

PHARMACEUTICAL AND MEDICINAL PREPARATIONS LAW 1

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For the regulation related to this Law, refer to the numerical index of the "Compendium of Regulations" arranged according to the laws.

Article 1 – All kinds of simple and compound medicinal preparations used in treatment, which are placed on the market in a definite and fixed manner in accordance with technical rules, other than the form and formula written in the Codex, under the name of their active ingredient or under a special name, shall be called pharmaceutical and medicinal preparations. 2

Those which are required to be dispensed with a physician's prescription shall be sold exclusively in pharmacies and pharmaceutical trading establishments, against prescription, and the others without prescription, in accordance with the special law. (Last sentence repealed: 23/2/1994 - Law No. 3977, Article 4)

Article 2 – (Amended: 4/1/1943 - Law No. 4348, Article 1) A) Medicinal foods which do not fall within the class of medicinal soaps and medicines and do not contain chemical substances, and (...) all toilet requisites not containing active and toxic substances shall not be considered medicinal preparations. 3 B) The preparations written below are not subject to the authorization required to be obtained pursuant to the third article of this Law: I – All kinds of sera and vaccines that are not mixed with other active substances or not manufactured under a special name, and protective and therapeutic substances of this nature; II – Extracts intended for vital uses, amboceptors and similar substances; III – Simple tablets, ampoules, tinctures, all kinds of extracts and similar galenical preparations whose forms are written in the Codex, which are not suitable to be sold directly to the public and which are made only to bear the chemical name of the medicinal substance they contain, without being named under a special name or after the manufacturer; IV – Equivalents bearing only the chemical name of preparations licensed under a special name. The Ministry of Health and Social Assistance is authorized to restrict or prohibit the entry into the country of all or part of the substances written in subparagraph I of paragraph B, to determine the qualities and conditions of those to be brought into the country from abroad, and to supervise them. Such substances that enter the country despite being prohibited, or are found to have been manufactured without authorization in violation of Article 95 of the Public Health Law, shall be seized and destroyed by the Ministry of Health and Social Assistance. Furthermore, criminal proceedings shall be initiated in accordance with the general provisions against those who import such substances from abroad without authorization. It is mandatory that the substances written in subparagraph III of the same paragraph be manufactured in a preparations laboratory authorized by the Ministry of Health and Social Assistance pursuant to Article 26 of the Law on Pharmacists and Pharmacies. It is prohibited to sell such preparations to any place other than pharmacies and pharmaceutical warehouses.

Article 3 – It is required to obtain authorization from the Ministry of Health and Social Assistance prior to placing on the market the pharmaceutical and medicinal preparations manufactured domestically, and prior to the importation into the country of those manufactured abroad.

Article 4 – Official authorization shall also be obtained from the Ministry of Health and Social Assistance at the time of importation of chemical and medicinal substances which, although not included in the Codex, do not possess the characteristics of pharmaceutical and medicinal preparations mentioned in the first article, present a chemical unity, and are newly placed on the market by chemical industry factories for use in the treatment of diseases.

Article 5 – (Amended: 8/2/1954 - Law No. 6243, Article 1) Real and legal persons are authorized to manufacture pharmaceutical and medicinal substances and preparations in Türkiye and to open a laboratory or factory for this purpose, under the responsibility of a responsible manager who is a Turkish physician, pharmacist and chemist, and, for substances pertaining to

their specialties, a veterinarian or dentist. (Additional sentence: 21/2/2024 - Law No. 7496, Article 5) The qualifications and conditions to be sought in legal persons holding such authorization shall be determined by the Ministry of Health. (Amended paragraph: 15/11/2018 - Law No. 7151, Article 8) Pharmaceutical and medicinal substances and preparations must be manufactured, in accordance with their license or authorization, in a laboratory or factory that possesses all kinds of technical requirements and Good Manufacturing Practice conditions and contains sufficient equipment. 4

Pharmaceutical and medicinal substances and preparation laboratories and factories are subject to the inspection and supervision of the Ministry of Health. 5

Article 6 – (Amended: 4/1/1943 - Law No. 4348, Article 1) 6

In order to obtain authorization for preparations to be manufactured in compliance with the conditions mentioned in Article 5, an application shall first be made to the Ministry of Health with a petition. Together with this petition, (...) a certified formula stating the substances composing the preparation, with their type and quantity explicitly determined, and the containers and the like intended for the packaging of the preparation, and a description (...) and copies thereof shall be submitted (...). 6

Article 7 – (Amended: 4/1/1943 - Law No. 4348, Article 1) Upon examination of the petition written in Article 6, the transaction related to the granting of authorization shall be carried out in the presence of the conditions written below: 7

A) The person requesting authorization possesses the qualifications determined by this Law; B) There is benefit in presenting the submitted formula to the market in the form of a preparation; C) There is no health-related objection to its use; D) It is manufactured in accordance with the state of the art and is not susceptible to deterioration when kept for a long time; E) It conforms to its formula and possesses the therapeutic properties declared; 8

F) Its price is reasonable and its name is found appropriate. The matter of whether the preparation is to be sold with a physician's prescription or freely without the need for a prescription shall be determined by the Ministry and stated in the license. The names of preparations whose manufacture is authorized pursuant to this Law shall be announced in the Official Gazette. (Repealed sentence: 21/2/2024 - Law No. 7496, Article 7) 9

The Ministry of Health may request the amendment of preparation prices in accordance with market requirements. 8

Article 8 – (Amended: 4/1/1943 – Article 1 of Law No. 4348) Applications for permission for preparations brought from foreign countries shall be accepted only if submitted by owners of pharmacies and pharmaceutical trading enterprises licensed to practise their profession within Turkey, or by the representatives residing in Turkey of the factories and laboratories manufacturing such preparations. For such preparations, an application shall be made to the Ministry of Health and Social Welfare, as in the case of domestic preparations, by means of a petition in order to obtain permission. 10

Together with the petition submitted, the place of manufacture of the preparation, its formulae and package leaflets certified by Turkish consulates, and, if a permit exists in the country of origin allowing its sale freely or by prescription, a certified copy of such permit (...) 11 shall be deposited with the representative. (Repealed sentence: 21/2/2024 – Article 8 of Law No. 7496) This petition shall be processed in the manner set out in Article 7, the import of the preparations to be permitted shall be ensured by the customs authorities, and their names shall be announced in the Official Gazette. 12

7 By Article 9 of Law No. 7151 dated 15/11/2018, the phrase "the samples by the Ministry of Health and Social Welfare" in this paragraph was amended to read "the samples by the Ministry of Health or in laboratories authorised by the Ministry of Health". 8 By Article 7 of Law No. 7496 dated 21/2/2024, the phrase "and the samples shall be audited and analysed by the Ministry of Health or in laboratories authorised by the Ministry of Health" in the first paragraph of this Article was amended to read "audit"; the phrase "As a result of analysis and audit, the formula" in

paragraph (E) was amended to read "The formula"; and the phrase "Ministry of Health and Social Welfare" in the third paragraph was amended to read "Ministry of Health". 9 For the application of this provision, see Article 1 added. 10 For the application of this provision, see Article 7 added. 11 By Article 8 of Law No. 7496 dated 21/2/2024, the phrase "and five samples" in the first sentence of this paragraph was removed from the text of the Article. 12 For the application of this provision, see Article 1 added.

Representatives of preparation factories and laboratories who are not pharmacists or who do not own a pharmaceutical trading enterprise licensed under special law may not keep, in the places where they operate, quantities of the preparations of the factories and laboratories they represent exceeding the amount to be shown or distributed as samples. If they wish to keep larger quantities, they are obliged to employ a pharmacist responsible manager in accordance with the provisions of Law No. 984 concerning pharmaceutical trading enterprises.

Article 9 – (Amended: 4/1/1943 – Article 1 of Law No. 4348) As of the date on which applications concerning preparations to be manufactured in or imported into the country are received by the Ministry of Health, their processing shall be completed in accordance with the legislation, and a licence shall be issued to the applicant. 13

(Second paragraph repealed: 21/2/2024 – Article 9 of Law No. 7496)

Article 10 – The manufacturer of domestic preparations for which permission has been obtained and which have been placed on the market shall be liable for their purity and for whether they have been manufactured in conformity with their formula, and, for those imported from foreign countries, the representatives who have submitted the import permit application shall be liable; where deemed necessary, the Ministry of Health shall exercise permanent supervision by means of the analysis of samples to be taken at random, with the sample and analysis costs being borne by the licence holder. 14

Article 11 – Any kind of modification to be made to the composition, external form, package leaflets and name of preparations must be accepted and approved by the Ministry of Health and Social Welfare.

Article 12 – (Amended: 4/1/1943 – Article 1 of Law No. 4348) On the outer packaging of preparations and in the package leaflets contained within the packaging, the name and address of the licence holder and of the laboratory where the preparation was manufactured, the licence number, and how the medicinal product is to be used (...) 15 shall be written clearly and in Turkish, and if the preparation contains potent and toxic substances, their type and quantities, and, in cases deemed necessary by the representation, the date of manufacture shall be recorded and marked in a conspicuous manner. Where the preparation is permitted to be sold only upon a physician's prescription, this fact shall also be expressly stated.

Article 13 – (Amended: 4/1/1943 – Article 1 of Law No. 4348) It is prohibited to advertise preparations by means of fixed or moving cinema films, illuminated or non-illuminated notices, radio or any other medium, in a manner that exaggerates their healing properties or attributes to them healing properties they do not possess, or magnifies their existing therapeutic effects. However, advertisements in package leaflets and newspapers in the form of "it is beneficial to use in ... diseases" may be permitted. However, preparations that are not permitted to be sold without prescription may not be advertised anywhere other than medical journals. Advertising materials must be approved in advance by the Ministry of Health and Social Welfare. Films prepared on the scientific characteristics of a preparation may be shown with the permission of the Ministry of Health and Social Welfare and at the places it designates.

Article 14 – The Ministry of Health and Social Welfare is authorised to permit the importation into the country, without any application by the manufacturer or owner, of chemical and biological compounds used in scientific and technical investigations, and of medicinal products whose benefit in use is recognised in the world of medicine, which are not included in the Codex and which are not of the nature of a preparation.

Article 15 – (Repealed: 21/2/2024 – Article 12 of Law No. 7496)

Articles 16 – 17 – (Repealed: 25/5/1938 – Article 2 of Law No. 3402)

Article 18 – (Amended: 2/1/2014 – Article 31 of Law No. 6514) Where, as a result of the analysis referred to in Article 10, it is established that the substances contained in the preparations are not pure or do not conform to the formula submitted for obtaining the licence, or that the preparations have been manufactured in such a way as to reduce or eliminate their therapeutic properties, provided that the act does not constitute a crime, an administrative fine of from ten thousand Turkish Liras to five hundred thousand Turkish Liras shall be imposed on the licence holder and on those who knowingly sell, offer for sale or cause to be sold preparations manufactured in this manner. An administrative fine of up to five times the total sales value of the product in the last year shall be imposed on those who promote and sell preparations in violation of this Law, those who market them outside the approved indications, and those who thereby encourage their prescription. However, this fine shall not be less than one hundred thousand Turkish Liras. Where promotion or sales are carried out over the internet, the Ministry shall immediately decide to block access, and this decision shall be notified to the Information and Communication Technologies Authority for enforcement. An administrative fine of from twenty thousand Turkish Liras to three hundred thousand Turkish Liras shall be imposed on those who promote and sell products with health claims without permission from the competent authority or in breach of the permission granted. In the event of repetition of the acts, the administrative fine to be imposed shall be twice the previously imposed fine.

13 By Article 9 of Law No. 7496 dated 21/2/2024, the phrase "to the Ministry of Health and Social Welfare" in this paragraph was amended to read "to the Ministry of Health"; the phrase "within two months at the latest" was amended to read "in accordance with the legislation"; and the phrase "a reply shall be given" was amended to read "a licence shall be issued". 14 By Article 10 of Law No. 7496 dated 21/2/2024, the phrase "and by means of the analysis of samples to be taken occasionally, with the price to be settled, by the Ministry of Health and Social Welfare" in this paragraph was amended to read "by the Ministry of Health by means of the analysis of samples to be taken at random, with the sample and analysis costs being borne by the licence holder". 15 By Article 11 of Law No. 7496 dated 21/2/2024, the phrase "and the price" in the first sentence of this paragraph was removed from the text of the Article.

Article 19 – (Amended: 23/1/2008-5728/43 art.)

(Amended first paragraph: 2/1/2014-6514/32 art.) Those who manufacture medicinal products without a licence, or who knowingly sell, offer for sale or have others sell medicinal products manufactured in this manner, shall be sentenced to imprisonment from one year to five years. Where it is established that these medicinal products do not possess the therapeutic attributes attributed to them, or that they have been manufactured in a manner that reduces or eliminates these attributes, or from impure substances, the penalty shall be increased by one third. Those who, although not medicinal products, sell, market or advertise any product with the claim that it diagnoses or treats diseases shall be sentenced to imprisonment from one year to five years. Furthermore, where the promotion or sales of such products are conducted via the internet or any other electronic medium, the third paragraph of Article 18 shall apply. 16

Importing medicinal products manufactured abroad without a licence for commercial purposes, or knowingly selling or offering for sale or having others sell such products, constitutes smuggling. The provisions of the Anti-Smuggling Law shall apply to those who commit the offences set forth in this paragraph.

Article 20 – (Amended: 23/1/2008-5728/44 art.) Except for the circumstances mentioned in Articles 18 and 19, those who act contrary to the provisions of this Law shall be imposed an administrative fine of two hundred and fifty Turkish Liras. Administrative fines and other administrative sanctions written in this Law shall be decided upon by the local civil administrator.

Article 21 – The manner of implementation of this Law shall be determined by a regulation.

Additional Article 1 – (Being the provision of an unnumbered article introduced by Law No. 1557 of 6/2/1930, numbered for continuity.) Where the manufacturers or responsible managers of domestic medicinal products, or the representatives domiciled in Turkey of factories or laboratories manufacturing medicinal products entering from foreign countries, die, the licences granted shall cease to have effect. If the heirs of the domestic medicinal product manufacturers or responsible managers are qualified to manufacture medicinal products, they shall obtain a new licence directly in their own names; where they are not so qualified, they shall obtain a new licence by designating a responsible manager qualified to manufacture them. The new representatives to be designated by foreign factories and laboratories shall also be subject to the same obligation. (Repealed sentence: 21/2/2024-7496/13 art.)

Additional Article 2 – (Being the provision of Article 1 of Law No. 3940 of 16/12/1940, numbered as an additional article for continuity.; Repealed: 11/6/2010-5996/47 art.)

16 The word "and" in this paragraph was amended as "or" by Article 10 of Law No. 7151 dated 15/11/2018. 17 The word "regulation (nizamname)" in this Article was amended as "yönetmelik (regulation)" by Article 3 of Decree-Law No. 698 dated 2/7/2018.

Additional Article 3 – (Being the provision of Article 2 of Law No. 3940 of 16/12/1940, numbered as an additional article for continuity.; Repealed: 11/6/2010-5996/47 art.)

Additional Article 4 – (Being the provision of Additional Article 1 introduced by Law No. 4348 of 4/1/1943, with the article number maintained for continuity. Amended; 23/1/2008-5728/45 art.) 18

Those who manufacture medicinal products by imitating them in a manner that reduces or eliminates their therapeutic attributes or that causes more or less harm to the health of users, or who knowingly sell, offer for sale or have others sell products manufactured in this manner, shall be punished in accordance with the Turkish Penal Code or the provisions of other relevant laws.

Additional Article 5 – (Being the provision of Additional Article 2 introduced by Law No. 4348 of 4/1/1943, with the article number maintained for continuity. Repealed: 23/1/2008-5728/578 art.)

Additional Article 6 – (Being the provision of Additional Article 3 introduced by Law No. 4348 of 4/1/1943, with the article number maintained for continuity. Amended; 23/1/2008-5728/46 art.) Medicinal products constituting the subject matter of the misdemeanours defined in Articles 18 and 19 of this Law shall be seized, and it shall be decided that their ownership be transferred to the public.

Additional Article 7 – (Being the provision of Additional Article 4 introduced by Law No. 4348 of 4/1/1943, with the article number maintained for continuity.) Permission may be granted by the Ministry of Health for the importation into the country, from abroad, of medicinal products not holding a licence, for the purpose of being audited or tested or for use in personal treatment and not exceeding the quantity to be accepted by the Ministry of Health and Social Welfare, and of those entering in the name of official institutions or charitable societies serving the public interest, on condition that they are not placed on the market.

Provisional Article 1 – (Added: 2/1/2014-6514/33 art.) Pursuant to the Council of Ministers Decisions No. 2004/6781 dated 6/2/2004 and No. 2007/12325 dated 12/6/2007 concerning the pricing of medicinal products for human use and their amendments, the remaining portion of the amounts collected from marketing authorisation holders, determined by the Ministry of Health on account of unjust enrichment arising from the failure to notify price changes based on the reference price system within the envisaged period, after the amount transferred to the Social Security Institution, shall be recorded as revenue to the general budget, without prejudice to statutory interest and rights relating to outstanding receivables. Based on a period equal to half of the total period between the date of entry into force of the first price determination made by the Ministry of Health within the framework of the Council of Ministers Decisions No. 2004/6781 dated 6/2/2004 and No. 2007/12325 dated 12/6/2007 concerning the pricing of medicinal products for human use and their amendments, following the date by which the price changes

were required to be notified by the marketing authorisation holders, and the date of collection by the Ministry of Health, calculated backwards from the date of collection, and by applying the statutory interest rate applicable on the relevant dates, the amount of statutory interest, to be jointly calculated by the Ministry of Health and the Ministry of Finance on the total amount deposited by the marketing authorisation holders, shall also be collected from the marketing authorisation holders by the Ministry of Health.

Article 22 – This Law shall enter into force on the date of its publication. However, provided that an application is made within three months for the obtainment of a new licence for medicinal products for which permission for manufacture or import has currently been granted by the Ministry of Health and Social Welfare, the continued manufacture and import thereof shall be permissible until the end of six months, and the application of the provisions of Articles 16, 17, 18 and 19 of the Law shall commence six months after the date of its publication. As of the said date, the quantity of medicinal products existing within the country shall be determined, and on the basis of a list to be arranged by the Ministry of Health and Social Welfare according to the counterparts of each, subject to the levy of duties, permission shall be granted for the sale of these medicinal products within Turkey for a further period of six months.

Article 23 – The Ministers of Justice, Finance, and Health and Social Welfare shall be charged with the enforcement of the provisions of this Law.

LIST SHOWING THE DATE OF ENTRY INTO FORCE OF THE LEGISLATION AMENDING LAW NO. 1262 OR OF THE PROVISIONS ANNULLED BY THE CONSTITUTIONAL COURT

Number of the Amending Law / Decree-Law / Annulment Decision of the Constitutional Court

Articles of Law No. 1262 amended or annulled

Date of Entry into Force 1557 — 12/2/1930 3304 — 11/1/1938 3402 — 1/6/1938 3940 — 20/12/1940 4348 — 8/1/1943 6243 — 13/2/1954 3977 — 26/2/1994 4854 — 6/5/2003 5728 18, 19, 20, Additional Articles 4, 5 and 6 8/2/2008 5996 Additional Articles 2 and 3 13/12/2010 6514 18, 19, Provisional Article 1 18/1/2014 Decree-Law/698 21 The date on which the President assumed office by taking the oath, following the Grand National Assembly of Turkey and Presidential elections held together on 24/6/2018 7151 5, 7, 19 5/12/2018 7496 5, 6, 7, 8, 9, 10, 12, 15, Additional Article 1 1/3/2024