The law of Practicing the Pharmaceutical Profession and Trading in Medications and Medical Preparations

The Council of Ministers approved this law by its decision No. 335, dated 7/3/1398H(1)
And was crowned by the royal decree No. 18, dated 18/3/1398H
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Practicing Pharmaceutical Profession

Article (1)

Practicing the pharmaceutical profession shall mean preparing or compounding or partitioning or possessing any medication or drug or substance externally used, or intracorporeally administered as treatment of the human being or animal from disease or as protection from such, or described as possessing both such properties, with the intention of wholesale or retail or distribution.

Article (2)

It shall not be permissible to practice the pharmaceutical profession save with a license from the Ministry of Health and such shall not be granted save to a Saudi pharmacist, holder of a Bachelor Degree in Pharmacology from one of the Kingdom universities or equivalent; and the Minister of Health may exempt from the nationality term in case of unavailability of the adequate number of Saudis "Saudi Nationals".

Article (3)

No person shall be permitted to work as an assistant pharmacist in the Kingdom unless registered in the assistant pharmacists register at the Ministry of Health; and to record in such register, the following two terms shall be satisfied:

a- The applicant shall be a Saudi national; and the Minister of Health shall be entitled to exempt from this term.

b- Shall be holder of an assistant pharmacist certificate from a recognized institute in the Kingdom or an equivalent certificate.

Article (4)

The pharmaceutical profession shall not be practiced save at the installations hereunder:

Public pharmacies, private- sector pharmacies, pharmaceutical preparations factories and drugs stores.

Article (5)

It shall not be permissible to open a pharmaceutical installation save with a license from the Ministry of Health; and granting license shall be subject to satisfying the terms hereunder:

a- The license applicant shall be a Saudi national of twenty- one years old.

b- Shall be of good behavior and conduct, and not adjudged guilty of a crime violating honors or trust.

c- Shall submit a pledge from a licensed pharmacist to be fully dedicated to run the pharmaceutical installation.

d- Shall submit a diagram indicating the installation location and its area.

e- Shall submit a pledge that his pharmaceutical installation shall satisfy the terms and specifications stipulated by the law and its regulations.

Article (6)

The license shall be granted to the installation proprietor personally; and in case he changes, it shall be obligatory for his substitute to satisfy the terms stipulated in Article (5) of this law, and shall submit to the Ministry of Health an application to sanction the license transfer to him.

Article (7)

The license for opening a pharmaceutical installation shall be considered automatically cancelled in the cases hereunder:

a- If not effected within six months as of its issuance date.

b- If the installation was moved from its location to another without the approval of the Ministry of Health.

c- If the installation was continuously closed for over a year.

d- If the installation is run for another purpose.

e- If the installation is liquidated.

f- If the manager in charge quits for any reason and no substitute is appointed within thirty days.

Article (8)

It shall be obligatory to write the name of the pharmaceutical installation, its proprietor and its manager in charge on the premises front in Arabic in clearly visible letters.

Article (9)

The Manager shall be responsible for the installation staff in whatsoever pertains to executing law with no prejudice to the violator's criminal liability and the private rights resulting from such.

Article (10)

If liquidation of a pharmaceutical installation is desired, the proprietor shall be obliged to inform the Ministry of Health thirty days at least prior to commencing such, provided that he attaches to the notification a list of the narcotic substances existing at the installation, and when selling such he shall ascertain that the buyer is licensed to trade in the items to be bought.

Article (11)

It shall not be permissible for the pharmacist to be manager in charge of more than one installation; and he may also not pluralize the pharmaceutical profession and the profession of human medication or dentistry or veterinary medicine even if he is a holder of pertinent Degrees.

Article (12)

It shall be obligatory for the herbs, chemical materials, medications and preparations existing at the pharmaceutical installation to be commensurate with the specifications mentioned in the pharmacopeia of the prescribed medications and their registered compounds, and shall be preserved as per technical rules.

Article (13)

It shall not be permissible to circulate the medication materials listed in Table No. (1) attached to this law, and their preparations amongst pharmaceutical installations save with a written order signed by the pharmaceutical installation manager and stamped by the (poisons) seal.

Article (14)

The pharmaceutical installations shall, in their sales of medications and pharmaceutical preparations, abide by the official prices.

Article (15)

It shall not be permissible to sell, or offer for sale, the medications or pharmaceutical preparations samples prepared for publicity; and it shall also be obligatory to clearly print in Arabic the phrase (Free Medical Sample) on the internal prescriptions and on the containers of such samples.

Article (16)

It shall not be permissible for a licensed practicing doctor to be a pharmacy, or a drug store, proprietor, or a partner in each of them, or has a share in profits; and the violator of such shall be subject to the penalties stipulated in Article (56) of this law.

Article (17)

The Ministry of Health shall be entitled to inspect the pharmaceutical installations at any time, and its representatives shall have the right to seize the violations and seek the assistance of security men when necessary.

Article (18)

Each company marketing its products in the Kingdom of Saudi Arabia shall be obliged to have a scientific office within the Kingdom, provided that such shall be effected within a year as of enforcing this law.

Article (19)

The pharmacists shall be committed to preserve the profession secrets, and may not show any person the prescriptions delivered to them.

Pharmacies

Article (20)

It shall not be permissible to sell medications to the public save at the pharmacies, and excluded from such shall be some medications of which a decision by the Minister of Health shall be issued.

Article (21)

Wholesale of medications and medical drugs at the pharmacies shall be prohibited; and shall be excluded from such the preparations registered in the pharmacy manager's name.

Article (22)

Trading at the pharmacies in commodities other than medications, drugs, chemical products, medical equipment and tools and cosmetics shall be prohibited.

Article (23)

It shall be prohibited to conduct medical consultations at pharmacies.

Article (24)

It shall be prohibited for the pharmacist to issue any medication save pursuant to a medical prescription prescribed by a doctor licensed to practice the profession in the Kingdom of Saudi Arabia, and shall countersign the issuance date and the pharmacy seal on such; and excluded from such shall be the restricted medications and preparations specified by a decision from the Minister of Health.

Article (25)

It shall be prohibited for the pharmacist to re- issue the prepared or the ready preparation containing any of the materials/substances listed in table No. (2) attached to this law.

Article (26)

It shall be obligatory for each medication prepared at the pharmacy to conform, in its ingredients and as a whole, to one of the international medications pharmacopeia until the Saudi medications pharmacopeia is issued.

Article (27)

It shall be obligatory to accurately issue the medical prescription items as per quantity and quality and whether ready or prepared; and it shall not be permissible to contradict such prior to the advance consent of the prescribing doctor.

Article (28)

The pharmacist shall be obliged to refrain from issuing the medication if any error on such is indicated to him; and in such a case, he shall enquire of the prescribing doctor about such error prior to issuing the medication.

Article (29)

a- It shall be prohibited for persons other than the pharmacy manager and his assistants of pharmacists to prepare the content of the medical prescription; and the manager shall be held responsible for the proper preparation of the prepared medications therein.

b- It shall be prohibited for persons other than the pharmacy manager, his assistants of pharmacists, the assistant pharmacists and the trainee pharmacology students to issue or sell pharmaceutical preparations.

Article (30)

If the pharmacy proprietor dies, it shall be permissible to keep the license for the heirs' interest, provided that they designate, within a year as of demise, a procurator approved by the Ministry.

Article (31)

The Minister of Health may specify the number of pharmacies at each town to be commensurate with its population; and he may also determine the locations of such when necessary.

Article (32)

The Ministry of Health shall prepare a table of the pharmacies on night and official holidays’ duty, and ach pharmacy shall abide by such table, and adhere to the official work hours specified by the Ministry.

Article (33)

In towns where the number of pharmacies does not allow night shifts, the Ministry of Health shall set the procedures that guarantee to the public checking with the pharmacist when required.

Medications Wholesale Stores

Article (34)

Whosoever desires to obtain a license for wholesale trading in medications and medical and chemical substances shall be subject to the provisions of Article Five of this law.

Article (35)

Wholesale medications shall be sold in their original packages.

Article (36)

Medications wholesale stores shall be prohibited from directly selling medications and pharmaceutical preparations to the public.

Article (37)

Whosoever desires to open premises for trading in pharmacopeia medical herbs, or parts of such, or their fluidextracts shall be obliged to obtain the pertinent license from the Ministry of Health.

Article (38)

It shall not be permissible to export medications from the Kingdom save pursuant to the Ministry of Health approval.

Medical Preparations Factories

Article (39)

It shall be obligatory for the pharmaceutical preparations factory to be properly equipped for preparing and analyzing the preparations; and a licensed chemo-pharmacist shall manage the factory, and shall directly supervise all the processes of preparation, shall examine the raw materials delivered to the factory, and shall analyze its products; and the factory staff shall include the number of pharmacist or holders of scientific degrees approved by the Minister of Health, and such shall be commensurate with the size of the factory according to whatsoever is prescribed by the Ministry of Health; and the factory manager shall be held responsible for the products conformity with their registered or pharmacopiea compounds, and for their suitability for usage.

Article (40)

It shall not be permissible to use the factory for purposes other than manufacturing the pharmaceutical preparations.

Article (41)

The pharmaceutical preparation shall be considered as pharmacopiea in the provisions of this law if it is of the fluidextracts or compounds mentioned in one of the international medication pharmacopiea issues and their official supplements, or if it is of the liquids or ready material prepared for disinfecting mentioned in such.

Article (42)

The pharmaceutical preparation shall be considered as special if it is not indicated in an issue of the medications pharmacopiea and their official supplements, and is of the fluid extracts or compounds containing, or described as containing, a substance of medical properties that cure man or animal from disease, or protect from such, and prepared for external or intrcorporeal use by means of injection; and hair- dyes, amber and nutmeg- based compounds and also the means and ready substance prepared for disinfecting shall be considered of these preparations.

Article (43)

It shall be permissible for the factory, and the pharmacist at his pharmacy, to compound the special pharmaceutical preparations, provided that the proper capabilities for such processes are available such as the location, instruments and tools necessary to these special processes, and for analyzing the products, and such shall be pursuant to the Ministry of Health approval.

Medications Registration

Article (44)

It shall be prohibited to circulate the locally prepared special pharmaceutical preparations, and also those imported from abroad, prior to registration of such at the Ministry of Health. Such registration shall be conducted by virtue of a decision from the Medications Registration Committee formed by a decision from the Minister of Health, and such shall be against two hundred riyals fees; and such committee shall be entitled to reject registration of any special pharmaceutical preparation provided that it states the reasons.

Article (45)

Each medications company marketing its products in the Kingdom, or any branch of such, shall be obliged to register against a one thousand riyals registration fees, besides taking into consideration whatsoever is ruled by other laws.

Article (46)

It shall be obligatory to re- register any pharmaceutical preparation subjected to modification in its ingredients.

Article (47)

In case the proprietorship of the preparation changes, it shall be obligatory for the former and current proprietors to inform the Ministry of Health of such within thirty days of the proprietorship transfer.

Article (48)

It shall not be permissible to commence preparing the pharmacopeia pharmaceutical preparation in commercial quantities at the pharmacy or the factory save pursuant to notification of the Ministry of Health and providing it with the name of the pharmacopeia wherein the preparation is mentioned, six of the tag to be affixed on such, six samples of the package and shall obtain its approval of such.

Article (49)

The Minister of Health shall be entitled, based on the Medications Registration Committee recommendation, to issue a decision banning introduction or circulation of any pharmaceutical substance or preparation he deems its circulation may jeopardize public health; and in this case, such preparation shall be deleted from the Minstry Registers if registered, and the existing qualities, wherever located, shall be administratively confiscated and destroyed without the proprietors being entitled to demand any compensation from the Ministry.

Article (50)

Allowing importing and introducing pharmaceutical preparations and extracts and medical herbs shall be subject to satisfying the terms hereunder:

1- Shall be registered at the Ministry of Health.

2- Shall carry the same name as in the manufacturing country.

3- Its accompanying data shall be in conformity with the terms set by the Ministry of Health.

4- Shall be in tightly sealed packages.

5- Shall not be loose or un- packed.

Article (51)

It shall be obligatory to obtain the Medications Registration Committee approval of the texts of statements, brochures and advertisements and their means prior to publishing such to ascertain they conform with whatsoever the medical preparations contain of substances and treatment properties; and it shall not be permissible for any person other than a licensed pharmacist or doctor to conduct publicity for medications and pharmaceutical preparations.

Transitional Provisions

Article (52)

Each pharmacist previously registered at the Ministry of Health prior to issuing this law shall submit to the Ministry, within six months as of its publication in the official gazette, an application for renewing his registration, with the necessary documents attached; and the previously issued license shall be considered cancelled at the end of the mentioned respite.

Article (53)

All assistant pharmacists working in the Kingdom shall be obliged, within six months as of the publication date of this law, to submit their applications for registration in the Ministry of Health Register; and whosoever fails to do so within the indicated respite shall be considered as practicing the profession without license.

Article (54)

The currently existing pharmaceutical installations shall be obliged to re- adapt pursuant to the provisions of this law within a year as of its publication date; and they may not, pursuant to such respite, resume their function save after obtaining a new license.

Article (55)

The currently existing retail drug stores shall opt either to be transformed into pharmacies, or be liquidated, within two years as of the publication date of this law.

Penalties

Article (56)

Whosoever practices the pharmaceutical profession without license shall be punished with an imprisonment for a period not exceeding two years and a fine not exceeding fifty thousand riyals or with one of such; and shall be inflicted with the same penalty the pharmacist who lends' his name for the purpose of opening a pharmaceutical installation, and proprietor of such, besides nullifying the license issued in his name.

Article (57)

Whosoever opens or establishes or manages a pharmaceutical installation without license shall be punished with an imprisonment for a period not exceeding six months and a fine not exceeding ten thousand riyals, or with one of such; and in all cases, closure of the installation shall be ruled.

Article (58)

Whosoever introduces to the pharmacy manufactured products other than those licensed shall be punished with a fine not exceeding five thousand riyals.

Article (59)

Whosoever violates the official medications prices shall be punished with a fine not exceeding fifty thousand riyals, and the license may temporarily or permanently be withdrawn.

Article (60)

An imprisonment not exceeding three years or a fine not exceeding fifty thousand riyals, or one of these two penalties shall be inflicted on..

1- Whosoever cheats or imitates a pharmaceutical preparation, or a medication, or a chemical substance; and

2- Whosoever sells expired or spoilt pharmaceutical preparation, or medication, or chemical substance or a medical herb.

Article (61)

Whosoever commits any other violation to the provisions of this law shall be punished with a fine not exceeding ten thousand riyals, and such with no prejudice to any severer penalty determined by any other law.

Article (62)

The violation of any of the provisions of the regulations pertaining to execution of this law shall be punished with a fine not exceeding (5,000 riyals).

Article (63)

The Minister of Health shall, in collaboration with the Minister of Justice, form a committee of three Saudi members one of whom shall be legal counsel, to consider violations to the provisions of this law and it regulations and to enforce the verdicts of imprisonment and fines exceeding ten thousand riyals; and shall issue its decisions by majority, and the Minister of Health shall approve such decisions.

Article (64)

The committee formed by virtue of the former Article shall be, besides inflicting the pre- scribed penalties, entitled to rule confiscation or destruction of the tools or medications or preparations and other substances seized upon commission of any violation to the provisions of this law and its regulations.

Article (65)

The committee's verdicts of fine and confiscation shall be final, where- as the adjudged guilty may appeal the imprisonment verdict before the Board of Grievances within thirty days as of the date of his notification of the verdict.

Article (66)

The license granted pursuant to this law shall not exempt from obtaining licenses necessitated by other laws.

Article (67)

This law shall supersede whatsoever is in conflict with it; and the Minister of Health shall issue the necessary regulations for implementing such, and shall be entitled to conduct any modification in the attached tables; and it shall be obligatory to publish such regulations and any modification in the table in the official gazette.

Table No. (1)
Poisonous Material

They are the material to be kept in separate isolated places, and "Poisonous Material" shall be inscribed on such, besides the drawing of a skull and two crossed bones.

Serial	
1	Arsenic, Arsenical derivatives and compounds
2	Antimony, Antimony derivatives and compounds
3	Mercury, Mercury derivatives and compounds
4	Hydrocyanic acid and its salts
5	Aconite tuber, its extract and tincture
6	Aconitine
7	Atropa Belladona and its extract
8	Digitalis and its pharmacological glucosides
9	Calabar beans
10	Escrine and its salts
11	Strophanthus and its pharmacological active glucosides
12	Jaborandi and its active alkoloids
13	Dionine
14	Codeine and its salts
15	Coniene and its salts
16	Cutarnine and its salts

17
Emertine and its salts
18
Homatropine and its salts
19
Yohimbin and its salts
20
Coca, leaves, its extract and tincture
21
Brucine and its salts
22
Tridione
23
Adrenaline and its salts
24
Oxalic acid and its salts
25
Iodine
26
Silver salts
27
Meta and Para Penylinediamine
28
Cresol and sodium cresilate
29
Hyoseine and its salts
30
Hysciamine and its salts
31
Nicotine and its salts
32
Papaverine and its salts
33
Strychinine and its salts
34
Arecoline and its salts
35
Thebaine and its salts
36
Ipeca and its extract
37
Barbituric acid, its salts and derivatives
38
Barium and its salts
39
Carbacol
40
Ouabaine
41
Picrotoxine
42

Savin tops and its volatile oil
43
Sadab and its volatile oil
44
Lobelia and its extract
45
Lobeline and its salts
46
Curare
47
Thallium salts
48
Gelsemium (Yellow Jasmine) and its alkaloids
49
Sabadella and its active alkaloids
50
Ergot and its active alkaloids
51
Atropine and its salts
52
Tribromonienthly alcohol
53
Zinc phosphide
54
Santonine
55
General and Local anaesthetics
56
Lead salts
57
Aloine and its derivatives
58
Cincophen and its derivatives
59
Chaulmoogra oil
60
Colchicine
61
Colchicines and its salts
62
Datura and its extract
63
Hyocsyamus and its extract
64
Phenol
65
Picric acid
66
Nux vomica and its extract
67
Sulphanilamide and its derivatives

68
Bromine
69
Chloral hydrate
70
Amyl Nitrate
71
Pyridine
72
Acridine Derivatives
73
Chenopodium oil
74
Hydnocarpus oil
75
Croton oil
76
Amidoprine and its salts
77
Cantharidis and its tincture
78
Podophyllin

Table No. (2)

The material hereunder, or the ready pharmaceutical preparations containing one of such, shall not be issued by pharmacies save with a medical prescription, and shall not be re- issued save with the doctor's written countersignatures:

Adrenaline injections.

General and local anesthetics, save their externally used preparations, liquid chloroform and other spirit also.

Opium active alkaloids, their salts and derivatives, save Papaverine in general, dionine and codeine in oral or external usage.

Cantharidis, save its externally used preparations.

Croton oil, curare, its active alkaloids, derivatives and salts.

Hydrocynic acid salts, except orally used preparations.

Hydrocyanic acid, save its preparations containing less than 0.15% of such.

Digitalis and its types; leaves, powder, tincture, extract, active ingredients and pharmacological glucosides.

Thyroid gland extract, thyroxin and antimony salts and derivatives.

Emetine and its salts, save its preparations containing less than 1% of Emetine.

Emetine salts and derivatives.

Yellow Jasmine and its alkaloids.

Coca leaves, fruits and powder, save the preparations containing less than 0.001% of alkaloids.

Mercury salts and compounds.

Cotton roots extract, tincture and active ingredients.

Savin and sadab and their powders and roots.

Barbituric acid derivatives.

Ergot and its compounds.

All preparations containing anaesthetics less than 0.002% of morphine or ceniene.

All salpha ompounds, retard salpha such as salpha gnandeine, salpha saxydeine and salpha taldyne and their externally used preparations also.

Theorasyl and its compounds.

Thalium and its compounds ; Bichrotoxin and its compounds.

Cortisone and whatever of similar effect.

Brsenic salts, compounds and derivatives.

Corium and its compounds.

Tribromomenthyl ammonia or whatsoever of similar effect, and also the other compounds used in symphathicotonia.

Materia listed in Table No. (1) & (2) of the Narcties law

Hybarine and whatsoever similar in effect.

Abortive medications save chinine and its salts.

Strychinine and its salts.

Biteothryn injections and whatsoever of similar effect.

Hormones with exception of Insoline.

Numeg compounds.

Intra- marrow injections.

Anti- biotic preparations and also the externally used preparations.

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(1) 15 Feb 1978.