

ROYAL DECREE NO. 41/96
Regarding the issuance of the Law of Pharmacy Practice &
Organization of Pharmaceutical Institutions

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On perusal of Royal Decree No. 26/75 of state organizational structure and its amendments, Law No. 10/73 regarding practice of pharmacy profession and organization of pharmacies, storage and sale of drugs and for the public interest, the following have been decided:

Article (1): The attached law on pharmacy practice and organization of pharmaceutical institutions, will be put into force.

Article (2): The Minister of Health will issue rules and decisions required to enforce the articles of this law.

Article (3): Law No. 10/73 of pharmacy practice, organization of pharmacies, storage and sale of drugs is deemed cancelled.

Article (4): This Decree will be published in the official Gazette and put into effect from the date of its publication.

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Issued on : 21-1-1417 H
Corresponding to: 8-6-1996

**LAW OF PHARMACY PRACTICE AND
ORGANIZATION OF PHARMACEUTICAL
ESTABLISHMENTS**

CHAPTER (1)

DEFINITIONS

Article (1) : In the execution of this Law, the following words and expressions will have the following interpretations, unless the context necessitates different meanings:

1. The Ministry: Ministry of Health
2. The Minister: Minister of Health
3. Drug: Any thing comprising of one or more substances comprising medical characteristics, such as drugs, pharmaceutical preparations, etc.
4. Pharmacy Profession: Any preparation or compounding or manufacturing or storage or sale or distribution of a drug that aims to prevent or cure humanbeing or an animal from diseases.
5. Licenced Pharmacist: Holder of a Bachelor degree in pharmacy or equivalent from a recognized university or a higher institute who is licenced to practise the profession according to the Law.
6. Pharmaceutical Establishment:
 - a. Pharmacy: Any licenced place that is equipped for preparation and retail – sale of drugs, either in general or particular to those who attend medical complexes and the like.

- b. Drug Store: Any licenced place that is equipped for drug preparation and whole sale.
- c. Pharmaceutical companies: Any licenced place that is equipped for drugs manufacturing, repacking and wholesale.
- d. Scientific Offices: Any centre that introduces drugs by the available scientific means that are approved by the ministry.

7. Toxins : As mentioned in Table (1)

8. Narcotics: As mentioned in Table (2)

9. Psychotropics: As mentioned in Table (3)

CHAPTER II

ORGANISATION OF PHARMACY PROFESSION & PHARMACEUTICAL ESTABLISHMENTS

- Article (2) : No person is allowed to practise pharmacy profession unless he holds a Bachelor Degree in Pharmacy or equivalent from a recognized university or higher institute and licenced by the Ministry.
- Article (3) : The licenced pharmacist may employ Pharmacy assistants provided his full responsibility for their performance is assured.
- Article (4) : No one is allowed to work as an Assistant Pharmacist prior to procurement of required licence from the Ministry of Health and unless holding a diploma in pharmacy or its equivalent as per the terms and conditions stipulated by a decision issued by the concerned authorities that determine the Diploma level and issuing institution.
- Article (5) : Pharmacists and Assistant Pharmacists licencing are according to terms and procedures stipulated by a ministerial decision.
- Article (6) : The Ministry shall maintain a register to enter particulars of Pharmacists and another for Assistant Pharmacists containing the name of licenced person, details of certificate, date obtained, issuing institution, number and date of registration, place of residence and place of work.
- Article (7) : The Pharmacist and Assistant Pharmacist are granted the licence by the Ministry upon registration. Name, place of residence, work address, number and date of registration and place / places where he is authorized to practice at, shall be included in the licence.

Article (8) : It is not allowed to practice as a Pharmacist or an Assistant Pharmacist in places other than pharmaceutical establishments. The pharmacist is not authorized to be a Manager for more than one pharmaceutical establishment. He is also not allowed to combine pharmacy with medical profession or any other profession that contradicts pharmacy profession. Financial sharing between pharmacists and physicians is absolutely forbidden. The pharmacist may render first-aid services in emergency cases only.

Article (9) : Establishment or proprietorship of pharmaceutical establishment shall be subject to the following:

- a. To be licenced by the Ministry.
- b. To comply with hygienic and technical terms and conditions shown in a decision issued by the Minister.
- c. To be managed by a licenced pharmacist.
- d. The distance between a pharmacy and another is not to exceed the distance determined by a ministerial decision. The Ministry's approval to be obtained in the event of licence transfer.

A ministerial decision will be issued with a view to regulating the functions of pharmaceutical establishments.

Article (10): With provision of the Ministry's approval, the pharmaceutical institution may arrange training programmes for students of the Colleges of pharmacy and the Omani Institutes of Assistant Pharmacists, under supervision and full responsibility of a licenced pharmacist.

Article (11) : A Technical Pharmaceutical Committee or more shall be formed by a ministerial decision, with the following terms of reference:

- a. Determine the practice licencing requests.
- b. Determine applications for licencing and transfer submitted by pharmaceutical institutions.
- c. Approval of registration requests of pharmaceutical companies and their products.
- d. Maintain professional standards and decide upon offences arising from non-compliance with the Articles of this Law and the executive Ministerial Decisions, according to procedures stated in Article No. (21).

Article (12) : Subject to approval of the Ministry of Finance, the following fees shall be determined by a ministerial decision.

- a. Establishing or proprietorship of a pharmaceutical institution - **R.O. 500/- as maximum.**
- b. Pharmacy Practise Licencing - **R.O. 100/- as maximum.**
- c. Assistant Pharmacist Licencing - **R.O. 50/- as maximum.**

Note: It is already approved in the Ministerial Decision No. 91/98.

Article (13): **The pharmaceutical establishment licence is cancelled in the following situations:**

- a. If the licence has not been implemented within six months from the date of issue.
- b. Transfer of proprietorship or shifting to another place or transfer of Licence without prior approval from the Ministry.
- c. Close down for (3) consecutive months or (6) non-consecutive months within a Gregorian year, without an excuse accepted by the Ministry.
- d. If the establishment is exploited for purposes other than those shown in the licence.

Article (14): The Ministry may assign pharmacists to carry out surprise inspections to the pharmaceutical establishments without early notice, and report their findings to Ministry.

CHAPTER III

Registration of Pharmaceutical Companies & their products, import and export of drugs

- Article (15): A ministerial decision will be issued to illustrate procedures and fees for registration of pharmaceutical companies and their products. The fees will be decided by a ministerial decision, upon approval of the Finance Ministry. Registration fees are not exceeding **R.O. 100/-** for the company and **R.O.50/-** for the product.
- Article (16): A ministerial decision will be issued regarding terms of drug import and export. Based on a recommendation from the committee stated in Article (11), the Minister may ban entry or use of any drug that is proved to be harmful to public health. The said drug will be deleted if registered, stock shall be administratively confiscated and the owners will be denied the right for compensation.

CHAPTER IV

POISONS, NARCOTICS & PSYCHOTROPICS

- Article (17): It is not allowed to import, export, produce or deal with poisons, narcotics and psychotropics shown in the attached tables, without a licence from the Ministry. Terms and procedures of the said licence will be determined by a Ministerial decision, which will also decide methods of storage, prescribing and dispensing of these items. A ministerial decision may amend the above tables by adding, deleting or transferring from one table to another.
- Article (18): It is not allowed to grow plants and herbs containing narcotic substances, shown in Table 2/D. The Minister may license government authorities, specialized colleges and institutes to grow, export or import any of these plants and herbs for scientific purposes.
- Article (19): A Technical Committee or more will be constituted upon a ministerial decision for destruction of plants and herbs mentioned in the above two articles that need to be destroyed.

CHAPTER V

PENALTIES

Articles (20) : Without prejudice to any severe penalty stipulated by another law any person practising as a Pharmacist or an Assistant Pharmacist in a way contradicting the Articles of this Law and the executive ministerial decisions will be subject to imprisonment for a maximum period of (1) year and be liable to a fine not exceeding R.O. 1000/-, or any of the two penalties. In all circumstances, the practise licence may be withdrawn temporarily or permanently in case the offender is a Pharmacist or an Assistant Pharmacist. The place of work may also be closed down, sign boards removed and all materials relating to the profession will be confiscated.

The verdict shall be published in the official Gazette on the expense of the sentenced. Anybody being harmed will have the right to claim compensation from the sentenced.

Article (21): Without prejudice to any penalty stated in this law or another law or the jurisdiction of the Penal Court. The Technical Committee stated in Article No. 11 may look into offences committed by Pharmacists, Assistant Pharmacists and proprietors of pharmaceutical establishments, against the Articles of this Law. The offender will be summoned to appear personally before the Committee, notify him with the offence, hear his statement and investigate his rebuttals. The Committee may impose any of the following penalties in case the offence has been confirmed:

- a. Warning.
- b. A fine not exceeding R.O. 500/-
- c. Suspension from work for a maximum period of one year

In all circumstances, the Committee may withdraw the offender's licence and cancel his name from the register or cancel the licence of the pharmaceutical establishment. The Committee may also impose both penalties.

The offender shall be notified of the committee's decision within a month from the date it has been issued. The offender may appeal to the Minister within a month from the date he has been notified. The Minister will decide upon the appeal either by rejecting the case or referring it to the committee. The decision taken in this regard shall be approved by the Minister. The final decision with regard to withdrawal or cancellation of licence shall be published in the official Gazette on the offender's expenses.