

THE HISTORICAL EVOLUTION OF THE TURKISH PHARMACEUTICAL LEGISLATION FROM 1852 TO THE PRESENT

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Abstract

Pharmaceutical legislation plays a key role in providing regulatory norms for the practice of pharmacy. Knowing the historical background of legislation also promotes a better understanding of the interrelationship between pharmacy-related issues of the past and the present. This study aims to examine the historical evolution of Turkish pharmaceutical legislation from 1852 to the present. Pharmaceutical laws, regulations, and directives enacted in the Ottoman and the Republican periods were analysed from several different aspects (i.e., qualifications of pharmacists, requirements for setting up a pharmacy, and national pharmacopoeia). The first pharmaceutical regulation in Turkey, "Regulation of civil pharmacy in the Ottoman domains," (1852) stipulated for the first time that a pharmacy had to be operated by a diploma holder-pharmacist, and the quality and safety of the medicines prepared in a pharmacy were primarily under the pharmacist's responsibility. Despite a great number of pharmaceutical regulations enacted in the 19th century, it was after the proclamation of the Republican regime in 1923 that Turkey observed a sustainable development in its pharmaceutical legislation.

Rezumat

Legislația farmaceutică joacă un rol cheie în asigurarea normelor de reglementare în domeniul farmaciei. Cunoscând contextul istoric al legislației se promovează, de asemenea, o mai bună înțelegere a relației dintre aspectele legate de farmacie din trecut și prezent. Acest studiu își propune să analizeze evoluția istorică a legislației farmaceutice din Turcia din 1852 până în prezent. Legile farmaceutice, regulamentele și directivele adoptate în perioada Imperiului Otoman și perioadele republicane au fost analizate sub mai multe aspecte diferite (de exemplu, calificările farmaciștilor, cerințele pentru înființarea unei farmacii, implementarea farmacopeei naționale). În ciuda unui număr mare de reglementări farmaceutice adoptate în secolul al XIX-lea, numai după proclamarea regimului republican în 1923, Turcia a cunoscut o dezvoltare durabilă în legislația sa farmaceutică.

Keywords: history of pharmacy, pharmaceutical legislation, Turkey

Introduction

Pharmaceutical legislation plays a key role in providing regulatory norms for the practice of pharmacy. Knowing the historical background of legislation also promotes a better understanding of the interrelationship between pharmacy-related issues of the past and the present. A recent study, however, indicated that the history of pharmaceutical legislation in Turkey has been insufficiently investigated [12]. This study aims to fill this gap by examining the historical evolution of Turkish pharmaceutical legislation from 1852 to the present.

Materials and Methods

Pharmaceutical laws, regulations, and directives enacted in both the Ottoman (1852–1923) and the Republican (1923–present) periods were analysed from several different aspects, including the qualification of pharmacists, requirements for setting up a pharmacy, quality and safety of medicines, national pharmacopoeia, and pharmaceutical

ethics. Law or regulations concerning health/medicine that were found slightly relevant or irrelevant to the subject were excluded from the study.

Brief history of the pharmaceutical legislation in Turkey

The first pharmaceutical regulation in Turkey, "Regulation of civil pharmacy in the Ottoman domains," was issued on May 17, 1852 [4] (Figure 1). The purposes of this regulation included setting standards on general pharmacy practices around the country, ensuring the quality and safety of medicines prepared or sold in pharmacies and distinguishing pharmacists' rights in preparing medicines instead of those other professionals such as physicians, surgeons, barbers, spice sellers, and water sellers [14]. The regulation included 77 articles covering a variety of subjects on pharmacists, medicines, pharmacies and their inspection, pharmacist assistants, pharmacy students, and penalties [6]. The 1852 regulation was

followed by five other regulations enacted during the Ottoman period (Table I).

Among these, the 1861 and the 1916 regulations were of special interest due to implementing structural reforms in daily pharmacy practice (Figure 2).



Figure 1.

Regulation of civil pharmacy in the Ottoman domains (1852) (Istanbul University Rare Book Library, Istanbul)

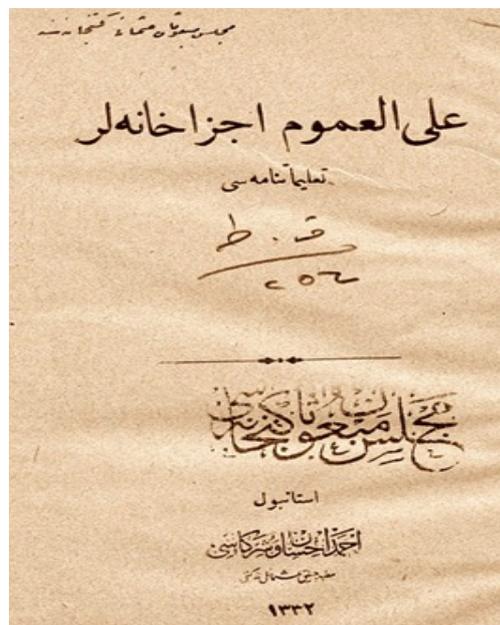


Figure 2.

General directive for pharmacies (1916) (Library of the Turkish Grand National Assembly, Ankara)

Table I
Pharmaceutical legislation enacted in Turkey (1852–2004)

Year	Title	Number/date	Desuetude
1852	Regulation of civil pharmacy in the Ottoman domains	n/a, May 17, 1852	1861
1861	Regulation concerning general practice of the art of pharmacy	n/a, February 3, 1861	1927
1884	Regulation of the duties of pharmaceutical inspectors	n/a, May 28, 1884	1927
1885	Regulation of pharmaceutical traders	n/a, May 7, 1885	1927
1888	Regulation concerning state physicians and pharmacists	n/a, April 17, 1888	1927
1916	General directive for pharmacies	n/a, n/a, 1916	1927
1926	Law for the Turkish codex	767, March 17, 1926	in force
1927	Law for pharmacists and pharmacies	964, January 24, 1927	1953
1927	Law for pharmacies and the places where toxic and effective chemicals are sold	984, March 12, 1927	1953
1928	Law for pharmaceutical and medicinal preparations	1262, May 26, 1928	in force
1935	Regulation of pharmaceutical and medicinal preparations	3113*, September 23, 1935	in force
1953	Law for pharmacies and pharmacists	6197, December 24, 1953	in force
1956	Law for the Turkish Pharmacists' Association	6643, February 2, 1956	in force
1968	Regulation of deontology for Turkish pharmacists	12961*, July 27, 1968	in force
1986	Regulation of withdrawing pharmaceutical and medicinal products, materials, and herbal compounds from the market	19196*, August 15, 1986	in force
1992	Regulation of pharmacies and pharmacy services	21374*, October 13, 1992	in force
1993	Convention on the elaboration of a European Pharmacopoeia	21724*, October 10, 1993	in force
1995	Regulation of the Turkish Pharmacists' Association	22422*, October 2, 1995	in force
2003	Regulation of advertising activities for medical products	25268*, October 23, 2003	in force
2004	Decision on the Turkish codex	25620*, October 21, 2004	in force

*Official gazette number

After the proclamation of the Republican regime on October 29, 1923, Turkey observed the rapid development in its pharmaceutical legislation until the 1950s. In particular, the law on national pharmacopoeia (1926), the law for pharmacies and

pharmacists (1953), and the law for the Turkish Pharmacists' Association (1956) were among the most significant steps forward to put Turkish pharmacy on a more solid base [3]. A great deal of changes have also been made within the past two

decades, particularly with the introduction of the *Health Transformation Program* establishing new pricing regulations for pharmaceuticals based on reference prices and developing better computer-based health information/record systems [13].

Qualification of pharmacists, requirements for setting up a pharmacy, quality and safety of medicines, national pharmacopoeia and pharmaceutical ethics were mentioned in the Turkish legislation as follows.

Qualification of pharmacists: In the Ottoman era, the 1852, the 1861, and the 1916 regulations mandated that pharmaceutical practitioners have a pharmacist diploma either from the Imperial School of Medicine (Istanbul) or other schools of pharmacy in Europe. However, considering the lack of pharmacist graduates in the Ottoman domains, both the 1852 and the 1861 regulations enabled professionals who had already been managing a pharmacy to get a license after passing the related examinations before the state jury. Interestingly, this license could also be bequeathed from father to his children or relatives [14]. Furthermore, the 1888 regulation defined the qualifications of pharmacist state employees, their salaries, and promotions [10]. While the 1953 law preserved the abovementioned qualifications except the board examination, in November 2014, a new article was added into this law that enables pharmacists to specialize in clinical pharmacy and phyto-pharmacy [2].

Requirements for setting up a pharmacy: According to the 1852 and the 1861 regulations, pharmacists were allowed to set up only one pharmacy, and a pharmacy license could be obtained by having a 6-year of experience in pharmacy and presenting a pharmacist diploma from the Imperial School of Medicine [1, 4]. While the 1852 regulation restricted the number of pharmacies *per* population for the first time, the 1861 regulation repealed this article [1, 14]. Both the 1861 and the 1916 regulations interdicted in military or hospital pharmacists setting up a pharmacy [1, 5]. The 1927 law restricted the number of pharmacies for the second time. The 1953 law required pharmacists willing to set up a pharmacy to be a citizen of the Republic of Turkey and to have an admissible pharmacist diploma. The applicant could not have an incurable disease, be totally blind, or have been imprisoned in the past [3]. This law was partially modified in 2012, then in 2014, and the number of pharmacies was restricted for the third time. According to this article, applicants have to meet the demographic criteria of one pharmacy *per* minimum 3,500 inhabitants *per* district and to have at least a year of experience in pharmacy [2, 13].

Quality and safety of medicines: The 1852 regulation brought several penal sanctions on

pharmacists for giving medicines other than those written in the prescription or miscalculating the dosages. It also mandated that hazardous drugs be placed in separate places [4]. The quality and safety of the medicines, together with proper labelling, were also under a pharmacist's responsibility, according to all subsequent regulations up to the present [1, 3, 5]. The 1885 regulation prohibited pharmaceutical wholesalers from making medicines and then retailing them to patients [10]. The 1956 law and its modified article in 2014 imposed some detailed obligations on pharmacists, initiated the pharmaceutical tracking system to prevent counterfeiting, and prohibited the selling of medicines *via* the Internet or any other electronic media [2].

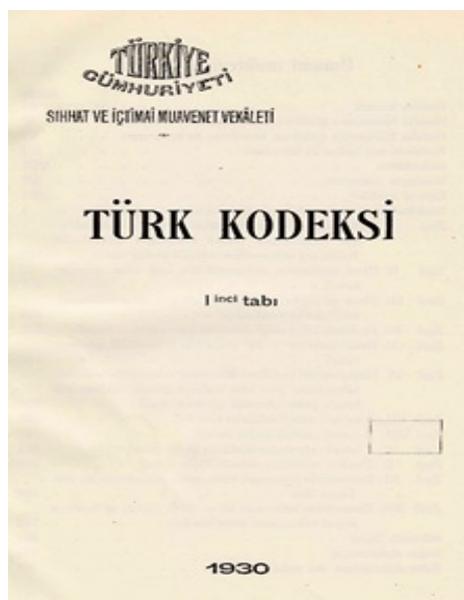


Figure 3.

The Turkish Codex (1930) (H. Tekiner Collection)

National pharmacopoeia: In 1844, the first and sole military pharmacopoeia of the Ottoman Empire, *Pharmacopoeia Castrensia Ottomana*, was published in Istanbul [11]. It was, however, in the Republican period that a specific regulation for a national pharmacopoeia was brought forward: the “Law for the Turkish Codex” was enacted in 1926, and the first national pharmacopoeia of Turkey, the *Turkish Codex*, was published in 1930 (Figure 3). This pharmacopoeia was followed by several editions published in 1940, 1948, 1954, and finally 1974. As a member state of the Council of Europe, Turkey signed the “Convention on the Elaboration of a European Pharmacopoeia,” a protocol to harmonize national regulations on the manufacture, circulation, and distribution of medicines through Europe, in 1993. Hence the *Turkish Pharmacopoeia* (1974) was replaced with the *Adoption of the European Pharmacopoeia* in accordance with the “Decision on Turkish Codex,” that was enacted in

2004. Today, the *European Pharmacopoeia* is the official pharmacopoeia of the country [13], as well as in other European countries [11].

Pharmaceutical ethics: The 1861 regulation included one of the earliest articles dealing with proper ethical relationships, particularly between pharmacists and physicians [1]. Likewise, the 1916 regulation prohibited pharmacists from establishing any kind of partnership with physicians or to fill prescriptions that were written in cipher [5]. However, in 1968, a specific regulation, the “Regulation of deontology for Turkish pharmacists” was enacted [4].

Conclusions

In Turkey, the first modern regulations pertaining the pharmacies came into existence in 1852, which was the same year as in Great Britain, later than France (1803), Serbia (1845), and the United States of America (1848), but still earlier than Romania (1874) [7-9, 11]. According to Baytop, this regulation was partially influenced by a French law entitled, “Loi contenant organisation des Écoles de pharmacie” (April 11, 1803) [6].

In conclusion, despite the great number of pharmaceutical regulations enacted in the 19th century, it was after the proclamation of the Republican regime in 1923, that Turkey observed the rapid and sustainable development of its pharmaceutical legislation.

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