

Unofficial Translation

**REPUBLIC OF TURKEY
MINISTRY OF HEALTH
General Directorate of Pharmaceuticals and Pharmacy**

PHARMACEUTICAL AND MEDICAL PREPARATIONS LAW

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PHARMACEUTICAL AND MEDICAL PREPARATIONS LAW

Article 1- Every kind of simple or compound therapeutical preparation used in medical treatment outside the forms and formulae stated in the Codex and made in a specified and permanent form conforming to scientific principles produced for trade in the name of the maker under a special name is called pharmaceutical medical preparation.

Those specified to be taken by the physician's prescription can be sold by prescriptions and the others without prescriptions only from drugstores or drug trade houses in conformity with the relevant Law. Tooth powders, solutions and pastes are not subject to this provision.

Article 2-

A) Therapeutic soaps and foods are not included in medicinal groups and do not contain chemical matters (excluding hair lotions and pigments, toothpowders, solutions and pastes) all toilet materials not including active and toxic matters are not regarded as medical preparations.

B) The preparations indicated hereunder, are according to Art. 3 of this Law, not subject to the permit required to be obtained.

I. All kinds of serums and vaccines and protective and therapeutical matters of this nature which are not mixed with other active substances or are not processed under a special name,

II. Extracts pertaining to biological treatment, ambeceptors and similar products,

III. Simple pills, ampoules, tencures and all kinds of extracts and similar galenic preparations whose forms are indicated in the Codex, made to bear only the chemical name without mentioning them under any special name or the name of the maker and which are not suitable to sell directly to the public.

IV. The equivalents bearing only the chemical name of a preparation granted a health permit under a special name.

The Ministry of Health is authorized to limit or prohibit, the entry to the country from outside, all or part of the substances set under section

(B) I. and to determine the qualities and conditions of those to be brought to the country from outside and to control same. The Ministry seizes and destroys any such substances that are introduced into the country in spite of the prohibition or are established to be preparad without a permit despite Art.95 of the Public Hygiene Law. Legal procedures shall be applied against those who import them from abroad without permission.

It is obligatory that the substances, under paragraph III of the same section are prepared at a preparation laboratory permitted by the Ministry of Health and Public Welfare conforming to Art.26 of Pharmacists and Pharmacies Law. It is forbidden to sell such preparations outside the pharmacies and stock carrying little drugstores.

Article 3- It is necessary that a permit is obtained from the Ministry of Health and Public Welfare for pharmaceutical and medical preparations made locally before they are marketed and for those made abroad before they are imported.

Article 4- Official permit is also obtained from the Ministry of Health and Public Welfare for chemical and medical products which, although not included in the Codex, show a chemical unity not having the properties of pharmaceutical and medical preparation mentioned in Art. 1 and which are marketed anew for treatment of diseases by factories of chemical industry.

Article 5- Natural persons or corporations are authorized to manufacture pharmaceutical and medical substances and preparations in Turkey and to open laboratories or factories under the responsibility of a Turkish doctor, pharmacist, chemist and for matters concerning specialization, a veterinary doctor or a dentist, with a capacity of a responsible manager.

It is mandatory that pharmaceutical and medical substances and preparations are made in a laboratory or factory processing till kids of scientific conditions and sufficient installations.

The pharmaceutical and medical substances and preparations laboratories and factories are subject to the inspection and control of the Ministry of Health and Public Welfare.

Article 6- In order to obtain a permit for the preparations to be made under the conditions set in Art.5, an application should be made in the first place to the Ministry of Health and Public Welfare. Together with this application five samples of the preparations, legalized formulae of the substances provided that the kind and quantity is clearly indicated, constituting the preparation, and containers etc. pertaining to the package of the preparation and copies of the prospectus are submitted and the wholesale and retail selling price is indicated.

Article 7- The application and samples set in Art.6 shall be examined and analysed by the Ministry of Health and Public Welfare and, in case the conditions indicated hereunder are provided , formalities related to granting of permit shall be carried through:

- A) That the applicant for the permit possesses the authorization specified in this Law.
- B) That the submitted formula renders advantage when marketed as preparations.
- C) That its use presents no objection for health.
- D) That it is processed in conformity with the related technique and that it tends not to be spoiled when kept for a lengthy time.

E) That, on analysis, it is established to conform to its formula and to possess the indicated properties..

F) That the price is convenient and its name adequate.

The Ministry shall determine and register in the Health Permit the fact whether the preparation is to be sold by presentation of the physician a prescription or freely without prescription. The names of preparations, permitted to be processed in conformity with this Law, shall be announced in the Official Gazette. Cost of analyses shall be the burden of the applicant.

Article 8- Applications for preparations to be imported from foreign countries shall be acceptably if they are made by owners of pharmacies or of trade houses dealing with pharmaceuticals, authorized to do business within Turkey or by the agents residing in Turkey, off the factory or laboratory manufacturing such preparations. For such preparations, as is the case for local preparations applications are made by petitioning for a permit, to the Ministry of Health and Public Welfare.

Together with the submitted petition, information regarding the place of manufacture of the preparation, the formulae of the preparation legalized by the Turkish Consulate, prospectuses and a legalized copy of the permit as to whether the preparation is permitted to be sold freely or by prescription and five samples shall be submitted . The cost of analysis shall be the burden of the applicant. This petition shall be treated in the manner specified in Art. 7 and these preparations for which permit is granted shall be insured to be cleared from the customs and their names shall be published in the Official Gazette.

If the agents of the factories and laboratories of preparations are not pharmacists, or not owners of pharmaceuticals trade house granted permit under a special law, they may not make available, at their work premises, quantities exceeding those indicated as samples or to be distributed. Should they desire to carry more stock they are not obliged to employ a pharmacist responsible manager in conformity with the provisions of Law No. 984.

Article 9- The applications pertaining to permits of preparations to be made locally or to be imported from abroad shall be treated and completed within two months from their receipt by the Ministry of Health and Public Welfare.

However, in cases necessitating scientific examination of the preparation or subjecting its action to therapeutical tests such period may be extended as much as may be necessary.

Article 10- For the purity of local product for which a permit has been granted and which is marketed, and for its having been processed in conformity of its formula or not , the maker shall be responsible. As to these imported, from foreign countries, the agency who submitted application of importation shall be responsible and the Ministry of Health and Public Welfare shall execute continuous control by analyzing samples to be taken at random whenever necessary and the value of such samples shall be assumed by the responsible maker.

Article 11- Any modification in the composition and the external shape and prospectus and the name of the preparation shall be subject to the approval of the Ministry of Health and Public Welfare.

Article 12- The name of the permit holder, the name and address of the laboratory where the preparation is processed, permit number and manner of use of the preparation and its price shall be clearly written in Turkish on the external part of the package and in the insert of the preparation , and if its composition contains active and toxic substances their kind and quantities, and when deemed necessary by the Ministry the date of manufacture shall be conspicuously recorded and pointed out. Whenever its sale is permitted only by the physician's prescription, this fact also shall be clearly indicated.

Article 13- It is forbidden to advertise by stable or moving cinema films. Illuminated or nonilluminated advertisements, radio or any other media with a view to praise the preparation or to exaggerate its therapeutical action. However, it is permitted to make such announcements in the prospectuses and dailies: "It is useful in treatment ofdiseases. Nevertheless, preparations not permitted to be sold except by prescriptions may not be advertised in any other places save in medical publication. Samples of advertisements have to be approved, in advance, by the Ministry of Health and Public Welfare.

Films prepared concerning the scientific properties of a preparation may be demonstrated by the permit of the Ministry of Health and Public Welfare and at the place indicated by the said Ministry.

Article 14- The Ministry of Health and Public Welfare is authorized to permit the importation of some drugs which, although not included in the Codex, are not in the form of a preparation and whose use is established by the medical world to be advantageous and of so chemical and biological compositions used in scientific and technical researches -in importation of which benefit is envisaged - even though no application has been made by the maker and the owner thereof.

Article 15. The cost of analysis and fees of the health permit mentioned in Arts. 7 and 8 amount to TL..... The cost of analysis is collected on submitting the application and the fees of the permit on remittance.

Article 16- Abrogated.

Article 17- Abrogated.

Article 18- If, as a result of the analysis set in Art. 10, it is established that the substance entering into the composition of the preparation, are impure, or do not conform to the formula for which permit is granted, or the preparation is processed as to decrease or lose its therapeutic quality the permit holder, and the party who although aware of its being so processed, sells it, who markets it or make it sold, shall be liable to heavy pecuniary punishment not less than double the profit they have derived. However, such penalty shall not be under TL. In case of repetition the permit shall be withdrawn.

Article 19- Those who make preparations without permission, or those who knowingly sell preparations so made, who market same or have them sold, shall be liable to have pecuniary punishment amounting to TL..... up to TL..... if they are of those authorized to process preparations and to TL..... up to TL..... if they are not so authorized. If it is established that such preparations do not possess the properties attributed thereto or that they are made in a manner as to reduce or lose such properties or are made of impure substances the penalty set in Art. 18 shall be applicable.

To import, without permission and for trade purpose, preparations made abroad , or knowingly to sell or market same for purpose of sale or to make them sold, shall be an act of smuggling. The provisions of Law No. 1918 shall be applicable to the committing the offence specified in the present paragraph.

Article 20- Excluding the conditions specified under Arts. 18. and 19. a fine of TL..... to TL..... shall be collected from those who act contrary to the provisions of this Law.

Article 21- The manner of application of this Law is determined by a regulation.

Article 22- This Law is enforced as of date of promulgation. However, provided that application is made within the months with a view to obtain a new permit, the preparations whose processing and/or importing is currently permitted by the Ministry of Health and Public Welfare, may be continued to be so processed or imported until the end of six months, likewise, the application of the provisions of Arts. 16. 17. 18. 19. shall start six months later from the date of promulgation of the Law. And on the mentioned date, an inventory of the stock of preparation available in the country shall be made and fees shall be collected of ease on basis of a list to be prepared by the Ministry of Health and Public Welfare and such preparations shall be permitted to be sold for a further six months period.

Article 23- The Ministries of Justice, Finance and Health and Public Welfare are charged with the execution of the provisions of this Law.

Appendix Art. 1- Those who sham the preparations and produce same in a manner as to reduce or lose their therapeutic properties and/or those who, although know they are so produced, sell, market or make sell such preparations shall be liable to punishment by imprisonment of from three months to one year and by heavy pecuniary penalty amounting to not under double fold of the profit earned. However, such pecuniary penalty shall not be under TL.....

Appendix Art. 2- In the cases specified in Arts. 18. 19. and App. Art. 1. , if the preparations are made as to cause damage in any manner, whatsoever, little or much, to the health of the users, the provisions of Art. 395 of the Criminal Code shall also be applied in addition to the punishments specified in these articles.

Appendix Art. 3- In cases specified in Arts. 18. 19. and in Appendix Art. 1. , the preparations shall be seized and by the order of the Court be destroyed.

Appendix Art. 4- The Ministry of Health and Public Welfare may permit the importation to the country of preparations not having permits, for purpose of examination and trial and /or for personal treatment in quantities not to exceed what may be acceptable by the Ministry of Health and Public Welfare and of those arriving in the names of official institutions and welfare societies in the service of the public, provided that such shall not be placed on the market.