exchange date, lot number and expiration date.
4. Pharmacist's instructions for the patient and the method of preservation.

B. Shall not be permissible to deliver narcotics or psychoactive substances only to those prescribed to him/her, or to one of his/her relatives (parents, children, brothers, husband-wife) after confirming identity, if the recipient is a person on his/her behalf, it is necessary to attach proof of the patient's consent to bring the drug after confirming identity and the intended person.

C. Shall be the pharmacist before dispensing drugs to the patient to fill all data required packaged (exchange administration of narcotics and psychotropic substances to patients) for pharmaceuticals narcotics and psychotropic substances in Saudi Food and Drug Authority electronicsystem as described in the user manual

The electronic system of narcotics and psychotropic substances and attached to these procedures, provided that before inquiring about patient to ensure the patient has never been disbursed the same drug or remained on the end of the treatment period of previous prescription spent more than seven days.

- D. Shall be not prescribe narcotics and psychotropic substances only once.
- E. The prescription of inpatients shall not be discharged outside the therapeutic institution issued by it.
- F. The pharmacist shall have non-prescriptions drugs, narcotics and psychotropic substances in the following cases:

1. Violation of the regulations and instructions contained in the Regime for Law of Combating Narcotics and Psychotropic Substances and its implementing regulations or procedures and controls.
2. The patient shall have more than seven days remaining on the end of the treatment period of the previous prescribed prescription.
3. Shall not be suitable for the patient or having a conflict with other drugs until after consultation with the attending physician.
4. When there is a write-off or modify, or any sign of forgery inform the patient due to not dispense.

#### **7 - Dispensing narcotics and psychotropic substances in laboratories and research centers:**

- A. Estimated analyst or researcher request for exchange substance and ratified by line manager immediate and manager of establishment (or behalf) is recommended in the following:
  1. Order number and date.

2. Name of analysis or research.
  3. The product generic name of the substance and the dosage form (concentration and size, if possible) and the required quantity of each substance number and write.
- B. The application shall be of origin and copy. Also, the original shall be saved with the custodial responsibility of the establishment and the copy of the analyst or researcher.
- C. According to the minutes shall be a delivery statement indicating the date of receipt, lot number and validity date and signed by custodial responsibility of the establishment line manager immediate and manager of establishment (or behalf) and the analyst or researcher receiving the substances. Although, the original copy of the receipt shall be saved with the custodial responsibility of the establishment and a copy of the analyst or researcher.
- D. The receiving analyst or researcher registry the quantity and specifications in his/her custody registry and then placed inside the treasury and kept in a safe place.
- E. A statement of each operation on narcotic substances and psychotropic substances shall be undertaken containing the following data:
1. Name of analysis or research and date.
  2. Used quantity, produced, remaining and damaged.
  3. Name and signature of the analyst or researcher and line manager immediate and manager of establishment (or behalf).
- F. The quantity produced, remaining and damaged from the analysis or research shall be returned to the custodial responsibility of the establishment and delivered under a delivery seizure signed by custodial responsibility. Moreover, the analyst or researcher and line manger immediate then it is saving the original to analyst and researcher also a copy to the custodial responsibility.

**8 - Medical drugs containing narcotics or psychotropic substances in transportation for emergency and first aid cases are dispensed as follows:**

A. The attending doctor (or paramedic if there is not doctor) in the mode of transport shall be submit the request for the disbursement of substances and approved by the official of the mode of transport (or behalf) the application explains the following:

1. Order number and date.
2. Product generic name of the substance, dosage form, concentration, size, packaging and quantity required of each substance by number and writing.
3. Reason for ordering.

B. Oral orders are accepted by the attending doctor (or paramedic if There is not a doctor) to request the dispensing of substances in ambulatory cases only. The doctor or paramedic shall be signing the exchange order for twenty-four hours.

C. Ambulatory drugs are given to the patient by the attending doctor (or paramedic if there isnot doctor)

D. The empty drug container is returned to the dispenser, and the patient's name is registry in the custody register. The name of the attending doctor or paramedic also the time and date of the giving.

E. If the prescribed amount of the patient is less than the capacity of one injection, the doctor or paramedic who gave the drug and the custodial responsibility of the transport or the official of the transport mode (or the behalf ) destroy the remaining quantity, they sign it in the patient's emergency report .

**9 - Dispensing of narcotics and psychotropic substances registered and priced sold from the drugs agent or the local pharmaceutical manufactory to licensed bodies to acquire these drugs is the following bug:**

A - The drugs agent or the local pharmaceutical manufactory shall submit the application for approval of the sale and transfer of narcotics or psychotropic substances to the beneficiary through the electronicsystem of narcotics and psychotropic substances of Saudi Food and Drugs Authority as described in the user manual of narcotics and psychotropic substances system.

B - If the access to narcotics and psychotropic drugs electronicsystem is not possible, the following steps are followed:

1. Lead the beneficiary to apply narcotics and psychotropic substances - certified establishment manager (or behalf) to the managing agent or the local pharmaceutical manufacture.
2. The application shall be accompanied by the approval of Saudi Food and Drug Authority branch in the region or province (or Saudi Food and Drug Authority if there is not a branch of Authority in region or province) to purchase all the beneficiary body.
3. The application is in the form of a copy and the original is saved with the custodial responsibility at the local pharmaceutical manufacture or the drugs agent and the copy with the custody recipient at the requesting establishment.
4. The substances are disbursed under a seizure indicating the date of receipt, the lot number and validity date signed by the custodial responsibility in the warehouse.

Local pharmaceutical manufactory or drugs agent and warehouse manager (or behalf) and the recipient of custody in the requesting establishment. Although, the original copy seizure of the receipt shall be saved with custodial responsibility in the warehouse and a copy of the custodian in the requesting establishment. However, if the substances will be transferred to the beneficiary body registration in accordance with paragraph B of No. 3 in Article (3)of these procedures and controls.

5. The disbursed seizure or delivery of the purchase invoice shall be accompanied by the following:

- A. Invoice number, date, signature of the salesperson and seal of the establishment.
- B. Scientific and commercial name of substance, dosage form, concentration, size and packaging, quantity sold, lot number, date of production and validity.

6. The original invoice shall be filed with the recipient of the custody at the requesting establishment and the copy shall be filed with the custodial responsibility at the local drug agent or pharmaceutical manufactures.

◆ 14 Article:

**Procedures and controls for the registration of narcotics and psychotropic substances and the submission of periodic register data (records) :**

1.The custodial responsibility checks custody regularly (at least once every three Gregorian months), registration it in a special register and stating the date each time.

2. In case of an increase, loss, deficiency or damage in the custody of narcotics and psychotropic substances, the procedures set out in paragraph 4 of the Article shall be followed

(19) of implementing regulation Law of Combating Narcotics and Psychotropic Substances the establishment shall be submit the report to the Health Investment Development Department of Health Affairs to the Department of medical supply or branch of Saudi Food and Drug Authority (or Saudi Food and Drug Authority if there is not a branch of Authority in region or province ) the health Investment Development Department shall be provide the compliance department with a copy of the report.

3. The data of narcotics or psychotropic substances are registration every six months (of the Gregorian year) and this periodic registry (records) is sent as follows:

A - Government establishment under the Ministry of Health and supervised by the public administration of medical supply:

1. The records will send to the Inventory Control Department of the region or province to be audited and save them then send a copy of them to the Medical Supply Department of the region or the province. The copy of psychotropic substances records to the public administration of mental and social health.
2. The Department of medical supply in the region or province sends records to the Department of inventory control in region or province and copy to public administration of medical supply in Ministry of Health.
3. The medical supply warehouse in the Ministry's office sends their records to the public administration of Inventory Control of the Ministry of Health.
4. Public administration of inventory control at the Ministry of Health sends the total records to Saudi Food and Drug Authority.

B. Pharmacy establishment and private therapeutic institutions licensed by the Ministry of Health:

1. Sent records to the Health Affairs Compliance Department of the region or province.
2. In case the private body has several health establishments, a receiver record shall be sent to each establishment.
3. The Compliance Department of Health Affairs in the region or province shall audit and preserve it, then send a copy of it for investment development of the health. Also, a copy of records and psychotropic substances to the public administration of mental health and social.

C. Warehouses of registered and priced drugs agents and local pharmaceutical manufacture licensed by Saudi Food and Drug Authority:

1. The total records of narcotics and psychotropic substances are sent to Saudi Food and Drug Authority.
2. As for its warehouses in the regions and provinces sends records to each warehouse to Saudi Food and Drug Authority branch in the region or provinces (or Saudi Food and Drug Authority if there is not a branch of Authority in the region or province)

D. Private veterinary establishment licensed by the Ministry of Environment Water and Agriculture:

1. Records sent to the public administration of Livestock Services at the Ministry of Environment Water and Agriculture in the region or provinces to be audited and conserved and send a copy to the Saudi Food and Drug Authority branch.

(or Saudi Food and Drug Authority if there is not a branch of Authority in the region and province)

E. All other establishments, the record is sent to the branch of Saudi Food and Drug Authority in the region or province of the establishment (or Saudi Food and Drug Authority if there is not a branch of Authority in the region and province).

F. Saudi modes of transport contained in Article (2) Law of Combating Narcotics and psychotropic Substances and implementing regulation:

1. It sends the transport means, the record to the government body responsible for the means of transport to be audited and preserved.
2. The government body responsible for the transport means shall submit the total of its preserved record to Saudi Food and Drug Authority.
4. The Ministry of Health and Saudi Food and Drug Authority shall be audit and review the record reached by each in respect of and in case of notice:

- A. The appearance of a discrepancy in balances informs the concerned establishment to report the reasons for this.
- B. The presence of excess or stagnant quantities is treated in accordance with paragraph (6) of Article (8) of these procedures and controls.
5. The competent governmental and private regulatory bodies monitor the disbursement of narcotics and psychotropic substances in their units by means of a sudden and periodic inspection and ascertain the application of the Law of Combating Narcotics and psychotropic Substances and implementing regulation and these procedures and controls, in terms of receipt.

And storage, drainage, registration and saving of these items with matching the actual existing with the credit balance and making reports all notes and a copy of them shall be submitted to the responsibility administration in body.

6. The Saudi Food and Drug Authority allows anybody to lifting the total records of establishment for this body whenever the need arises.

◆ 15 Article:

**Procedures and controls abusing medical prescriptions and registry of narcotics and psychotropic substances:**

1. The recipes and registry are destroyed after the expiration of the specified period of preservation by a committee formed by decision of the establishment manager or the behalf, it consists of at least three members, one of whom is responsible for the custodial responsibility of narcotics and psychotropic substances at the establishment.

2. Shall be works a seizure of destruction and signed by the members and seal with the establishment seal and keeps the original with the custodian and send a copy thereof to the management of inventory control establishment, or what it represents.

3. Establishment that have pending cases of substance abuse and psychotropic substances such as burglary, theft, deficiency, etc. Although, they shall be saved the prescriptions and registry of these substance until their outstanding cases are resolved and then be destroyed as usual.

4. In case of loss or damage of covenant registry or prescription registry:

A. Create a new registry.

B. The manager of the establishment shall be forming an investigation committee at least three members, one of whom shall be from the inventory control of the establishment or similar to do the following:

1. Inventory and quantities of items and their registration in the new register.
2. To investigate the causes of loss or damage, and whether this is the result of negligence or any other emergency symptom. Besides, determining the liability of the defaulter or negligent.

C. The director of the establishment shall be submitting the report of the committee to the branch of Saudi Food and Drug Authority in the region or province of the establishment (or Saudi Food and Drugs Authority if there is not a branch in the region or province) or management commitment to health affairs in the region or province established affiliate if the pharmacy established or a medical institution licensed by the Ministry of Health. In order to proceed the necessary action in respect of each and the establishment saved a form of it in the custody registry provided the commitment administration to provide the health investment development rent to be delivered.

#### ◆ 16 Article:

Procedures and controls for the preservation and destruction of damaged items and empty packages of narcotics and psychotropic substances:

First: damaged items:

1. Narcotics and psychotropic substances are considered damaged according to the following:

- A. If it is expired.

- B. If it is not usable because it does not conform to the specifications and conditions approved by the Ministry of health or does not conform to the specifications and conditions under which the supplier was awarded or in violation of the manufacturer's specifications and conditions, broken, open or for any other reason that prevents its use.
  - C. If the natural or chemical properties of narcotics and psychotropic substances change before their expiration and samples are sent to the analysis laboratory and proved invalid.
  - D. If the Competent Authority of Saudi Food and Drug Authority decides to cancel the use of any class of narcotics and psychotropic substances, whether for the establishment of harmful side effects or for other reasons.
2. Damaged narcotics and psychotropic substances are destroyed by a committee formed by the decision from Saudi Food and Drugs Authority branch director in the region or province (or Deputy Executive vice president for Saudi Food and Drug Authority or behalf if there is not an Authority branch in region or province). As for the pharmaceutical establishments and private therapeutic institutions licensed by the Ministry of Health, the decision shall be by the director of the administration of compliance for Health Affairs in the region or province established and the destruction committee shall be composed of:
- A. At least two delegates from Food and Drug Authority branch in the region or province (or Saudi Food and Drug Authority if there is not branch of the Authority in the region or province) or delegates from the administration of health compliance in the region or province for pharmaceutical establishments and private therapeutic institutions licensed by the Ministry of Health.

B. Narcotics and psychotropic substance custodial responsibility at the establishment.

3 - The custodial responsibility shall be applying for the destruction of narcotics or psychotropic substances through the electronic drug and psychotropic substances electronicsystem as described in the user manual of the electronic electronicsystem attached to these procedures.

4. Damaged narcotics and psychotropic substances shall be destroyed in a period of not more than one year, and the destruction shall be implemented in accordance with the destruction procedures contained in the unified system of health care waste management in the GCC states and implementing regulation. This shall be under the supervision of the committees charged with the destruction mentioned in paragraph (2) of this Article.

5.Upon destruction of narcotics and psychotropic substances damaged, a seizure of destruction is released indicating the product generic name of the substance or psychoactive substance, dosage form, concentration, size, lot number and quantity destroyed number and writing. Moreover, the reason for the destruction and the time and date of the destruction and sign the seizure from all members of the destruction committee and seal the official seal and save the original seizure of the destruction to the custodial responsibility and a copy of it to the other members of the committee and copy of the health Investment Development Department in Region or province. Also, copy management inventory control region, or province affiliate steroids government of the Ministry of Health and supervised by the public administration of the medical supply.

6. Establishment that has pending cases of narcotics and psychotropic substances such as burglary, theft, lack or other they shall be saved these substances and their packaging until their pending cases are resolved and then destroyed as is the practice.

7. Narcotics and psychotropic substances shall be stored for damage in their packaging in a separate place and in accordance with the conditions stipulate in paragraphs (B), (C) and (D) of No. 1 of Article (13) of the implementing regulation Law of Combating Narcotics and Psychotropic Substances.

8. The establishment manager shall be ensuring the damage to narcotics and psychotropic substances was not caused by negligence in storage or misconduct by the custodian.

**Second: empty packaging:**

1. Empty package is destroyed by a committee formed by the decision of the establishment director or the behalf, consisting of the director of the pharmacy or the behalfand the custodial responsibility of narcotics and psychotropic substances in the establishment.

2. Package of narcotic substances and psychotropic substances are destroyed in a period of not more than six months according to the procedures for the destruction of the standard system for the management of health care waste without the GCC and the implementing regulation. After making sure the amount, weight or number of empty packages delivered is identical to the number of injections spent in the prescriptions and is identical to the amount, weight or number of what has been destroyed and a copy of the statement of destruction is preserved in the custody register.

**General procedures and controls:**

**1. The following cases are dealt with in the treatment establishment according to the following:**

A. The cases are:

1. When a quantity of an injection of narcotics or psychotropic substances remains during giving.
2. When a syringe, vial or packaging narcotics or a psychoactive substance is accidentally broken.

3. When a narcotic drug or a psychoactive substance is accidentally wasted.
  4. When an empty syringe of a narcotics or a psychoactive substance is lost or broken after it is used.
  5. In case the doctor changes the order of treatment after the narcotics or psychoactive substance has been prepared to give.
  6. If the patient refuses to take the narcotics or the psychoactive substance after it has been prepared to give, or the patient's health or mental condition at the time of giving does not allow it.
- B. After a seizure of damage, the treatment establishment are signed by the doctor or nurse who administered the drug and the doctor or other nurse who supervised it. In private doctors ' clinics signed by nurses or doctor, nurse and owner of the clinic, and in the ambulance means signed by paramedics if possible. The head of the ambulance and transport team is signed by the doctor, if any, or the paramedic, who is responsible for the transport.
- C. The seizure of the damage shall be registry in the form prepared for it and copy of the registry shall be sent to the custodial responsibility to save in the registries, and a copy of the Inventory Control Department of the region or province. In the case the establishment is governmental, it belongs to the Ministry of Health and is supervised by the public administration of medical supply.
- D - The substance is damaged at the time and the packaging is damaged in accordance with the destruction procedures contained in the unified system for the management of healthcare waste in the GCC states and implementing regulation.

**2. The following situations are handled in warehouses as follows:**

A. The cases are:

1. When a syringe, vial, or small package of a narcotics or a psychoactive substance is accidentally breaking.
2. When a substance or a psychoactive substance is accidentally wasted.
3. When an empty syringe of a narcotics or a psychoactive substance is lost after it is used in analysis or research.

B. After the seizure of destruction, the warehouse shall be signed by the warehouse employee, line manager immediate or director warehouse, the custodial responsibility in the manufactory departments, laboratories, analysis laboratories and research centers, sight by line manager immediate director of the department or the establishment director and the custodial responsibility.

C. The seizure of the destruction is registry in the form prepared for this and copy of the registries is sent to the custodial responsibility of the registry, copy administration inventory control region, or provincial affiliate in the case the establishment is a Government Ministry of Health and supervised by the public administration of the medical supply.

D. The substrates are destroyed at the time and the packaging is damaged in accordance with the destruction procedures contained in the unified system of health care waste management in the GCC states and implementing regulations.

**3.** In case of repetition of paragraphs (1) or (2) of this Article, from the employer for more than two times a year, shall be inform the health affairs compliance department, the medical supply department or the branch of Saudi Food and Drug Authority in the region or province established to have the necessary action.

**4.** In the case of a syringe, vial or container of a drug substance or a mental effect closed from the manufacturer is not opened, but empty or incomplete, a seizure shall inform Saudi Food and Drug Authority and save the substance and packaging in the establishment with the damaged substance.

◆ 17 Article:

**Procedures and controls for the disposal of confiscated drugs containing narcotics or psychotropic substances:**

**1. Procedures for receiving and keeping confiscated drugs:**

- A. The confiscated drugs are received by the inspection committee referred to in paragraph (3) of Article (23) of these procedures and controls. Besides, according to a statement of seizure and signed by the establishment directors (or the behalf), the custodial responsibility of establishment or the source of it, and members of the inspection committee and in case the confiscated drugs are present at customs port, customs representative signs the seizure and a copy of it.
- B. The original seizure report is saved at administration of the Control Authority of the region or province of the establishment and a copy at the establishment sources.
- C. Delivery of confiscated drugs to the nearest medical supply depot of the Ministry of health or Saudi Food and Drug Authority in the region or proves, the source of these drugs. Although, the delivery shall be below according to a delivery seizure signed by the members of the inspection committee, custodial responsibility of the warehouse, the warehouse manager or behalf, the original is preserved with the inspection committee in the region or province and a copy with the custodial responsibility of the warehouse.

D. If there is not a medical supply depot or Saudi Food and Drug Authority in the region or province, the drugs are delivered for confiscation to the nearest medical supply depot at the Ministry of health or Saudi Food and Drug Authority.

E. The movement and preservation of drugs and exported according to Articles (13) and (19) of the implementing regulations of Law of Combating Narcotics and Psychotropic Substances.

**2.** If the specialist of the Ministry of health or Saudi Food and Drug Authority, which has criminal seizure, finds the confiscated drugs are the result of a criminal act, seizure report incident shall be prepared and report it to the DEA and public prosecution.

**3.** Confiscated drugs shall be treated in accordance with Article (36) of implementing regulations the control of narcotics and psychotropic substances.

◆ 18 Article:

**Procedures, and controls the use of modern technology in substances handling of narcotics and psychotropic substances.**

A. The applicant shall be submitting a letter of approval to Saudi Food and Drug Authority for the use of modern technology the application shall include the following:

1. The reason for choosing this technique.
2. The name of this technique in both Arabic and English languages.
3. Name and address of manufacturer.
- 4 . Features of the technology and how it works in detail in Arabic language.
5. Attach catalogs, copy and documents for this technique.

B. The application shall be submitted to the joint commission referred to in Article (22) of these procedures and controls to consider the application and the commission shall have the right to accept or reject the application with an explanation of the reason.

C. Controls the general use of computer in dealing with narcotics and psychotropic substances:

1. It shall be to verify that the computer electronicsystem and all processes are working properly in accordance with the procedures and acceptance standards approved by the competent authority of the establishment and to document this in own registry.

2. Shall be verified through work for all during work the same connectors and methods previously adopted when was the installation of the system is done through formal proceedings documented and a specific time period. Also, registry the results of the installation of the validity of the system, evaluate, report and article with the previously defined acceptance criteria.

3. Before starting the installation of the validity of the electronicsystem, the procedures for calibration of devices and registration and control systems shall be provided and train operators, supervisors and individuals working in the inspection, maintenance and operation of all operations.

4. Any problems observed during electronicsystem validation should be reported, evaluated and recorded.

5. Suitable and efficient equipment and operation method shall demonstrate the suitability of hardware and software to perform assigned tasks.

6. Individuals authorized to use the electronicsystem and their powers shall be identified, and each one shall have own user number and secret code documented in their own registry and approved by Authoritarianism.

7. The electronicsystem shall be registry the identity of users or operators and the timeand date of entry and exit.
8. The electronicsystem shall have a mechanism to prevent unauthorized persons usingthe system.
9. The electronicsystem shall have mechanism that prevents the change, modificationor deletion of saved data, or the introduction of false data, or the user performs operationsthat are not prerogative.
- 10.The electronicsystem shall have a mechanism to prevent data loss before saving it incase of electronicsystem shutdown, power failure or otherwise.
11. The electronicsystem shall have a mechanism to registry all the data entered andthe time and date of entry and who entered it, and any changes made to it from adding, deleting or modifying and who did it and the time and date of the change.
12. The working procedures shall be written, approved and available to all users of the electronicsystem and include the date on which these procedures shall be reviewed bythe competent authority.
- 13.The electronicsystem maintenance procedures shall be written and approved, and each maintenance process shall be registry, the time and date of operation and who performed and supervised it.
14. When entering the information, there shall be additional review by another user or by the electronicsystem itself to confirm the correctness of the entered data.

15. Mistakes relating to the functioning of the electronic system which affect the quality of the work or products or health registry and data saved or otherwise, shall be registry and investigated by specialists in it.
16. Any change or modification in the electronic system computer shall be in accordance with the procedures change approved by the competent authority at the establishment. Moreover, all changes shall be saved in own registry, including modifications and improvements to hardware, software and any other sensitive and important components, and the registry shall show the electronic system is approved and valid.
17. There shall be an electronic system back-up electronic system for all computers in order to protect data and registry from loss or damage in case of electronic system crashes or failures.
18. Shall be undertaken the actions in case of an electronic system crashes or failure identified and documented, and any electronic system crashes or failure shall be registry and which action has been undertaken.
19. The data may be registry by other means in addition to the computer electronic system such as handwriting or printing the data entered in the electronic system and then saving it in logs or otherwise.
20. Documents, registry and data saved by electronic means such as a computer, shall be easily traced, examined and always reproduced, and shall be not subject to the risk of damage or change and distortion, and be stored in a safe manner.

D. Controls the electronic prescription of drugs containing narcotics or psychotropic substances in therapeutic institutions and how to dispense them:

1. Article (20), paragraph 2, of implementing regulations on the law of Combating Narcotics and psychotropic Substances shall be complied with.
2. The doctor's electronic signature or code shall be printed on the prescription.
3. The patient shall be giving the patient a copy of the prescription and sign the receipt of the drug.
4. In case the drug is a sleeping patient, the nurse signs the receipt of the drug and gives a copy to save in the custody record of the department.
5. More than one drug may be prescribed in the electronic prescription, but if there is not drug in the establishment, the patient shall be given a prescription for each drug separately and according to the paragraphs (1), (2) and (3) of (20) from the implementing regulation of Law of Combating Narcotics and psychotropic Substances.

E. Controls the preservation of drugs containing narcotics or psychotropic substances in electronic devices in the departments of therapeutic institutions and how to dispense them:

1. The device shall have a mechanism that prevents the dispensing of the drug only after the doctor or nurse and another doctor or nurse is documented electronically or by the PIN number in the device.
2. The device shall have a mechanism that prevents the disbursement of more than the amount of drugs specified in the prescription.
3. The device shall have a mechanism to prevent the opening of the drug drawers by an unauthorized person or in case of electronic system failure or power failure and the presence of a security alarm electronic system in case of occurrence.

4. Article (19) paragraph 1 of the implementing regulations on Law of Combating Narcotics and psychotropic substances shall be complied with.
5. The device shall have special drawers for the preservation of drugs containing narcotics or psychotropic substances only.
6. The device shall have a mechanism to prevent the return of the spent drug that narcotics or psychoactive substance has been prepared to be given to the device by the pathogen in case of non-use.
7. In case the device electronic system allows the return of unused drugs that hasnot been prepared for narcotics or psychoactive substance for given, it shall be in a drawer separated from the drugs containing narcotics or psychotropic substances drawer. Although, if they are in the same drawer, the entire contents of the lists shall be stripped and signed by two doctors, a doctor, a nurse or nurses.
8. In case the device electronic system allows the return injection vortex, it shall bein separate drawer dedicated to narcotics and psychotropic substances only.
9. The persons authorized to fill the device and follow up the inventory of it is contents and the time periods for this and depends on the custodial responsibility, the pharmacy manager and the manager of establishment.
10. There shall be at least two persons about filling the device with drugs containing narcotics or psychotropic substances to ensure the packaging was done in a proper manner and the names and quantities of the drugs are correct and sign this in a statement sent to the custodial responsibility of the pharmacy to

The register shall have in the device a signature method that documents the confirmation process of filing electronic ally.

11. The expense and the remainder of the drugs containing narcotics s or psychotropic substances in the device shall be accounted for by at least two people, or they do so through the same device if the inventory process is electronic ally documented and signed each time and a copy of the registry is sent to the custodian of the pharmacy for a registry saved.

◆ 19 Article:

Ambulatory drugs containing narcotics or psychotropic substances allowed in cases of abuse, and licensed to doctors to possess, prescribe and dispense them in their own clinic, and to be provided in the ambulatory centers and ambulatory mode:

1 - Ambulatory drugs are:

	<b>Drug name</b>	<b>Dosage form</b>
1	DIAZEPAM	AMPOULE
2	MORPHINE	AMPOULE
3	LORAZEPAM	AMPOULE
4	TRAMADOL	AMPOULE
5	PETHIDINE	AMPOULE
6	MIDAZOLAM	AMPOULE

2 - These drugs shall be injectable for one-time use only, and all or part of these drugs may be insured as needed.

3 - The maximum amount to be provided in the ambulance is as follows:

	Type of ambulance mode	Maximum drugs
1	Ambulance	Five injections
2	marine ambulance	Five injections
3	medical evacuation plane	Determined by the Saudi Red Crescent Authority, whether the size and nature of the aircraft

◆ 20 Article:

Drugs containing narcotics or psychotropic substances allowed to be prescribed in therapeutic institutions in Saudi Arabia are:

First: narcotic drugs:

No	Narcotic Drug	No	Narcotic Drug
1	ALFENTANIL	11	LEVOMETHORPHAN
2	ALPHACETYLMETHADOL	12	LEVORPHANOL
3	CODEINE	13	METHADONE
4	DEXTROPROPOXYPHENE	14	MORPHINE
5	DIHYDROCODEINE	15	OXYCODONE
6	DIPHENOXYLATE	16	OXYMORPHONE
7	ETORPHINE	17	PETHIDINE
8	FENTANYL	18	REMIFENTANIL
9	HYDROCODONE	19	SUFENTANIL
10	HYDROMORPHONE	20	TRAMADOL

(The dosage forms, concentrations and sizes of these drugs are approved by the Saudi Food and Drug Authority)

Second: psychotropic substances:

No	Psychotropic Substances	No	Psychotropic Substances
1	ALPRAZOLAM	22	KETAMINE
2	AMPHETAMINE	23	LORAZEPAM
3	AMOBARBITAL	24	MEPROBAMATE
4	BARBITURIC ACID	25	METHOHEXITAL
5	BENZHEXOL	26	METHYLPHENIDATE
6	BIPERIDINE	27	MIDAZOLAM
7	BROMAZEPAM	28	MODAFINIL
8	BUPRENORPHINE	29	NALBUPHINE
9	BUTORPHANOL	30	NITRAZEPAM
10	CHLORAL HYDRATE	31	NOREPHEDRINE
11	CHLORDIAZEPOXIDE	32	OXAZEPAM
12	CHLORMETHIAZOLE	33	PEMOLINE
13	CLOBAZAM	34	PENTAZOCINE
14	CLONAZEPAM	35	PENTOBARBITAL
15	CLORAZEPATE	36	PHENOBARBITAL
16	DEXAMFETAMINE	37	PHENPROBAMATE
17	DIAZEPAM	38	PREGABALIN
18	EPHEDRINE	39	PRIMIDONE
19	ETHANOL	40	TEMAZEPAM
20	FENOZOLE	41	THIOPENTAL
21	FLURAZEPAM	42	ZOLPIDEM

(Dosage forms, concentrations and sizes of these drugs are approved by the Saudi Food and Drug Authority)

◆ 21 Article:

- A. Strictly prohibited the distribution or handling of free samples for drugs or psychotropic substances.
- B. Advertising of narcotics and psychotropic substances is prohibited except in journals, conferences, seminars and scientific publications dedicated to professional practitioners as stated in Article (63) of the regulations on pharmaceutical establishments and implementing regulations.

◆ 22 Article:

**Joint committee between the Ministry of Health and Saudi Food and Drugs Authority.**

**1.The functions of the committee:**

- A. Approved requests for the use of modern technology in substances handling of narcotics and psychotropic substances.
- B. Modify the drugs list containing narcotics and psychotropic substances allowed for handling by means of transportation.
- C. Update procedures and controls description and dispensing.
- D. Modify the conditions, statements and validity period of the restricted prescription conditions and data.
- E. Modify ambulatory drugs list containing narcotics or psychotropic substances that are allowed in ambulatory cases.
- F. Modify the schedules accompanying the Law of Combating Narcotics and psychotropic Substances.

**2. The committee includes delegates from the following bodies:**

1. General administration of medical supply, Ministry of Health.
2. General administration of mental and social health, Ministry of Health.
3. General administration of pharmacy care, Ministry of Health.
4. General administration of inventory control, Ministry of Health.
5. Ministry of Health Investment Development Assistance Agency.
6. Assistant compliance agency of the Ministry of Health.
7. Consultant doctor nominated by the General Administration of hospitals.
8. Saudi Food and Drug Authority.

**3 - Proceedings of the committee:**

- A. The committee chairman for three years, renewable only one time and alternating between the Saudi Food and Drug Authority of the Ministry of health are chosen chairman of the committee by the minister of Health in coordination with the CEO of Saudi Food and Drug Authority.
- B. The Committee shall meet periodically every three months and may meet at the request of the chairman when the need arises.
- C. The decisions of the committee shall be issued by majority and shall be submitted to the author for adoption.
- D. May the Committee, in some of tasks use of whatever it deems appropriate.

◆ 23 Article:

**Execution of judgments:**

1. Specialists who have the status of criminal seizure in the provisions of Law of Combating Narcotics and psychotropic substances and implementing regulation and these procedures and controls are doctors, pharmacists and technicians working in the following competent authorities:
  - A. Saudi Food and Drug Authority.
  - B. The public administration of medical supply and the public administration of inventory control at Ministry of Health.
  - C. Medical supply administration and inventory control departments in regions and provinces.
  - D. Committed to health affairs in the regions and provinces.
2. The implementation of the provisions of Law of Combating Narcotics and psychotropic Substances implementing regulations of these procedures and controls by the competent authorities shall be as follows:
  - A. The Saudi Food and Drug Authority shall be implementation the provisions on all bodies and establishment.
  - B. The public administration of medical supply and public administration of inventory control at the Ministry of health are competent to implement the provisions on the establishment under supervision of the Ministry of Health.
  - C. The Compliance administration of Health Affairs in the regions and province is competent to implement the provisions on private establishment licensed by Ministry of Health.
  - D. The administration of medical supply and warehouse control departments in the regions and province implement the provisions on the establishment belonging to Ministry of Health and supervise on them by public administration of medical supply at Ministry of Health in the region or provinces.

3. The competent authorities referred to in Paragraph (1) of this Article, the formation of committees of inspection no less members of three specialists who are criminal seizure status in the implementation of the provisions of Law of Combating Narcotics and psychotropic Substances and the possible development of these procedures and controls. Although, to ensure the application of steroids to the provisions of Law of Combating Narcotics and psychotropic Substances implementing regulation of these procedures and controls.

◆ 24 Article:

The user manual for the electronic system of medicines attached to these procedures, controls and modifications is an integral part of it.

◆ 25 Article:

These procedures and controls nullify all ministerial decisions and provisions that conflict with them.

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**Check regular updates for the tables accompanying electronic system of Law of Combating Narcotics and psychotropic Substances and user guide for electronic system by visiting the website of the Saudi Food and Drug Authority.**

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