الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products

1442 H

Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products

Article One:

The following terms and phrases, wherever mentioned in this Law, shall have the meanings expressed next to them, unless otherwise required by context:

- **Law**: Law of Pharmaceutical and Herbal Establishments and Products.
- **Authority**: Saudi Food and Drug Authority.
- **Board**: Authority Board of Directors
- **CEO**: Chief Executive Officer of the Authority.
- **Pharmacist:** A person who holds a bachelor's degree in Pharmaceutical Sciences or Doctor of Pharmacy (PharmD) degree from a Saudi Pharmacy College or equivalent.
- **Pharmacy Technician:** A person who holds a Pharmacy Technician diploma from a Saudi health institute or college or equivalent.
- **Pharmaceutical Product (Medication):** A pharmaceutically manufactured product containing one substance or more, and used externally or internally in treatment or prevention of human or animal diseases.
- **Herbal Products:** Any plant or herb that have medical claims and manufactured in a pharmaceutical form.
- **Counterfeit Pharmaceutical or Herbal Product**: A product that its content, identity, or source is changed intentionally for the purpose of deception, even if it contained the same ingredients, including the trademarks and generic drugs. The pharmaceutical or herbal product is deemed counterfeit if it is polluted, contained pollutants, has wrong ineffective or inadequate potency ingredients, included non-effective ingredients or packed in fake packages.
- **Spoilage Pharmaceutical or Herbal Product:** the product that its qualities changed and becomes unusable.
- **Pharmaceutical Establishment**: a manufacturer of pharmaceutical and herbal products, a pharmaceutical and herbal product sale warehouse, the scientific office, or a center of pharmaceutical consultation or pharmaceutical and herbal products analysis.
- **Pharmacy**: A pharmaceutical establishment where pharmaceutical and herbal products are prepared and dispensed .
- **Pharmaceutical and Herbal Products Sale Warehouse**: A pharmaceutical establishment licensed to import, distribute or wholesale pharmaceutical and herbal products.

- **Scientific Office**: A pharmaceutical establishment that provides scientific, technical and marketing information on pharmaceutical and herbal products in the Kingdom.
- **Herbal Products Selling Establishment**: A pharmaceutical establishment where herbal products are prepared and dispensed sold.
- **Center of Pharmaceutical Consultation or Pharmaceutical and Herbal Products Analysis:** A pharmaceutical establishment that provides medicinal consultations, carry out analysis of pharmaceutical and herbal products, conduct bioavailability and bioequivalence studies, quality control of pharmaceuticals and determine drug levels in biological fluids.
- **Regulations**: The Implementing Regulations of this Law.

Article Two:

The owner is not allowed to operate Pharmaceutical Establishment before acquiring the required license from the Authority.

Article Three:

Granting a license for the **Center of Pharmaceutical Consultation or Pharmaceutical and Herbal Products Analysis** shall be subject to the following conditions:

1- The manager shall be a full-time pharmacist holding a practice license.
2- The center shall comply all conditions and specifications set forth in the Regulations.

Regulations:

3.1. It is required to submit a request for a license, showing the type and location of the requested activity. The relevant forms shall be filled in.
3.2. A copy of the Commercial Registration including the Establishment's activity shall be submitted.
3.3. Required licenses shall be obtained from the competent authorities.
3.4. The pharmaceutical Consultation Center shall be separated to an independent place if the activities of the Center included bioequivalence and bioavailability studies or laboratory for pharmaceutical and herbal products analysis.
3.5. The technical requirements for each activity that published on the Authority website shall be met.
3.6. In the case of licensing the activity of pharmaceutical and herbal products analysis, the technical requirements and conditions stipulated under the Guidelines for Licensing Private Laboratories shall be met.

3.7. Any other conditions, requirements or circulars required by the Authority and published on its website shall be met.

Article Four:

Granting a license for wholesaling and trading pharmaceutical and herbal products shall be subject to the following:

1- The manager must be a full-time pharmacist or pharmacy technician holding a practice license; and
2- The warehouse shall comply the conditions and specifications set forth in the Regulations.

Regulations:

4.1. The Authority shall grant the licenses of the wholesale pharmaceutical and herbal products warehouses after meeting the licensing requirements that published on the Authority website.

4.2. If the warehouse trades and storages narcotic and psychotropic substances, a full-time licensed Saudi pharmacist shall be appointed as a warehouse manager and shall be in charge of narcotic and psychotropic substances. If the store manager is a pharmacist, it is allowed to appoint a licensed Saudi pharmacy technician to be in charge of the narcotic and psychotropic substances.

4.3. The warehouse shall be committed to the Good Storage and Distribution Practice.

4.4. The branches of the warehouse shall meet the same conditions, which applied to the original warehouse.

4.5. The approval of the Authority shall be obtained in case of desire to change the name, address, location or the manager in charge.

4.6. The licensing conditions stipulated under this Law and its Implementing Regulations shall be met in the cases of sale, waiving or transfer of the warehouse ownership or any other procedure.

4.7. The warehouse shall sell the medications to all establishments licensed to sell the pharmaceutical and herbal products in a balanced manner that prevents the monopoly of a specific item to some pharmaceutical or herbal products sale establishments.

4.8. The Warehouse shall have an electronic system approved by the Authority and integrated with the Authority electronic tracking system.

4.9. Necessary licenses shall be obtained from the competent authorities.

4.10. Provisions and responsibilities between the lessor and lessee and the conditions for

storage for the third party, which are published on the Authority website, shall be complied.

4.11. The fulfillment of any other conditions, requirements or circulars specified by the Authority and published on its website.

Article Five:

Licensing for a pharmaceutical and herbal products factory shall be subject to the following:

1- Obtaining a manufacturing license issued by the relevant authority;
2- The technical manager of the factory shall be a full-time Saudi pharmacist who holds a practice license; and
3- The factory shall satisfy the conditions and specifications set forth in the Regulations.

Regulations:

5.1. The Authority shall grant the licenses the pharmaceutical and herbal products factories after meeting the licensing requirements that published on the Authority's website.

5.2. The technical manager of the factory shall be a full-time Saudi licensed pharmacist in accordance with the requirements stipulated by the Authority and published on the Authority website.

5.3. A qualified person shall be appointed to release batches in accordance with the requirements stipulated by the Authority and published on the Authority's website.

5.4. Factories of pharmaceutical and herbal products shall comply with the good manufacturing practices which published on the Authority's website.

5.5. If the narcotic substances or psychotropic substances are being manufactured in the establishment, a licensed Saudi pharmacist shall be appointed to be responsible of observing them.

5.6. The Authority shall be informed if the owner desired to expand the factory or performing construction works on production lines.

5.7. The licensing conditions stipulated under this Law and its Implementing Regulations shall be met in the cases of sale, waving or transfer of the factory ownership or any other procedure.

5.8. The branches of the manufacturer shall meet the same conditions which are applied to the original manufacturer.

5.9. The approval of the Authority shall be obtained in case of desire to change the

name, address, location or the technical manager.

5.10. The factory shall have an electronic system approved the Authority and integrated with the Authority electronic tracking system.

5.11. Necessary licenses shall be obtained from the relevant authorities.

5.12. The fulfillment of any other conditions, requirements or circulars specified by the Authority and published on its website.

Article Six:

Each company or a pharmaceutical product manufacturing establishment, which has a registered factory in the Kingdom, shall have a scientific office. Granting the license for the scientific office shall be subject to the following:

1- The office manager shall be a full-time Saudi pharmacist who holds a practice license; and

2- The office shall comply the conditions and specifications set forth in the Regulations.

Regulations:

6.1. The Authority shall grant the license of the Scientific Offices after meeting the licensing requirements that published on the Authority's website.

6.2. The Scientific Office shall be located in an independent building or as a part of the company building.

6.3. The Scientific Office shall be equipped with necessary materials and references to carry out its assigned tasks.

6.4. The technical manager shall be a Saudi full-time licensed Pharmacist.

6.5. Meeting any other conditions, requirements or circulars specified by the Authority and published on its website.

6.6. The Scientific Office shall undertake the following tasks:

A. Provide the accurate pharmaceutical information about the company's products which are traded in the Kingdom to the beneficiary authorities and employees in the healthcare and regulatory fields in accordance with the scientific basis of practicing the pharmacy profession.

B. Ensure the accuracy of the information that used in marketing the company's registered products and its conformity with the submitted information approved by the authority.

C. Verify the compliance of the company represented by the office with the provisions of the Saudi Code of Pharmaceutical marketing Practices ethics.

D. Implement the laws and instructions issued by the Authority.

E. Support the scientific activities in the fields related to the company products traded in the Kingdom, participate in the activities of the scientific associations and contribute to the continuing education programs.
F. Contribute to the scientific studies and researches in cooperation with the specialized scientific centers in accordance with the rules and ethics of the scientific research.
G. Educate the company employees and the pharmacy students to become familiar with the scientific office tasks.
H. Following up the registration statues of the company's products in the Kingdom.
I. Contribute to spread the health awareness and the pharmaceutical education in the Kingdom.
J. Provide the free samples of the registered products, if possible, and keep them in accordance with the technical principles' requirements of storage.
K. Following up the company's registered products after marketing to inform the Authority about any remarks related to the quality and effectiveness of the registered product or in case adverse reactions or pharmaceutical errors emerged after marketing.

The following table provides the maximum periods of informing the Authority:

Type of Report	**Period**
Reports of serious unexpected side effects	Within 15 days
Reports of non-serious unexpected side effects	Within 15 days
Reports of serious expected side effects	Within 15 days
Reports of non-serious expected side effects	Within 90 days
Reports of products quality	Immediately
Report of lack of effectiveness	Within 15 days

L. Supporting the health sector staff to attend scientific conferences.
M. Following up the update of the internal leaflet and the external package of the registered product and ensure that its information conforms to the information approved with the Authority.
N. The Scientific Office shall establish a Pharmacovigilance Section and appoint a licensed full-time Saudi pharmacist to monitor the section and undertake its tasks in accordance with the Good Pharmacovigilance Practices guideline.
O. Provide the instruments for risk reduction approved by the Authority for the pharmaceutical and herbal products in all health establishments and pharmacies where such products are sold and dispensed, along with supporting healthcare

practitioners to apply them.

Article Seven:

The period of a pharmaceutical establishment license shall be five renewable years.

Regulations:

7.1. The period of the pharmaceutical establishment license shall begin from the date of its issuance.

7.2. The owner of the pharmaceutical establishment shall apply for licensing renewal at least three months before the expiration date.

7.3. The Authority shall renew the license of the pharmaceutical establishment after completing all legal requirements, and the establishment shall bear no responsibility due to delay in license renewal process when applying for renewal during the legal period and completing all renewal requirements.

Article Eight:

An applicant for a pharmaceutical establishment license or renewal thereof shall pay the fees as follows:

Pharmaceutical Establishment	License or Renewal Fee
factory of pharmaceutical and herbal products	10,000 Riyals
Pharmaceutical and herbal products sale warehouse	3,000 Riyals
Pharmaceutical consultation and pharmaceutical and herbal products analysis center	1,000 Riyals
Scientific office	1,000 Riyals

Article Nine:

A pharmaceutical establishment shall not employ unlicensed pharmacists, pharmacy technicians or healthcare practitioners.

Regulation:

9.1. The pharmaceutical establishment shall not employ pharmacists, pharmacy technicians or other health practitioners unless obtaining the license from the competent authority.

9.2. The percentage of the Saudi pharmacists out of the total pharmacists working in the pharmaceutical establishments owned by the same owner shall be subject to the criteria of the Ministry of the Human Resources and Social Development within the

scope of professions as per the regions and governorates.

9.3. The health practitioners working in the pharmaceutical establishment shall comply with provisions of the Law of Practicing Healthcare Professions and its Implementing Regulations.

9.4. The pharmaceutical establishment owner shall notify the Authority in case the establishment manager desired to leave work, provided that a new manager shall be appointed in accordance with the provisions of this Law and its Implementing Regulations no later than ninety days. The pharmaceutical establishment shall not operate after ninety days unless new manager is appointed.

9.5. Apart from the exception stipulated under Article (4/9), it is not permissible to operate the pharmaceutical establishment without a manager.

9.6. If the person in charge of the custody desires to leave work, he shall deliver the custody of narcotic and psychotropic substances in accordance with the procedures and conditions of the substances and psychotropic substances.

Article Ten:

Only a full-time licensed Saudi pharmacist who holds a practice license may work in the field of advertising and promoting pharmaceutical and herbal products. The CEO may grant exemption from the nationality condition in the absence of an adequate number of Saudi pharmacists.

Regulations:

10.1. The jobs of advertising of the pharmaceutical and herbal products are restricted to the Saudi Pharmacists, in accordance with the mechanism for Saudization of the jobs of advertising of the pharmaceutical and herbal products which issued by the Authority and published on its website.

10.2. Professionals in advertising pharmaceutical and herbal products shall comply with the Saudi Code of ethics for Pharmaceutical Promotional Practices in the Kingdom of Saudi Arabia published on the Authority's website.

10.3. Complying any other conditions, requirements or circulars specified by the Authority and published on the website.

Article Eleven:

Pharmaceutical or herbal products shall be priced according to the factory price or price of export to the Kingdom in the currency of the country of origin or any other currency designated by the Authority. The Authority shall periodically review the prices of products.

Regulations:

11.1. The Authority shall determine the price of the pharmaceutical or herbal product in accordance with the procedures stated in the Pharmaceutical and Herbal products Pricing Guidelines.

11.2. The Authority shall review the prices of the pharmaceutical and herbal products and re-price them in accordance with the procedures stated in the Pharmaceutical and Herbal products Pricing Guidelines.

Article Twelve:

The evaluation of the profit margin added to the price of each pharmaceutical and herbal products for a pharmaceutical and herbal products trading-warehouse, pharmacy and herbal products warehouse shall be as follows:

Factory or Export Price	Warehouse Profit Margin (Based on Factory or Export Price)	Pharmacy or Herbal Products Store Profit Margin (Based on Pharmaceutical Sale Warehouse Price)
Fifty Riyals or less	15%	20%
More than Fifty Riyals up to Two Hundred Riyals	10%	15%
More than two hundred Riyals	10%	10%

Article Thirteen:

Samples of pharmaceutical and herbal products intended to be used for promotional purposes shall not be sold.

Regulations:

13.1. The phrase “Free Sample” shall be printed on the package of the pharmaceutical and herbal product sample in Arabic and English.

13.2. Distribution of the free samples shall be restricted to the physicians and pharmacists to become familiar with such products; also, they shall not be sold or dispensed to the patients or the public. Further, the free samples shall not be kept in the pharmacies and the herbal products sale store.

13.3. It is prohibited to distribute or trade free samples of narcotic or controlled drugs.

13.4. The free samples permitted to be distributed shall not exceed (1%) of the quantity of the imported or locally manufactured pharmaceutical or herbal product.

13.5. The health practitioners licensed in a pharmaceutical establishment shall not receive any financial or in-kind benefit from companies, agents, distributors, or warehouse for the purpose of promotion, marketing, or directing the patient to a product with a specific brand name.

Article Fourteen:

1- Pharmaceutical products can only be sold at retail pharmacies. As an exception, the CEO shall issue a list of pharmaceutical products that might be sold in retail stores besides pharmacies.

2- The herbal products can only be sold at pharmacies and Herbal products Selling Establishment. As an exception, the CEO shall issue a list of herbal products that may be sold in retail warehouses besides pharmacies and herbal products selling establishment.

Regulations:

14.1. The Authority shall prepare a list of the pharmaceutical and herbal products that can be sold in places beside the pharmacies and herbal products sale establishments.

14.2. The Authority shall define the places and requirements for selling pharmaceutical and herbal products beside the pharmacies and herbal products sale establishments.

14.3. All establishments that sell pharmaceutical and herbal products shall inform about the selling process on the tracking system. The sale systems shall be integrated with the electronic tracking system that approved by the Authority.

Article Fifteen:

1- The Pharmaceutical establishments shall not possess any amount of pharmaceutical and herbal products, without having documents that declare their purchase origin and quantities.

2- The factory of pharmaceutical and herbal products shall replace any quantity of the products sold to the Pharmaceutical and Herbal products trading Warehouse if they would expire within one month only and the warehouse shall bear the same obligation towards the pharmacy.

Regulations:

15.1. The pharmaceutical establishment shall keep the documents proving the source of

purchasing the pharmaceutical and herbal products, their quantity, name of the product, the registration number, and the batch number on the package. In addition, the establishment shall keep the purchase invoices at least three months after the date of running out.

15.2. Non-pharmaceutical establishments that sell the excluded pharmaceutical and herbal products shall comply with the provisions of Article (15/1).

15.3. Pharmaceutical establishments shall not sell or purchase any expired or non-registered pharmaceutical or herbal products.

15.4. The sources of purchasing the pharmaceutical and herbal products shall be licensed by the Authority.

Article Sixteen:

It is required from who dispenses or sells a counterfeited, spoilage, expired or unregistered pharmaceutical or herbal product to immediately notify the Authority when becomes aware of the situation. The notification shall include all information related to what has been dispensed or sold, its quantity and the name and address of the receiver or purchaser. The seller is obligated to return the money to the purchaser.

Regulations:

16.1. The informer shall use the electronic reporting system (SFDA Vigilance) as soon as he is aware about the issue and provide the details of the counterfeited, spoilage, expired or non-registered product as follows:

A. Scientific name of the product.
B. Trade name of the product.
C. Batch details.
D. Details of the expected side effect on the end user of the product.
E. Product storage method.
F. The way through which the informer obtained the product.
G. Means of communication with the informer.
H. Details of the individuals used the product, if available.
I. Details of the institutions, hospitals or others that received the Product.
J. Gather and delivery of the samples of the notified product to the Authority via post.

Article Seventeen:

Trading of pharmaceutical and herbal products prior to their registration shall be prohibited.

Regulations:

17.1. Without prejudice to the provisions of Article Twenty-Three of this Law, it is prohibited to import, trade or possess any pharmaceutical or herbal Product for the purpose of trading before registration by the Authority.

17.2. The Authority – when necessary – has the right to permit trading and selling of non-registered products in pharmaceutical establishments.

Article Eighteen:

The pharmaceutical or herbal products shall be registered for a renewable five-year term for a fee of (one thousand) Riyals for any concentrates, pharmaceutical form or package paid upon registration or renewal.

Regulations:

18.1. The period of registration of the pharmaceutical or herbal product shall begin from the issuance date of the registration certificate by the Authority.

18.2. The pharmaceutical establishment shall pay the fees within three months as of the date of being informed about the approval of registration or renewal.

Article Nineteen:

Registered pharmaceutical and herbal products shall not be sold before the Authority determines their prices in accordance with their packages.

Regulations:

19.1. It is permitted in the pharmacies and herbal products sale stores to sell a part of the registered package or refill the medication for the patient's need, and the price of the fragmented unit shall be calculated as per the price of the registered package, as well as the obligation to write the trade name, the scientific name, shelf life and storage conditions on the package, except the antibiotic and the medications require using the whole quantity.

19.2. The pharmaceutical and herbal products shall only be sold when they are registered on the electronic tracking system, and the manager of the pharmaceutical establishment shall reject the acceptance and storage of the violated products. Furthermore, the manager of the pharmaceutical establishment shall inform the

Authority about such violations.

Article Twenty:

Committees for registration of pharmaceutical and herbal factories and their products shall be formed by a CEO's decision. The Regulation shall determine registration conditions and means of forming the committees as well as their work procedures. Remuneration of committee members shall be determined by the Board's decision.

Regulations:

20.1. Committees for studying the registration of pharmaceutical and herbal factories and their products shall be formed by a CEO's decision. Such committees shall consist of competent and experienced professionals. The decisions of such committees shall become effective after being approved by the CEO or his duly authorized representative.

20.2. The committee meeting shall be deemed valid when the majority of members are present in the presence of the Head of the Committee or his duly authorized representative. The decisions of the committee are issued by the absolute majority of the present members. In the case of equal votes, the Head of the Committee shall have the casting vote.

20.3. In carrying out their tasks, the registration committees shall comply with the provisions of this Law and its Implementing Regulations.

20.4. The registration committees shall carry out the following tasks:

A. Approving the registration of pharmaceutical and herbal companies, factories along with their products, pricing them, determine the method of dispensing them and distribution places.
B. Consider the objections that belong to the registration of the new pharmaceutical and herbal products and make decisions regarding them.
C. Update the principles of registration of the pharmaceutical and herbal products, and pricing guidelines for pharmaceutical and herbal products.
D. Suspend, withdraw or revoke the registered pharmaceutical or herbal products.
E. Consider the subjects that the Authority refers to them.
F. Pricing and repricing of the pharmaceutical and herbal products.

Article Twenty-One:

Pharmaceutical and herbal products manufacture registered in the Kingdom and the pharmaceutical and herbal products sale warehouses representing them shall ensure the

availability of registered pharmaceutical and herbal products thereof regardless of price or consumption rate.

Regulations:

21.1. Pharmaceutical and herbal products factories and sale warehouses shall develop a plan to provide all their registered products including the consumption of the previous year and assessment of their needs within the next year and inform the Authority on an annual basis.

21.2. Pharmaceutical and herbal products factories and sale warehouses shall provide the details of the received items, inventory of all their registered products, and provide the Authority with a copy thereof upon request.

21.3. The Authority shall review the statistics of the plans for providing the registered products to ascertain the sufficiency of the planned market needs.

21.4. Pharmaceutical and herbal products factories and sale warehouses shall have a permanent inventory of all registered products that is enough for 6 months as per the data of annual consumption and needs, which were reviewed with the Authority and compensate any inventory shortage within 3 months as maximum, unless the Authority issues a decision revoking their registration.

Pharmaceutical and herbal products factories and the pharmaceutical and herbal products sales warehouses representing them shall inform the Authority in case of expected shortage or interruption in supplying the company's registered products at least six months prior to the expected time when the supply is interrupted or the inventory is affected and provide the solutions contribute to compensate the shortfall.

Article Twenty-Two:

Pharmaceutical and herbal products shall not be exported without Authority's approval.

Regulations:

22.1. For export purposes, the Authority issue a pharmaceutical or herbal product certificate, or a certificate of free sale for the locally manufactured products.

22.2. The pharmaceutical establishment shall comply with the export and re-export conditions issued by the Authority.

22.3. The pharmaceutical establishment shall not re-export the cleared products, provided that they shall not be traded due to reasons related to the product quality and safety.

22.4. The pharmaceutical establishment shall not re-export the products without ensuring that quantities which covering the local needs for 6 months are available.

Article Twenty-Three:

The Authority may, if necessary, approve the import of non-prohibited pharmaceutical and herbal products prior to their registration.

Regulations:

23.1. The non-prohibited pharmaceutical and herbal products may be imported before registering them subject to the following:

A. Obtaining prior approval for import from the Authority.
B. The product shall be one of the important products which have no alternative registered with the Authority.
C. Import shall be under the name of hospitals directly or via the company's agent that registered with the Authority.
D. The product required to be imported shall be marketed in the Country of Origin.
E. Companies registered with the Authority shall import the product, and the company registration condition may be exempted as per the Authority's approval.
F. The imported quantity shall cover the need of the applicant authority for six months as maximum.
G. According to the above-mentioned conditions, it is prohibited to trade in the non-registered imported products or sold to an entity other than the beneficiary without the Authority's approval.
H. Establishments that stores the products for a third party is prohibited from importing the non-registered products.
I. Private warehouses, which are licensed by the Authority and have registered drugs, are permitted to import unavailable and non-registered drugs.

23.2. Universities and research institutions are permitted, in limited quantities, to import non-registered drugs, herbal products and products with medical claims to conduct scientific studies and researches after obtaining the Authority's approval.

23.3. The importer shall be responsible for the safety and effectiveness of using the product.

23.4. The imported product shall be in conformity with the requirements of the electronic tracking system.

Article Twenty-Four:

Based on a recommendation by the competent registration committee, the CEO may issue a decision to revoke the registration of pharmaceutical and herbal products factories or any pharmaceutical or herbal product or ceasing of its trading. The Authority may approve re-export or dispose of those products.

Regulations:

24.1. in the following cases, the CEO may issue a decision to revoke the registration of any of the pharmaceutical or herbal products factories as be the recommendation of the Authority Registration Committee:

A. If the factory failed to apply for registration of any of its products within one year of informing the Authority about the factory registration.
B. If forgery or manipulation of the submitted documents is proved.
C. If the factory's activity was prohibited in the Country of Origin or in the Kingdom.
D. If the factory violations repetition has been proved.
E. If the factory manipulated the product ingredients by violating of the Registration Committee decision about the registration of the product.
F. If the committee has the evidence and presumptions confirming that the factory failed to comply with the registration certificate conditions or failed to continue the implementation of Good Manufacturing Practices for Pharmaceutical Products were available before the Committee.

24.2. The CEO may issue a decision prohibiting the import, ceasing the distribution, prohibiting the trading, suspending the registration, revoking the registration or returning the pharmaceutical and herbal product based on the recommendation of the Authority Registration Committee in any of the following cases:.

A. If its use ceased in accordance with the recommendation of the World Health Organization or the global health organizations.
B. If the reports proving its toxicity were available for the Registration Committee or has serious side effects or for any other technical reasons as per the Committee's discretion.
C. If it was deregistered or ceased to be manufactured in the Country of Origin (exporting country).
D. If it was not marketed or imported for two years throughout its registration period.
E. If it is proved that the submitted information about the pharmaceutical or herbal product in the registration committees are not true.

F. If the pharmaceutical establishment or its agent did not submit a request for the registration renewal of the product.

24.3. The following procedures shall be taken when a decision of withdrawing or returning a pharmaceutical or herbal product is issued:

A. The Authority shall issue a memo to all governmental health sectors regarding the decision on withdrawal or returning the product.

B. Address the importing or manufacturing pharmaceutical establishment or its agent to withdraw all quantities of the product in the public and private health sector establishments and prepare lists of the received, dispensed and remaining quantities of the withdrawn product to all authorities from which it was withdrawn and provide the Authority with a copy of the quantities gathered in a table including all areas.

C. The importing or manufacturing pharmaceutical establishment or its agent shall coordinate with the Authority to destroy the withdrawn or returned quantities from the governmental and private sectors or re-export them.

24.4. The competent authority may approve re-export of the non-spoilage and non-counterfeited pharmaceutical and herbal products after removing any logo, information about its registration or price in the Kingdom.

24.5. Any pharmaceutical or herbal product that is no longer traded or any of its batches were rejected shall be destroyed by a company that specialized in the disposal of the medical wastes and in the presence of the Authority's representative to supervise the destruction process. The pharmaceutical establishment will pay the fees for the disposal of the product.

Article Twenty-Five:

Pursuant to a medical report, the Authority may approve the entry of non-prohibited pharmaceutical and herbal products in limited quantities for personal use.

Regulations:

25.1. The non-prohibited pharmaceutical and herbal products that are brought from abroad for personal use are permitted to be entered in accordance with the following conditions:

A. There shall be a medical report on the patient's health status issued from the treatment institution that prescribed the medication.

B. The quantity which desired to be cleared shall be non-commercial and for the personal use only.

25.2. Pharmaceutical and herbal products and products with medical claim that are personally requested from abroad via internet or express mail shall not be permitted to be entered without obtaining a permission from the Authority.

Article Twenty-Six:

Taking into consideration the exception stipulated in Article (14) hereof, pharmaceutical and herbal products sale warehouses are prohibited to sell pharmaceutical and herbal products except to licensed pharmaceutical establishments and pharmacies.

Article Twenty-Seven:

Pharmaceutical and herbal products sale warehouses may import registered pharmaceutical and herbal products if they are not available with the factory, based on the Authority's approval.

Regulations:

27.1. If the factory failed to provide the pharmaceutical or herbal product, it shall be permitted to import the same product in accordance with the following conditions:

A. The Authority may allow the licensed pharmaceutical and herbal products sale warehouse to import the product in accordance with the provisions the Authority determines and publishes on its website.
B. The Authority shall issue an import permission includes the product name, pharmaceutical form, concentration, size of the package, the imported quantity, manufacturer and the Country of Origin.
C. The Authority shall determine the product sale price if the size of the imported package differ as per the principles of products pricing.
D. The importer shall sell the product at the official price.
E. The imported products shall conform to the requirements of the electronic tracking system.
F. The importer shall be responsible for following up the imported products in terms of safety and effectiveness and inform the Authority immediately on any issues in this regard.

Article Twenty-Eight:

A pharmaceutical and herbal products factory shall not begin manufacturing pharmaceutical and herbal products in commercial quantities prior to their registration.

Article Twenty-Nine:

A pharmaceutical and herbal products factory shall not be used for any purpose other than manufacturing pharmaceutical and herbal products, which the factory is licensed to produce.

Article Thirty:

A pharmaceutical and herbal products factory shall implement the guidelines of Good Manufacturing Practice (GMP).

Article Thirty-One:

Advertising of pharmaceutical and herbal products in the media shall be subject to controls set forth in the Regulations.

Regulations:

31.1. It is prohibited to advertise the pharmaceutical and herbal products that require a medical prescription, except in scientific magazines, conferences, symposiums, publications or other means allocated for the health practitioners, in accordance with the controls set by the Authority.

31.2. The provisions of the announcements, publications and advertisements of the pharmaceutical and herbal product that require medical prescription shall conform to their therapeutic substances and features in accordance with the leaflet of the product or summary of the product features, which are approved with the Authority.

31.3. It is permissible to advertise the pharmaceutical and herbal products that the Pharmaceutical Law authorizes to dispense them without a medical prescription in different advertising media after obtaining the Authority's approval in accordance with the controls set by the Authority.

31.4. Scientific lectures delivered to the health practitioners and campaigns for awareness about the diseases and health education, which are subjected to the conditions and controls approved by the Authority.

31.5. The Authority's approval shall be obtained before holding the scientific lectures delivered to the health practitioners and before deploying the campaigns for awareness about the diseases and health education directed to the public.

31.6. The product intended for advertisement shall be registered or listed in the Authority. The Authority may exclude some non-registered innovative products to promote them in the conferences and symposiums intended for the health practitioners only.

31.7. All pharmaceutical establishments shall register in Transparency and Disclosure

System which approved by the Authority.

Article Thirty-Two:

A pharmaceutical establishment shall be liquidated according to procedures set forth in the Regulations.

Regulations:

32.1. The pharmaceutical establishment under liquidation my continue to sell the products in the establishment during the period of liquidation under the responsibility of the owners – or its representative in case of his/her death – and by the knowledge of the establishment manager without carrying out new transactions for purchasing new products.

32.2. The pharmaceutical establishment owner – or its representative in case of his/her death – shall inform the Authority in writing at least thirty days before proceeding with the liquidation procedures.

32.3. The pharmaceutical establishment manager shall attach the following information with the notice:

A. Establishment name, address, license number and telephone number.
B. List of the narcotic substances, psychotropic substances, and their quantities, if any.
C. Set the liquidation and closure date.

32.4. The pharmaceutical establishment owner shall announce (declare) the liquidation of the establishment in two local newspaper, one of them is issued in the location of the pharmaceutical establishment. In case there was no newspaper issued in the area where the establishment located, the announcement (declaration) can be published on a newspaper in the nearest area, which shall state the closure date, name, address and telephone number of the pharmacy. A copy of the announcement shall be placed at the entrance of the pharmacy.

32.5. The pharmaceutical establishment owner shall inform the Authority about a copy of the announcement and set the date on which the inventory of narcotic drugs and psychotropic substances would occur, if the establishment were licensed to sell such products.

32.6. Pharmaceutical and herbal products in the pharmaceutical establishment shall be dealt with in one of the following methods:

A. Returning them to the factory or the distributor.
B. Selling them to a licensed pharmaceutical establishment under the supervision of

the pharmacy owner – or its representative in case of his/her death.

32.7. Narcotic and psychotropic substances shall be dealt with in accordance with the Guidelines for the Control of the Narcotic and Psychotropic Substances.

32.8. On the date set for the closure of the establishment, the pharmaceutical establishment owner – or its representative in case of his/her death – shall carry out the following:

A. Remove all signs and advertisements from the establishment if the transfer of its title to another owner is not approve.
B. Submit a request to revoke registration to the Authority.
C. Submit the results of the inventory of the pharmaceutical and narcotic products to the Authority.

Article Thirty-Three:

The Authority inspects pharmaceutical and herbal products along with pharmaceutical establishments to ensure their compliance with provisions of this Law and its Regulations through the Authority inspectors appointed as per the CEO's decision. The inspectors – within the provisions of the Regulations – shall do the following:

1- Seize the pharmaceutical and herbal products violating the provisions of Law; and
2- Deal with the seized violated products as follows:
   A- Keep the seized products and the related documents, if applicable;
   B- Sampling and analysis;
   C- Provide recommendation to destroy the products proved to be spoilage, counterfeit, expired or have health damages, if they were registered;
   D- Provide recommendations to destroy the unregistered seized products;

Destruction shall be conducted after the issuance of the Authority's decision as per the accepted technical forms, and one committee – or more – formed as per the CEO's decision shall be execute the destruction process. The violator shall bear the costs of destruction.

Regulations:

33.1. The Authority shall inspect the pharmaceutical and herbal products and the pharmaceutical establishment in accordance with the inspection's procedures approved by the Authority.

Article Thirty-Four:

A person shall be considered in violation of this Law if he:

1- Committed or engaged in counterfeiting any pharmaceutical or herbal product;
2- Sold, dispensed or possessed a counterfeited, spoilage, expired or unregistered pharmaceutical or herbal product with an intention of dealing in the product;
3- Manufacture or formulated a pharmaceutical or herbal product in violation of the registration conditions or any provision of the Law and its Regulations;
4- Brought to the Kingdom any counterfeited, spoilage, expired or unregistered pharmaceutical or herbal product or attempted to bring any of the aforementioned products;
5- Used false information in promoting and advertising the pharmaceutical or herbal product, or to violate the registration conditions;
6- Transport or warehouse a pharmaceutical or herbal product in violation of the transport and storage conditions set by the Authority;
7- Brought to or attempted to bring any packages or covers for a pharmaceutical or herbal product with an intention to fraud to the Kingdom;
8- Manufactured, printed, possess, sold or offered any packages or covers for a pharmaceutical or herbal product with an intention to fraud; and
9- Committed any other violation of the Law.

Article Thirty-Five:

1- Without prejudice to any severer penalty prescribed by another law, any person committed any of the violations stipulated under Article (Thirty-Four) of the Law should be punished by one or more of the following penalties:
   A- A fine not exceeding (five million) Riyals;
   B- Closure of the pharmaceutical establishment for a period not exceeding one hundred eighty days; and
   C- Revocation of the license.

Penalties stipulated under paragraphs (A and B) may be doubled in case of the repetition of the violation.

2- If the violation is reflected in committing any of the actions stipulated under paragraphs (1, 2, 4, 7 and 8) of Article (Thirty-Four) of the Law, the penalty will be imprisonment that not exceeding (ten) years and/or the fine not exceeding (ten million) Riyals. Moreover, any one of the penalties stipulated under paragraphs (1/B) or (1/C) of this Article may be imposed.

Article Thirty-Six:

The Authority shall impose the fines as following:

- Fines that not exceeding (100,000) Riyals (one hundred thousand Riyals) on the violating Scientific Offices and Medicinal Consultation, and Pharmaceutical Products Analysis Centers,
- Fines that not exceeding (200,000) Riyals (two hundred thousand Riyals) on the violating Pharmaceutical and Herbal Products Sale Warehouses and
- Fines that not exceeding (300,000) Riyals (three hundred thousand Riyals) on the violating factories of pharmaceutical and herbal products.

Such fines shall be imposed in accordance with a schedule including a classification of violations and penalties issued by the Board. The CEO or his duly authorized representative shall approve such penalties as per the decision thereof. In all events, the Authority shall have the right to take the precautionary measures, as it may deem necessary.

Article Thirty-Seven:

1- Pursuant to the Board's decision, forming one committee (or more) including of at least three members, one of them – at least – shall be a legal consultant.
2- Without prejudice to Article (Thirty-Six) of the Law, the committee – referred to in paragraph (1) of this Article – shall undertake the following:
   A- Consider the violations of the provisions of this Law – except the violations stipulated under paragraph (2) of Article (Thirty-Five) – and impose the penalties stipulated under paragraph (1) of Article (Thirty-Five) of the Law; and
   B- Consider the appeals brought before the Authority against the decisions imposing penalties issued in accordance with Article (Thirty-Six) of the Law.
3- The Board shall issue a decision determining the rules and procedures of the committee and the remuneration of its members.
4- Committee decisions may be appealed before the Administrative Court within (sixty) days from the notification date. If the Administrative Court canceled the penalty decision issued by the committee, the Court should consider the violation and impose the appropriate penalty as stipulated under Article (Thirty-Five) of the Law.

Article Thirty-Eight:

If the violation was punishable by paragraph (2) of Article (Thirty-Five) of the Law, the violation should be referred to the Public Prosecution for investigation and referral to the competent court as per the legal procedures.

Article Thirty-Nine:

The judgment or the decision imposing the penalty – as the case may be – may include a provision to publish its operative part at the expense of the violator in a local newspaper issued in the area where his residence is located. If there was a newspaper in his residence, it may be published in a newspaper in the nearest area, or published in any other proper means as per the type, severance and effect of the violation. However, the publication shall be after the judgment becomes final or if the decision was declared immune by the lapse of the time for appeal or endorsed by the competent court.

Article Forty:

The Board shall issue the Implementing Regulations of this Law within (one hundred and twenty days) from date of publication in the Official Gazette and shall become effective upon entry into force of this Law.

Article Forty-One:

This Law shall replace the Law of Pharmaceutical Establishments and Products issued by the Royal Decree No. (M/31) dated 01/06/1425 H and shall repeal all provisions contrary the provisions hereof.

Article Forty-Two:

This Law shall be published in the Official Gazette, and shall enter into force (one hundred and twenty days) from its publication date.

/ Seal of the Kingdom of Saudi Arabia – General Secretariat of the Council of Ministers/
/Seal of the Kingdom of Saudi Arabia – Bureau of Experts at the Council of Ministers/