The emergence of the dominance of synthetic medicines before the era of modern clinical trials – a Hungarian perspective; Part I.

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The emergence of the dominance of synthetic medicines is not only due to their purely scientific value, as is generally believed, but has been fundamentally facilitated by a number of societal factors that are usually overlooked: the patent system, demography, modern wars, the emergence of social insurance and mass health care, with the widespread operation of medical practices and pharmacies, the spread of industry-made finished medicinal products, the emergence of marketing by the pharmaceutical industry and the drug authorization system. This article analyses their role in the emerging dominance of synthetic medicines. Part I. of this publication discusses the significance of science, patent legislation and the legal system, demography, wars, and social insurance and public health (the medicalization of society).
Keywords: synthetic, patent, war, demography, pharmacy, pharmacist, insurance, industry, authorization

Introduction

In universities, mostly only the natural-scientific aspects of the emergence of modern synthetic medicines are taught: the development of chemistry, biology, physiology, pharmacology, and clinical sciences. However, these are not in themselves enough to understand and explain the historical processes (paradigm shift) described in the title. This paradigm shift refers to the transition from traditional, pharmacy-based compounding of medicines to the industrial production of synthetic and semi-synthetic drugs. In addition, natural sciences are not only driving forces but at the same time, also the consequences of the transformation of the socio-legal environment that was essential on the road to the modern armamentarium of medicinal products.

This process had started before the first double-blind controlled clinical trial (patulin against rhinitis, England, 1943) (1, 2) and the first randomized controlled clinical trial (streptomycin against pulmonary tuberculosis, also in England, 1947-1951) (1, 3). In Hungary, clinical trials became mandatory in 1951 (Ordinance 3180-173/1951./III.l./EÜ.M.).

In the following, the complex historical process of the rise to dominance of the synthetic medicines is presented in Hungary, broken down into the following fields:

– *Science;*
– *Patent legislation and the legal system;*
– *Demography;*
– *Wars;*
– *Social insurance and public health, i.e. the medicalization of society;*
– *Pharmacies becoming a significant public health factor;*
– *The paradigm shift in pharmaceutical companies and the pharmaceutical marketing;*
– *The reactions of pharmacists to the changing reality*
– *The beginnings of the official mandatory registration of medicinal products.*

Part I. of this publication below discusses the significance of science, patent legislation and the legal system, demography, wars, and social insurance and public health, i.e. the medicalization of society

Science

In the 18th century, ie., during the last century before the emergence of the pharmaceutical industry (and homeopathy) there was the golden age of herbal therapy (i.e. phytotherapy). An analysis of the 18th century armamentarium of Hungarian medicines reveals that of the 2733 medicines identified, about 52% were exclusively of plant origin; and about 10% were exclusively animal-derived medicines, while the proportion of chemicals was about 12%, with 82% of the latter being of inorgan-

Table I. *Changes in the number of inorganic and organic active substances, drugs of animal and plant origin and galenicals in the first six editions of the Hungarian Pharmacopoeia (Ph. Hg.) with their addenda from 1871 to 1967* (based on Reference 5.)

Pharmacopoeias/ drugs	Ph. Hg. I.	Add.	Ph. Hg. II.	Add.	Ph. Hg. III.	Ph. Hg. IV.	Ph. Hg. V.	Add.	Ph. Hg. VI.
Inorganic active substances	26.7% (n=79)	21.7% (n=5)	33.3% (n=100)	3.4% (n=1)	31.6% (n=96)	24.3% (n=81)	22.5% (n=104)	0% -	22.8% (n=102)
Organic active substances	23.5% (n=69)	65.2% (n=15)	28.0% (n=84)	69% (n=20)	32.6% (n=99)	46.5% (n=155)	56.9% (n=263)	100% (n=18)	61.1% (n=273)
Animal drugs	2.0% (n=6)	-	2.0% (n=6)	6.9% (n=2)	1.3% (n=4)	0.6% (n=2)	0.4% (n=2)	-	0.4% (n=2)
Plant drugs	47.6% (n=140)	13% (n=3)	36.7% (n=110)	20.7% (n=6)	34.5% (n=105)	28.5% (n=95)	20.1% (n=93)	-	15.7% (n=70)
Total	**294**	**23**	**300**	**29**	**304**	**333**	**462**	**18**	**447**
Galenics	215	5	208	7	187	186	289	40	274

ic origin; the remaining group contained complex mixtures (4).

However, from the 19th century onwards, with the rapid development of chemistry and, more specifically, organic chemistry, it was made possible to produce an increasing number of natural compounds in pure form to perform partial chemical transformations and to create fully synthetic organic compounds. In addition, many inorganic compounds have been produced. Their application to humans has begun.

In the meantime, the discovery and marketing of newer plant and animal substances continued, and while the intensity of the introduction of newer plant substances into therapy slowed, the popularity of drugs of animal origin and organotherapy proliferated in the late 19th century.

The number of chemical preparations in Hungary increased significantly from the early period of the emergence of synthetic drugs from the First Hungarian Pharmacopoeia (1871) to the Sixth Hungarian Pharmacopoeia (1967) respectively, while the number of herbal and animal-derived drugs has decreased. These changes can be seen in Table 1.

It should be noted that Table 1 does not reflect the proliferation of increasingly novel active substances entering the pharmaceutical market without any meaningful regulatory control. These substances, often categorized as 'non-official medicines' were not included in the pharmacopoeias.

Table 2. below shows the number of newer drugs reported in the Pharmacist Yearbooks, after eliminating duplicates and combinations of drugs introduced earlier (6-12). Note that we do not know the sources of the original data, how complete they are, or whether the drugs were actually used in Hungary, and, if so, in what quantities. Thus, the data presented below are only suitable for a comparative assessment. In any case, it is clear and consistent with the changes in the pharmacopoeia that the already high proportion of organic compounds continued to increase in the 15 years (1886-1900) during which such lists were published, while the proportion of herbal or animal medicines decreased. Although not shown separately, the proportion of medicines of animal origin increased at the expense of herbal medicines.

In addition, there has been a massive emergence of largely unknown combinations of substances in the form of so-called 'secret preparations' (i.e. products with formulations that have not been made public and brought to the attention of the authorities) (13, 14).

Predictions of a famous Hungarian pharmacist

Table II. *Number of new medicines listed in Pharmacist Yearbooks* (6, 7, 8, 9, 10, 11, 12)

Year/Type of active substance	1886[6] (n= 138)	1890[7] (n= 123)	1891[8] (n=31)	1897[9] (n= 215)	1898[10] (n=79)	1890[11] (n=86)	1900[12] (n=52)
Organic compounds (natural, semi-synthetic, synthetic)	60.9% (n=84)	60.2% (n=74)	77.4% (n=24)	72.6% (n=156)	73.4% (n=58)	72.1% (n=62)	73.1% (n=38)
Herbal or animal medicines	37.7% (n=52)	37.4% (n=46)	12.9% (n=4)	20.9% (n=45)	22.8% (n=18)	23.3% (n=20)	19.2% (n=10)
Inorganic compounds	1% (n=1,4)	2.4% (n=3)	9.7% (n=3)	3.7% (n=8)	3.8% (n=3)	4.7% (n=4)	3.8% (n=2)
Sera	0	0	0	2.8% (n=6)	0	0	3.8% (n=2)

and public figure of his time, Gyula Muzsa (in 1891) were proven to be false when he wrote the following:

"*The fever of syntheses, which today wants to produce all medicines or at least to replace them by cheaper ones, will in time cease and the many new drugs of uncertain efficacy, produced in mass, will disappear from the horizon, giving place to the old medicines of real value*." (15).

A key driving force was the development of experimental pharmacology, which meant, for example, that experiments had to be carried out with pure, isolated chemicals in a reproducible way. As written in the Memorial Book of the Chemical Works of Gedeon Richter in 1942:

'*The new pharmacological principle stimulated synthetic chemistry and its development raised new pharmacological problems. More and more physiological laws could be recognized from the changes in organ functions produced by drugs, and the development of physiology made it possible to solve more and more pharmacological questions. The improvement of naturalistic and chemical methods of measurement, but above all the incredible sensitivity of the effects observed in animal experiments, helped to develop modern biochemistry, which then slowly became a stable basis of biomedical research*." (16).

Many drugs were introduced into therapy after some animal experiments and human administrations, before these experiments and studies had provided a valid or at least approximate scientific-theoretical explanations for their mode of action. Examples of such drugs include anaesthetic gases and liquids, salicylic acid and its derivatives and other minor analgesics, major analgesics (morphine and its salts), hypnotic medicines (diethylmalonyl urea, chloral hydrate, ethylurethane, paraldehyde, sulphonal - for a time the ethyl group was thought to be responsible for the hypnotic effect), antiepileptic barbiturates, then the hydantoin derivatives, the local anaesthetic cocaine and its synthetic derivatives such as cocainum novum or novocaine (for a while it was thought that the local anaesthetic effect was due to the phenyl group, with the rest of the molecule only facilitating cellular entry), the antibacterial sulphonamides and a host of other agents (16).

Pharmacopoeias proved to be increasingly inadequate for the regulations of drug therapy, which finally led to the establishment of the legal institution of mandatory registration of medicinal products in Hungary in 1933 (see below) (13, 14).

However, this was the era before human clinical trials, when it seemed natural to design drugs at the planning table, using the principles of experimental pharmacology, just like the engineers plan trains, cars, ships or houses. This principle is also reflected in the compilation of the Hungarian National Formulary of Compounded Medicines, i.e., the Formulae Normales. It was later shown that only with adequate clinical trial data is it possible to understand the true clinical characteristics and value of drugs.

That is, in this era, we cannot yet talk about formal drug development in the modern sense. However, the path leading to the discovery and production of insulin (the discovery and study of the role of the pancreas in glucose metabolism), neurohormones (acetylcholine, adrenaline and their artificial derivatives), sex hormones and vitamins are classic examples of rational scientific research.

Patent legislation and the legal system

For a long time (in Hungary from 1895 to 1994), synthetic active substances were protected by process patents (and afterwards by product patents), i.e., the method of manufacturing synthetic medicines (the synthetic route) could be patented, but not the compound itself (17, 18).

Originally, according to Article 54 of Law XIV of 1876, medicines could not be patented at all:

"*No patent shall be granted for the preparation of medicines or protective products against diseases, nor for discoveries, inventions or improvements the use of which is not permitted by public health considerations*." (18).

However, Article 2 of Act XXXVII of 1895 stated that *"No patent shall be granted for an invention ... . 4. articles intended for human or animal consumption, medicines and articles* ***obtained by chemical means****; the process for their manufacture may, however, be patented."* (18).

Since patent protection was available only for synthetic (chemically produced) compounds, or more precisely for their synthetic route until 1994 (when the product patent system was launched in Hungary), the focus of research and product development was naturally shifted towards these compounds.

It is very important to know that neither Article XIV of Law 1876 nor subsequent legislation gave pharmacists the exclusive right to prepare medicines. The legal loophole here was that while pharmacies had a monopoly on the retail distribution of medicines, there was no monopoly on the man-

ufacture of medicines, the legal regulation of the latter was not clear, and what is more, it was not even clear that only a pharmacist could manufacture medicines.

In essence, this loophole opened the way for the emergence of the modern pharmaceutical industry. The Hungarian pharmacist, Gedeon Richter (1872-1944), for example, is rightly considered the founder of the domestic pharmaceutical industry. However, his historical merit did not lie in the fact that he began to manufacture medicines on an industrial scale, as others had already done that, but in the fact that he, being a pharmacist, devoted his life to the industrial production of pharmaceuticals, abandoning his career as a pharmacist and completely breaking away from community pharmacy. Pharmacists, with a few exceptions, did not take this step, because they were very attached to community pharmacy, even if they produced medicines on an industrial scale. Richter, along with many others worldwide - both pharmacists and non-pharmacists alike - began to operate in this legal vacuum, perfectly legally.

In this context, it should be noted that when we talk about the pharmaceutical industry, we associate it with the term "pharmaceutical factory", but it is not as simple as that. There was also once a legally distinct 'pharmaceutical laboratory'. The fundamental difference between the two was that while the factory required both an industrial premises license (ie. license for running a factory in a given plot) and an industrial license, the laboratory only required an industrial licence, namely under Article 14(2) of the 1922: X II. law. As a consequence, many pharmacists who did not abandon their community pharmacies produced industrial quantities of medicines in the framework of a 'pharmaceutical laboratory'. The largest of these in Hungary between the two World Wars, the Eri Laboratorium, for example, had more registered medicines than the Richter factory in 1937 (19). Over time, the laboratories were also owned partly by pharmacists who had become detached from their community pharmacies and other professionals (e.g. doctors, chemists), so much so, that the distinction between factory and laboratory was in reality completely blurred, but the legal distinction remained until nationalization in 1948.

Demography

From the early 1870s until the outbreak of World War I in 1914, Hungary's population grew from almost 14 million to about 19 million, an increase of about 36%. In addition, infant mortality fell significantly and life expectancy at birth increased (from 21.83 years to 41.04 years for men and from 23.56 years to 43.12 years for women between 1870 and 1920/21) (20).

This has also meant that the market for medical-pharmaceutical service was growing considerably. Since it also meant that the number of pharmacies and medical practices has been growing intensively, from the end of the 19th century until the beginning of World War I, the share of health care expenditures in the Hungarian budget increased more than fourfold (from slightly less than 0.5% to over 2%) (20).

Wars

Wars and military interests have also played an important role in the economic and technological developments of the modern age.

As far as pharmacy is concerned, the free supply of medicines to poor patients at the expense of the public health care system in Hungary, as in other countries of the Habsburg Empire, was once based on magistral (compounded) prescriptions listed at the end of the Austrian Military Pharmacopoeia. This practice, although accepted, was not officially introduced.

However, the Norma Pauperum (a collection of medicines that could be prescribed for the poor at the expense of the public treasury), which was published in six editions between 1850 and 1934, was already made mandatory by law. The Norma Pauperum was the predesessor of the National Formulary of Compounded Medicines (a.k.a the Formulae Normales), which began its publication in 1940 and published its eight edition, Formulae Normales Editio VIII, on July 7, 2021. In its own right, at least in part, the Military Pharmacopoeia inspired the creation of an important civilian collection of magistral (compounded) prescriptions.

In addition, military interests and wars have shaped the medicine supply. The French blockade of the continent during the Napoleonic Wars, for example, helped to stimulate practical and scientific interest in willow bark.

Hungary was a net importer of pharmaceutical products between 1913 and 1916 (39). Chinoin, a pharmaceutical company founded in 1910, and later noted as being a "flagship" of the Hungarian pharmaceutical industry, mostly profited from the production of war gases (bromoacetone, bromocy-

anate and the filling of KLARK I (diphenylarsine chloride) and KLARK II (diphenylcyanoarsine) imported from Germany into grenade shells), the last of which started to be produced on government orders from 1916 (21).

During World War I, there were shortages of British, French, Russian and other raw materials, and shortages of many chemical products (e.g. medical gasoline, paraffin, petroleum jelly, iodine, bromine, sulphur, mercury, etc.) (23, 24). There were also restrictions on sugar, glycerol and fatty oils (22).

Various substitutes were used to try to solve the shortage of medicines, including synthetic, industrially produced drugs (indicated in bold) (23, 24)

- *Aloe, castor oil: sea buckthorn, dogbane,* **phenolphthalein, sulphates, calomel**
- *Ipecachuana: apomorphine,* **antimony potassium tartrate**
- *Hydrastis canadensis: ergot alcaloid preparations, cotarnine salts*
- *Peru balsam:* **Perugene artificial product** *(cinnamic and benzoic acid benzyl esters)*
- *Starch and lycopodium: talc, caoline*
- *Santonin: flower and essential oil of wormwood,* **calomel**
- *Bark of china:* **synthetic antipyretics (acetanilide, azophene, amidazophene)**
- *Cocaine:* **synthetic local anaesthetics**
- *Silver and lead salts: aluminium salts, tannic acid, possibly copper and zinc salts*

In addition, the production of **disinfectants** (mainly phenol - or as it was called at the time - carbolic acid and hydrogen peroxide) and **vaccines** became more important.

Although the Hungarian pharmaceutical industry as a whole - with the exception of Chinoin - did not benefit from World War I, the war did push the pharmaceutical industry towards the use of synthetic medicines.

More examples:

- *The first modern anti-tumor drugs (the first representatives of* **the alkylating agents***) were later developed from the mustard gas derivatives used in World War I (25).*
- *World War II accelerated research and production of the first antibiotic,* **penicillin** *(26, 27, 28). The penicillin initially produced consisted predominantly of penicillin-G, also known as benzyl penicillin. By adding precursors during fermentation, it was possible to shift the biosynthesis of penicillin towards other compounds (e.g. penicillin V, also known as phenoxymethylpenicillin). From 1960 onwards, semi-synthetic penicillin derivatives also appeared (26). The history of the beginnings of penicillin research and production in Hungary (World War II) has also been published (29).*
- *The 'gold standard' for repellents against blood-sucking insects, including mosquitoes, was* **N,N-diethyl-3-methylbenzamide (DEET)***, also known as N,N-diethyl-m-toluamide, patented by the US Army in 1946 (30).*
- *Nazi Germany was the first country in Europe to use* **multivitamin** *tablets on a mass scale to enhance workers' performance and protect their health (31).*
- **Dimenhydrinate***, one of our most popular antiemetic drugs for motion sickness (due to air and sea travel), was first developed for military use in the USA in 1948: the first large trial of the drug was conducted on a warship bound for Germany in 1948, on 1366 soldiers, and then in 1949 on military pilots at Randolp Air Force Base, Texas (32).*

Social insurance and public health, i.e. the medicalization of society

From the middle of the 19th century, and especially towards the end of the century, the institution of social insurance was launched and expanded. Until 1891, there were various forms of voluntary self-help organizations. Mandatory sickness insurance was introduced in Hungary by Act XlV of 1891. This was followed by Act XlX of 1907, which introduced mandatory employment accident insurance. Article XL of 1928 further extended the scope by introducing a more comprehensive mandatory social insurance in the event of old age, invalidity, widowhood, orphanhood (33).

In 1893, the total amount of all domestic sickness funds, excluding Croatia and Slavonia, was only 323 thousand Forints (Hungarian currency of the time) for "medical drugs"; by 1896 the amount had doubled. In 1897 1,385,000, in 1898 1,552,000 thousand Coronas (the new Hungarian currency of the time) were spent on medicine. In 1899, the amount rose by another 30%. As with the doctors' fees, the sickness funds also reduced the medicinal fees. Village pharmacies only received a fraction of the payments due from the employment sickness funds. However, industrial workers' insurance was considerably more developed than village health care; industrial companies were established mainly in towns. As the number of the insured increased, medicines dispensed at the expense of the sickness funds accounted for an increasing proportion of the total turnover. Pay-

Table III. *Changes in the number of insured persons in Hungary between 1885 and 1947* (35)

Year	Number of insured persons	% of population
1885	147 000[1]	0.9
1891	447 000	2.6
1900	594 000	3.1
1903	634 000	3.3
1911	1 155 000	5.5
1913	1 204 000	6.3
1915[2]	835.000	4.4
1927[3]	2 000.000	24
1931	2 200.000	25
1938	2 800.000	31
1947	3 000.000	33

[1]except trade association funds; [2]until 1915, the combined annual number of insured persons in all sickness funds; [3]from 1927 family members included

ments from the sickness funds were obtained by pharmacies at a discount of 20-40% and usually transferred after a long period of time. The funds required rigorous cost savings from their doctors in their prescription practices. The increase in pharmacy turnover was generally not proportional with profitability due to tightening profit margins and rising costs (34).

The evolution of the number of insured persons between 1885 and 1947 is shown in Table 3. below (35).

The growing importance of social insurance in patient care is shown, for example, by the fact that the National Social Insurance Institute (OTI) has seen a growing number of patients in its specialist clinics, especially in the capital. While there were 517 doctors in 1934 and 538 doctors in 1942, the annual patient turnover rose from 3.6 million to over 6 million. In 1928, general medical care was provided by 1326 doctors, while 202 doctors were working in company sickness funds. In the 1920s, one general practitioner had to treat 8-9 patients in 1-2 hour, whereas in the late 1930s he/she had to treat 20-30 insured patients. The time per patient was reduced to 4-5 minutes (33).

So, when the mass flow of people/patients to the doctors started, as described above,a huge market for the pharmaceutical companies was provided, especially as the increasingly limited time per patient was less and less able to accommodate the writing of long magistral prescriptions (compounded in pharmacies). It was much simpler to write the name of one of the factory-made preparations on the prescription (the Formulae Normales tried to compete with this by giving each prescription a serial number and a name just to be written in the prescription instead of the whole composition). This revenue stream to the pharmaceutical industry was naturally used partially to finance more research and development.

In addition, health insurers had also been reimbursing more and more factory products. In this way, the state - by creating a legal option - essentially channeled part of the society's financial resources into the pharmaceutical industry.

While in the early 19th century, during cholera epidemics, people in some places would chase away the doctor and not trust him or the pharmacists at all, this has radically changed in one century: The real progress in medical and pharmaceutical sciences, along with the mass doctor-patient/pharmacist-patient contacts created by social insurance, have medicalized society, a society, which has become increasingly dependent on the use of medicines. The partial irrationality of this process is illustrated by the fact that, while the average life expectancy of Hungarian men was 64.5 years from birth in 1992, more than two years less than in the mid-1960s (36), the number of prescriptions increased 13-fold between 1955 and 1982 alone (37).

The emergence of mass healthcare in Hungary seems to have had consequences for the life expectancy of doctors (38). Examination of morbidity and mortality data from 1964-2010 consistently indicates that the mortality of Hungarian doctors over the age of 40 years exceeds that of the corresponding age groups in the population. The literature identifies as the root cause the unresolved serial stress situations, role conflicts, duties, constant on-call work and financial problems that very often accompany the medical profession, which can be summarized as burnout syndrome. Another

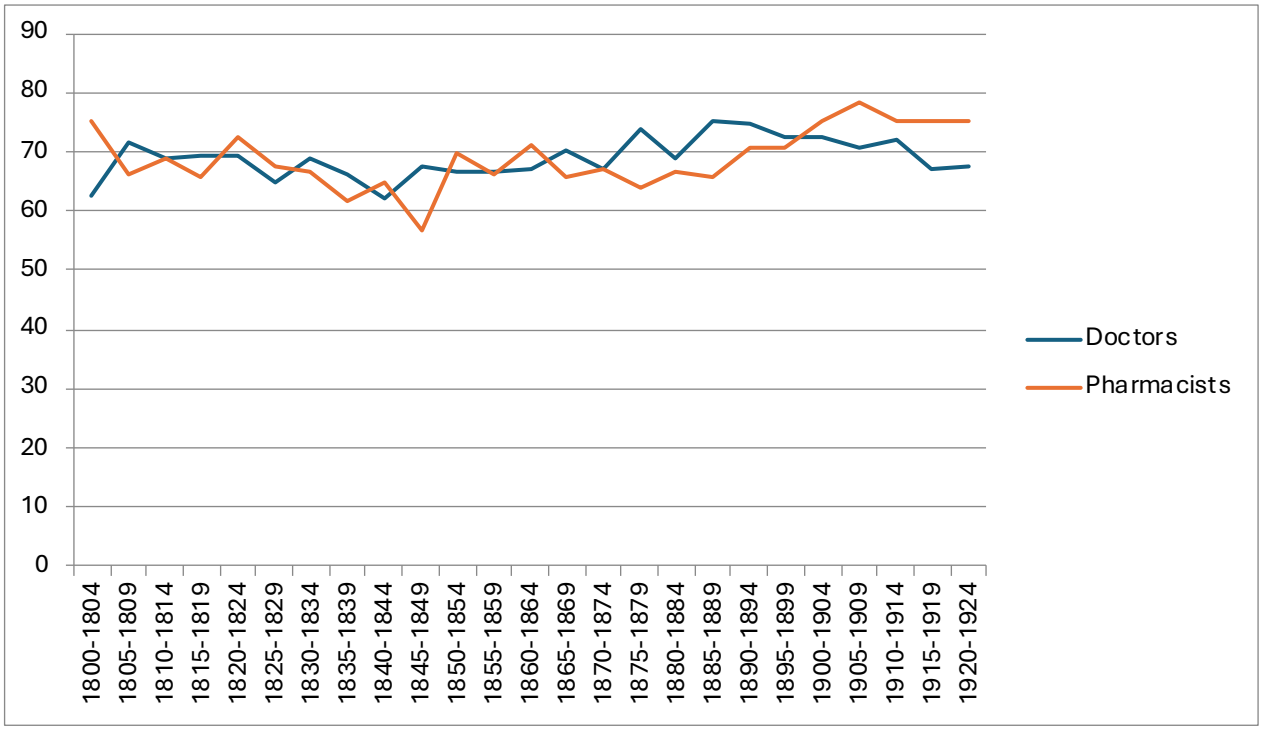

Figure 1 *Graphical representation of the life expectancy (in years) of doctors and pharmacists born between 1800 and 1925 as a function of year of birth* (38)

study has looked at the life expectancy of Hungarian male doctors and pharmacists who died of natural causes in a sample of those born between 1800 and 1925, in the context of a comparative historical demographic study. The results show that from the end of the 19th century onwards, the average life expectancy of doctors and pharmacists followed opposite trends: the life expectancy of pharmacists rose to about 75 years of age in the first quarter of the 20th century, while that of doctors fell to just over 67 years. Hungarian doctors born in 1920-1924 lived about as long as those born more than 100 years earlier, between 1810 and 1814, despite all the scientific, technical and health advances that took place in the meantime (see Figure 1.) (38).

The age-disaggregated data also showed that this was mainly due to the higher mortality of doctors aged 40-60 years compared to pharmacists (38).

These results show a significant decrease in the life expectancy of Hungarian doctors born between 1885-1889 and 1925, which is consistent with the burnout syndrome explanation described in the literature, as they were doctors born around 1885-1889 who were drawn into the highly stressful world of mass health care after the age of about 40 (38).

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