

## **Federal law NO 20 of 1995**

### **Re: Medicines and Products Derived from Natural Sources**

We Zayed Bin Sultan Al Nahyan, president of the United Arab Emirates, in cognizance of the provisional constitution.

Federal law No (1) of 1972 Re: Capacities of ministries, and authorities of ministers as amended,

Federal law No (4) of 1982 Re: Pharmacy and Pharmaceutical establishments,

Federal law No (6) of 1986 Re: Fighting of drugs and the like,

Federal law No (2) of 1987 Re: Penal law.

Federal law No (35) of 1962 Re: Organization of the affairs of Industry,

Federal law No (44) of 1992 Re: Penal Procedural law

And under the proposal of Minister of Health, sanction of the Cabinet and approval of the High Federal Council, issue the following law,

#### **Article (1)**

The following words and expressions herein shall bear the meanings assigned to each, unless the context otherwise indicates:

State: United Arab Emirates

Ministry: Ministry of Health

Minister: Minister of Health

Concerned Directorate: Directorate of Medicine Control of the Ministry Health or any other directorate assuming their specialties in accordance with this law.

Concerned committee: The committee concerned in consideration of registration of medicines and products derived from natural source or sources of Ministry of Health, the formation and organization of work of which shall be under the decision of the Minister.

Medicine and product derived from natural source or sources: Any medicine or product including active ingredients of botanic, animal or any other natural source filled in a final pack and prepared for treatment of man or animal against diseases or for protection therefrom, whether such medicine or product be in its natural form or in the form of powder, extract, dyes, juice or any other extracts resulting from purification, splitting or concentration.

Any medicine or product including any chemical or semi-synthetic materials shall not be considered as derived from natural source.

### **Article (2)**

Special records shall be prepared by the concerned directorate of the Ministry for registration of the medicines and products derived from natural sources.

Registration shall be restricted to the medicines and products set for local use or orally or by rectum. Registration shall be effected under the decision of the minister upon a proposal of the concerned committee.

### **Article (3)**

Conditions and procedures of registration shall be under the decision of the minister upon proposal of the concerned directorate. On consideration of registration for registration of any medicine or product derived from natural source or sources, the information given by the experience in use of plants and other natural sources in the popular medicine throughout an appropriate period of time and the studies given in the specialized references and scientific books and researches published shall be taken into consideration.

### **Article (4)**

The Minister may under recommendation of the concerned committee exempt from certain conditions of registration in case the medicines or products are included in the medicine codes internationally acknowledged or if handling of the medicine or product is for scientific purposes but not for treatment.

### **Article (5)**

The following information and data in both Arabic and English should be put on the external pack and the internal literature for each medicine or product derived from natural source or sources, as minimum:

1. Name of medicine or product, and number of registration thereof by the Ministry, with reference to the code or scientific or heritage reference, if any, under which the medicine has been prepared.
2. Names of active natural materials included in the composition of the medicine or product and quantities thereof.
3. Date of manufacturing of the medicine or product and date of expiration if such validity expires by lapse of a certain time.
4. The name of the party producing such medicine or product.
5. Instructions and warnings of use of the medicine or product.

### **Article (6)**

The Minister may upon recommendation of the concerned committee decide as follows:

1. To authorize registration of any medicine or product derived from natural source or sources if fitness for use thereof is established.
2. Prohibit handling of any medicine or product, which in a certain time is proved to be harmful to health. In such case the medicine or product shall be deleted from the records of the Ministry if registered, and the quantities thereof available wherever they be shall be confiscated and destroyed, and the owners thereof shall have no recourse on the ministry for compensation.
3. Prohibit handling of any medicine or product if the contents thereof are found to be amended and set for handling before re-registration.
4. Fix the rates of medicines or products derived from natural source or sources and reconsider such rates.

### **Article (7)**

No medicine or product derived from natural source or sources may be handled except after registration thereof by the Ministry.

The medicine or product shall be re-registered if any amendment is made on its ingredients.

Any party producing a medicine or product derived from natural source or sources, desiring to market such medicine or product in the state shall be registered.

### **Article (8)**

Import, manufacturing, marketing or export of the medicine or product derived from natural source or sources shall not be allowed except after obtaining a permit for this purpose from the Ministry.

Conditions for licensing to import, manufacture, market or export and the procedures for obtaining such permit shall be decided by the Minister.

### **Article (9)**

Any interested party may complain against the decision passed for rejection or deletion of registration or rejection of licensing.

The complaint shall be submitted within thirty days maximum from handing the decision of rejection. The Ministers decision on the complaint shall be final.

### **Article (10)**

Obtaining the licenses provided for herein shall not exempt from obtaining the other licenses required by the other laws or regulations in force.

### **Article (11)**

The concerned directorate of the Ministry shall implement this law and the decisions passed for implementation thereof, and the employees of such directorate who shall be specified by the decision of the minister of Justice in agreement with the Minister shall have the capacity of judicial warrants. Within such capacity they shall have the right of access to the premises whose activities fall within the scope of this law with the exception of the premises allocated for living, in order to ensure implementation of this law and the executive regulations thereof and to check the violations. The local authorities of the emirates shall give the necessary facilities to such employees to enable them to perform their duties.

### **Article (12)**

Without prejudice to any severer penalty provided for in any other law, a penalty of imprisonment for a period not less than six months but not more than one year and a fine not less than five thousand Dirham's (Dh 5.000) but not more than ten thousand Dirhams (Dh10.000) or either one of these two penalties shall be effected against any one who commits any of the following acts:

1. Submits documents or gives misrepresentations or resorts to illicit ways ensuing in registration of a medicine and product derived from natural sources, or granted a license for import, manufacturing, export or handling thereof against this law.
2. Import, exports, manufactures, or handles a medicine or product derived from natural sources before obtaining a license to this effect from the Ministry.
3. Handles a medicine or product derived from natural sources for which a decision was passed by the concerned authority preventing handling thereof, which he is aware of.
4. Fraudulates or imitates a medicine or product derived from natural sources or promotes for a fraudulated or imitated medicine or sells it to others, which he is aware of the fraud or imitation thereof.

### **Article (13)**

Without prejudice to any severer penalty provided for in any other law, a penalty not less than one thousand Dirhams (Dh 1.000) but not more than five thousand Dirhams (Dh 5.000) shall be effected against any person licensed to deal in

medicines or products derived from natural sources who violates the price list specified by the Ministry for the medicine or product.

#### **Article (14)**

Any violation against this law or its executive regulations not provided for under articles (12) and (13) hereof, the perpetrator thereof shall be penalized by a fine not less than one thousand Dirhams but not more than five thousand Dirhams, without prejudice to any severer penalty provided for in any other law.

#### **Article (15)**

No medicine or product shall be registered or licensed as provided for herein except after payment of the specified fees.

Registration, re-registration and licensing fees shall be specified under the decision passed by the Council of Ministers. The Minister may under recommendation of the concerned committee exempt from all or part of such registration or licensing fees, and the decision for exemption shall be grounded.

#### **Article (16)**

Application of this law shall not be in prejudice to the provisions of the other laws regarding organization of pharmacy or prevention of drugs and the like or intoxicant harmful materials.

#### **Article (17)**

The Minister shall issue the decisions necessary for implementation of this law.

#### **Article (18)**

Any provision against this law shall be annulled.

#### **Article (19)**

This law shall be published in the official gazette and shall be put in effect six months after publication thereof.

**Zayed Bin sultan Al Nahyan**  
**President of the United Arab Emirates**

Issued by us at the presidential court in Abu Dhabi  
This 27th day of Jumadi II, 1416 AH  
Corresponding to 20.11.1995